Doctors' Guide

for the Coronavirus Disease 2019 (COVID-19)

Vaccination Programme at Clinics

under the Vaccination Subsidy Scheme (VSS) and

Private Clinic COVID-19 Vaccination Station

(PCVS) -mRNA vaccines

For doctors providing COVID-19 mRNA vaccines

Produced and Published by
Programme Management and Vaccination Division
Emergency Response and Programme Management Branch

Centre for Health Protection
Department of Health
The Government of Hong Kong Special Administrative Region

Always make sure that you have the latest version on the designated COVID-19 vaccine website https://www.chp.gov.hk/en/features/106934.html

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Disclaimer

This Doctors' Guide provides guidance for Coronavirus Disease (COVID-19) Vaccination Programme at Clinics under the Vaccination Subsidy Scheme (VSS) and Private Clinic COVID-19 Vaccination Station (PCVS). This Doctors' Guide is provided as a living document which will be updated from time to time according to the latest development. Please always make sure that you have the latest version. We welcome doctors' questions, comments or feedback on this Guide so that we can improve on it.

There should be clear segregation in the arrangement for the different type of vaccines at the site, the logistics of storage and administration for each type of vaccine should be followed accordingly.

If you have any comment or question, please send to – Programme Management and Vaccination Division Centre for Health Protection

Department of Health

Email: covid19 vss@dh.gov.hk

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1 Introduction

1.1 To protect members of the public against COVID-19, a territory-wide COVID-19 Vaccination Programme free of charge and on a voluntary basis for eligible Hong Kong residents is implemented by the Government.

Some Non Hong Kong Residents may be eligible for receiving the vaccination. Please refer to section 2.2.3 and the following webpage for more information: https://www.chp.gov.hk/en/features/106952.html
https://www.info.gov.hk/gia/general/202301/12/P2023011200426.htm?fontSize=1

1.2 This Doctors' Guide is prepared for doctors providing vaccination for mRNA vaccine. For designated PCVSs offering mRNA vaccine in paediatrics and toddler formulations, please also refer to the notes for PCVS administering Paediatric and Toddler formulation of mRNA vaccine:

https://www.chp.gov.hk/files/pdf/notes_mrna_pcvs_paedi.pdf.

- 1.3 The BioNTech Pilot Scheme (renamed as "mRNA Vaccine Scheme") is regularised starting from 23 August 2022. Comirnaty Original/BA.4-5 bivalent vaccine (15/15 micrograms per dose) were no longer available for ordering via the web-based ordering platform since 27th Mar 2024. For the principle agreements for this scheme, please refer to the following appendix:

 https://www.chp.gov.hk/files/pdf/agreement_covid19 bnt pilot.pdf.
- 1.4 Starting from 19 November 2024, PCVSs provide monovalent JN.1 mRNA vaccines to eligible persons. For the supplemental agreements for PCVS, please refer to the following appendix:
 https://www.chp.gov.hk/files/pdf/agreement_covid19 but pilot pcvs.pdf.
- 1.5 The VSS, administered by the Department of Health (DH), is a scheme that subsidises target groups of Hong Kong residents to receive vaccinations from private medical doctors enrolled in VSS. The Government would reimburse vaccination subsidies to enrolled doctors for each dose of vaccination administered to eligible groups.

1.6 Resources

- (a) Designated website: https://www.chp.gov.hk/en/features/106934.html
- (b) Doctor's Guide: https://www.chp.gov.hk/files/pdf/vssdoctorsguide_covid19_bnt_pilot.pdf
- (c) User Manual of eHealth System (Subsidies) [eHS(S)] for COVID-19 Vaccination: https://www.ehealth.gov.hk/en/covidvaccine/ehs.html
- (d) The link to login the eHS(S) to record the COVID-19 vaccination: https://apps.hcv.gov.hk/HCSP/login.aspx?lang=en
- (e) Interim Guidance Notes on Common Medical Diseases and COVID-19 Vaccination In Primary Care Settings:

 https://www.chp.gov.hk/files/pdf/guidance_notes.pdf
- (f) Consensus Interim Recommendations on the Use of COVID-19 Vaccines in Hong Kong by the Scientific Committee on Emerging and Zoonotic Diseases and Scientific Committee on Vaccine Preventable Diseases: https://www.chp.gov.hk/en/static/24005.html

2 Vaccines covered, target groups and reimbursement level

2.1 Vaccines covered

- 2.1.1 COVID-19 vaccines would be supplied to VSS doctors by the Government.
- 2.1.2 Since 16 December 2022, a number of COVID-19 vaccines have been registered in Hong Kong under the Pharmacy and Poisons Regulations (Cap. 138A). The registration details can be found on the website of the Pharmacy and Poisons Board of Hong Kong

(https://www.drugoffice.gov.hk/eps/do/en/consumer/search_drug_database2.html).

Different COVID-19 vaccines are used under the Government Vaccination Programme, including the Vaccination Subsidy Scheme (VSS) and Private Clinic COVID-19 Vaccination Station (PCVS). For the details of available COVID-19 vaccines under the Government Vaccination Programme, please refer to FAQ#3 (https://www.chp.gov.hk/en/features/106953.html).

Registered medical practitioners can also provide vaccination service outside the Government COVID-19 Vaccination Programme. For details, please visit: https://www.chp.gov.hk/files/pdf/cap138a covid19 requirement.pdf.

2.1.3 Currently, monovalent JN.1 mRNA vaccines are supplied under government programme in Hong Kong.

The latest version of publicity and package insert are available at:

Fact sheet -

https://www.chp.gov.hk/files/pdf/factsheet covidvaccine mrna eng.pdf

Package inserts –

https://www.chp.gov.hk/en/features/106959.html

(a) Dosage, interval and other useful information

	Comirnaty JN.1 dispersion for injection COVID-19 mRNA Vaccine 30 micrograms/dose	Spikevax JN.1 dispersion for injection in pre-filled syringe COVID-19 mRNA Vaccine 50 micrograms/dose 0.5 mL
Presentation	Multi-dose vial (Grey cap)	Pre-filled syringe
Fill volume	2.25mL	0.5mL
Volume of each dose	0.3mL [30 micrograms of bretovameran]	0.5mL [50 micrograms of SARS-CoV-2 JN.1 mRNA]
Number of doses per unit	<u>6</u> doses*	<u>1</u> dose
Pack size available	1 or 10 vials per box	10 pre-filled syringes per box
Consumables available for ordering	1ml LDV syringe with 25G x 1" fixed needle (100 pcs/box)	25G x 1" luer-lock needle (100 pcs/box)

^{*}Low-dead volume (LDV) syringes should be used in order to extract 6 doses from a single vial

Please refer to **section 6.5** for details on preparation.

For vaccination schedules for different age groups of COVID-19 vaccination, please refer to the following webpages: https://www.chp.gov.hk/en/features/106951.html

Please be reminded that PCVSs can provide mRNA vaccine to appropriate clients of age \geq 12 years old only, except the designated PCVSs.

(b) Route of administration

The vaccine is administered intramuscularly in the deltoid muscle of non-dominant

arm (for individuals aged 18 and above). Mid- anterolateral thigh injection **should be offered to all adolescents** (both male and female) aged 12 – 17 years as the site of vaccination. Adolescents aged 12 – 17 years could make an informed choice to opt-out from thigh injection and receive vaccination in deltoid. Individuals aged 18 years and above could choose to receive mRNA vaccine in their mid-anterolateral thigh on an **on-demand basis**. Please refer to **section 6.6.9** – **6.6.11** for the technique of mid-anterolateral thigh injection.

(c) Contraindications

Please refer to the package insert of mRNA vaccines (https://www.chp.gov.hk/en/features/106959.html) and the Interim Guidance Notes On Common Medical Diseases and COVID-19 Vaccination In Primary Care Settings (https://www.chp.gov.hk/files/pdf/guidance_notes.pdf) for the most updated information.

- i. Hypersensitivity to the active substance or to any of the excipients as listed in section 6.1 of the package insert (Annex II).
- ii. Another dose of the vaccine should not be given to those who have experienced anaphylaxis to the previous dose.

(d) Special warnings and precautions for use

- i. VSS doctors may refer the following cases to the Vaccine Allergy Safety Clinic of Hospital Authority for medical consultation/ investigation as deemed appropriate:
 - (i) persons with immediate (within 1 hour) severe allergic reaction to prior COVID-19 vaccination or to more than one class of drugs;
- (ii) persons with allergic reaction to prior COVID-19 vaccination which is not self-limiting or did not resolve by oral anti-allergy

Please see details in section 6.4.2 - 6.4.3

- ii. Events of anaphylaxis have been reported. Appropriate medical treatment and supervision should always be readily available in case of anaphylactic reaction following the administration of the vaccine. Close observation for at least 15 minutes is recommended following vaccination (see **sections 6.8**).
- iii. Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.
- iv. Vaccination should be postponed in individuals suffering from acute severe

- febrile illness or acute infection.
- v. As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.
- vi. The efficacy, safety and immunogenicity of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of the mRNA vaccine may be lower in immunosuppressed individuals.
- vii. The duration of protection afforded by the vaccine is unknown as it is still determined by ongoing clinical trials. As with any vaccine, vaccination with the mRNA vaccine may not protect all vaccine recipients
- viii. Animal studies do not indicate direct or indirect harmful effects with respective to reproductive toxicity.
 - ix. There is an increased risk of myocarditis and pericarditis after vaccination with mRNA vaccines supplied under Government programme in Hong Kong. These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen.
- iv. The Scientific Committee on Emerging and Zoonotic Disease and Scientific Committee on Vaccine Preventable Diseases under the Centre for Health Protection of the Department of Health (JSC) provides recommendations on the use of COVID-19 vaccines in Hong Kong. VSS doctors and the staff of PCVSs should always refer to latest recommendations of the COVID-19 vaccines at https://www.chp.gov.hk/en/static/24008.html.

The latest updates and implementation schedule will also be communicated to the responsible staff of PCVSs by means of email. The responsible staff of PCVSs should check their registered email account for the latest updates. VSS doctors and other staff may also refer to the Government's thematic webpage for the latest updates (https://www.chp.gov.hk/en/features/106934.html).

