THE LANCET
Infectious Diseases

Supplementary appendix 2

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplementary Appendix

Supplementary Table 1. Vaccination program priority groups rollout schedule in Hong Kong

Order of expansion	Date of rollout	Vaccination group
First [1]	26 Feb, 2021	• Healthcare workers and staff involved in anti-epidemic work • Persons aged 60 or above and a maximum of 2 carers accompanying elderly people aged above 70 • Residents and staff of residential care homes for the elderly and persons with disabilities • People providing essential public services • People providing cross-boundary transportation or working at control points and ports
Second [2]	8 Mar, 2021	• Staff of food and beverages premises, markets, supermarkets, convenience stores, couriers and takeaway delivery • Staff of local public transport service operators • Registered construction workers • Staff of property management • Teachers and school staff • Staff in the tourism industry • Staff of scheduled premises under the Prevention and Control of Disease
Third [3]	16 Mar, 2021	• People aged between 30 and 59 • Students aged 16 or above studying outside Hong Kong • Domestic helpers
Four [4]	15 Apr, 2021	• People aged 16 to 29 (18 for person receiving Sinovac vaccine)

References:
1. The Government of the Hong Kong Special Administrative Region. Government announces 2019 COVID-19 Vaccination Programme. Press Releases. 18 Feb 2021 (https://www.info.gov.hk/gia/general/202102/18/P2021021800767.htm?fontSize=1)
2. The Government of the Hong Kong Special Administrative Region. Government expands scope of priority groups and opens more CVCs. Press Releases. 8 Mar 2021 (https://www.info.gov.hk/gia/general/202102/18/P2021021800767.htm?fontSize=1)
3. The Government of the Hong Kong Special Administrative Region. Vaccination priority groups to be expanded to cover people aged 30 or above. Press Releases. 15 Mar 2021 (https://www.info.gov.hk/gia/general/202103/15/P2021031500626.htm?fontSize=1)
4. The Government of the Hong Kong Special Administrative Region. COVID-19 Vaccination Programme opens to persons aged 16 or above. Press Releases. 15 Apr 2021 (https://www.info.gov.hk/gia/general/202104/15/P2021041500565.htm?fontSize=1)

Supplementary Table 2. Characteristics of the reported cases of Bell's palsy to the Department of Health

Case No.	Sex	Age	COVID-19 Vaccine Dose Received	Interval to symptom onset	Side affected	Clinical outcomes (As of 31 May 2021)	Causality assessment (For clinically confirmed Bell's palsy case)†
Clinically confirmed cases after CoronaVac vaccination							
S1	M	69	First	2 hours	Left	Fully recovered with treatment.	B2
S2	M	72	First	6 days	Right	Almost fully recovered with treatment.	B1
S3	M	86	First	13 days	Left	Good recovery with treatment. Mild left angle of mouth weakness at last follow-up on 13 Apr 2021 (28 days after symptom onset.)	B1
S4	M	52	First	16 days	Left	Almost fully recovered with treatment.	B1
S5	M	54	First	8 days	Left	Good recovery with treatment. Slight residual palsy on left corner of mouth at last follow-up on 9 Apr 2021 (24 days after symptom onset).	B1
S6	M	74	First	6 days	Left	Lost to follow up.	B1
S7	M	58	First	17 days	Left	No follow up was scheduled.	B1
S8	M	79	First	14 days	Left	Follow up was scheduled and pending assessment.	B2
S9	M	76	First	14 days	Left	Fully recovered with treatment	B1
S10	M	26	First	1 hour	Left	Almost fully recovered with treatment. Minimal drooping of left angle of mouth at last follow up on 6 May 2021 (43 days after symptom onset).	B2

S11	M	67	Second	3 days	Right	Good recovery with treatment. Facial weakness improved at last follow-up on 5 May 2021 (37 days after symptom onset).	B1
S12	M	48	First	2 days	Left	Lost to follow up.	B1
S13	F	36	Second	3 days	Right	Almost fully recovered without treatment.	D
S14	F	38	First	3 days	Left	Good recovery with treatment. Complete eyelid closure with mild decreased left face movement at last follow-up on 20 May 2021 (51 days after symptom onset).	B1
S15	M	63	Second	1 day	Left	Good recovery with treatment. Facial asymmetry improved at last follow-up on 7 May 2021 (32 days after symptom onset).	B1
S16	F	31	First	19 days	Left	Good recovery with treatment. Complete eyelid closure at last follow-up on 6 May 2021 (29 days after symptom onset).	B1
S17	F	66	Second	2 days	Right	Follow up was scheduled and pending assessment.	B1
S18	F	64	First	1-2 weeks	Left	Good recovery with treatment. Facial asymmetry improved at last follow-up on 4 May 2021 (40-47 days after symptom onset).	B1
S19	M	35	Second	1 day	Right	Good recovery with treatment. Facial weakness improved with complete eyelid closure at last follow-up on 26 Apr 2021 (16 days after symptom onset).	B1
S20	M	44	First	16 days	Right	Good recovery with treatment. Functions of right facial nerve improved at last follow-up on 10 May 2021 (30 days after symptom onset).	B1
S21	F	50	First	17 days	Left	Good recovery with treatment. Facial weakness improved at last follow-up on 28 May 2021 (48 days after symptom onset).	B1
S22	M	35	Second	13 days	Left	Similar left facial weakness at last follow-up on 18 May 2021 (33 days after symptom onset).	B1

