## **Myocarditis**

Myocarditis and pericarditis are recognised side effects from mRNA vaccination since June 2021. However, the incidence of these side effects are **rare**. The rates have been reported to be low at 0.4 per 100,000 doses (0.0004%) for the bivalent vaccines and 1.0 per 100,000 doses (0.001%) for the original vaccines as of September 2023<sup>i</sup>. Most of these cases are mild, with patients responding well to treatment. This rare risk is predominantly observed in men aged 12 years to 29 years and largely occurs within the first week after vaccination. Locally, since the recognition of this side effect, MOH has been advising relevant male vaccinees to refrain from participating in strenuous physical activities for one week after their COVID-19 vaccination as a precautionary measure, and seek medical attention immediately if unwell.

It is important to know that the risk of myocarditis/pericarditis occurring is in fact **higher after COVID-19 infection**, as compared to after receiving the vaccine.

## **Excess Deaths**

Contrary to the suggestion that COVID-19 vaccination has led to excess deaths, multiple studies have demonstrated that COVID-19 vaccination **reduces the risk of death** as compared to the unvaccinated during the period of the pandemic, including in countries that predominantly use the mRNA vaccines<sup>ii, iii, iv, v</sup>. In fact, 19.8 million deaths from COVID-19 were prevented globally within the first 12 months that vaccines became available (from December 2020 to December 2021)<sup>vi</sup>.

In Singapore, excess mortality during the COVID-19 pandemic were attributable to deaths occurring in persons with COVID-19 infection or those with a recent COVID-19 infection. Of the COVID-19 deaths, there was an over-representation of persons who were not fully vaccinated, reflecting that they were more likely to die from COVID-19 infection compared to persons who were fully vaccinated<sup>vii</sup>.

S/N Authors cited and views quoted	Background info of author	MOH's response
"His research highlighted a high correlation between the vaccination and an increased incidence of myocarditis, particularly among young individuals. In a comprehensive review, Dr McCullough noted that the risks of myocarditis, particularly among males under 30 appeared to outweigh the benefits of vaccination."	<ul> <li>American cardiologist</li> <li>Involved in the activities of the Association of American Physicians and Surgeons which publishes articles that cast doubts on COVID-19 vaccination risk-benefit and call for suspension of COVID-19 vaccination.</li> <li>Promoted misinformation about COVID-19, its treatments and mRNA vaccines, such as mRNA vaccines caused a wave of severe side effects and called for the vaccines to be banned.</li> <li>Advocated for early treatment using the discredited treatments hydroxychloroquine and ivermectin.</li> <li>There were reports which indicated that in October 2022, the American Board of Internal Medicine recommended that Dr McCullough's board certification be revoked due to his promotion</li> </ul>	MOH does not dispute that myocarditis/pericarditis is a possible serious adverse event post mRNA or Nuvaxovid COVID-19 vaccination. This is a recognised side effect of these vaccines that was picked up by safety monitoring by health regulators.  However, data and experience that have accrued to date confirm that the risk of myocarditis and pericarditis continue to be very rare after vaccination. This rare risk is predominantly observed in men aged 12 to 29 years and largely occurs within the first week after vaccination. Risk of myocarditis and pericarditis occurring after vaccination is less likely than after a COVID-19 infection.  In consultation with the Expert Committee On COVID-19 Vaccination (EC19V), male vaccinees aged 12 to 29 years who are receiving any dose of Moderna/Spikevax, Pfizer-BioNTech/Comirnaty or Novavax/Nuvaxovid COVID-19 vaccines would have been advised to refrain from participating in strenuous physical activities for one week after vaccination.  The benefits of being vaccinated continues to outweigh the risks of doing so, including in men aged 12 to 29 years, and individuals are encouraged to do so based on prevailing recommendations.

S/N	Authors cited and views quoted	Background info of author	MOH's response
		of misinformation about COVID- 19 vaccines.	In addition, we note that Dr McCullough's study on "A Systematic Review of Autopsy Findings in Deaths after COVID-19 Vaccination" was removed by Preprints with the Lancet as "the study's conclusions are not supported by the study methodology". Dr McCullough was the co-author, and the first author – Nicolas Hulscher is a research fellow at the McCullough Foundation started by Dr McCullough.
2	"expressed significant concerns regarding the potential long-term impact of mass vaccination during a pandemic. Dr. Vanden Bossche's studies indicated that widespread vaccination could potentially lead to the evolution of more virulent strains of the virus.	Wrote an open letter to WHO, which claimed that large-scale COVID-19 vaccination would lead to "monster" variants when the virus spreads from older people to those who are younger.	MOH notes that although the PPP did not provide any references for studies done by Dr Bossche, his open letter to WHO in March 2021, and in his book published in 2023, "The Inescapable Immune Escape Pandemic", he discussed that COVID-19 mass vaccination (mRNA vaccines in particular) during the Omicron phase of the pandemic has expedited the selectional adaptive evolution of the virus, as booster doses and growing vaccine coverage rates allowed for more frequent and widespread infections.  We note that viruses naturally mutate as they replicate, and there is no evidence that the mRNA vaccines contribute to this.  The SARS-CoV-2 Delta variant which caused a major COVID-19 wave globally, rapidly emerged even before the introduction of the COVID-19 vaccines. This demonstrates that the virus mutates substantially even without the vaccine.