2.2 Target groups/ eligibility

2.2.1. The Government provides COVID-19 vaccination to eligible Hong Kong resident and non-Hong Kong residents who belong to certain category* on a

voluntary basis under the COVID-19 Vaccination Programme. Persons aged ≥ 6 months# can receive the initial dose(s), and people belonging to specific priority groups can receive the additional booster(s) <u>free of charge</u> under government vaccination programme.

Simplified regimen for initial vaccination has been implemented since 19 August 2024. Regardless of history of infection, immunocompetent person aged 5 years or above would only need to receive one dose of mRNA vaccine or two doses of inactivated vaccine to complete the initial doses. Please refer to "How many doses of COVID-19 vaccine are recommended for me" at: https://www.chp.gov.hk/en/features/106951.html for further details.

For the vaccination schedule of immunocompetent person aged 6 months to 4 years old, please refer to the to the notes for PCVS administering Paediatric and Toddler formulation of mRNA vaccine, which is only applicable to the designated PCVSs offering mRNA vaccine in paediatrics and toddler formulations.

For the vaccination schedule of immunocompromised person, please refer to section 6.15.

People belonging to the following priority groups can receive an additional vaccine booster 180 days after their last dose or COVID-19 infection (whichever is later) free of charge after completed the initial doses, regardless of the number of vaccine doses they received in the past:

- (a) Persons aged 50 years and above # including those living in residential care homes;
- (b) Persons aged 18 to 49 years # with underlying comorbidities@
- (c) Persons with immunocompromising conditions aged 6 months and above#;
- (d) Pregnant women (once during each pregnancy) and
- (e) Healthcare workers

Count by Date of Birth

@ Persons with underlying comorbidities include individuals having chronic cardiovascular (except hypertension without complications), lung, metabolic or kidney disease, obesity (body mass index 30 or above), children and adolescents

(aged six months to 18 years) on long-term aspirin therapy, and those with chronic neurological condition that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration or those who lack the ability to take care for themselves.

^ Include frontline health workers, supporting staff working in the healthcare setting, staff in residential care homes and laboratory personnel handling SARS-CoV-2 virus

VSS doctors should always refer to latest recommendations of the COVID-19 vaccines at: https://www.chp.gov.hk/en/static/24008.html.

Please refer to the thematic website at https://www.chp.gov.hk/en/features/106934.html for details.

The Government would announce from time to time the different target groups to receive COVID-19 vaccination. VSS Doctors and the staff of PCVSs should always refer to the latest announcement about the target groups and eligibility at https://www.chp.gov.hk/en/features/106952.html.

2.2.2 Eligible Hong Kong residents can receive COVID-19 vaccination under VSS.

A Hong Kong resident is defined as a person possessing any of following documents:

- (i) Hong Kong Identity Card 香港身份證 #
- (ii) Consular corps Identity Card 領事團身份證
- (iii) Certificate of Exemption 豁免登記證明書 (for adults only)

Sample of documents for reference:

https://www.chp.gov.hk/files/pdf/vssdg ch5 appendix a.pdf

In general, eligible adult Hong Kong residents should use the HKID Card for vaccination. However, when the client presented HKSAR passport but not HKID Card under special circumstances for vaccination, VSS doctor / staff may arrange the vaccination according to the following scenarios:

<u>Scenario 1</u>: The client can provide a **photocopy of Hong Kong Identity Card** (**HKID card**) together with the HKSAR passport

- Please verify the identity of the client with reference to both documents and allow the client to proceed further along the workflow HKID card should be selected for creation of eHS(S) record with manual input of information as provided by the photocopy of HKID.
- The VSS doctor / staff should advise the client to bring along HKID card for subsequent dose (where appropriate).

<u>Scenario 2</u>: The PBV uses **solely HKSAR passport** as the identity document for his/her **first dose in eHS(S)**

- For PCVS, please advise and assist the client to cancel his/her original booking made with HKID card (if any) to prevent system sending the wrong notification due to client's use of different identity document onsite.
- The VSS doctor / staff should select passport as the identity document used under eHS(S), manual input of the HKSAR passport number is required for creation the account for vaccine recipient or entering into his/her existing eHS(S) account.
- At the COVID-19 Vaccination programme landing page, VSS doctor / staff should check against, if any, pre-existing vaccination record, confirm the prior COVID-19 vaccination history with the vaccination recipient and other information as appropriate. The client's HKID number as listed in the HKSAR passport.
- Please assist the client to bring along HKID for his/her subsequent dose and to complete the designated form on Personal Particular Amendment Form by then, so that a vaccination record (with HKID number) can be issued after completion of the change/amend of particulars

<u>Scenario 3</u>: The PBV uses **solely HKSAR passport** as the identity document for his/her **subsequent dose in eHS(S)**

- (3A) Previous dose record created under HKID in eHS(S):
- -The VSS doctor / staff should make reference to the HKID number documented on the HKSAR passport to enter the eHS(S) record of the vaccine recipient previously created for the previous dose under his/her HKID.

- (3B) Previous dose record created under HKSAR passport in eHS(S):
- The VSS doctor / staff should make reference to the client's passport number to log into his/ her vaccination record for vaccine documentation and recording.
- Please assist the client to complete the Personal Particular Amendment Form when his/her HKID is available so that a vaccination record (with HKID number) can be issued after completion of his/her personal particular amendment.
- 2.2.3 Some Non Hong Kong residents are eligible to receive COVID-19 vaccination under VSS

Following the Government's press release on 12 January 2023 (https://www.info.gov.hk/gia/general/202301/12/P2023011200426.htm?fontSize=1), the eligibility in COVID-19 Vaccination Programme has been updated with effect from 16 January 2023 as follows:

- (a) Non-Hong Kong residents are generally not eligible for receiving any type of COVID-19 vaccines under the Government COVID-19 vaccination programme (the Government Programme), except for persons belonging to the following categories:
- (i) The vaccine recipient has received COVID-19 vaccines under the **Government Programme** before. Please verify the COVID-19 vaccination record of the vaccine recipients as shown in the eHS(s);

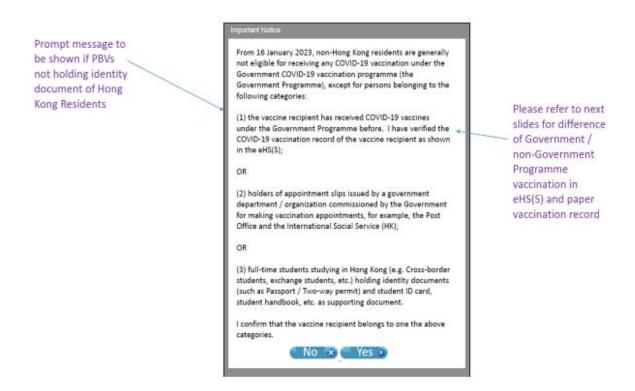
 OR
- (ii) Holders of appointment slips issued by a government department / organization commissioned by the government for making vaccination appointments, for example. the Post Office and the International Social Service (HK);

OR

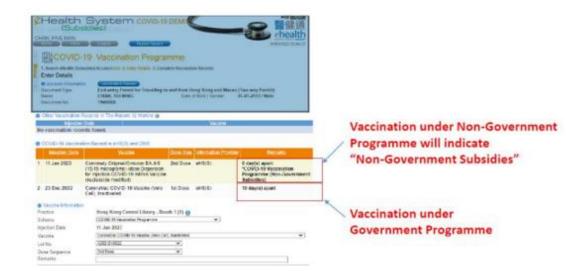
(iii) Full-time students studying in Hong Kong (e.g. Cross-border students, exchange students, etc.) holding identity documents (such as Passport / Two-way permit) and student ID card, student handbook, etc. as supporting document.

- (b) Non-Hong Kong Residents (if fulfilled exception criteria) are required to present relevant identity documents, supporting document and relevant vaccination records/ appointment records (for PCVS) at vaccination venue. Private clinics that are <u>under the Government Programme</u> and PCVS can provide vaccination to non-Hong Kong residents fulfilling the exception criteria (i) to (iii) above.
- (c) Even if the non-Hong Kong resident is eligible to receive COVID-19 vaccination under the exception arrangement, the <u>remaining limit of stay</u> in Hong Kong as stated in the landing slips or extension of stay labels issued by the Immigration Department should <u>not less than 30 days</u> on the date of the additional dose(s) vaccination.
- (d) For non-eligible clients not fulfilling the exception arrangement, they may receive COVID-19 vaccination at their own cost from private doctors outside the Government programme, that is, vaccines procured by the doctor.
 Government-supplied vaccines should not be used for non-Government vaccination.
- (e) Doctors should check whether the person coming for vaccination fulfills the exception criteria above, before giving vaccination. Please refer to the (i) prompt message, (ii) indicator of vaccinations given outside Government programme and (iii) the vaccination records for further details.

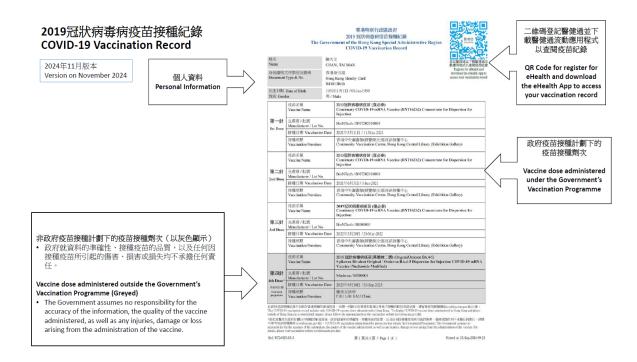
(i) The screen cap of the prompt message in eHS(s) is attached for your easy reference.



(ii) The screen cap of indicator of vaccinations given outside Government programme is attached for your easy reference.



(iii) The screen cap of COVID-19 vaccination record is attached, or please visit: https://www.chp.gov.hk/files/pdf/sample_covidvaccinationrecord.pdf for reference.



For vaccines procured by doctors from the private market (i.e. private vaccines outside the Government's vaccination programme), an additional remark "COVID-19 Vaccination Programme (Non-Government Subsidies)" has been added to both the electronic vaccination record in eHS(S) and the paper vaccination record. In contrast, there is no such remark for vaccines administered under the Government's vaccination programme. The vaccination under **non**-Government Programme should **not** be regarded as fulfilling exception criteria (ai) above.

