



## **Press Release**

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### **Risk of myocarditis in adolescents significantly reduced after receiving only one dose of Comirnaty, HKUMed finds; adolescents urged to get first dose of COVID-19 vaccine**

Researchers at the Departments of Paediatrics and Adolescent Medicine, Pharmacology and Pharmacy, and Medicine, LKS Faculty of Medicine of The University of Hong Kong (HKUMed) have studied the reported myocarditis and pericarditis cases following the use of COVID-19 vaccines (Comirnaty and CoronaVac) in Hong Kong, and found preliminary evidence of an interventional success with the recommended single-dose regimen of Comirnaty underlain by a seven-fold risk difference between the first and second doses. In view of the potential threat of the Omicron variant, adolescents aged 12 or above are recommended to receive their first dose of COVID-19 vaccine as soon as possible.

#### **Background**

In mid-July 2021, a cluster of adolescents developed acute myocarditis and pericarditis after receiving the Comirnaty vaccine in Hong Kong. A working group consisted of experts of paediatric infectious diseases, paediatric immunology, paediatric cardiology, pharmacology and microbiology was formed to formulate a standardised clinical investigation protocol for the workup and follow-up of these cases. This protocol, which consisted of microbiological, radiological and immunological investigations, has been approved by the Hospital Authority Paediatric Coordinating Committee and was adopted in all Hospital Authority Paediatric Units on cases with suspected myocarditis and pericarditis following the COVID-19 vaccine.

#### **Research methods and findings**

The research team at HKUMed have recently conducted three population-based research studies which are accepted for publication or published in international medical journals, including *Clinical Infectious Diseases* and *Annals of Internal Medicine*. The three studies used data acquired under the COVID-19 vaccine Adverse Event Response and Evaluation Programme (CARE), which is an active surveillance system, to evaluate adverse events following immunisation (AEFI) data from the general population using electronic medical records from Hospital Authority and vaccination records from the Department of Health (DH) of the Government of the Hong Kong Special Administrative Region.

The first study, currently in press with an impactful international journal, is a population-based cohort study comparing the incidence of myocarditis in adolescents aged 12-17 years before and after the recommended single-dose regimen of Comirnaty starting from 16 September 2021.

Up till 18 October 2021, 43 out of 224,560 vaccinated adolescents had myocarditis-related hospitalisation following Comirnaty vaccination, 36 of them occurred after the second dose (22.15 per 100,000 persons), while the rest after the first dose (3.12 per 100,000 persons). The estimated relative risk following the second dose, if taken three weeks after the first dose, is 7.11 times as high as first dose. There were 40,167 adolescents whose second doses were deterred following the announcement of the single-dose recommendation, and it was estimated that approximately nine myocarditis cases were prevented.



The second study published in *Clinical Infectious Diseases* (<https://doi.org/10.1093/cid/ciab989>)<sup>1</sup>, is a population cohort study in Hong Kong that monitored adverse events following immunisation through the CARE Programme. Between 14 June and 4 September 2021, 305,406 doses of Comirnaty vaccine were administered to 178,163 individuals aged 12-17 years (88,357 [49.59%] are female). A total of 33 adolescents developed acute myocarditis/pericarditis following Comirnaty vaccination. Of them, 29 (87.88%) were males and 4 (12.12%) were females, with a median age of 15.25 years. Most of them (27 cases, 81.82%) developed acute myocarditis/pericarditis after receiving the second dose, while only six did after the first dose. These patients developed myocarditis/pericarditis at a median of two days after receiving the last dose of the vaccine. All patients had mild diseases requiring no treatment or symptomatic relief by non-steroidal anti-inflammatory drugs (NSAIDs). They spontaneously recovered without the need of systemic steroids, intravenous immunoglobulins, inotropic or circulatory support.

“These studies demonstrate that the COVID-19 vaccine monitoring system in Hong Kong operated by a multidisciplinary team of healthcare professionals is comprehensive and robust to detect rare adverse events after vaccination. The vaccination policy in Hong Kong has timely response to the latest scientific evidence. The medical care provided to patients with myocarditis/pericarditis by the Hospital Authority is timely and effective, resulting in a good prognosis of all admitted patients”, remarked Prof. Ian Chi Kei Wong, HKUMed.

The third study published in *Annals of Internal Medicine*<sup>2</sup> (<https://doi.org/10.7326/M21-3700>) is a case-control study targeting both adolescents and adults aged 12 or above in Hong Kong using a territory-wide de-identified electronic healthcare database provided by the Hospital Authority with linkage to anonymised population-based vaccination records provided by the Department of Health.

Up to 2 August 2021, 2,291,444 doses of CoronaVac and 3,496,629 doses of Comirnaty were administered in Hong Kong and 160 cases of myocarditis/pericarditis were identified according to our operational definition. We estimated the incidence of myocarditis/pericarditis per 100,000 doses of CoronaVac and Comirnaty administered to be 0.31 and 0.57 respectively. Compared with hospital controls, it was found that Comirnaty recipients had about three-fold higher risks of myocarditis/pericarditis (adjusted odds ratio (OR)=3.57) than unvaccinated individuals. The risk was mainly observed following the second dose of Comirnaty rather than the first. No statistically significant association of CoronaVac with myocarditis/pericarditis was observed.

“Even if adolescents receive the second dose, preliminary data from other countries have shown that the longer the dosing interval, the lower the risk of carditis” said Dr Patrick Ip, HKUMed. Meanwhile Dr Mike Kwan of HKUMed said: “Based on the findings, adolescents are strongly recommended to receive the first dose of COVID-19 vaccine as soon as possible, in bid to ward off the fifth wave of COVID-19 in Hong Kong”.

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<sup>1</sup> Chua GT, Kwan MYW, Chui CSL, Smith RD, Cheung ECL, Tian T, et al. Epidemiology of Acute Myocarditis/Pericarditis in Hong Kong Adolescents Following Comirnaty Vaccination. *Clinical Infectious Diseases*. 2021.

<sup>2</sup> Tsun Lai FT, Li X, Peng K, Huang L, Ip P, Tong X, et al. Carditis After COVID-19 Vaccination With a Messenger RNA Vaccine and an Inactivated Virus Vaccine: A Case-Control Study. *Ann Intern Med*. 2022.



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### **About the research team**

The research team includes Department of Paediatrics and Adolescent Medicine, HKUMed; Department of Medicine, HKUMed; Department of Pharmacology and Pharmacy, HKUMed; Department of Pathology, HKUMed; Department of Microbiology, HKUMed and Department of Paediatrics from Hospital Authority.

### **Speakers:**

Dr Patrick Ip, Clinical Associate Professor, Department of Paediatrics and Adolescent Medicine, HKUMed;

Dr Mike Kwan Yat-wah, Honorary Clinical Associate Professor, Department of Paediatrics and Adolescent Medicine, HKUMed, Consultant, Department of Paediatrics and Adolescent Medicine, Princess Margaret Hospital;

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