S23	F	52	First	26 days	Left	Lost to follow up.	B1
S24	M	59	Second	< 1 day	Left	Fair recovery with treatment. Symptoms slightly improved at last follow up on 5 May 2021 (9 days after symptom onset).	B1
S25	F	57	Second	16 days	Left	Follow up was scheduled on 20 May 2021 and pending follow up information on clinical progress.	B1
S26	M	71	Second	17 days	Left	Follow up was scheduled on 31 May 2021 and pending follow up information on clinical progress.	B1
S27	M	32	First	21 days	Right	Fully recovered with treatment.	B1
S28	F	87	First	42 days	Left	Follow up was scheduled and pending assessment.	B1
Excluded cases after CoronaVac vaccination							
S29	M	57	First	1 day	Left	Attending physician reviewed the case and revised the diagnosis to Ramsay Hunt Syndrome.	
S30	M	55	First	2 days	Not Applicable	Attending physician reviewed the case and considered not Bell's palsy. The case discharged against medical advice and no specific diagnosis was concluded.	
S31	M	56	Second	2 hours	Left	Attending physician reviewed the case and considered not Bell's palsy.	
S32	F	40	First	3 days	Left	Attending physician reviewed the case and revised the diagnosis to rhinitis.	
S33	M	69	Second	28 days	Right	Attending physician reviewed the case and revised the diagnosis to Ramsay Hunt Syndrome.	
Clinically confirmed cases after Comirnaty vaccination							
B1	M	37	First	6 days	Right	Good recovery with treatment. Complete eyelid closure at last follow-up on 20 Apr 2021 (32 days after symptom onset).	B2

B2	F	48	First	18 days	Left	Lost to follow up.	B1
B3	M	58	Second	1 day	Left	Good recovery with treatment. Complete eyelid closure at last follow-up on 14 May 2021 (37 days after symptom onset).	B1
B4	M	46	Second	3 days	Left	Good recovery with treatment. Facial weakness much improved at last follow-up on 5 May 2021 (26 days after symptom onset).	B1
B5	F	65	First	20 days	Right	Good recovery with treatment. Facial weakness much improved at last follow-up on 10 May 2021 (30 days after symptom onset).	B1
B6	F	50	Second	1 day	Left	Almost fully recovered with treatment.	B1
B7	M	33	First	4 days	Left	Lost to follow up	D
B8	M	69	Second	12 days	Left	Good recovery with treatment. Complete eyelid closure at last follow-up on 28 Apr 2021 (8 days after symptom onset).	B1
B9	M	52	Second	14 days	Right	Good recovery with treatment. Lower face asymmetry resolved and only minimal different in forehead wrinkles noted at last follow-up on 20 May 2021 (27 days after symptom onset).	B1
B10	F	46	First	16 days	Right	Good recovery with treatment. Facial weakness improved at last follow-up on 26 Apr 2021 (4 days after symptom onset).	B1
B11	M	54	First	18 days	Right	Good recovery with treatment. Facial weakness improved, complete eyelid closure, forehead wrinkle reappeared at last follow-up on 6 May 2021 (8 days after symptom onset).	B1
B12	M	47	Second	18 days	Right	Lost to follow-up	B1
B13	F	20	Second	17 days	Left	Follow up was scheduled on 13 May 2021 and pending follow up information on clinical progress.	B1
B14	F	42	First	17 days	Right	Lost to follow up.	B1

B15	M	78	First	2 days	Right	Good recovery with treatment. Facial weakness improved at last follow-up on 27 May 2021 (26 days after symptom onset).	B1
B16	M	41	Second	13 days	Left	Fair recovery with treatment. Facial asymmetry improved as reported by the case at last follow-up on 7 May 2021 (13 days after symptom onset).	B1
Excluded cases after Comirnaty vaccination							
B17	M	58	First	1 day	Left	Attending physician reviewed the case and considered not Bell's palsy.	
B18	M	72	First	3 days	Right	Attending physician reviewed the case and revised the diagnosis to ischemic stroke.	
B19	M	71	First	2 days	Right	Attending physician reviewed the case and revised the diagnosis to Ramsay Hunt Syndrome.	
B20	F	71	Second	8 days	Right	Attending physician reviewed the case and revised the diagnosis to Ramsay Hunt Syndrome.	

† WHO classification:

A. Consistent causal association to immunization

• A1. Vaccine product-related reaction; or

• A2. Vaccine quality defect-related reaction; or

• A3. Immunization error-related reaction; or

• A4. Immunization anxiety-related reaction/Immunization stress related response (ISRR).

B. Indeterminate

• B1. Temporal relationship is consistent but there is insufficient definitive evidence that

vaccine caused the event (it may be a new vaccine-linked event). This is a potential

signal and needs to be considered for further investigation.

• B2. Reviewing factors result in conflicting trends of consistency and inconsistency with causal association to immunization (i.e. it may be vaccine-associated as well as coincidental and it is not possible clearly to favour one or the other).

C. Inconsistent causal association to immunization (coincidental). This could be due to underlying or emerging condition(s) or conditions caused by exposure to something other than vaccine. Events which could have occurred naturally are generally assigned this classification.