More details on the eligibility criteria for non-Hong Kong resident receiving COVID- 19 vaccination at Hong Kong can be found at the following link: https://www.chp.gov.hk/en/features/106952.html

2.3 Reimbursement level

- 2.3.1 The subsidy per dose of COVID-19 vaccination given to eligible person is as follows:
 - (a) HK\$160 per dose (regardless of whether it is the first, second, third or booster dose^) if the eligible person still has not reached or will not reach the age of 60 years in the calendar year when the vaccination is administered;
 - (b) HK\$240 per dose (regardless of whether it is the first, second, third or booster dose^) if the eligible person who has reached or will reach the age of 60 years or above in the calendar year when the vaccination is administered;
 - ^ Starting from 20 April 2023, the Government will only provide <u>additional</u> <u>booster</u> to persons who belong to the <u>priority groups as</u> mentioned in section 2.2.1. Persons who do not belong to these priority groups and members of the public wishing to receive vaccine boosters exceeding the specified free doses under the Government COVID-19 Vaccination Programme will need to get the vaccine in the private market at their own expense. VSS doctors <u>SHOULD NOT</u> administer COVID-19 vaccines under the Government's COVID-19 Vaccination Programme to these persons.
- 2.3.2 No extra charge of any service fees is allowed. The VSS doctors should not require the recipient to pay any service fee for the vaccination under the COVID-19 Vaccination Programme.

3 Responsibilities of doctors

3.1 Requirement for doctors

- 3.1.1 VSS Doctors should comply with all the requirements mentioned in this Doctors' Guide including:
 - (a) Vaccine ordering, delivery and storage (Section 4)
 - (b) Infection control practice, hand hygiene and sharps handling (Section 5)
 - (c) Vaccination procedures (Section 6)
 - (d) Waste management (Section 7)
 - (e) Reporting of adverse event following immunisation (Section 8)
 - (f) Management of clinical incident (Section 9)
- 3.1.2 The clinic / PCVS should be equipped with the following items:
 - (a) Medical equipment and consumables (Section 3.2)
 - (b) Vaccine storage facilities (Section 4.3)
 - (c) Smart HKID Card Reader (Section 6.4)
 - (d) Printer (Section 6.7)
- 3.1.3 Clinics / PCVS may be randomly selected for conduction of onsite quality assurance activities. Please see **Annex III** for a checklist of items during onsite inspection.
- 3.1.4 VSS Doctors are encouraged to register as healthcare providers under the eHealth. Please find details in the website https://www.ehealth.gov.hk/en/healthcare-provider-and-professional/index.html.
- 3.1.5 VSS Doctors and healthcare professionals of the clinic /PCVS are required to complete the online training for COVID-19 Vaccination Programme offered by the Hong Kong Academy of Medicine (HKAM). Please find details in the website https://elearn.hkam.org.hk/en.

3.2 Medical equipment and consumables

- 3.2.1 VSS doctor should ensure all medical consumables and adrenaline are sufficient, registered in Hong Kong and not expired.
- 3.2.2 The clinic / PCVS should be equipped with adrenaline auto-injector or 1:1000 adrenaline ampoule for injection for management of anaphylaxis. Please ensure sufficient stock of adrenaline and that it is not expired.
- 3.2.3 Please refer to Section **6.9** for the equipment for management of emergency conditions.
- 3.2.4 The following medical consumables are required for COVID-19 vaccination:
 - (a) 70%-80% alcohol-based hand rub
 - (b) Alcohol preps/ alcohol swab for skin disinfection before vaccination
 - (c) Dry sterile gauzes/ non-woven balls for post-injection compression to injection site
 - (d) Sharps boxes/ clinical waste containers

4 <u>Vaccine ordering, delivery and storage</u>

4.1 Vaccine ordering

4.1.1 VSS doctors will be responsible for ordering the vaccines on a web-based ordering system (https://covid_vac.chp.gov.hk/). Please regularly estimate the quantity of vaccines, needles and syringes you need and place order at least 5 working days before the delivery date.

In view of the limited shelf-life of COVID-19 mRNA vaccine after thawing, the target stock level should not be more than the estimated **2-week consumption**. The web-based ordering system only allows ordering quantity less than or equal to estimated 2-week consumption for PCVS.

	Comirnaty JN.1 dispersion for injection COVID-19 mRNA Vaccine 30 micrograms/dose	Spikevax JN.1 dispersion for injection in pre-filled syringe COVID-19 mRNA Vaccine 50 micrograms/dose 0.5 mL
Presentation	Multi-dose vial (6 doses)	Pre-filled syringe (Single dose)
Pack size available	(i) 1 vials per box (6 doses)Dimensions: 48 x 90 x 26mm(ii) 10 vials per box (60 doses)Dimensions: 90 x 48 x 42 mm	(i) 10 pre-filled syringes per box (10 doses) Dimensions: 110 x 102 x 35 mm
Consumables available for ordering	1ml LDV syringe with 25G x 1" fixed needle (100 pcs/box)	25G x 1" luer-lock needle (100 pcs/box)

4.1.2 Before placing the vaccine order, it is the responsibility of the doctors to ensure adequate storage capacity including but not limited to adequate storage space and refrigerators with temperature (2 °C to 8 °C) and cold chain maintained. As prefilled syringes require more storage space compared to the multi-dose vial presentation, please refer to the dimensions given above and assess the available storage capacity in the PBVR before placing order.

- 4.1.3 It is crucial to monitor the stock level to avoid overstocking which may lead to running out of storage space and/or increased wastage. The "first-expired, first-out" principle on the use by date and time should be followed for the same product to avoid wastage.
- 4.1.4 The vaccine usage of each doctor / clinic / PCVS will be monitored closely according to eHealth System (Subsidies) [eHS(S)] records. Voided vaccines should be reported daily on the web-based ordering system via the online Daily Report Form.
- 4.1.5 If the vaccine wastage of the Medical Organisation is found unnecessary and avoidable and it has reached an unacceptable rate during the month, the participation of the Medical Organisation to continue the programme may be affected.
- 4.1.6 Vaccine and other essential supplies will be delivered within 5 working days after order placing. The delivery of other supplies for the purpose of the Vaccination Programme would be arranged separately.
- 4.1.7 Vaccine brand supplied to PCVS is subject to availability and allocation by the Department of Health.

4.2 Vaccine delivery

- 4.2.1 Vaccines must only be received by the designated clinic / PCVS staff. When receiving the vaccines, the designated clinic / PCVS staff must check the vaccine type, brand, quantity, lot number, expiry date, Batch Packaging Record (BPR) number assigned by the vaccine distributor and use by date and time after thawing, whether the seal is intact and whether cold chain is maintained; and record the date, time, and temperature of the vaccines delivered on a delivery note provided by the vaccine distributor. The designated clinic / PCVS staff should sign and then chop with the stamp after confirmation of the above.
- 4.2.2 The delivery note should be kept appropriately for future reference and inspection.
- 4.2.3 The designated clinic / PCVS staff should reject the vaccines if temperature excursion occurred during delivery and inform Programme Management and Vaccination Division (PMVD) immediately for replenishment arrangement, please see section 4.4.3.

4.2.4 The designated clinic / PCVS staff should also report to PMVD in case of discrepancies, leakage or damages to the vaccine.

4.3 Vaccine storage

- 4.3.1 A dedicated person-in-charge, who is a registered medical practitioner, registered nurse, enrolled nurse, pharmacist or dispenser, should be arranged to oversee vaccine cold chain and vaccine inventory management including but not limited to segregating the vaccines with different use by date and time after thawing.
- 4.3.2 Purpose-built vaccine refrigerators (PBVR) must be used for the storage of vaccines. PBVR should be equipped with a maximum-minimum thermometer(s) or temperature data logger(s) to monitor the temperature of vaccines.
- 4.3.3 Different types or brands of COVID-19 vaccines should be segregated in the PBVR. In case there are different lots of the same type of vaccine inside the fridge, they should be segregated as well.
- 4.3.4 The "first-expired, first-out" principle for the same product should be followed, and vaccine stock should be rotated within the refrigerator so that those with shorter use by date and time are used first. Please exhaust on-hand product before switching to another product. Vaccines with different use by date and time / expiry date should be segregated as well.
- 4.3.5 Colored trays, etc. may be used for segregation of vaccines in the PBVR.
- 4.3.6 [Comirnaty JN.1 vaccine (in multi-dose vials)] Thawed vials could be stored at 2-8°C up to 10 weeks (70 days). Thawing details are shown on the yellow label on the outer carton of the vaccine only. For daily operation, please check the remaining shelf-life of the vial after thawing by referring to the "Use by Date (at 2°C to 8°C)" (DD MMM YYYY) on the yellow label on the outer carton on a regular basis and prior to vaccine preparation, as the information is not shown on the label of individual vial. Vaccines that are beyond the Use by Date should not be used. Please note that after first puncture, the vaccines should be used within 12 hours. Any unused vaccines should be discarded 12 hours after first puncture. For example:

Outer carton



Yellow label on the outer carton



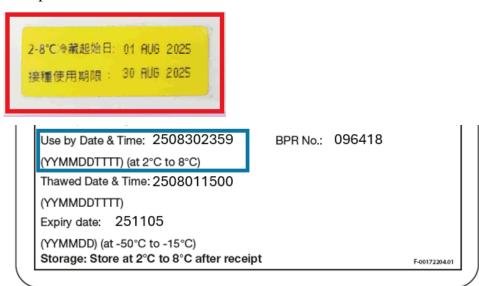
The Use by Date is read in DD MMM YYYY. "14 OCT 2025" means that the vaccine can be used until 11:59 pm on that date and should not be used afterwards. Please refer to Section 4.5.5 for the handling of expired Government-supplied vaccines.

