

HSA's Safety Update #9

COVID-19 Vaccines

(30 December 2020 – 31 December 2021)

Introduction

This is HSA's 9th safety update of the COVID-19 vaccines covering the period from the roll-out of the vaccines on 30 December 2020 to 31 December 2021. It provides an overview of the reports by healthcare professionals of **suspected adverse events¹ (AEs)** associated with COVID-19 vaccines to the Health Sciences Authority (HSA) and our current assessment of these AEs.

Summary (as of 31 December 2021)

- A total of 11,490,023 doses of the Pfizer-BioNTech/Comirnaty and Moderna/Spikevax mRNA vaccines have been administered, out of which 14,729 suspected AE reports (0.13% of administered doses) were received. Of these, 747 reports (0.007% of administered doses) were classified as serious AEs.
- The most commonly reported AEs were consistent with those typically observed following vaccination. They include allergic reactions (such as rash, itch, hives and swelling of eyelids, face and lips), dizziness, shortness of breath, chest tightness/discomfort, palpitations, fever and injection site reactions such as pain and swelling. These typically resolve within a few days. Among the serious AE reports, the most frequently reported AEs were anaphylaxis and other severe allergic reactions.
- In the age group of 5 to 11 years, the reports described non-serious AEs such as hives, dizziness, fever and shortness of breath. There were no serious AEs reported for this age group.
- In the age group of 12 to 18 years, the most commonly reported AEs include rash, hives, angioedema (swelling of the eyelids, face and lips), shortness of breath, palpitations, chest tightness/discomfort, fever, dizziness, light headedness and syncope (fainting and brief episode of loss of consciousness).
- The AEs reported in individuals who had been administered booster doses of the mRNA vaccines were similar to the profile of AEs associated with Dose 1 and Dose 2 of the vaccines and there was no observed increase in frequency of events. These include allergic reaction such as rash, hives and angioedema (swelling of the eyelids, face and lips), chest tightness/discomfort, palpitations, increase in blood pressure, shortness of breath, fever, generalised weakness and dizziness. Ten cases of myocarditis and pericarditis have also been reported following 2.2 million booster doses.

¹ An adverse event is any untoward medical occurrence in a patient administered a pharmaceutical product (including vaccines) but does not necessarily have a causal relationship with this treatment/vaccination.

- Rare instances of anaphylaxis, a severe life-threatening allergic reaction, have occurred after administering the COVID-19 vaccines. It is a known adverse reaction associated with vaccines in general. The local incidence rate of anaphylaxis with mRNA vaccines is estimated at 0.88 per 100,000 doses administered and is similar to those reported overseas. So far, no anaphylaxis reports have been received for the booster doses.
- Rare cases of myocarditis and pericarditis have been reported with various COVID-19 vaccines both overseas and locally. They are caused by inflammation of the heart muscles and outer lining of the heart, respectively. Myocarditis and pericarditis are not heart attacks, which are usually caused by blockage of the blood vessels that supply the heart. As with elsewhere, the incidence of myocarditis and pericarditis with the primary series of the mRNA vaccines is observed to be highest in young males below 30 years old. Most of the patients were reported to have recovered or are recovering. COVID-19 infection is also known to be associated with myocarditis. In one study, the extra myocarditis events in the month following vaccination was estimated to be between 1 and 10 per million persons, which is substantially lower than the 40 extra events per million persons observed following COVID-19 infection.
- There have been rare cases of cerebral venous thrombosis (CVT) reported with the Pfizer-BioNTech/Comirnaty and Moderna/Spikevax COVID-19 vaccines, both overseas and locally. CVT is very rare and involves blood clots occurring in the veins of the brain, which can happen naturally regardless of whether people have been vaccinated. HSA's analysis found a small increase in incidence of CVT with mRNA vaccines, which translates to about 1 additional case of CVT per million doses. Considering that the risk of CVT after COVID-19 infection is much higher than CVT after mRNA vaccination, the benefits of vaccination continue to outweigh the small increased risk of CVT.
- Two hundred and seventy-one suspected AEs (0.08% of doses administered) including twenty serious ones (0.006% of doses administered) were reported following the administration of 332,379 doses of Sinovac-CoronaVac COVID-19 vaccine.
- Thirty-five suspected AEs (0.05% of doses administered) including four serious AE (0.005% of doses administered) were reported with Sinopharm COVID-19 vaccine after 75,440 doses were administered.
- It should be noted that the type and number of reports received for different COVID-19 vaccines are not directly comparable as the vaccines have been used in the vaccination programme for different durations of time. The inactivated COVID-19 vaccines have been administered only to a very small proportion (3.5%) of the population compared to the much larger scale of deployment for the mRNA vaccines.
- Overall, based on the data to date, the benefits of the Pfizer-BioNTech/Comirnaty, Moderna/Spikevax and Sinovac-CoronaVac COVID-19 vaccines continue to outweigh the known risks when used in a pandemic. HSA will continue to closely monitor the safety profile of the COVID-19 vaccines and relevant regulatory actions will be taken to safeguard public health.