D. Case without adequate information for causality conclusion.

Supplementary Table 3. Standardized rate ratios of reported and clinically confirmed Bell's palsy cases following vaccination with CoronaVac and Comirnaty by sex, with reference to 2019

	Age-standardised background incidence rate in 2019* per 100,000 person-years (95% CI)	Age-standardised incidence per 100,000 person-years (95% CI)		Standardised incidence difference per 100,000 person-years (95% CI)		Standardised rate ratio (95% CI)	
		Reported	Clinically confirmed	Reported	Clinically confirmed	Reported	Clinically confirmed
CoronaVac							
Total	27.7 (24.8-30.7)	75.3 (44.7-105.9)	66.9 (37.2- 96.6)	47.6 (16.8- 78.3)	39.2 (9.3-69.0)	2.72 (1.78-4.14)	2.41 (1.53-3.81)
Male	30.3 (25.6-34.9)	88.7 (45.7-131.6)	77.6 (36.1-119.2)	58.4 (15.2-101.6)	47.4 (5.6-89.2)	2.93 (1.76-4.87)	2.57 (1.47-4.48)
Female	25.7 (21.9-29.6)	55.9 (15.1- 96.6)	51.9 (11.9- 91.9)	30.1 (-10.8- 71.0)	26.2 (-14.0-66.3)	2.17 (1.03-4.56)	2.02 (0.92-4.42)
Comirnaty							
Total	26.2 (23.1-29.3)	57.8 (30.1- 85.5)	42.8 (19.4- 66.1)	31.6 (3.7- 59.5)	16.6 (-7.0-40.2)	2.21 (1.35-3.62)	1.63 (0.93-2.86)
Male	28.5 (23.7-33.4)	65.5 (26.9-104.2)	46.1 (14.6- 77.5)	37.0 (-1.9- 76.0)	17.5 (-14.3-49.4)	2.30 (1.24-4.24)	1.61 (0.80-3.26)
Female	24.3 (20.3-28.4)	46.1 (8.7- 83.5)	36.4 (4.2- 68.7)	21.7 (-15.9- 59.4)	12.1 (-20.4-44.6)	1.89 (0.83-4.33)	1.50 (0.61-3.68)

*The background incidence rates were calculated using the same reporting period in 2019 as for each vaccination programme in 2021 (for CoronaVac, February 23, 2021-May 4, 2021; For Comirnaty, March 6, 2021-May 4, 2021).

Supplementary Table 4. Standardised rate ratios of reported and clinically confirmed Bell's palsy cases following vaccination with CoronaVac and Comirnaty by sex, with reference to 2018

	Age-standardised background incidence rate in 2018 per 100,000 person-years (95% CI)	Age-standardised incidence per 100,000 person-years (95% CI)		Standardised incidence difference per 100,000 person-years (95% CI)		Standardised rate ratio (95% CI)	
		Reported	Clinically confirmed	Reported	Clinically confirmed	Reported	Clinically confirmed
CoronaVac							
Total	25.8 (22.9-28.7)	75.3 (44.7-105.9)	66.9 (37.2- 96.6)	49.5 (18.8- 80.3)	41.1 (11.3-71.0)	2.92 (1.92-4.45)	2.60 (1.64-4.10)
Male	28.7 (24.1-33.3)	88.7 (45.7-131.6)	77.6 (36.1-119.2)	60.0 (16.8-103.1)	48.9 (7.2-90.7)	3.09 (1.86-5.14)	2.70 (1.55-4.73)
Female	23.4 (19.7-27.1)	55.9 (15.1- 96.6)	51.9 (11.9- 91.9)	32.5 (-8.4- 73.3)	28.5 (-11.6-68.7)	2.39 (1.13-5.03)	2.22 (1.01-4.87)
Comirnaty							
Total	25.5 (22.4-28.6)	57.8 (30.1- 85.5)	42.8 (19.4- 66.1)	32.3 (4.4- 60.2)	17.3 (-6.3-40.9)	2.27 (1.38-3.72)	1.68 (0.96-2.94)
Male	29.0 (24.0-33.9)	65.5 (26.9-104.2)	46.1 (14.6- 77.5)	36.6 (-2.4- 75.5)	17.1 (-14.8-49.0)	2.26 (1.23-4.18)	1.59 (0.79-3.22)
Female	22.6 (18.7-26.5)	46.1 (8.7- 83.5)	36.4 (4.2- 68.7)	23.5 (-14.1- 61.1)	13.8 (-18.7-46.3)	2.04 (0.89-4.67)	1.61 (0.65-3.97)

*The background incidence rates were calculated using the same reporting period in 2018 as for each vaccination programme in 2021 (for CoronaVac, February 23, 2021-May 4, 2021; For Comirnaty, March 6, 2021-May 4, 2021).

Supplementary Table 5. Standardised rate ratios of reported and clinically confirmed Bell's palsy cases following vaccination with CoronaVac and Comirnaty by sex, with reference to the average background incidence rate from 2015 to2019.