4.3.7 [Spikevax JN.1 vaccine (in pre-filled syringes)] Thawed syringes could be stored at 2-8°C up to 30 days. Thawing details are shown on the outer carton of the vaccine only. For daily operation, please check the remaining shelf-life of the prefilled syringes after thawing by referring to the "Use by Date & Time" on the outer carton on a regular basis and prior to vaccine preparation, as the information is not shown on the label of individual prefilled syringes. An additional yellow

label is affixed to the front of the outer box of Spikevax JN.1 vaccine to enhance the visibility of use by date, as illustrated below.



Vaccines that are beyond the Use by Date & Time should not be used. For example:



The Use by Date & Time is read in YYMMDDTTTT. 2508302359 indicates that the vaccine would be expired on 30 Aug 2025 at 23:59 and should not be used afterwards. Please refer to Section 4.5.5 for the handling of expired Government-supplied vaccines.

Labelling on the syringe and/or tray with Use by Date & Time should be done

unless the syringe is obtained from packaging box immediately before vaccination.

4.3.8 Comparison of Shelf-life of different mRNA COVID-19 vaccines

	Comirnaty JN.1 dispersion for injection COVID-19 mRNA Vaccine 30 micrograms/dose	Spikevax JN.1 dispersion for injection in pre-filled syringe COVID-19 mRNA Vaccine 50 micrograms/dose 0.5 mL
Frozen	18 months (-90°C to -60°C)	9 months (-50°C to -15°C)
Thawed	10 weeks (70 days) (2°C to 8°C)	30 days (2°C to 8°C)
Unopened prior to use	12 hours (8°C to 30°C)	24 hours (8°C to 25°C)
Opened vial (after first puncture)	12 hours (2°C to 30°C)	N.A.

- 4.3.9 Modify and stabilize the refrigerator temperature before stocking with vaccine. The cold chain temperature range during storage should be +2°C to +8°C and it is a good practice to aim for +5°C, the midpoint of +2°C to +8°C.
- 4.3.10 Do not store vaccines directly under cooling vents, in drawers, on the floor or door shelves of the refrigerator. The instability of temperature and air flow in these areas may expose vaccines to inappropriate storage temperature.
- 4.3.11 Clinic / PCVS staff who is responsible for the maintenance of cold chain should strictly follow the manufacturers' recommendation on storage temperature of the vaccine, referencing to the package insert.
- 4.3.12 The refrigerator's user manual should be in place and clinic / PCVS staff should have basic operation technique to operate the refrigerator.
- 4.3.13 The refrigerator should be used exclusively for the storage of pharmaceutical products including vaccines. No food or drink is allowed in the medical fridge.

- 4.3.14 Good air circulation around the refrigerator is essential for proper cooling functions. The refrigerator should be placed away from heat sources and according to the manufacturer's user guide allowing sufficient ventilation around the refrigerator. Do not block the ventilation grid.
- 4.3.15 Ensure the refrigerator door is properly closed. The door should be opened as few as possible and closed as quickly as possible in order to maintain a constant temperature and prevent unnecessary temperature fluctuation. It is desirable to store the vaccines in their original packaging. Allow sufficient space between stocks for good air circulation.
- 4.3.16 The VSS doctor should follow the requirements and recommendations regarding vaccine storage mentioned in Chapter 6 of VSS Doctors' Guide (https://www.chp.gov.hk/files/pdf/vssdg_ch6_vaccine_storage_and_handling.pdf) and Section 3.3 of the Hong Kong Reference Framework for Preventive Care for Children in Primary Care Settings Module on Immunisation. Revised Edition 2019. (https://www.healthbureau.gov.hk/pho/rfs/english/pdf_viewer.html?rfs=Preventive CareForChildren&file=ModuleOnImmunisation_Chapter3).
- 4.3.17 Please have segregation between government-supplied COVID-19 vaccine and self-procured COVID-19 vaccine.

4.4 Cold chain management

- 4.4.1 Clinic / PCVS staff should check the current, maximum and minimum temperature of the refrigerator by generating a temperature log from data logger daily. If a maximum-minimum thermometer is used, record the forementioned readings in the "Daily Fridge Temperature Chart" (Annex IV) manually 3 times daily each working day, preferably in the morning, at noon and in the afternoon, and post the chart at readily accessible and visible location such as on the refrigerator door. The reading on the maximum-minimum thermometer should be reset after each checking. Onsite healthcare personnel should be able to retrieve temperature records and document temperature proficiently.
- 4.4.2 Contingency plan should be established and well understood by staff in case of temperature excursion (outside the recommended range of +2°C to +8°C) to minimize vaccine wastage for example, fridge malfunctioning or power outage, use of Uninterrupted Power Supply or a spare fridge in the premises is preferable but

not mandatory.

- 4.4.3 In case of temperature excursion, clinic / PCVS staff should consult the pharmacist of PMVD at 5394 3508 in normal working hours or email to pharm_cmt@dh.gov.hk and the vaccines involved should not be administered until advice given from the PMVD based on the recommendation from vaccine manufacturer on vaccine stability. The vaccines involved should be quarantined inside the refrigerator at 2-8°C and marked "DO NOT USE".
- 4.4.4 Temperature range, date and duration of the temperature excursion should be recorded and reported via the "Temperature Excursion Incident Report Form" (Annex V) not later than one working day.
- 4.4.5 Remedial actions should be taken in order to ensure the cold chain is re-established as soon as possible.
- 4.4.6 Clinic / PCVS staff should keep all reports related to the incident e.g. temperature records, Temperature Excursion Incident Report, etc., at the clinic / PCVS for at least one year in case record tracing or inspection in the future is needed.

4.5 Unserviceable vaccines

- 4.5.1 Unserviceable vaccines should never be administered. Separately, the number of unserviceable vials / prefilled syringes should be reported at online Daily Report Form for estimation of vaccine usage. For defective vaccine, please also submit the Vaccine Report Form Relating to Discrepancy/Defective (Annex V).
- 4.5.2 Clinic / PCVS staff should record the cause, lot number and quantity of the vaccines involved, and take photos if the vaccine, needle or syringe was deemed defective.
- 4.5.3 In doubt of quality, vaccine should be quarantined at 2-8°C cold chain environment with temperature monitoring device, and marked "Do Not Use" on the vaccines boxes until further instruction by the Department of Health. Examples are listed as follows:
 - (a) Defect of the vaccine (e.g. drug label misprinting, presence of foreign particles)
 - (b) Temperature excursion
 - (c) Others as instructed by the Department of Health

- 4.5.4 Vaccines being unserviceable with the following reasons should be discarded into sharps box and disposed of as clinical waste. Examples are listed as follows:
 - (a) Damaged or contaminated
 - (b) Unused after twelve hours after first puncture (Comirnaty JN.1 vaccine)
 - (c) Patient unfit or patient reject injection
 - (d) Blood aspirated before injection
 - (e) Patient default booking
- 4.5.5 For handling expired Government-supplied vaccines, please take the following steps:
 - (a) Check the use by date on the yellow label on the outer carton.
 - (b) The expired vaccines (beyond use by date labelled on the outer carton) should be removed from fridge, quarantined in a lockable cabinet and marked "DO NOT USE".
 - (c) Retain the expired vaccines to be collected by the Department of Health.
 - (d) Report the expired vaccines via the online Daily Report Form.

4.6 Lot management

- 4.6.1 As batches of COVID-19 vaccines delivered to the clinic / PCVS may have different lot numbers, VSS doctor/ trained personnel under the VSS doctor's supervision must check the lot number of vaccines for each vaccine recipient.
- 4.6.2 Correct lot number should be marked on the label of each vaccine syringe.
- 4.6.3 Correct lot number should be selected from the pull-down menu in the field "Lot No." in the eHS(S) to ensure accuracy of the vaccination record. Any discrepancy between lot of vaccine used and data entry in eHS(S) must be reported to PMVD immediately.

4.7 Wastage reduction

- 4.7.1 Preventative measures should be in place to avoid unnecessary vaccine wastage.
- 4.7.2 Scenarios that may lead to unnecessary vaccine wastage includes:
 - (a) High rate of absenteeism
 - (b) Inappropriate vaccine storage condition
 - (c) Vaccine exposed to room temperature beyond allowed duration, such as
 - 12 hours of unopened vials prior to use and 12 hours after first puncture

(Comirnaty JN.1 vaccine)

- 24 hours of unopened prefilled syringes prior to use (Spikevax JN.1 vaccine)
- 4.7.3 Wastage rate will be reviewed by the PMVD periodically.

4.8 Wastage Reporting via the Online Daily Report Form

- 4.8.1 Designated clinic / PCVS staff or doctor should report in term of the clinic / PCVS as a single unit, for any wasted unserviceable doses (e.g. defective, damaged or contaminated, expired or unused etc.) through the online Daily Report Form on the web-based ordering system.
- 4.8.2 Designated clinic / PCVS staff or doctor should **submit the online Daily Report**Form preferably by the end of each day which includes number of vaccine vials / prefilled syringes at start and end of clinic / PCVS operation, number of vaccine vials / prefilled syringes received, taken out of fridge, inoculation made within the day and any other information as specified by the PMVD.

Designated clinic / PCVS offering should submit the online Daily Report Form for each type of vaccine been taken out of fridge on the same day.

4.9 Management of surplus vaccines

- 4.9.1 The vaccines are Government Property and are provided to the doctors solely for the purpose of providing vaccination to target recipients. VSS doctors must return any surplus unopened vaccine vials / prefilled syringes supplied by government at the end of the programme.
- 4.9.2 VSS doctors may be liable to costs related to broken or missing vaccines and the Government reserves the right to demand VSS doctors for payment due to broken vaccine or missing vaccines.
- 4.9.3 All Government-supplied COVID-19 vaccines should be stored securely to prevent theft, diversion, tampering, substitution, resale, or exportation. They should be stored and used properly in accordance with the manufacturer's recommendations to maintain vaccines' integrity, efficacy and safety.

