

School of Clinical Medicine Department of Family Medicine vied & Primary Care 香港大學家庭醫學及基層醫療學系













BIG-DATA PHARMACOVIGILANCE OF COVID-19 VACCINES SHAPES PUBLIC HEALTH POLICIES

以大數據對新冠疫苗效用及安全性的監察幫 助制訂公共衞生政策

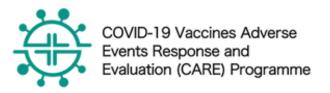


Prof Esther Chan Dr Celine Chui Dr Francisco Lai Dr Shirley Li Dr Eric Wan Dr Carlos Wong Prof Ian Wong



COVID-19 Vaccines Adverse Events Response and Evaluation (CARE) Programme





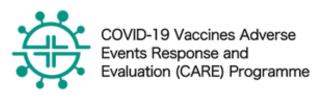
Summary of impact

- Science:
 - Linked up population-based records to identify potential adverse events after COVID-19 vaccination
 - Among the first teams in the world to analyze Bell's palsy and carditis following vaccination
- Impact on patients and practice:
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Impacts to Hong Kong

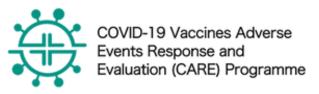
- Policy impact-Fulfillment of CAP 599K: Our team monitors adverse events of COVID-19 vaccines on behalf of Drug Office of the DH so that DH can comply with CAP599K Part 3:7(3)
- Research impact-Established model for pharmacovigilance:
 - Territory-wide public healthcare database (Hospital Authority) linked with populationbased vaccination records and COVID infection records. (Department of Health) No precedent case, history was made.





The CARE Programme is a comprehensive surveillance programme implemented under The University of Hong Kong Department of Pharmacology & Pharmacy Team that closely monitors known and potential adverse events of COVID-19 vaccines. It aims to ascertain details of adverse events and inform the public in a timely manner.





Underpinning Research (1) Bell's palsy following CoronaVac

- Nested case-control study
- 298 cases of Bell's palsy were matched to 1,181 controls, and the adjusted odd ratio (OR) was <u>2.4 (95% CI:1.4-4.0) for</u> <u>CoronaVac</u>
- The Lancet Infectious Diseases (Impact Factor = 71) <u>https://doi.org/10.1016/S1473-3099(21)00451-5</u>

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World-wide press-release by Lancet Press Centre



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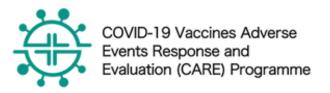
The Lancet Infectious Diseases: Benefits of COVID-19 vaccines far outweigh very rare risk of Bell's palsy, study confirms

 Study is the first large-scale population analysis of the risk of Bell's palsy following vaccination with CoronaVac (Sinovac Biotech vaccine, an inactivated vaccine) or BNT162b2 (Fosun-BioNTech, equivalent to Pfizer-BioNTech vaccine, an mRNA From: https://www.COVIDvaccine.gov.hk/pdf/CO VID19VaccinationFactSheet_CoronaVac_E NG.pdf

4 Possible side effects¹

| | Side effects | may affect | | | |
|-------------|--|------------------------|--|--|--|
| Very common | injection site: painheadachefatigue | ≥ 10% people | | | |
| Common | injection site swelling, pruritus, erythema, induration myalgia nausea diarrhea arthralgia cough chills pruritus loss of appetite rhinorrhea sore throat nasal congestion abdominal pain | 1% -10% people | | | |
| Uncommon | burn at injection site vomit hypersensitivity abnormal skin and mucosa fever tremor flushing edema dizziness drowsiness | 0.1% -1% people | | | |
| Rare | Rare• muscle spasms • eyelid edema • nosebleeds • abdominal distension • constipation• ocular congestion • hot flashes • hiccup • conjunctival congestion | | | | |
| Very rare | Bell's palsy[#] [#]Observed post-authorisation in Hong Kong | <0.01% people | | | |
| Serious | Serious • No serious adverse event related to vaccination was identified up to 3 February 2021. | | | | |

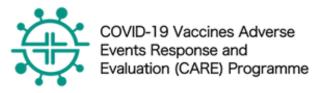




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Underpinning Research (2) Elevated risk of carditis following BNT162b2