Background

2 HSA has granted interim authorisation for two mRNA COVID-19 vaccines and an inactivated COVID-19 vaccine in Singapore under the Pandemic Special Access Route (PSAR) (Table 1). On 10 December 2021, the interim authorisation for Pfizer-BioNTech/Comirnaty COVID-19 vaccine was transitioned to product registration.

Table 1. Authorisation of COVID-19 vaccines in Singapore

Vaccines	Authorisation date	Vaccination roll-out date
Pfizer-BioNTech /Comirnaty [^] Vaccine*	14 December 2020	30 December 2020
Moderna/Spikevax [^] Vaccine	3 February 2021	12 March 2021
Sinovac-CoronaVac Vaccine	23 October 2021	18 June 2021 ⁺

*HSA extended the use of the Pfizer-BioNTech/Comirnaty vaccine to adolescents aged 12-15 years on 18 May 2021 and to children aged 5-11 years old on 10 December 2021.

[^]HSA approved the new brand names Comirnaty and Spikevax for Pfizer-BioNTech and Moderna vaccines respectively on 14 September 2021

⁺Sinovac-CoronaVac vaccine was first made available for use in Singapore under the Special Access Route (SAR)²

3 As with all other vaccines, HSA actively monitors the safety of the COVID-19 vaccines to ensure that the benefits of the vaccines continue to outweigh the risks. This is achieved through AE monitoring systems to detect any potential safety concerns so that relevant measures can be taken to ensure that the vaccines remain safe for use. HSA reviews the submitted AE reports, in consultation with our expert panels³.

How to interpret the data

4 AEs are reported by healthcare professionals to HSA when they suspect that the AEs may be associated with the vaccine. This does not necessarily mean that the vaccine has caused the AEs. In some instances, these AEs are related to an underlying or undiagnosed disease or the natural progression of an underlying disease. It may be coincidental that the event occurred around the same time when the vaccine was given but is not caused by the vaccine. The causality based on isolated cases of individual events usually cannot be established as many illnesses cause the same symptoms and signs, and there are generally no confirmatory tests for diagnosing an AE. Hence, AEs are assessed and interpreted in the context of background incidence rates of such occurrences (i.e., historical rates in our general population unexposed to the COVID-19 vaccines). While each individual report is carefully reviewed, the totality of data from all sources (e.g., mechanistic actions, clinical assessments of local AE reports from healthcare professionals, public self-reported AEs, epidemiological studies, literature and overseas reports) has to be considered before drawing any evidence-based conclusions on the safety of the vaccine.