5 Infection control practice

5.1 Infection control practice in healthcare setting

- 5.1.1 Clinic /PCVS staff are advised to take precautionary measures to minimise the risk of contracting and spreading of COVID-19. Please refer to the Guide to Infection Control In Clinic Setting at CHP website

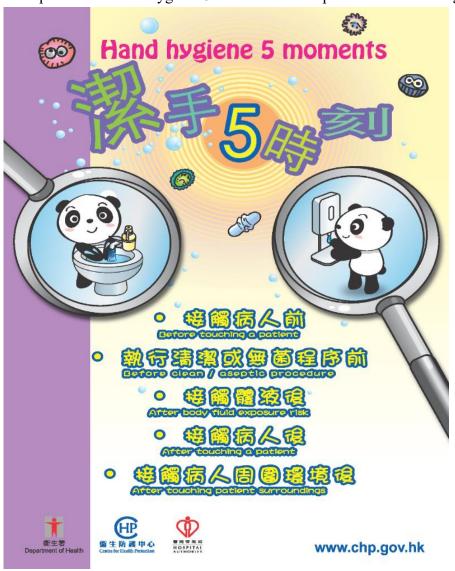
 (https://www.chp.gov.hk/files/pdf/guide_to_infection_control_in_clinic_setting.pdf).
- 5.1.2 Please refer to Personal Protective Equipment Section of ICB Infection Control Guidelines for detailed PPE indications, usage, and doffing and donning procedures (https://www.chp.gov.hk/en/resources/346/365.html).
- 5.1.3 Wear gloves if in contact with blood, body fluids, secretions, excretions, mucous membrane and non-intact skin, or items that are contaminated by these materials.
- 5.1.4 If gloves have been worn, it should be removed immediately after use for each client, followed by proper hand hygiene.
- 5.1.5 Gloves should be discarded immediately after removal. Gloves should not be washed, decontaminated, or reprocessed for any reuse purpose. Disinfection of gloved hands with alcohol-based handrub is not recommended. The use of gloves does not replace the need for hand hygiene.
- 5.1.6 Clean and disinfect all areas including, but not limited to, the working area inside vaccination areas, with 1 in 99 diluted household bleach (mixing 1 part of household bleach containing 5.25% sodium hypochlorite with 99 parts of water), especially high-touch areas, at least twice daily or whenever visibly soiled. Leave for 15-30 minutes, and then rinse with water and keep dry.
- 5.1.7 For metallic surface, disinfect with 70% alcohol.
- 5.1.8 Please refer to Use Mask Properly

 (https://www.chp.gov.hk/files/pdf/use_mask_properly.pdf) for the recommendations on use of surgical mask.

5.2 Hand hygiene

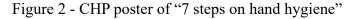
- 5.2.1 Hand hygiene practice should be adopted and strictly followed during vaccination procedure. Staff should perform hand hygiene for the following 5 moments (Refer to Figure 1 CHP poster of "Hand Hygiene 5 Moments in Hospital or Clinic Settings"):
 - (a) Before touching a patient
 - (b) Before clean / aseptic procedure
 - (c) After body fluid exposure risk
 - (d) After touching a patient
 - (e) After touching patient surroundings

Figure 1 – CHP poster of "Hand Hygiene 5 Moments in Hospital or Clinic Settings"



5.2.2 Hand hygiene with proper hand rubbing by using soap and water or alcohol-based

handrub for at least 20 seconds and 7 steps of hand hygiene techniques should be performed in between each and after last vaccination. (Refer to Figure 2 - CHP poster of "7 steps on hand hygiene")





- 5.2.3 Clean hands with liquid soap and water when hands are visibly soiled or likely contaminated with body fluid.
- 5.2.4 When hands are not visibly soiled, clean them with 70-80% alcohol-based handrub is also effective.
- 5.2.5 Apply a palmful of alcohol-based handrub to cover all surfaces of the hands. Rub hands according to the 7 steps of hand hygiene technique for at least 20 seconds until the hands are dry.

5.2.6 Please refer to the Recommendations on Hand Hygiene and Use of Gloves in Health Care Settings.

(https://www.chp.gov.hk/files/pdf/recommendations_on_hand_hygiene_and_use_ofgloves in health care settings.pdf)

5.3 Safe injection practices and sharps handling

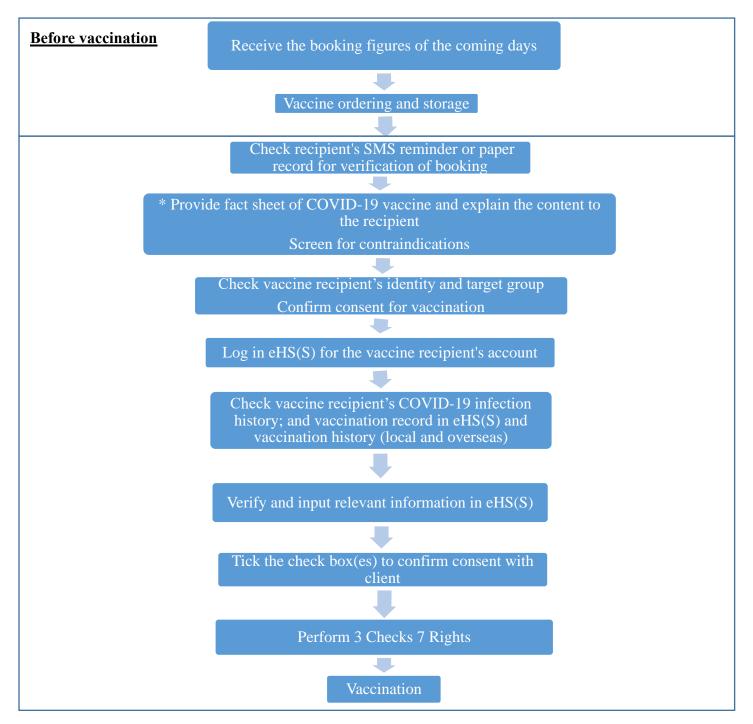
- 5.3.1 Precautions should be taken to prevent sharps injury. For details, please refer to "Prevention of Sharps Injury and Mucocutaneous Exposure to Blood and Body Fluid in Healthcare Setting", published by the Centre for Health Protection, Department of Health.

 (https://www.chp.gov.hk/files/pdf/prevention_of_sharps_injury_and_mucocutaneous_courses.)
 - (https://www.chp.gov.hk/files/pdf/prevention_of_sharps_injury_and_mucocutaneo us exposure to blood and body fluids.pdf)
- 5.3.2 Avoid work practices that pose sharps injury hazards, for example: recap, bend, break or hand-manipulate used needles.
- 5.3.3 Identify the location of the clinical waste container, if moveable, place it as near the point-of-use as appropriate for immediate disposal of the sharps.
- 5.3.4 Inform patients of what the procedure involves and explain the importance of avoiding any sudden movements that might dislodge the sharps, for successful completion of the procedure as well as preventing injury to healthcare personnel.
- 5.3.5 Discard used needles or sharps promptly in appropriate clinical waste containers.
- 5.3.6 Dispose any sharps with caution. Never throw the sharps into the clinical waste container.
- 5.3.7 Avoid overfilling a clinical waste container. The container should be disposed when it is 3/4 full or having its content reached the demarcated level.
- 5.3.8 Keep clinical waste containers securely in safe and upright position so as to prevent them from being toppled over.
- 5.3.9 Report all mucosal contacts of blood and body fluids, needle stick and other sharps-related injuries promptly to ensure that appropriate follow-up is received.

5.3.10 For post-exposure management, please refer to the CHP guideline "Recommendations on the Management and Postexposure Prophylaxis of Needlestick Injury or Mucosal Contact to HBV, HCV and HIV" at https://www.chp.gov.hk/files/pdf/recommendations_on_postexposure_management_and_prophylaxis_of_needlestick_injury_or_mucosal_contact_to_hbv_hcv_and_hiv_en_r.pdf.

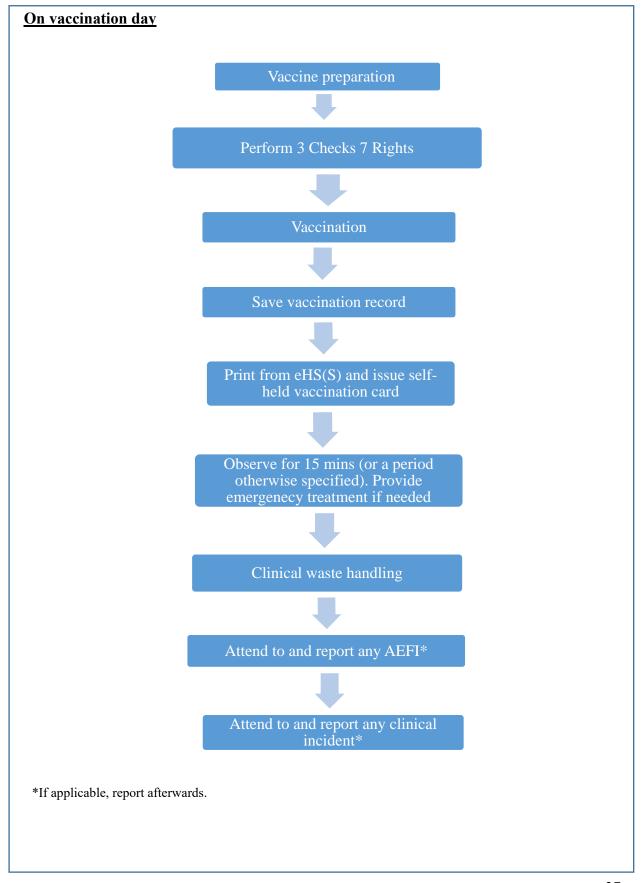
6 Vaccination procedures

6.1 Flow chart of vaccination (before vaccination)



^{*} Subject to the settings and workflow at individual clinic, the information might be provided at different steps of workflow.