	Average age-standardised background incidence rate from 2015 to 2019* per 100,000 person-years (95% CI)	Age-standardised incidence per 100,000 person-years (95% CI)		Age-standardised incidence difference per 100,000 person-years (95% CI)		Age-standardised rate ratio (95% CI)	
		Reported	Clinically confirmed	Reported	Clinically confirmed	Reported	Clinically confirmed
CoronaVac							
Total	27.0 (25.7-28.4)	75.3 (44.7-105.9)	66.9 (37.2- 96.6)	48.3 (17.6- 78.9)	39.8 (10.1-69.6)	2.78 (1.85-4.19)	2.47 (1.58-3.87)
Male	29.6 (27.5-31.7)	88.7 (45.7-131.6)	77.6 (36.1-119.2)	59.1 (16.1-102.1)	48.1 (6.5-89.6)	3.00 (1.84-4.89)	2.62 (1.53-4.50)
Female	25.0 (23.3-26.7)	55.9 (15.1- 96.6)	51.9 (11.9- 91.9)	30.8 (-9.9- 71.6)	26.9 (-13.1-66.9)	2.23 (1.07-4.64)	2.08 (0.96-4.50)
Comirnaty							
Total	26.8 (25.3-28.2)	57.8 (30.1- 85.5)	42.8 (19.4- 66.1)	31.0 (3.3- 58.8)	16.0 (-7.4-39.4)	2.16 (1.33-3.50)	1.60 (0.92-2.77)
Male	29.3 (27.0-31.5)	65.5 (26.9-104.2)	46.1 (14.6- 77.5)	36.3 (-2.5- 75.0)	16.8 (-14.8-48.3)	2.24 (1.23-4.06)	1.57 (0.79-3.13)
Female	24.7 (22.8-26.6)	46.1 (8.7- 83.5)	36.4 (4.2- 68.7)	21.4 (-16.1- 58.8)	11.7 (-20.6-44.0)	1.86 (0.83-4.21)	1.47 (0.61-3.58)

*The background incidence rates were calculated using the same reporting period from 2015 to 2019 as for each vaccination programme in 2021 (for CoronaVac, February 23, 2021-May 4, 2021; For Comirnaty, March 6, 2021-May 4, 2021).

Supplementary Table 6. Standardised rate ratios of reported and clinically confirmed Bell's palsy cases following vaccination with CoronaVac and Comirnaty by sex, excluding Bell's palsy cases with onset time less than 1 day after vaccination.

	Age-standardised background incidence rate in 2020* per 100,000 person-years (95% CI)	Age-standardised incidence per 100,000 person-years (95% CI)		Age-standardised incidence difference per 100,000 person-years (95% CI)		Age-standardised rate ratio (95% CI)	
		Reported	Clinically confirmed	Reported	Clinically confirmed	Reported	Clinically confirmed
CoronaVac							
Total	25.3 (22.6-28.1)	64.8 (36.8- 92.7)	58.1 (31.0-85.3)	39.4 (11.4-67.5)	32.8 (5.5-60.1)	2.56 (1.64-3.99)	2.29 (1.42-3.71)
Male	29.0 (24.5-33.4)	70.5 (33.5-107.5)	62.4 (26.6-98.2)	41.5 (4.3-78.8)	33.4 (-2.6-69.5)	2.43 (1.41-4.20)	2.15 (1.19-3.90)
Female	22.4 (18.9-26.0)	55.9 (15.1- 96.6)	51.9 (11.9-91.9)	33.4 (-7.4-74.3)	29.5 (-10.6-69.6)	2.49 (1.18-5.25)	2.31 (1.05-5.08)
Comirnaty							
Total	25.7 (22.7-28.8)	57.8 (30.1- 85.5)	42.8 (19.4-66.1)	32.1 (4.2-59.9)	17.0 (-6.6-40.6)	2.25 (1.37-3.68)	1.66 (0.95-2.91)
Male	28.9 (24.1-33.8)	65.5 (26.9-104.2)	46.1 (14.6-77.5)	36.6 (-2.3-75.5)	17.1 (-14.7-49.0)	2.26 (1.23-4.18)	1.59 (0.79-3.22)
Female	23.1 (19.2-27.0)	46.1 (8.7- 83.5)	36.4 (4.2-68.7)	23.0 (-14.6-60.5)	13.3 (-19.2-45.8)	1.99 (0.87-4.56)	1.58 (0.64-3.88)

*The background incidence rates were calculated using the same reporting period in 2020 as for each vaccination programme in 2021 (for CoronaVac, February 23, 2021-May 4, 2021; For Comirnaty, March 6, 2021-May 4, 2021).

Supplementary Table 7. Standardised rate ratios of reported and clinically confirmed Bell's palsy cases following vaccination with CoronaVac and Comirnaty by sex, assuming actual background incidence rates were 50% higher than reported.

	Age-standardised background incidence rate in 2020* per 100,000 person-years (95% CI)	Age-standardised incidence per 100,000 person-years (95% CI)		Age-standardised incidence difference per 100,000 person-years (95% CI)		Age-standardised rate ratio (95% CI)	
		Reported	Clinically confirmed	Reported	Clinically confirmed	Reported	Clinically confirmed
CoronaVac							
Total	38.0 (34.6-41.4)	75.3 (44.7-105.9)	66.9 (37.2- 96.6)	37.3 (6.5-68.1)	28.9 (-1.0-58.8)	1.98 (1.31-3.00)	1.76 (1.12-2.77)
Male	43.4 (38.0-48.9)	88.7 (45.7-131.6)	77.6 (36.1-119.2)	45.2 (2.0-88.5)	34.2 (-7.7-76.1)	2.04 (1.24-3.37)	1.79 (1.03-3.10)
Female	33.6 (29.3-38.0)	55.9 (15.1- 96.6)	51.9 (11.9- 91.9)	22.2 (-18.7-63.1)	18.3 (-21.9-58.5)	1.66 (0.79-3.48)	1.54 (0.71-3.37)
Comirnaty							
Total	38.6 (34.9-42.3)	57.8 (30.1- 85.5)	42.8 (19.4- 66.1)	19.2 (-8.8-47.2)	4.2 (-19.5-27.8)	1.50 (0.92-2.44)	1.11 (0.64-1.93)
Male	43.4 (37.5-49.3)	65.5 (26.9-104.2)	46.1 (14.6- 77.5)	22.1 (-17.0-61.2)	2.7 (-29.4-34.7)	1.51 (0.82-2.77)	1.06 (0.53-2.13)
Female	34.7 (29.9-39.5)	46.1 (8.7- 83.5)	36.4 (4.2- 68.7)	11.4 (-26.3-49.1)	1.7 (-30.9-34.3)	1.33 (0.58-3.03)	1.05 (0.43-2.57)

*The background incidence rates were calculated using the same reporting period in 2020 as for each vaccination programme in 2021 (for CoronaVac, February 23, 2021- May 4, 2021; For Comirnaty, March 6, 2021-May 4, 2021).