5 The type and number of reports received for the different COVID-19 vaccines are not directly comparable as the vaccines may have been used in the vaccination programme for different lengths of time, and may have been administered to different numbers of people with different underlying medical conditions and across different settings. In the case of the inactivated COVID-19 vaccines (Sinovac-CoronaVac and Sinopharm) which were first made available for use (via the SAR) at a later date, these were administered only to a very small

² <https://www.hsa.gov.sg/therapeutic-products/register/special-access-routes/SAR-covid19>

³ HSA has appointed five Expert Panels to adjudicate neurological AEs, cardiac AEs, thromboembolic and haematological AEs, renal AEs and severe hypersensitivity reactions such as anaphylaxis.

proportion (3.5%) of the population compared to the much larger scale of deployment for the mRNA vaccines (Pfizer-BioNTech/Comirnaty and Moderna/Spikevax). Similarly, the AE numbers or rates between countries should not be directly compared as the usage of the vaccines may be different and the AE reporting systems are often also different.

6 The description of suspected AEs in this update reflects the available information known at the time by HSA. These data may undergo changes as more information on individual reports becomes available through follow-up, and as more data are reported and evaluated.

mRNA COVID-19 Vaccines

7 As of 31 December 2021, HSA has received 14,729 suspected AE reports (0.13% of doses administered) associated with the use of Pfizer-BioNTech/Comirnaty and Moderna/Spikevax COVID-19 vaccines. Table 2 gives the breakdown on the vaccination data and the number of suspected AE reports associated with the two mRNA vaccines.

Table 2. Overview of vaccination data and no. of suspected AE reports reported by healthcare professionals for mRNA COVID-19 vaccines (as of 31 December 2021)

	Pfizer-BioNTech/Comirnaty	Moderna/Spikevax	Total
No. of persons who have received at least D1	3,710,851	1,014,141	4,724,992
No. of persons who received two doses*	3,667,572	880,298	4,547,870
No. of persons who received booster doses	1,613,806	603,355	2,217,161
Total no. of doses administered	8,992,229	2,497,794	11,490,023
No. of suspected AE reports	12,000 (0.13% of doses administered)	2,729 (0.11% of doses administered)	14,729 (0.13% of doses administered)
No. of suspected serious⁴ AE reports	604 (0.007% of doses administered)	143 (0.006% of doses administered)	747 (0.007% of doses administered)

*The primary vaccination regimen for Pfizer-BioNTech/Comirnaty and Moderna/Spikevax COVID-19 vaccines comprise 2 doses. The no. of persons who received two doses includes those who had received the first dose.