6.2 Flow chart of vaccination (after vaccination)



6.3 Appointment booking

- 6.3.1 The vaccine recipients are required to make an appointment via the online booking system, where he/ she would be informed of the information about COVID-19 vaccines including the contraindications for vaccination during the process of making appointment. The strain or brand of vaccine offered would be subject to availability in the venue and experts' recommendation as announced by Government from time to time.
 - A SMS reminder of the vaccination would be sent prior to day of vaccination.
- 6.3.2 Walk-in quotas should be given to eligible persons aged below 18 years and 50 years or above and special cases who are not able to make an appointment via the public online system. PCVS should use their own booking system / arrangement (including but not limited to mobile app and telephone booking) for these recipients to book any dose of COVID-19 vaccinations. PCVS should trace and contact the recipients who defaulted the vaccination and re-arrange the vaccination for the recipients as soon as possible; and also contact the recipients to remind the schedule of their next dose(s). If daily walk-in quota is full, PCVS should provide assistance to help those in need to book vaccination on another date and time.
- 6.3.3 VSS doctors, during vaccine ordering, must ensure sufficient quantity for doses for each client as needed.
- 6.3.4 In addition, information on the eHealth would be shown to the vaccine recipient during the process of online booking. The vaccine recipient could indicate his/her consent for joining eHealth in the booking system.
- 6.3.5 Upon entering PCVS, vaccine recipients would have to show his/ her SMS reminder or paper record for verification of booking. Please check the venue code and other related information on the SMS to confirm if right person goes to the right venue to receive the right vaccine. Please check with recipients their intended choice of vaccine by checking the SMS and open-ended question. PCVSs should refer to the recommendation by Government from time to time and offer default vaccine to eligible clients.

Please segregate PBVs receiving different platform, variants or brands of vaccines (e.g. by providing different coloured chits along with the corresponding fact sheet). Vaccine recipients who require special assistance with booking arrangements should be provided with assistance.

6.3.6 Latest version of publicity materials including but not limited to factsheets and posters should be displayed in waiting area / information room and injection room to avoid injection of wrong type of vaccine to recipients.

Operating Hours during inclement weather - Applicable to PCVS only

6.3.7 Vaccination service of Private Clinic COVID-19 Vaccination Stations will continue as usual under the Amber and Red Rainstorm Warning.

Rainstorm Warning Signal is	Private Clinic COVID-19 Vaccination Stations
Issued before opening hours	PCVSs will remain closed while the Black Rainstorm Warning Signal is in force. Vaccination service will be resumed 2 hours after the warning signal is cancelled.
Issued during opening hours	Clinics would take care of persons who have arrived. Vaccination service would be provided as far as possible.

Vaccination service of Private Clinic COVID-19 Vaccination will continue as usual under the Standby Signal No.1 and the Strong Wind Signal No.3.

The time when the Tropical Cyclone Warning Signal No. 8 or above is hoisted	Private Clinic COVID-19 Vaccination Stations
Issued before opening hours	PCVSs will remain closed while the Tropical
	Cyclone Warning Signal No. 8 or above is in force.
	If the warning signal is cancelled before 1:00 pm,
	vaccination service will be resumed 2 hours after the
	warning signal is cancelled.
Issued during opening hours	Admission will be stopped immediately after the
	issuance of Pre-No.8 Special Announcement (issued
	about two hours before T8 is issued) and vaccination
	will be arranged for persons who have already
	entered at PCVSs. PCVSs will be closed for the rest
	of the day.

Private Clinic COVID-19 Vaccination Stations will be closed for "Extreme Condition" announcement. Please refer to the relevant press release for details.

There would be **NO** rescheduling of booking appointments for the affected clients. For persons with their booking affected by the inclement weather, they can make another new vaccination appointment date and time through the booking system on the website of the COVID-19 Vaccination Programme (booking.covidvaccine.gov.hk) after the scheduled time.

Please refer to

https://www.chp.gov.hk/files/pdf/annexesinclementweatherarrangementenglish.pdf for more information.

Please also stay alert for the latest Government announcement (if any) for the opening arrangement for PCVS during inclement weather and extreme conditions.

6.4 Information provision, screening for contraindications, checking identity and target group, and obtaining informed consent

- 6.4.1 Information provision and screening for contraindications
- (a) Fact sheet (Annex I) available at (https://www.chp.gov.hk/files/pdf/factsheet_covidvaccine_mrna_eng.pdf) about mRNA vaccines should be displayed in the waiting area / injection room to avoid injection of the wrong type of vaccine to recipients.
- (b) Before vaccination, clinic/PCVS staff should provide vaccine recipients with the fact sheet (**Annex I**) of the relevant COVID-19 vaccine with information about potential side effect, authorised and not registered status of the vaccines, and vaccine-related adverse events following immunisation (AEFI); and another leaflet with information on enrolment in eHealth. VSS doctors are able to order the factsheet and other pamphlet through vaccine ordering system. Please make sure you have distributed the latest version of publicity materials to vaccine recipients.
- (c) The VSS doctor/ trained personnel under the VSS doctor's supervision should go through with the vaccine recipients on the content of the factsheet, allow questions and answer enquiries, conduct health assessment, check for any contraindications, special precautions, assess suitability of the recipient to receive the COVID-19 vaccine and handle enquiries. Please see Sections 2.1.3 on the contraindications

and precautions of the COVID-19 vaccine. Inside the vaccination booth/room, vaccinators should confirm the recipient's choice of vaccine and one's eligibility by (1) Open-ended question for the vaccine to be received, (2) Checking against the eligibility of the recipients for the type of vaccine. Other measures may be adopted to facilitate confirmation on choice of vaccine eg. use of identification photos of vaccine packaging and vial to counter-check with the recipient, checking the coloured chits, SMS messages etc.).

- (d) As myocarditis and pericarditis are known potential adverse reactions of mRNA vaccines that are supplied in Hong Kong, the recipients should be advised to avoid strenuous exercise for one week after mRNA vaccination, and seek immediate medical attention when signs such as breathlessness, palpitations or chest pain occur.
- (e) The DH has issued an interim guidance notes on common medical diseases and COVID-19 vaccination in primary care settings. VSS Doctors could refer to the interim guidance notes in making clinical judgement on the suitability for COVID-19 vaccination. The interim guidance notes is a living document which will be updated from time to time. VSS Doctors and health professionals of the clinic /PCVS should obtain the latest version at the designated website at https://www.chp.gov.hk/en/features/106957.html.
- 6.4.2 VSS doctors may refer the following cases to the Vaccine Allergy Safety Clinic of Hospital Authority for medical consultation/investigation as deemed appropriate:
 - (i) persons with immediate (within 1 hour) severe allergic reaction to prior COVID-19 vaccination or to more than one class of drugs;
 - (ii) persons with allergic reaction to prior COVID-19 vaccination which is not self-limiting or did not resolve by oral anti-allergy drug.

Clients with allergic rhinitis, asthma, atopic dermatitis, chronic urticaria, <u>drug and</u> <u>food allergies</u>, <u>and anaphylaxis unrelated to COVID-19 vaccines</u> (without other precautions) do <u>not</u> need to see an Allergist for evaluation of COVID-19 vaccine allergy risk.

Clients with the following reactions to prior COVID-19 vaccines can proceed to receive the next dose with post-vaccination observation for at least <u>30 minutes</u> after vaccination:

(i) <u>superficial symptoms like rash, itchiness, urticarial, etc. that appear within 1</u> <u>hour, but without other systemic allergic symptoms such as shortness of breath, wheezing, low blood pressure, etc.;</u>

(ii) symptoms that appear later than 1 hour that are self-limiting or resolve by an oral anti-allergy drug.

Please refer to the "An Interim Guidance Notes on Common Medical Diseases and COVID-19 Vaccination in Primary Care Settings" for further details. (https://www.chp.gov.hk/files/pdf/guidance_notes.pdf)

- (a) To make the referral, VSS doctors are required to issue a referral letter to these cases and ask them to bring along the following documents for making appointment:
 - i. referral letter issued by a local registered medical practitioner within three months;
 - ii. the original or copy of valid identification document (e.g. HKID); AND
 - iii. address information
- (b) The methods of making appointment and details of the clinics are as follow:
 - i. in person / by authorized representative;
 - ii. by facsimile to Vaccine Allergy Safety Clinic;
 - iii. telephone booking by the referral doctor/ nurse; or
 - iv. through smartphone mobile application "BookHA"
- (c) The address and contacts of the clinics are as follow:

Vaccine Allergy Safety Clinic at Grantham Hospital			
Address:	Rheumatology and Clinical Immunology Unit,		
	G/F, Block A, Grantham Hospital, 125 Wong Chuk		
	Hang Road, Aberdeen, Hong Kong		
Tel. No.:	2518 2620		
Fax No.:	2518 6716		
Service Hours:	Mon to Fri: 08:30 to 17:00; Sat: Closed		
Vaccine Allergy	Safety Clinic at Queen Mary Hospital		
Address:	6/F., S Block, Queen Mary Hospital, 102 Pokfulam		
	Road, Hong Kong		
Tel. No.:	2255 4186		
Fax No.:	2255 3018		
Service Hours:	Mon to Fri: 09:00 to 17:00; Sat: 09:00 to 13:00		

6.4.3 VSS doctors may also refer children and adolescents in the prevailing age indications for mRNA COVID-19 vaccines who are deemed eligible for COVID-

- 19 vaccination and are holders of Hong Kong birth certificates and/or identify cards with the following medical history to the Paediatric Allergy Clinics in four tertiary hospitals for further allergy assessment:
- (i) History of an immediate and severe allergic reaction to components of the COVID-19 vaccines; or
- (ii) History of immediate allergic reaction to the previous dose of inactivated or mRNA COVID-19 vaccines
- (a) VSS doctors may refer eligible adolescents to the Allergy Clinics using the referral form accessible on the website of the Hong Kong Society for Paediatric Immunology Allergy Infectious Diseases (HKSPIAID) and (https://www.hkspiaid.org/download/COVID19 vaccination referral letter 20210804.pdf). Doctors are required to specify the referral reason on the form which should be submitted to the respective hospitals / clinics by fax. Paediatric Allergy Clinic staff would perform risk stratification on individual recipients, followed by a reply either to the referrers or via direct contact with recipients regarding the fitness for vaccination or for further arrangement of vaccine allergy safety assessment. More information could be found at HKSPIAID's website at https://www.hkspiaid.org/covid19/.
- (b) Doctors, vaccine recipients and recipients' family are free to decide which hospital / clinic to be referred to and are not bound by geographical regions. The contact and fax numbers of the clinics are as follow:

Name of hospital / clinic	Contact	Fax
	number	number
Prince of Wales Hospital Paediatric Specialist Out-	3505 4440	3505 4633
patient Clinic		
Queen Elizabeth Hospital Paediatric Specialist Out-	3506 6226	3506 6140
patient Clinic		
Queen Mary Hospital Paediatric & Adolescent	2255 3237	2819 3655
Medicine Specialist Out-patient Clinic		
Yan Chai Hospital Paediatrics and Adolescent	2417 5817	2149 6039
Ambulatory Centre		

6.4.4 Check vaccine recipient's eligibility, identity document, priority group and obtain informed consent via eHealth System (Subsidies) before administration of vaccine.