Supplementary Table 8. Baseline characteristics of case and controls in the nested case-control study, stratified by vaccine exposure.

	Cases			Controls		
	No vaccine (N=256)	**CoronaVac** (N=28)	**Comirnaty** (N=14)	**No vaccine** (N=1097)	**CoronaVac** (N=53)	**Comirnaty** (N=31)
Age - mean (SD)	57.62 (17.62)	56.76 (15.11)	52.38 (16.35)	57.63 (17.47)	56.47 (12.88)	50.07 (13.62)
Male – no. (%)	128 (50.0)	22 (78.6)	8 (57.1)	575 (52.4)	35 (66.0)	17 (54.8)
Admission setting – no. (%)						
Inpatient	98 (38.3)	8 (28.6)	6 (42.9)	425 (38.7)	14 (26.4)	8 (25.8)
Emergency room	158 (61.7)	20 (71.4)	8 (57.1)	672 (61.3)	39 (73.6)	23 (74.2)
Smoker – no. (%)	2 (0.8)	0 (0.0)	0 (0.0)	10 (0.9)	0 (0.0)	0 (0.0)
Pre-existing comorbidities† – no. (%)						
Diabetes mellitus	55 (21.5)	3 (10.7)	0 (0.0)	189 (17.2)	3 (5.7)	6 (19.4)
Hypertension	79 (30.9)	5 (17.9)	0 (0.0)	319 (29.1)	11 (20.8)	7 (22.6)
Asthma	7 (2.7)	0 (0.0)	0 (0.0)	26 (2.4)	0 (0.0)	0 (0.0)
Neoplasms	14 (5.5)	0 (0.0)	0 (0.0)	147 (13.4)	3 (5.7)	1 (3.2)
Acute respiratory infections	1 (0.4)	0 (0.0)	0 (0.0)	14 (1.3)	0 (0.0)	0 (0.0)
Viral infections	3 (1.2)	0 (0.0)	1 (7.1)	2 (0.2)	0 (0.0)	0 (0.0)
Rheumatoid Arthritis	0 (0.0)	0 (0.0)	1 (7.1)	5 (0.5)	0 (0.0)	0 (0.0)
Head trauma	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stroke	17 (6.6)	1 (3.6)	0 (0.0)	68 (6.2)	1 (1.9)	0 (0.0)
Guillain–Barré syndrome	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Migraine	2 (0.8)	0 (0.0)	0 (0.0)	7 (0.6)	0 (0.0)	0 (0.0)
Medication use within 90 days – no. (%)						
Antiviral drugs	12 (4.7)	0 (0.0)	1 (7.1)	35 (3.2)	4 (7.5)	1 (3.2)
Systemic corticosteroids	18 (7.0)	1 (3.6)	0 (0.0)	48 (4.4)	0 (0.0)	0 (0.0)
Antibacterial drugs	20 (7.8)	1 (3.6)	0 (0.0)	156 (14.2)	0 (0.0)	0 (0.0)
Immunosuppressants	1 (0.4)	0 (0.0)	0 (0.0)	24 (2.2)	0 (0.0)	0 (0.0)
Statins	73 (28.5)	5 (17.9)	1 (7.1)	302 (27.5)	8 (15.1)	5 (16.1)

| Isoniazid | 0 (0.0) | 0 (0.0) | 0 (0.0) | 3 (0.3) | 0 (0.0) | 0 (0.0) |

†For pre-existing comorbidities, diagnosis within 90 days before index date were considered for acute respiratory infections and viral infections, and diagnosis before index date were considered for other diseases.

Supplementary Table 9. Risks of Bell's palsy among participants in the nested case-control study, excluding cases and controls with onset time less than 1 day after vaccination.

	Case patients (N=296)	Controls (N=1174)	Crude odds ratio (95% CI)	P-value	Adjusted odds ratio (95% CI)	P-value
Total						
Not vaccinated	256	1090	(Ref)		(Ref)	
CoronaVac	26	51	2.362 (1.403 – 3.978)	0.0012	2.296 (1.341 – 3.932)	0.0025
Comirnaty	14	29	2.223 (1.132 – 4.368)	0.02	1.901 (0.949 – 3.81)	0.07
Subgroup analysis						
Male						
Not vaccinated	128	568	(Ref)		(Ref)	
CoronaVac	20	34	2.894 (1.544 – 5.426)	0.0009	2.658 (1.392 – 5.075)	0.0031
Comirnaty	8	15	2.514 (1.023 – 6.178)	0.044	2.234 (0.908 – 5.497)	0.08
Female						
Not vaccinated	128	522	(Ref)		(Ref)	
CoronaVac	6	17	1.507 (0.568 – 3.999)	0.41	1.428 (0.526 – 3.877)	0.48
Comirnaty	6	14	1.882 (0.678 – 5.221)	0.22	1.784 (0.633 – 5.03)	0.27
Age<60						
Not vaccinated	125	533	(Ref)		(Ref)	
CoronaVac	13	27	2.256 (1.078 – 4.72)	0.031	2.295 (1.081 – 4.872)	0.03
Comirnaty	10	22	1.998 (0.914 – 4.368)	0.083	1.803 (0.818 – 3.977)	0.14
Age≥60						
Not vaccinated	131	557	(Ref)		(Ref)	
CoronaVac	13	24	2.507 (1.197 – 5.252)	0.015	2.508 (1.152 – 5.463)	0.021