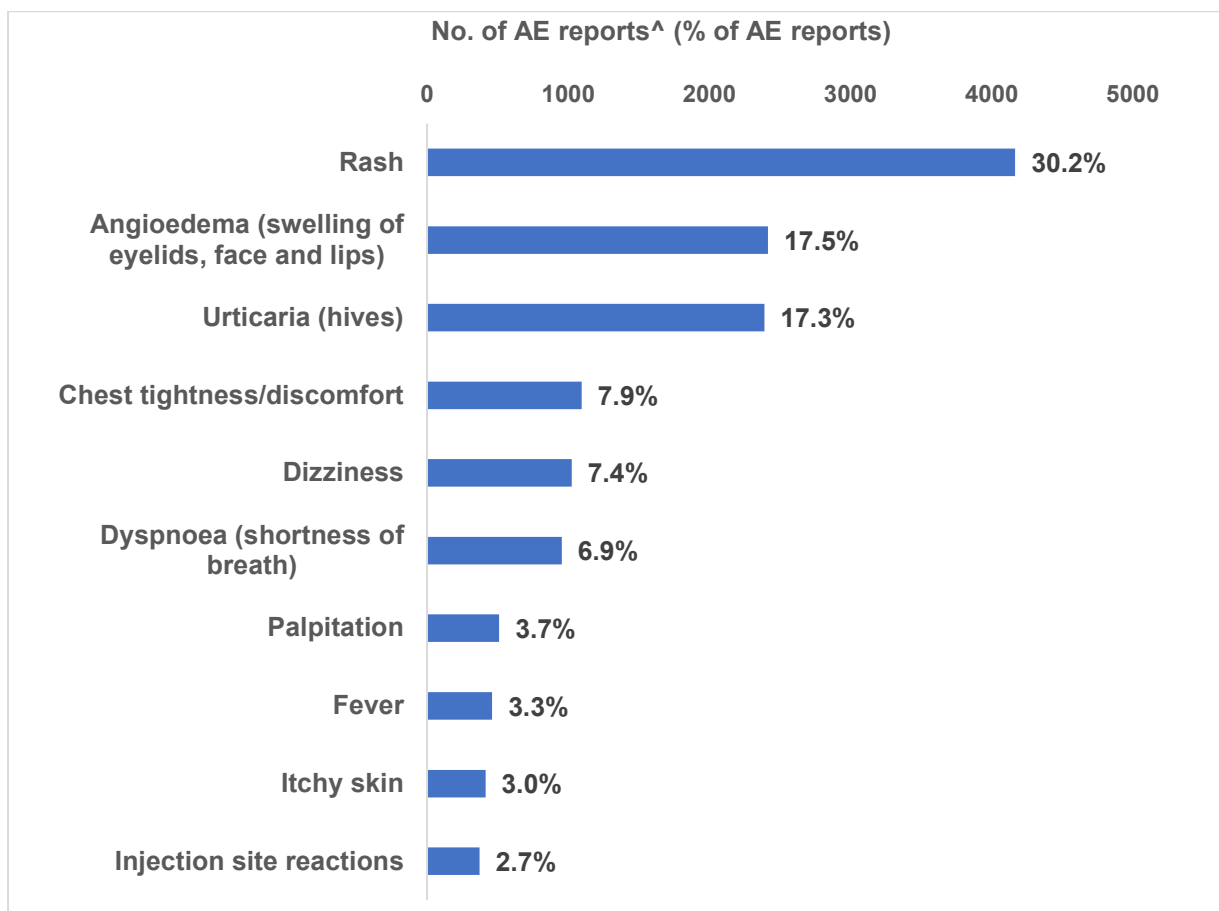
8 About 78% of the AEs were reported in individuals less than 60 years old. This is in line with the observation in the clinical trials of both vaccines whereby persons younger than 60 years of age tend to experience more reactogenic AEs than those aged 60 years and above. Generally, younger individuals have more active immune responses and may experience more AEs with the vaccines. This is part of the body's natural response to build immunity against COVID-19 infection. About 64% of the AEs were reported in females.

Commonly reported adverse events

9 The most commonly reported AEs (Figure 1) are consistent with those typically observed following vaccination. These include allergic reactions (such as rash, itch, hives and swelling of eyelids, face and lips), dizziness, shortness of breath, chest tightness/discomfort, palpitations, fever and injection site reactions such as pain and swelling. These reported AEs generally resolved within a few days. These AEs are also in line with those reported overseas.

⁴ An adverse event is classified as serious when the event resulted in hospitalisation/extended stay in hospital, resulted in a significant reduction in functioning level/disability, resulted in a life-threatening illness (e.g. anaphylaxis) or death, resulted in birth defects or is a medically important event.

Figure 1. Most commonly reported AEs associated with the use of Pfizer-BioNTech/Comirnaty and Moderna/Spikevax COVID-19 vaccines (as of 31 December 2021)



[^] Each report may describe more than 1 adverse event

10 Among the reports of syncope reported for all ages, there were 38 cases which had occurred 1 to 5 days after receiving vaccination, which is within the background incidence. Syncope is common in the general population.⁵ The most common type of syncope is vasovagal syncope, which may be triggered by physical or psychological stress, dehydration, bleeding, or pain and emotional responses. In some cases, no trigger can be identified. Such syncopal episodes are largely not serious as individuals recover spontaneously but may result in injury due to falls in rare instances. Some warning signs of vasovagal syncope may include dizziness, feeling hot or cold, nausea, pale skin, "tunnel-like" vision, disturbance of hearing and profuse sweating. While the causal link to the vaccines remains to be ascertained, individuals may wish to take note of the possible triggers and warning signs of syncope.