S/N	Authors cited and views quoted	Background info of author	MOH's response
			The mRNA vaccine generates a protective immune response by our bodies and does not interact directly with the SARS-CoV-2 virus to result in mutations or variants.
3	Dr Robert Malone  "He pointed out potential	American physician and biochemist	We note that Dr Malone did not author any of the quoted articles.
	issues with vaccine safety profiles and called for more transparency and rigorous post-marketing surveillance. Dr. Malone stressed that comprehensive data was needed to fully understand the long-term safety and efficacy of the mRNA vaccines."	• Reported to be spreading falsehoods about vaccines, which have been debunked by US infectious diseases experts, including Prof C. Buddy Creech, former President of the Paediatric Infectious Diseases Society.	Nonetheless, MOH and the Health Sciences Authority (HSA) will continue to monitor local adverse reporting, as well as local and international safety data of COVID-19 vaccines, on an ongoing basis.
4	"analysed data from the Vaccine Adverse Event Reporting System (VAERS) and found a notable increase in reports of	Reported as a postdoctoral researcher (Biochemistry) from the Israel Institute of Technology from 2016 and an independent researcher currently.	The 2021 paper by Dr Rose, "A report on myocarditis adverse events in the U.S. Vaccine Adverse Events Reporting System (VAERS) in association with COVID-19 injectable biological product" has been indicated as "withdrawn at the request of the author(s) and/or editor".
	serious adverse events following the COVID-19 vaccination. Her findings indicated a need for immediate and thorough		MOH does not dispute that myocarditis/pericarditis is a possible serious adverse event post mRNA or Nuvaxovid COVID-19 vaccination. This is a recognised side effect of these vaccines that was picked up by safety monitoring by health regulators.

S/N	Authors cited and views quoted	Background info of author	MOH's response
	investigation into the reports."		
5	"highlighted potential risks associated with COVID-19 vaccines. He has been vocal about the need to reevaluate current vaccination strategies in light of emerging evidence. Dr. Malhotra pointed out that given the increasing reports of adverse events, there was a compelling case for reassessing the risk-benefit profile of these vaccines."	A cardiologist who has been reported to promote messages against mRNA vaccines.	We note that Dr Malhotra did not author any of the quoted articles.  We also note that he is known to be promoting messages against mRNA vaccines.
6	Professor Masanori Fukushima  "expressed concerns about the long-term effects of COVID-19 vaccines. Stressing the importance of transparency and rigorous scientific evaluation, Professor Fukushima remarked that comprehensive and transparent evaluations	<ul> <li>Representative Director of the Learning Health Society Institute and Professor Emeritus at Kyoto University; a senior medical oncologist in Japan. He is not an infectious disease expert.</li> <li>In an interview, he claimed that the vaccine "was from the beginning, based on</li> </ul>	We note that the study quoted "Autoimmune inflammatory reactions triggered by the COVID-19 genetic vaccines in terminally differentiated tissues" is co-authored by Prof Fukushima and Dr McCullough (see S/N 1), which "aims to draw attention to the critical need for biodistribution studies" for mRNA COVID-19 vaccines.  Biodistribution data based on animal studies was assessed for mRNA vaccines and the approval of the vaccines was based on totality of evidence supporting the vaccines' efficacy, safety and quality.

S/N	Authors cited and views quoted	Background info of author	MOH's response
	should be prioritised to ensure public trust and safety in vaccination programmes."	misconception, misconduct, and evil practices of science"	
7	"also raised concerns about the COVID-19 vaccines. He echoed that the potential for adverse effects, particularly with respect to immune responses, warranted a re-evaluation of the current vaccination strategies."	Professor of Oncology at St George's, University of London.	We note that Prof Dalgleish did not author any of the quoted articles.
8	"expressed apprehension regarding the long-term impact of the COVID-19 vaccines on immune system function. Professor Clancy said that there were unresolved questions about the long-term effects of these vaccines on immune memory and response, which needed to be addressed	<ul> <li>Retired Australian clinical immunologist in the field of mucosal immunology. Known for his research in Chronic Obstructive Pulmonary Disease.</li> <li>Reported to be in support of unverified info about claimed benefits of the drugs hydroxychloroquine and ivermectin during the pandemic.</li> </ul>	We note that Prof Clancy did not author any of the quoted articles.