VSS doctor/ trained personnel under VSS doctor's supervision should always refer

to the most update announcement from the Government and information on the website (https://www.chp.gov.hk/en/features/106952.html) for the eligibility and priority groups for vaccination.

(a) Check vaccine recipient's identity document. Vaccine recipient must show identity document to the VSS doctor/ trained personnel under VSS doctor's supervision before vaccination for registration use and for creating a vaccination record. Please see section 2.2 for details.

Please refer to the eHS(S) Guide reference:

https://www.ehealth.gov.hk/en/covidvaccine/doc/quick-guide-for-using-manual-input-of-other-document.pdf.

- (b) To facilitate accurate capturing of personal particulars from the HKID, VSS doctor/ trained personnel under VSS doctor's supervision should use the Smart HKID Card Reader and let the vaccine recipient insert his/ her HKID into the card reader for registration, retrieving the vaccine recipient's page on eHS(S), for creating the vaccination record and acting as an electronic consent to receive COVID-19 vaccination and use vaccination subsidy. For Acknowledgement of Application for an Identity Card and Certificate of Exemption, VSS doctor/ trained personnel under VSS doctor's supervision should enter the document number and other personal information as required into the eHS(S) manually.
- (c) For recipients without prior account opened under eHS(S), the clinic/PCVS staff have to obtain verbal consent from the recipient and open an eHS(S) account for him/her through insertion of HKID into the Smart HKID Card Reader by the recipient.
- (d) Electronic consent should be used for recipients in VSS clinics and PCVSs except for minors under 18 years old and exceptional cases such as mentally incapacitated persons. Hard copy of written consent (**Annex VI**) would be used for minors and these exceptional cases. Please refer to **section 6.14** for the vaccination arrangement for adolescents. In the "Remarks" field of the eHS(S), please record that the recipient is a minor or mentally incapacitated person and written consent has been obtained.
- (e) Vaccinator should collect and keep the signed consent forms for at least 7 years.
- (f) VSS doctor in private clinic should select the appropriate category on eHS(S) for

people belonging to the priority groups mentioned in Section 2.2.1. Both VSS doctor in private clinic and PCVS should confirm the client fall under the high risk priority group for free vaccination in the confirmation page.

6.4.5 Please refer to the following User Manual and Quick Guide for more information:

User Manual on COVID-19 Vaccination Programme:

https://www.ehealth.gov.hk/en/covidvaccine/ehs.html

Quick Guide for Private Clinics:

https://www.ehealth.gov.hk/en/covidvaccine/doc/quick-guide-for-private-clinics.pdf

- 6.4.6 The following information would be prefilled or required to be input into the vaccine recipient's page:
 - (a) Practice (name of the VSS clinic / PCVS)
 - (b) Name of vaccination scheme
 - (c) Injection date
 - (d) Category of target groups
 - (e) Sub-Category of target groups
 - (f) Vaccine (name and brand)
 - (g) Lot number
 - (h) Dose sequence
 - (i) Contact No.
 - (i) Remarks

Please see the screen cap of the page for further information.



Please ensure you choose the correct practice and input correct dose sequence.

- 6.4.7 Check vaccination record/ history
- (a) To ensure patient safety and assist assessment of vaccine recipient's suitability for COVID-19 vaccination, VSS doctor/ trained personnel under VSS doctor's

supervision should check the vaccine recipient's COVID-19 vaccination history (local and overseas) and other vaccination history **BOTH with the vaccine** recipient in-person AND against the eHS(S) BEFORE the administration of COVID-19 vaccine. The doctor cannot make claim for vaccination subsidy if the recipient has already completed the vaccination course.

(b) Vaccine recipient should provide his/her identity document and proof of the vaccination record with date, venue of vaccination and type of vaccine for checking by VSS doctor/ trained personnel under the VSS doctor's supervision.

The VSS doctor/ trained personnel under the VSS doctor's supervision may consider case-by-case, according to the JSC recommendation and assess on the interval, the contraindications, and provide additional dose vaccination using the COVID-19 vaccines available in HK, as appropriate. Please refer to the latest recommendation by the JSC (https://www.chp.gov.hk/en/static/24005.html).

For vaccine recipient who are eligible to receive COVID-19 vaccine under the Government vaccination programme, who have received COVID-19 vaccine outside Hong Kong and have not yet received the COVID-19 vaccine in Hong Kong, please check their identity document, proof of the previous dose vaccination record (with date, venue of vaccination and type of vaccine) issued outside Hong Kong. Vaccination may be provided by VSS doctor/ trained personnel under VSS doctor's supervision after clarification and consideration of relevant details, including those of the previous dose vaccination. For further details, please refer to #24 (https://www.chp.gov.hk/en/features/106953.html#FAQ B24)

For such cases, vaccinator should record the details of the previous doses received outside Hong Kong including the date, place and type of vaccination under "Remarks" in the eHS(S) while the vaccine provided by the clinic/PCVS should be entered as the next dose in eHS(S).

(c) VSS doctors may exercise one's clinical judgement and provide a different brand of COVID-19 vaccine to vaccine recipients if deemed clinically appropriate.

Please refer to the latest COVID-19 vaccination recommendation for individuals with previous COVID-19 infection by the JSC via https://www.chp.gov.hk/en/static/24008.html.

Please refer to "How many doses of COVID-19 vaccine recommended for me?"

for reference:

https://www.chp.gov.hk/en/features/106951.html

*The latest updates and implementation schedule will also be communicated to the responsible staff of PCVSs by means of email. The responsible staff of PCVSs should check their registered email account for the latest updates. VSS doctors and other staff may also refer to the Government's thematic webpage for the latest updates (https://www.chp.gov.hk/en/features/106934.html).

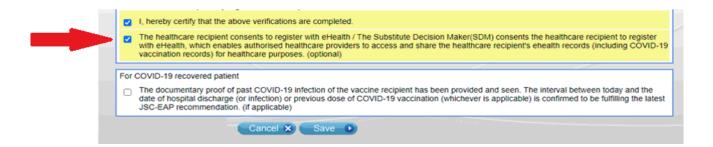
- 6.4.8 The VSS doctor/ trained personnel under the VSS doctor's supervision should check the recipient's personal particulars, vaccine name, type, and duration since last dose to ensure the type and interval of COVID-19 vaccination are correct.
- 6.4.9 The batches of COVID-19 vaccines delivered may have different lot numbers, VSS doctor/ trained personnel under the VSS doctor's supervision should **check the lot number of vaccines for each vaccine recipient and select a correct lot number** from the pull-down menu in the field "Lot No." in the eHS(S) to ensure accuracy of the vaccination record.
- 6.4.10 The VSS doctor/ trained personnel under the VSS doctor's supervision should verify the following as shown on eHS(S) and after verification tick the check box on eHS(S) for record:
 - (a) The identity of the vaccine recipient has been verified;
 - (b) The vaccine recipient has read and understood the information in the Vaccination Fact Sheet and information as published on CHP website in respect of the COVID-19 vaccine available under the Government COVID-19 Vaccination Programme for COVID-19 vaccine as documented above, including contraindications (and possible adverse events) of COVID-19 vaccination. The vaccine recipient understood that the provision, administration and use of the COVID-19 vaccine is subject to availability under the Government COVID-19 Vaccination Programme and that the vaccines are provided and administered in Hong Kong based on the following arrangements:
 - A) The vaccine product is registered under the Pharmacy and Poisons Ordinance (Cap.138); OR
 - B) The vaccine is permitted to be used under the Government COVID-19 Vaccination Programme; OR

C) The vaccine is used under circumstances not listed in the approved package insert of the vaccine product and this off-label use is permitted under the Government COVID-19 Vaccination Programme, having regard to the advice from panel(s)/ committee(s) of experts appointed by the Government upon review of the current and anticipated epidemic situation, as well as the relevant efficacy and safety published.

The vaccine recipient has provided the medical history with regard to the contraindications of the type of COVID-19 vaccine selected. The vaccine recipient has had the opportunity to ask questions and all of his/her questions were answered to his/her satisfaction. The vaccine recipient also fully understood his/her obligation and liability under this consent form and the Statement of Purpose of Collection of Personal Data;

- (c) Suitability for vaccination has been confirmed with reference to previous COVID-19 vaccination record (if any) and the vaccine recipient fall under the high risk priority groups for free vaccination;
- (d) The vaccine recipient consent to the administration of COVID-19 Vaccination under the COVID-19 Vaccination Programme; and the access and use by Department of Health and the relevant organizations collaborated with the Government (including the University of Hong Kong) of his/her clinical data held by the Hospital Authority and the relevant private healthcare facilities and healthcare professionals, for the purpose of continuously monitoring the safety and clinical events associated with COVID-19 Vaccination by the Department of Health insofar as such access and use are necessary for the purpose; and
- (e) If the recipient is not legally capable of giving consent to the administration of the vaccine, either a person who is legally capable of giving the relevant consent on the recipient's behalf or decision of vaccination is made considering the vaccination is necessary and in the best interest of the vaccine recipient by registered medical practitioner.
- 6.4.11 To facilitate the vaccine recipients to check their COVID 19 vaccination records, they are encouraged to join the eHealth (醫健通). With effect from 1 June 2022, the eHS(S) screen for COVID-19 vaccination input, will pre-set a "tick" in the box

of join eHealth (醫健通). VSS doctors and clinic /PCVS staff must ask for consent from recipients and should remove the "tick" if recipient does not give consent. Joining eHealth (醫健通) is optional for recipients. The screen cap is attached for your easy reference.