- Territory-wide case—control study
- BNT162b2 recipients had higher odds of carditis (adjusted OR, 3.57 [CI, 1.93 to 6.60])
 - Male: OR 4.68 (CI, 2.25 to 9.71)
 - Female: OR 2.22 (CI, 0.57 to 8.69)
 - Adults OR 2.41 (CI, 1.18 to 4.90)
 - Adolescents OR 13.79 (CI, 2.86 to 110.38)
- Risk mainly seen after the 2nd dose
- Annals of Internal Medicine (Impact Factor = 51) https://doi.org/10.7326/M21-3700

Annals of Internal Medicine

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Original Research | 25 January 2022

Carditis After COVID-19 Vaccination With a Messenger RNA Vaccine and an Inactivated Virus Vaccine 🚥

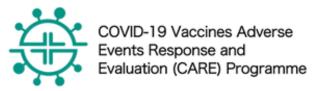
A Case-Control Study

Francisco Tiz Toun Lai, PhD* 😳, Xue Li, PhD* 😳, Kuan Peng, MHS, Lei Huang, MSc, Patrick Ip, MPH, Xinning Tong, PhD, Celine Sze Ling Chui, PhD 🤤

Eric Yuk Fai Wan, PhD 🥥, Carlos King Ho Wong, PhD 🔕, Eitther Wai Yin Chan, PhD 🥝, David Chung Wah Siu, MD 🤤, Ian Chi Kei Wong, PhD 🚭 Wey authors 🗙 Author, Article and Discloture Information

https://doi.org/10.7326/M21-3700 Eligible for CME Point-of-Care



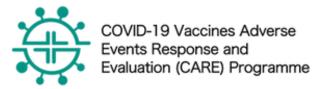


Underpinning Research (2) Overall safety of and risk of myocarditis following BNT162b2 in adolescents

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| Full Article Figures & data # References O Supplemental # Citations M Metrics O Lice | Francisco Tsz Tsun Lai, Min Fan, Caige Huang, Celine Sze Li | ng Chui Frie Yuk Fai Wan, Yua Li, Carlos King Ha | | |
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Government adjusts COVID-19 vaccination requirem ¥

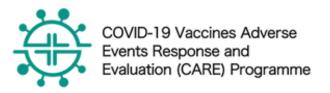




Government adjusts COVID-19 vaccination requirement under social distancing measures according to expert advice

The Government announced today (September 30) that in accordance with the advice of the Advisory Panel on COVID-19 Vaccines, from today onwards, persons aged 12 to 17 who have received one dose of Fosun Pharma/BioNTech COVID-19 vaccine (Comirnaty vaccine) at least 14 days ago are deemed to have complied with the requirement of completing the COVID-19 vaccination course under the Prevention and Control of Disease (Requirements and Directions) (Business and Premises) Regulation (Cap. 599F).

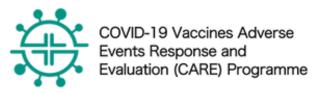




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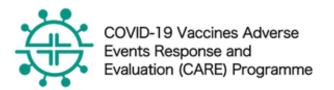


Effective engagement: Regulatory Authority and general public

- Direct Reports to DH for action
 - relevant public health policies and clinical recommendations
- Press Conferences
 - Sending reassurance to the public
 - Provide the best possible information to inform vaccine uptake
- Training course for DH staff
 - Offer training for public health policy makers



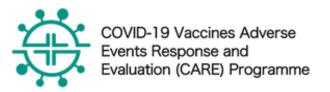




Long lasting impact on pharmacovigilance in Hong Kong

- Based on the success of CARE programme, our HKUMed team have demonstrated the untapped power of HA and DH databases.
 - It broke down the previous invisible barrier of data linkage.
- Drug office of DH is currently developing a new system in pharmacovigilance based on CARE programme and will continue to work with our team to create the next generation pharmacovigilance system.

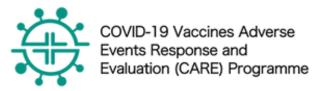




Knowledge to be Exchanged

- Identifying rare adverse events following COVID-19 vaccines which would otherwise be infeasible to detect
- Establishing a comprehensive safety profile of COVID-19 vaccines
- Developing data-linkage mechanisms for future pharmacovigilance purposes
- Innovating and refining pharmacoepidemiologic methods in vaccine safety monitoring





Thank you