Comirnaty	4	7	3.095 (0.795 – 12.047)	0.1	2.372 (0.522 – 10.785)	0.26
Post-hoc analysis						
Within 14 days between vaccination and diagnosis of Bell's palsy						
Not vaccinated	256	1,016	(Ref)		(Ref)	
CoronaVac	12	19	2.896 (1.273 - 6.588)	0.0112	2.800 (1.210 - 6.480)	0.0162
Comirnaty	6	17	1.423 (0.545 - 3.713)	0.4716	1.202 (0.458 - 3.156)	0.7082
Larger than 14 days between vaccination and diagnosis of Bell's palsy						
Not vaccinated	256	1,029	(Ref)		(Ref)	
CoronaVac	14	22	2.568 (1.282 - 5.144)	0.0078	2.456 (1.179 - 5.117)	0.016
Comirnaty	8	9	3.962 (1.418 - 11.076)	0.0087	3.785 (1.253 - 11.43)	0.018
Completed 1st dose only						
Not vaccinated	256	1,031	(Ref)		(Ref)	
CoronaVac	19	26	3.183 (1.663 - 6.091)	0.0005	3.081 (1.574 - 6.029)	0.0010
Comirnaty	5	16	1.229 (0.439 - 3.446)	0.69	0.967 (0.322 - 2.904)	0.95
Completed 1st and 2nd dose						
Not vaccinated	256	1014	(Ref)		(Ref)	

15

CoronaVac	7	19	1.459 (0.592 - 3.599)	0.41	1.457 (0.576 - 3.69)	0.43
Comirnaty	9	12	3.201 (1.287 - 7.962)	0.012	3.162 (1.244 - 8.039)	0.016

Cases and controls were matched according to age, sex, setting, and admission date. Odds ratios for Bell's palsy were estimated by conditional logistic regression adjusted for smoking status, pre-existing comorbidities (diabetes mellitus, hypertension, asthma, neoplasms, rheumatoid arthritis, stroke, migraine, infections in the past 90 days (acute respiratory infections, viral infections), and medication use in the past 90 days (antiviral drugs, systemic corticosteroids, antibacterial drugs, immunosuppressants). The list of confounders in the model for subgroup and post-hoc analyses is shown in the Supplementary table 10. CI denotes confidence interval.

Supplementary table 10. List of confounders in the regression model in the main and sensitivity analysis.

Confounder	Total	Subgroup and post-hoc analysis							
		Male	Female	Age<60	Age≥60	≤14 days between vaccination and diagnosis	> 14 days between vaccination and diagnosis	Completed 1st dose only	Completed 1st and 2nd dose
Smoker	✓	✓	×	✓	✓	✓	✓	✓	✓
Pre-existing comorbidities†									
Diabetes mellitus	✓	✓	✓	✓	✓	✓	✓	✓	✓
Hypertension	✓	✓	✓	✓	✓	✓	✓	✓	✓
Asthma	✓	✓	✓	✓	✓	✓	✓	✓	✓
Neoplasms	✓	✓	✓	✓	✓	✓	✓	✓	✓
Acute respiratory infections	✓	×	✓	✓	×	✓	✓	✓	✓
Viral infections	✓	×	✓	×	✓	✓	✓	✓	✓
Rheumatoid Arthritis	✓	×	✓	✓	×	×	✓	✓	×
Stroke	✓	✓	✓	✓	✓	✓	✓	✓	✓
Migraine	✓	✓	✓	✓	×	✓	✓	✓	✓
Medication use within 90 days									
Antiviral drugs	✓	✓	✓	✓	✓	✓	✓	✓	✓
Systemic corticosteroids	✓	✓	✓	✓	✓	✓	✓	✓	✓

Antibacterial drugs	✓	✓	✓	✓	✓	✓	✓	✓	✓
Immunosuppressants	✓	✓	×	×	✓	✓	✓	✓	✓
Statins	✓	✓	✓	✓	✓	✓	✓	✓	✓

†For pre-existing comorbidities, diagnosis within 90 days before index date were considered for acute respiratory infections and viral infections, and diagnosis before index date were considered for other diseases.

✓ included in the regression model

× not included in the regression model due to due to very rare number in case and control groups (e.g. smoker status was excluded in the regression model in the female subgroup analysis as all female were non-smoker in current study.)

