

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
助制訂公共衛生政策

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





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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 population-based vaccination records and COVID infection records. (Department of Health) No precedent case, history was made.





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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 2.4 (95% CI:1.4-4.0) for CoronaVac
- The Lancet Infectious Diseases (Impact Factor = 71) [https://doi.org/10.1016/S1473-3099\(21\)00451-5](https://doi.org/10.1016/S1473-3099(21)00451-5)

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Bell's palsy following vaccination with mRNA (BNT162b2) and inactivated (CoronaVac) SARS-CoV-2 vaccines: a case series and nested case-control study

Eric Yuk Fai Wan, PhD¹ · Online See Ling Chai, PhD¹ · Francisco Tai Tsun Lai, PhD¹ · Esther Hui Yu Chan, PhD¹ · Sue Li, PhD¹ · Vincent Ka Chun Yau, BPharm¹ · et al. · Show all authors · Show footnotes

Published: August 16, 2021 · DOI: [https://doi.org/10.1016/S1473-3099\(21\)00451-5](https://doi.org/10.1016/S1473-3099(21)00451-5) · Check for updates · PlanX Metrics

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Summary | Introduction | Methods | Summary | Background

World-wide press-release by Lancet Press Centre

THE LANCET Infectious Diseases

Embargo: 23.30 [UK time] Monday 16th August 2021 Please add pressoffice@lancet.com to your safe senders list to ensure that you always receive *The Lancet* press releases.

****Embargo: 23.30 [UK time] Monday 16th August 2021****

Peer-reviewed / Observational / People

***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***

4 Possible side effects¹

From:
https://www.COVIDvaccine.gov.hk/pdf/COVID19VaccinationFactSheet_CoronaVac_ENG.pdf

	Side effects	may affect
Very common	<ul style="list-style-type: none"> • injection site: pain • headache • fatigue 	≥ 10% people
Common	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • burn at injection site • vomit • hypersensitivity • abnormal skin and mucosa • fever • tremor • flushing • edema • dizziness • drowsiness 	0.1% - 1% people
Rare	<ul style="list-style-type: none"> • muscle spasms • eyelid edema • nosebleeds • abdominal distension • constipation • hyposmia • ocular congestion • hot flashes • hiccup • conjunctival congestion 	0.01% - 0.1% people
Very rare	<ul style="list-style-type: none"> • Bell's palsy* *Observed post-authorisation in Hong Kong 	<0.01% people
Serious	<ul style="list-style-type: none"> • 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>





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

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Research Article

Adverse Events of Special Interest Following COVID-19 Vaccination in Adolescents: A Population-Based Retrospective Cohort Study

Francisco Tsz Tsun Lai PhD, Gilbert T Chua MBBS, Edward Wai Wa Chan MPH, Lei Huang MSc, Tiantian Ma PhD, ...show all

Accepted author version posted online: 07 Mar 2022

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Article | Open Access | Published: 03 April 2023

Effectiveness of BNT162b2 after extending the primary series dosing interval in children and adolescents aged 5–17

Francisco Tsz Tsun Lai, Min Fan, Caige Huang, Celine Sze Ling Chui, Eric Yuk Fai Wan, Xue Li, Carlos King Ho Wong, Ching-Lung Cheung, Ian Chi Kei Wong & Esther Wai Yin Chan

Nature Communications 14, Article number: 1845 (2023) | [Cite this article](#)

1523 Accesses | 23 Altmetric | [Metrics](#)

mRNA COVID-19 Vaccination Compared With Inactivated Virus Vaccines

Lung Cheung, Celine Sze Ling Chui, Xue Li, Eric Yuk Fai Wan, in Chi Kei Wong

Healthcare Insurance in an Era of Dynamic Uncertainty



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The Government of the Hong Kong Special Administrative Region Press Releases

GovHK 香港政府一站通

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简体版

Government adjusts COVID-19 vaccination requirem ▾

GO



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





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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.



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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



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Thank you