Serious adverse events

11 Of the 14,729 suspected AE reports received for the mRNA vaccines (Pfizer-BioNTech/Comirnaty and Moderna/Spikevax), 747 of the reports were assessed as serious. Serious AEs comprised 0.007% of doses administered. The most frequently reported serious AEs were anaphylaxis (87 reports) and other severe allergic reactions (53 reports). Other serious AEs include:

⁵ UpToDate © 2021 (electronic version). Available at: <https://www.uptodate.com/contents/syncope-fainting-beyond-the-basics/print#> (last accessed 13 Dec 2021)

- immunological - rheumatoid arthritis and other autoimmune conditions;
- cardiovascular - chest pain, drop or increase in blood pressure, irregular heartbeat, tachycardia (fast heart rhythm), myocarditis and pericarditis (inflammation of the heart muscles and the outer lining of the heart, respectively);
- neurological - nerve damage or dysfunction resulting in numbness or tingling/ pricking sensation, muscle or limb weakness and pain in the affected area, syncope, seizures (fits), inflammation of the brain tissues, Bell's Palsy (facial muscle weakness or paralysis) and cerebral venous thrombosis (CVT);
- haematological involving the blood cells - low platelets and blood clots;
- musculoskeletal - joint pain or muscle injury;
- dermatological - severe skin reactions, eczema flare and skin blisters;
- renal - reduced kidney function and inflammation of the kidney;
- visual inflammation and visual disturbances;
- tinnitus (ringing in the ears) and hearing loss;
- respiratory - exacerbation of underlying asthma and breathing difficulties and
- other SAEs such as increase in liver enzymes, thyroid gland dysfunction, menstrual disorders, and infections.

These serious AEs are being closely monitored by HSA. Background disease incidence⁶ or underlying medical conditions are taken into consideration when determining if the vaccine had any contributory role to these events. Most of the individuals who developed serious AEs were reported to have recovered or are recovering. Patients who experience serious adverse events following vaccination are advised to seek prompt medical attention.

Adverse events in children and adolescents

12 On 27 December 2021, the COVID-19 vaccination programme was rolled out to children aged 5 to 11 years old.[∞] Six non-serious reports were received (0.03% out of 20,327 administered doses) in this age group. These comprised 3 reports of allergic reactions (hives and swelling of the eyelids, face and lips) and one report each of dizziness, fever and fast breathing. There were no serious AE reports amongst children aged 5 to 11 years thus far.

13 Since the roll out of the vaccination programme in students aged 12 years and above on 3 June 2021, HSA has received 1,170 AE reports (0.18% of doses administered) associated with the use of mRNA vaccines in adolescents aged 12-18 years old[∞], out of 663,239 administered doses. The commonly reported AEs include rash, hives, angioedema (swelling of the eyelids, face and lips), shortness of breath, palpitations, chest tightness/discomfort, fever, dizziness, light headedness and syncope (fainting and brief episode of loss of consciousness). These reported AEs generally resolved within a few days, and they are also in line with the events reported overseas. There were 83 serious AEs (0.013% of doses administered) including allergic reactions, skin conditions, seizures, dizziness, syncope, myocarditis, pericarditis and tachycardia.

Adverse events with booster doses

14 The national COVID-19 booster vaccination programme was rolled out on 15 September 2021 and 2,217,161 individuals have received the booster doses as of 31 December 2021. HSA has received 401 AE reports (0.03 % of doses administered) associated with the use of

⁶ The incidence of new cases of disease in a population over a specified period of time in the absence of vaccination

[∞] Pfizer-BioNTech/Comirnaty vaccine is approved for use in individuals aged 5 years and above, while Moderna/Spikevax vaccine is authorised for use in individuals aged 18 years and above

Pfizer-BioNTech/Comirnaty vaccine and 172 AE reports (0.03% of doses administered) with the Moderna/Spikevax vaccine as booster doses. The commonly reported AEs include allergic reactions such as rash, hives and angioedema (swelling of the eyelids, face and lips), chest tightness/discomfort, palpitations, increase in blood pressure, shortness of breath, fever, generalised weakness and dizziness.