S/N	Authors cited and views quoted	Background info of author	MOH's response
	continuing mass vaccination programmes."		
9	Increased risk of fetal loss after COVID-19 vaccination.  Human Reproduction, 38(12), 2536-2536  Thorp, J.A., Rogers et al. (2023).	<ul> <li>James A. Thorp is the Chief of Maternal and Pre-Natal Health, The Wellness Company</li> <li>He was reported to be a gynaecologist in Florida.</li> <li>Dr McCullough is a coauthor (see S/N 1).</li> </ul>	We note that this is a letter to the Editors of the <i>Human Reproduction</i> journal, on the fact that a separate systematic review by Rimmer et al. (2023) had omitted their manuscript which reported significant harms to pregnant women and infants from COVID-19 vaccination. This manuscript was published in the Journal of the American Physicians and Surgeons, which is the official journal of the Association of American Physicians and Surgeons (AAPS). AAPS is known to publish articles that cast doubts on COVID-19 vaccination risk-benefit and call for suspension of COVID-19 vaccination.  We note that the Rimmer team responded to point out that this said manuscript was based on a simulation model that was constructed using data from the Vaccine Adverse Events Reporting System (VAERS) database that compares adverse events between COVID-19 and influenza vaccines as opposed to true incidence.  The Rimmer team also said, "Should the authors provide robust factual data on the true incidence

S/N	Authors cited and views quoted	Background info of author	MOH's response
			of miscarriage following the use of COVID-19 vaccines, we would be more than happy to update our meta-analysis accordingly."
10	Research Paper:  Determinants of COVID-19	<ul> <li>Dr Jessica Rose,</li> <li>Independent Researcher (see S/N 4).</li> </ul>	We note an expression of concern has been issued for this article and investigations are underway. Nonetheless, myocarditis is a known side-effect and
	vaccine-induced myocarditis.	Dr McCullough is a co- author (see S/N 1).	necessary precautions have been instituted when it was first reported in 2021, ahead of this article in 2024.
	Therapeutic Advances in Drug Safety, 15, 20420986241226566		
	Rose. J, et al.		
11	News Article:	Apoorva Mandavilli is a Science and Global Health	We note that the article did not question the safety, effectiveness and risk-benefit of COVID-19
	Thousands believe COVID-vaccines harmed them. Is anyone listening?	reporter at The New York Times.	vaccination, nor ask for suspension of COVID-19 vaccination.
	The New York Times, 3 May 2024		

- Liu, B., Stepien, S., Dobbins, T., Gidding, H., Henry, D., Korda, R., Mills, L., Pearson, S.-A., Pratt, N., Vajdic, C. M., Welsh, J., & Macartney, K. (2023). Effectiveness of COVID-19 vaccination against COVID-19 specific and all-cause mortality in older Australians: a population based study. The Lancet Regional Health Western Pacific, 40, 100928. <a href="https://doi.org/10.1016/j.lanwpc.2023.100928">https://doi.org/10.1016/j.lanwpc.2023.100928</a> Pipers, Werkhoven, Van, Caroline, Susan J.M. Hahné, Hester, Knol, M., & Susan. (2023). Effect of COVID-19 vaccination on mortality by COVID-19 and on mortality by other causes, the Netherlands, January 2021- January 2022. Vaccine. <a href="https://doi.org/10.1016/j.vaccine.2023.06.005">https://doi.org/10.1016/j.vaccine.2023.06.005</a>
- <sup>v</sup> Nordström, P., Ballin, M., & Nordström, A. (2022). Effectiveness of a fourth dose of mRNA COVID-19 vaccine against all-cause mortality in long-term care facility residents and in the oldest old: A nationwide, retrospective cohort study in Sweden. The Lancet Regional Health Europe, 0(0). <a href="https://doi.org/10.1016/j.lanepe.2022.100466">https://doi.org/10.1016/j.lanepe.2022.100466</a>
- vi Watson, O. J., Barnsley, G., Toor, J., Hogan, A. B., Winskill, P., & Ghani, A. C. (2022). Global impact of the first year of COVID-19 vaccination: a mathematical modelling study. *The Lancet Infectious Diseases*, 22(9), 1293–1302. https://doi.org/10.1016/s1473-3099(22)00320-6
- vii Ministry of Health, Singapore. (2022). Report on excess mortality during the COVID-19 pandemic up to June 2022. <a href="https://www.moh.gov.sg/resources-statistics/reports/report-on-excess-mortality-during-the-covid-19-pandemic-up-to-june-2022">https://www.moh.gov.sg/resources-statistics/reports/report-on-excess-mortality-during-the-covid-19-pandemic-up-to-june-2022</a>

<sup>&</sup>lt;sup>i</sup> News highlights. (2023, October 28). Ministry of Health. <a href="https://www.moh.gov.sg/news-highlights/details/rollout-of-updated-covid-19-monovalent-vaccines">https://www.moh.gov.sg/news-highlights/details/rollout-of-updated-covid-19-monovalent-vaccines</a>

<sup>&</sup>lt;sup>ii</sup> Ylli, A., Burazeri, G., Wu, Y. Y., & Sentell, T. (2022). COVID-19 excess deaths in Eastern European countries associated with weaker regulation implementation and lower vaccination coverage. *Eastern Mediterranean Health Journal*, 28(10), 776–780. https://doi.org/10.26719/emhj.22.074