Supplementary Figure 1. Sample size calculation for nested case-control study

Number of matched sets for different odds ratios
for nested case-control study
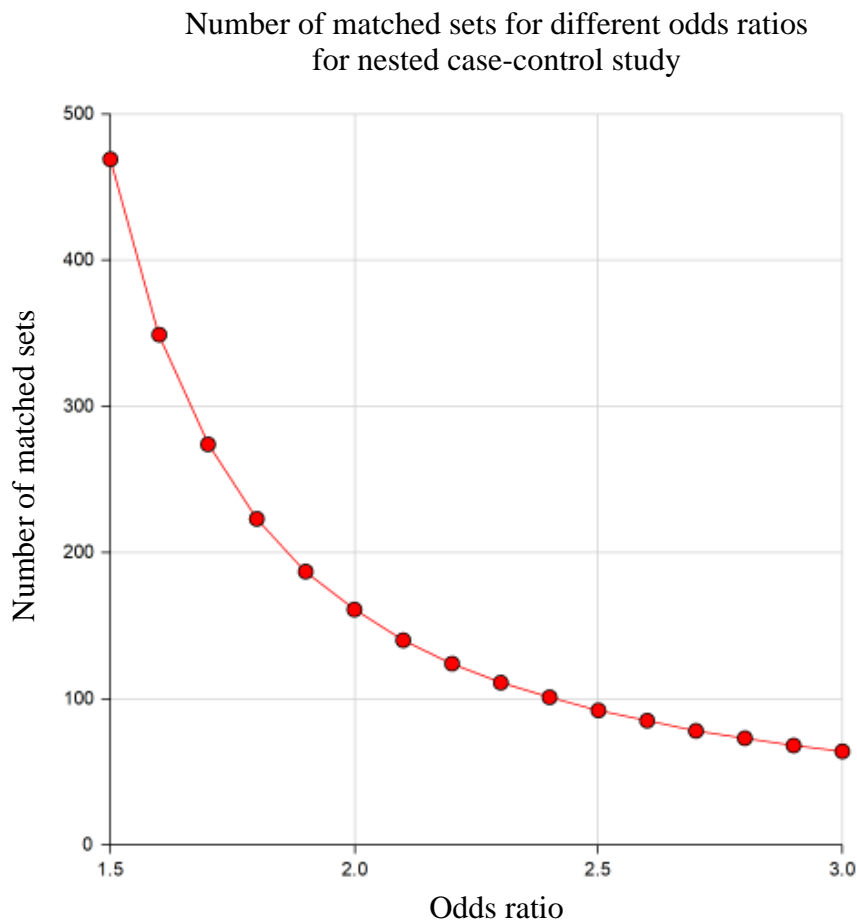
Remark: Assuming 15% of Hong Kong population aged 18 years with vaccination (1 million vaccine recipients among 6.5 million Hong Kong residents aged 18 years) by May 3 2021, the number of matched sets (1 case and 4 controls) ranging from 64 to 469 were required to achieve 80% power to detect the odds ratios from 1.5 to 3 at 0.05 significance level [1-3]. The red points were plotted for odds ratios from 1.5 to 3 by 0.1. The sample size calculation was conducted using the Power Analysis and Sample Size software version 2019 (NCSS, Kaysville, Utah, USA).

References:

1. Lachin, John M. Sample size evaluation for a multiply matched case-control study using the score test from a conditional logistic (discrete Cox PH) regression model. Stat Med, 2008;27:2509-2523.
2. Lachin, John M. Biostatistical Methods: The Assessment of Relative Risks, Second Edition. John Wiley & Sons, 2011.
3. Tang, Yongqiang. Comments on 'Sample size evaluation for multiply matched case-control study using the score test from a conditional logistic (discrete Cox PH) regression model. Stat Med, 2009;28:175-177.

Supplementary Figure 2. Onset distribution of clinically confirmed Bell's palsy cases by number of days past the most recent dose of vaccination