15 There were 49 SAE reports (0.002% of administered doses) describing myocarditis, pericarditis, heart failure, fluid overload, syncope, numbness and weakness of limbs, seizures and other neurological events, pneumonia, visual disturbance, blood clots, drop in platelet count, abnormal renal function, hearing loss and allergic reactions. Overall, the AE reports with the booster doses described similar AEs associated with Dose 1 and Dose 2 of the mRNA vaccines and there was no observed increase in frequency. There were 10 cases of myocarditis and pericarditis reported to HSA following more than 2.2 million booster doses administered. All 10 cases occurred with the Pfizer-BioNTech/Comirnaty vaccine, but it should be noted that a higher proportion of individuals (about 70%) received this vaccine as their booster dose. HSA continues to closely monitor the adverse events and will inform the public on any significant events and take relevant regulatory actions as required.

Adverse events of special interest⁷

16 An adverse event of special interest (AESI) is a medically significant event that has been observed historically with other vaccines, of which some examples include anaphylaxis, myocarditis, pericarditis and cerebral venous thrombosis. Hence, HSA is closely monitoring the occurrence of such adverse events to detect any increase over background incidences.

Anaphylaxis reports

17 Anaphylaxis is a rare and potentially life-threatening allergic reaction that can occur following vaccination in certain susceptible individuals. Safeguards have been implemented to mitigate this risk, which include pre-vaccination screening, post-vaccination observation period (30 minutes after vaccination with Dose 1 and Dose 2, and 15 minutes after booster vaccination) and ensuring that all vaccination centres are medically equipped and staffed by qualified medical professionals at all times to provide medical treatment in the rare event that they are needed.

18 There were 87 cases of anaphylaxis reported with the Pfizer-BioNTech/Comirnaty and Moderna/Spikevax vaccines. All the patients were reported to have recovered after medical treatment. The incidence rate of anaphylaxis reported locally with the vaccines is about 0.88 per 100,000 doses administered, which is similar to the incidence rates reported overseas.

19 The number of cases of anaphylaxis associated with Dose 2 is lower than with Dose 1 for the mRNA vaccines. To date, HSA has not received any cases of anaphylaxis associated with the booster dose.

Myocarditis and pericarditis reports

20 An increased incidence of myocarditis and pericarditis (inflammation of the heart muscles and outer lining of the heart, respectively) associated with the mRNA vaccines have been reported both overseas and locally. While myocarditis and pericarditis have many

⁷ Definition of AESI adapted from World Health Organization (WHO), Dec 2020. *COVID-19 Vaccines: Safety Surveillance Manual*[online] [24 Mar 2021 viewed]. Available from: <https://www.who.int/publications/i/item/10665338400>

different causes, most are due to viral infections and immunological reactions. The typical symptoms are chest pain, shortness of breath, and fast heartbeat. In most cases, the inflammation is mild. Myocarditis and pericarditis are separate and distinct from heart attacks. Heart attacks are generally caused by blockage of the blood vessels supplying the heart. In myocarditis and pericarditis, the blood vessels usually appear normal.^{8,9} Majority of the individuals who develop myocarditis or pericarditis respond well to treatment and recover. Locally, the background incidence of myocarditis or pericarditis leading to hospitalisation is estimated to be about 5 to 7 in 100,000 persons per year, or about 280 to 400 cases a year.

21 HSA has received 106 AE reports of myocarditis and pericarditis following more than 11.49 million doses of mRNA vaccines administered. The overall incidence for Dose 1 and 2 is estimated at 1.04 per 100,000 doses administered. Of the 51 cases which occurred in individuals below 30 years old following Dose 1 and Dose 2, 45 (88%) cases had occurred in males. The incidence is observed to be highest in younger males below 30 years old (incidence rate of 3.7 per 100,000 doses administered), compared to females in the similar age group (incidence rate of 0.5 per 100,000 doses administered) after Dose 1 and Dose 2 of the mRNA vaccines. The incidence of myocarditis and pericarditis is also observed to be higher with Dose 2 of the vaccine, comprising 64% of the reported cases in the primary vaccination series. While most of the patients were reported to have recovered or are recovering, six of the cases had more serious outcomes such as requiring an implantable pacemaker or had longer term cardiac effects. Such cases remain very rare. It should be noted that COVID-19 infection is also known to be associated with myocarditis. In one study, the extra myocarditis events in the month following vaccination were estimated to be between 1 and 10 per million persons, which is substantially lower than the 40 extra events per million persons observed following COVID-19 infection.¹⁰

22 Several countries have reported an increased incidence of myocarditis with the Moderna/Spikevax vaccine compared to the Pfizer-BioNTech/Comirnaty vaccine following Dose 1 and Dose 2 of the primary vaccination series in the younger population, in particular those aged below 30 years old. This trend is similarly observed locally, where the myocarditis incidence rate for Moderna/Spikevax vaccine following Dose 1 and Dose 2 of the primary series in the 18- to 29-year-old age group is about two times the incidence rate for the Pfizer-BioNTech/Comirnaty vaccine (i.e., 2.71 vs 1.43 per 100,000 doses respectively). As the booster dose of the Moderna/Spikevax vaccine is given at half the dose of the primary series, i.e., at 50 micrograms instead of 100 micrograms, there is no information whether it carries a similar higher risk. However, there has been no local myocarditis reports associated with the booster doses with Moderna/Spikevax vaccine out of 603,355 booster doses administered to date.

23 Aside from mRNA vaccines, myocarditis and pericarditis have also been reported with other vaccines, such as viral vector vaccines (i.e., Janssen/Johnson & Johnson and Oxford/AstraZeneca COVID-19 vaccines) internationally. Locally, one case of myocarditis with Sinovac-Coronavac vaccine has been reported.

⁸ Yilmaz A, Mahrholdt H, Athanasiadis A, et al. Coronary vasospasm as the underlying cause for chest pain in patients with PVB19 myocarditis. *Heart* 2008; 94:1456-63

⁹ Lim Y, Singh D, Loh PH, Poh KK. Multivessel coronary artery spasm in pericarditis. *Singapore Med J*. 2018;59(11):611-613. doi:10.11622/smedj.2018138

¹⁰ Patone, M., Mei, X.W., Handunnetthi, L. *et al.* Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection. *Nat Med* (2021). <https://doi.org/10.1038/s41591-021-01630-0>

Heart attacks and strokes

24 Heart attacks and strokes can occur naturally within our population, regardless of whether people are vaccinated. Due to the large numbers of people being vaccinated, it is expected that, by coincidence, some individuals may experience other medical events such as heart attacks and strokes in the days or weeks after vaccination, which may not be related to the vaccination. We will continue to monitor these events closely and update the public if there are significant findings.

Cerebral venous thrombosis reports

25 There have been rare cases of cerebral venous thrombosis (CVT) reported with the Pfizer-BioNTech/Comirnaty and Moderna/Spikevax vaccines, both overseas and locally. CVT is very rare and involves blood clots occurring in the veins of the brain, which can happen naturally regardless of whether people have been vaccinated. Some of the possible risk factors of CVT include a medical history of blood clotting disorder, head trauma and the use of medicines such as oral contraceptives and hormonal replacement therapies.¹¹ Patients with CVT are generally treated with anticoagulants (blood thinning medicines) for a few months. The yearly background incidence of CVT in the general population is about 1.3 to 2.0 per 100,000 persons. HSA has received 13 suspected reports of CVT with the Pfizer-BioNTech/Comirnaty and Moderna/Spikevax COVID-19 vaccines, where patients presented with progressive persistent headaches, altered consciousness or seizures, or neurological focal signs (symptoms affecting a specific location e.g., weakness in the left arm). All the patients were reported to be recovering upon discharge from hospital or undergoing rehabilitation to be able to resume their daily physical activities at the time of report.