Percentage of Bell's palsy Cases by Number of Days past CoronaVac (n=27*) or Comirnaty (n=16) Vaccination
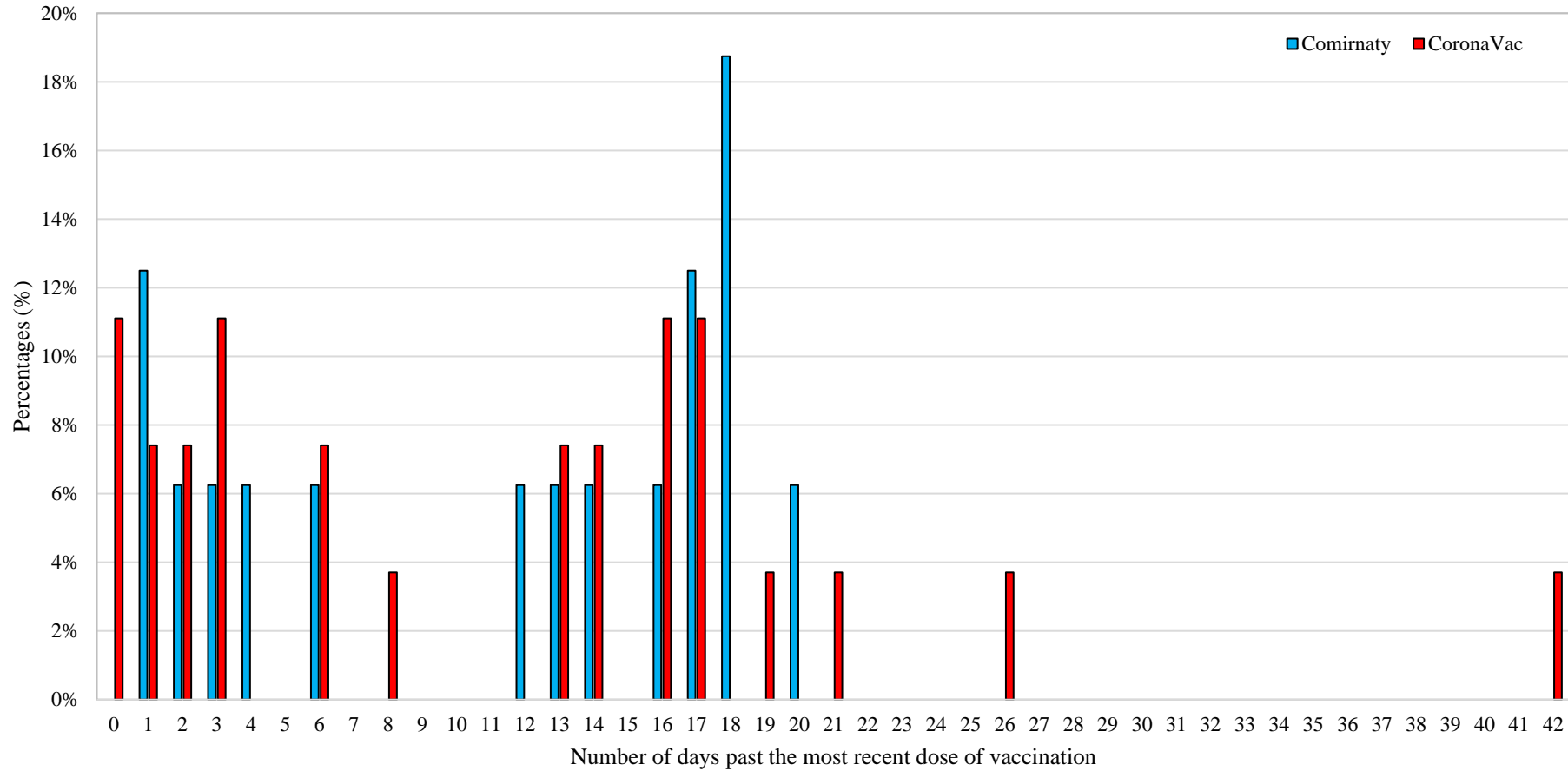
*Remark: There are 28 clinically confirmed Bell's palsy cases for CoronaVac. However, the onset date in one clinically confirmed Bell's palsy case following CoronaVac vaccination (Case no S18 in the Supplementary Table 2) is uncertain, and thus this case was excluded from the figure.

Supplementary information 1. The details of WHO classification.

The Expert Committee conducted causality assessment of clinically confirmed cases according to the WHO classification[1].

A. Consistent causal association to immunization

• A1. Vaccine product-related reaction; or

• A2. Vaccine quality defect-related reaction; or

• A3. Immunization error-related reaction; or

• A4. Immunization anxiety-related reaction/Immunization stress related response (ISRR).

B. Indeterminate

• B1. Temporal relationship is consistent but there is insufficient definitive evidence that vaccine caused the event (it may be a new vaccine-linked event). This is a potential signal and needs to be considered for further investigation.

• B2. Reviewing factors result in conflicting trends of consistency and inconsistency with causal association to immunization (i.e. it may be vaccine-associated as well as coincidental and it is not possible clearly to favour one or the other).

C. Inconsistent causal association to immunization (coincidental). This could be due to underlying or emerging condition(s) or conditions caused by exposure to something other than vaccine. Events which could have occurred naturally are generally assigned to this classification.

D. Case without adequate information for causality conclusion.

Reference

1. World Health Organization. Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO classification. https://apps.who.int/iris/bitstream/handle/10665/259959/9789241513654-eng.pdf?sequence=1&isAllowed=y.

Supplementary information 2. The details information of Clinical Data Analysis and Reporting System.

Hospital Authority has a comprehensive electronic health records system for clinical management. Each resident in Hong Kong has a unique Hong Kong Identity Card Number which allows the HA to create a unique electronic health record for each patient to link up all hospitals, ambulatory clinics, specialist clinics, general out-patients clinics, and emergency rooms. Data from the HA electronic health records are de-identified and pseudo-anonymised data are then transferred daily to Clinical Data Analysis and Reporting System (CDARS). Since 1995, the pseudo-anonymised clinical data from patients who had ever used any of the healthcare services at HA, including demographics, diagnosis, medication dispensing records, outpatient and primary care clinics, emergency room attendances, laboratory tests and hospitalisation details, have been made available on CDARS for research and audit purposes. CDARS has been used for pharmacovigilance studies to evaluate safety of medicine[1-4].

Reference

1. Lau WC, Chan EW, Cheung CL, et al. Association Between Dabigatran vs Warfarin and Risk of Osteoporotic Fractures Among Patients With Nonvalvular Atrial Fibrillation. JAMA 2017; 317(11): 1151-8.
2. Lau WCY, Cheung CL, Man KKC, et al. Association Between Treatment With Apixaban, Dabigatran, Rivaroxaban, or Warfarin and Risk for Osteoporotic Fractures Among Patients With Atrial Fibrillation: A Population-Based Cohort Study. Ann Intern Med 2020; 173(1): 1-9.
3. Man KKC, Chan EW, Ip P, et al. Prenatal antidepressant use and risk of attention-deficit/hyperactivity disorder in offspring: population based cohort study. BMJ 2017; 357: j2350.
4. Man KKC, Lau WCY, Coghill D, et al. Association between methylphenidate treatment and risk of seizure: a population-based, self-controlled case-series study. Lancet Child Adolesc Health 2020; 4(6): 435-43.