26 HSA's analysis has found a small increase in incidence of CVT with mRNA vaccines from expected baseline incidence locally, which translates to about 1 additional case of CVT per million doses. It is important to note that COVID-19 infections can also lead to CVT. Comparatively, based on local data, the additional number of CVT cases with COVID-19 infection is about 30 per million infected persons. Considering that the risk of CVT after COVID-19 infection is much higher than CVT after mRNA vaccination, the benefits of vaccination continue to outweigh the small increased incidence of CVT. Individuals who experienced persistent headaches, altered consciousness or seizures, or neurological focal signs are advised to seek prompt medical treatment. Patients who are diagnosed early can receive treatment earlier and have a better outcome.

Non-mRNA COVID-19 vaccines

1) Sinovac-CoronaVac Vaccine [authorised under PSAR]

27 As of 31 December 2021, HSA has received 271 AE reports (0.08% of administered doses) following the administration of 332,379 doses of Sinovac-CoronaVac vaccine (Table 3). The commonly reported AEs were rash, hives, angioedema, shortness of breath, chest discomfort and dizziness. Twenty serious AEs (SAEs) were reported (0.006% of administered doses). There were eleven reports of anaphylaxis and all the cases had occurred in individuals who had previous allergic reactions with the mRNA vaccines or had multiple drug allergies. The other 9 serious AE reports include myocarditis, Bell's Palsy, blood clots, numbness, muscle spasms, hypertension, vertigo with tinnitus (ringing of the ears) and serious allergic reaction.

¹¹ Saposnik, Gustavo et al. "Diagnosis and management of cerebral venous thrombosis: a statement for healthcare professionals from the American Heart Association/American Stroke Association." *Stroke* vol. 42,4 (2011): 1158-92. <https://www.ahajournals.org/doi/10.1161/STR.0b013e31820a8364>

Table 3. Overview of vaccination data and no. of suspected AE reports reported by healthcare professionals for Sinovac-CoronaVac Vaccine (as of 31 December 2021)

	Sinovac-CoronaVac COVID-19 Vaccine
No. of persons who have received at least Dose 1	137,443
No. of persons who received two doses	128,269
No. of persons who received three doses	66,667
Total no. of doses administered	332,379
No. of suspected AE reports	271 (0.08% of doses administered)
No. of suspected serious AE reports	20 (0.006% of doses administered)

2) Sinopharm COVID-19 Vaccine (supplied via HSA's Special Access Route)

28 Vaccination for Sinopharm vaccine was rolled out on 30 August 2021. As of 31 December 2021, HSA has received 35 suspected AE reports (0.05% of doses administered) following the administration of 75,440 doses of Sinopharm vaccine. The non-serious AEs include rash, angioedema, shortness of breath, numbness, syncope, chest discomfort and tinnitus. There were four serious AE reports (0.005% of doses administered) of low platelet count, chest pain with visual disturbance, flare of rheumatoid arthritis and relapse of thyroid dysfunction.

29 Overall, the AEs were consistent with those typically observed following vaccination. HSA will continue to monitor the AEs with Sinopharm COVID-19 vaccine.

Conclusion

30 Based on the local AE reports received, most of the AEs are largely expected with vaccination and reflect what has been reported globally. HSA's current assessment is that the benefits of the Pfizer-BioNTech/Comirnaty, Moderna/Spikevax and Sinovac-CoronaVac COVID-19 vaccines continue to outweigh the known risks in a pandemic.

31 HSA and MOH will continue to monitor the safety profile of the COVID-19 vaccines closely, take the necessary regulatory actions and update members of the public of any significant safety concerns detected with the vaccines.

**HEALTH SCIENCES AUTHORITY
SINGAPORE**