6.5 Vaccine preparation and administration

- 6.5.1 Vaccines are required to be prepared properly before use. Vaccine preparation varies depending on the type and brand of COVID-19 vaccines.
- 6.5.2 [Comirnaty JN.1 vaccine (in multi-dose vials)] Comirnaty can be optionally prepared by: (1) Preferably prepared as single dose immediately before vaccination inside the vaccination booth/room; OR (2) Follow prevailing practice to prepare in advance in batches (measures to clearly segregate e.g. clear labelling, coloured trays should be adopted).
- 6.5.3 [Spikevax JN.1 vaccine (in pre-filled syringes)] Spikevax attached with appropriate needle can be optionally prepared either (1) immediately before vaccination inside the vaccination booth/room; OR (2) in advance in batches (adopting measures to clearly segregate e.g. clear labelling, coloured trays should be adopted).
- 6.5.4 If venue allows, different booths/rooms should be assigned to provide different types or brand of COVID-19 vaccines. Clear signage should be shown at the booths/rooms. Recipients should be directed to the suitable booth/room according to their intended choice of vaccine.
- 6.5.5 If the clinic /PCVS administers different types or brand of COVID-19 vaccines, a mechanism, to the satisfaction of the Government, should be implemented to

segregate the handling of vaccines and inoculation workflow of different types or brand of vaccines, etc. to avoid inadvertent administration of the wrong type of vaccine.

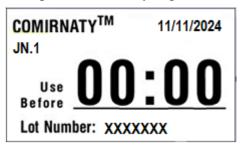
- 6.5.6 A dedicated person-in-charge, who is a registered medical practitioner, registered nurse, enrolled nurse, pharmacist or dispenser, should be arranged to ensure the adoption of "First Expired, First Out" principle for the same product during dispensing and labelling of the vaccine in the clinic/ PCVS. In addition, please exhaust the on-hand vaccine product before switching to another vaccine product (if any). For Comirnaty vaccine, please check the remaining shelf-life of the vial after thawing by referring to "Use by Date" on the yellow label on the outer carton prior to vaccine preparation, as the information is not shown on the label of individual vial (which rather shows the expiry date before thawing). For Spikevax vaccine, please check the "Use by Date & Time" on the outer carton (with an additional yellow label is affixed to the front of the outer box of Spikevax JN.1 vaccine to enhance the visibility of use by date) prior to vaccine preparation. Vaccines that are beyond the use by date and time should **not be used.** Procedures should be placed to ensure proper handling, distribution and administration of vaccines, including but not limited to proper labelling of syringes and vaccines.
- 6.5.7 The information regarding the handling procedure of different mRNA vaccines should be readily accessible in the designated area of vaccine preparation area to remind the staff about the proper handling procedure for the different variants or formulations of mRNA vaccine.
- 6.5.8 [Comirnaty JN.1 vaccine (in multi-dose vials)] **DO NOT DILUTE**. It is suggested that doses should be prepared immediately after withdrawal from refrigerator. Expiry of unopened vial at temperature **up to 30°C** is 12 hours prior to use. The unopened vaccine vial should be discarded 12 hours after taking out from the refrigerator.

After first puncture, the vaccines should be used within 12 hours. Do not use any remaining doses in the punctured vial after 12 hours. Any punctured vaccine vial should be put into the sharp box if there is no further vaccination activity to be conducted within 12 hours (from the time the vaccine vial has been taken out from the refrigerator).

- 6.5.9 [Spikevax JN.1 vaccine (in pre-filled syringes)] **DO NOT DILUTE**. Pre-filled syringes may be stored at 8°C to 25°C up to 24 hours after removal from refrigerated conditions.
- 6.5.10 All types of mRNA vaccines should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.
- 6.5.11 [Comirnaty JN.1 vaccine (in multi-dose vials)] Syringe should be properly labelled for traceability and compliance with "use within" requirement of the vaccine, including but not limited to the following:
- (a) Name of vaccine
- (b) Use before date and time after first puncture
- (c) Lot number
- (d) Recommend to use markings on syringe label (e.g. highlight/different colour) to clearly distinguish different types of vaccine

Used vial should also be labelled with above information.

Example of vial and syringe labels for Comirnaty JN.1 vaccine:



Please note that labelling of syringes is NOT required for vaccines **prepared as single dose immediately before vaccination** inside the vaccination booth /room, but used vial should be labelled with above information.

Please ensure the correct number of doses are withdrawn from each vial by proper documentation or measure.

Photos of the multi-dose vials of Comirnaty JN.1 vaccine are attached for easy reference.



6.5.12 [Spikevax JN.1 vaccine (in pre-filled syringes)] Please ensure compliance with "use within" requirement of the vaccine. Labelling on the syringe and/or tray with Use by Date & Time should be done unless the syringe is obtained from packaging box immediately before vaccination.

Photos of the pre-filled syringes of Spikevax JN.1 vaccine are attached for easy reference.



- 6.5.13 [Comirnaty JN.1 vaccine (in multi-dose vials)] The procedure for vaccine handling and preparation should be carried out according to the drug insert as illustrated below:
 - Verify that the vial has a grey plastic cap and the product name is Comirnaty JN.1 dispersion for injection COVID-19 mRNA Vaccine 30 micrograms/dose (12 years and older).
 - If the vial has another product name on the label, please make reference to the package insert for that formulation.
 - Unopened vials can be stored for up to 10 weeks at 2 °C to 8 °C; not exceeding the printed expiry date (EXP).
 - Prior to use, the unopened vial can be stored for up to 12 hours at temperatures up to 30 °C. Thawed vials can be handled in room light conditions.
- 6.5.14 The preparation of each 0.3mL dose using a new sterile 1mL low dead-volume (LDV) syringe is illustrated below:
 - Gently mix by inverting vials 10 times prior to use. Do not shake.
 - Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
 - After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
 - Check whether the vial is a multidose vial and follow the applicable handling instructions below:
 - Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
 - Withdraw 0.3 mL of Comirnaty JN.1.
 - Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
 - Each dose must contain 0.3 mL of vaccine.
 - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
 - Record the appropriate date/time on the multidose vial. Discard any unused vaccine 12 hours after first puncture.

6.5.15 [Spikevax JN.1 vaccine (in pre-filled syringes)] The procedure for vaccine handling and preparation should be carried out according to the drug insert as below:

6.5.15.1 Vaccine verification

 Verify that the product name of the pre-filled syringe is Spikevax JN.1 dispersion for injection in pre-filled syringe COVID-19 mRNA Vaccine 0.5 micrograms/dose 0.5 mL.

6.5.15.2 Prior to use

- Let each pre-filled syringe stand at room temperature (15°C to 25°C) for 15 minutes before administering.
- Do not shake.
- Pre-filled syringe should be inspected visually for particulate matter and discolouration prior to administration.
- Spikevax JN.1 is a white to off-white dispersion. It may contain white or translucent product-related particulates. Do not administer if vaccine is discoloured or contains other particulate matter.

6.5.15.3 Preparation

- Use a sterile needle of the appropriate size for intramuscular injection (21-gauge or thinner needles).
- With tip cap upright, remove tip cap by twisting counter-clockwise until tip cap releases. Remove tip cap in a slow, steady motion. Avoid pulling tip cap while twisting.
- Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe.
- Uncap the needle when ready for administration.

Please refers to the manufacturer video for vaccine preparation in Cantonese at https://mrna.care/mn00S7b66 for further details.

- 6.5.16 Staff of the designated preparation area should inform the nurse-in-charge and all related vaccinators immediately whenever there is a change in lot number. Before starting to use the new lot of vaccines, the new lot number should be entered into the eHS(S) lot management system for selection by vaccination staff.
- 6.5.17 Before administering the vaccine, clinic / PCVS staff should check the vaccine for any irregularity, e.g. damage, contamination, expiry date. Please check the use by date and time on the outer carton, as the information is not shown on the label of individual prefilled syringes for Spikevax JN.1 vaccine or individual vial for Comirnaty JN.1 vaccine. Vaccines that are beyond the use by date and time should

not be used.

- 6.5.18 All types of mRNA vaccines should be administered intramuscularly. For individuals aged 18 and above, the preferred site is the deltoid muscle of the upper arm. Mid-anterolateral thigh injection **should be offered to all adolescents** (both male and female) aged 12 17 as the site of vaccination. Adolescents aged 12 17 could make an informed choice to opt-out from thigh injection and receive vaccination in deltoid. Individuals aged 18 and above could choose to receive mRNA vaccine in their mid-anterolateral thigh on an **on-demand basis**. Please refer to **section 6.6.19 6.6.11** for the technique of mid-anterolateral thigh injection.
- 6.5.19 Checking of vaccines and rights of medication administration should be adopted, including:
 - (a) 3 checks:
 - when taking out the vaccine from storage;
 - before preparing the vaccine and;
 - before administering the vaccine
 - (b) 7 rights:
 - The right patient;
 - The right vaccine;
 - The right time (e.g. correct age, correct interval, use by date and time, vaccine not expired);
 - The right dosage (confirm appropriateness of dose by using current drug insert as reference.);
 - The right route, needle length and technique;
 - The right site; and
 - The right documentation (e.g. Document the name of recipient, vaccine provider, vaccine type/ name and date of vaccination on the vaccination card.)

6.6 Administration by the Intramuscular (IM) Route

- 6.6.1 The VSS doctor/ trained personnel under the VSS doctor's supervision should refer to the drug insert for complete vaccine administration information.
- 6.6.2 The VSS doctor/ trained personnel under the VSS doctor's supervision should use a new alcohol prep/ alcohol swab for skin disinfection from centre outwards, without touching the same area repeatedly; and allow the site to DRY completely before vaccination, and use a new dry sterile gauze/ non-woven ball for post vaccination compression of injection site.

- 6.6.3 Precautions should be taken to prevent sharps injury. Please refer to **section 5.3** for details.
- 6.6.4 The skin should be spread between the thumb and forefinger to avoid injection into subcutaneous tissue.
- 6.6.5 To avoid inadvertent intravascular administration, please aspirate before injection of COVID-19 vaccine by pulling back on the syringe plunger after needle insertion but before injection. If blood is noticed in the hub of the syringe, the needle should be withdrawn immediately. Please explain to the vaccine recipient before discarding the needle and syringe including vaccine contents into the sharp box. A new needle and syringe with vaccine will need to be prepared and used.
- 6.6.6 The needle at 90-degree angle should be fully inserted into the muscle and inject the vaccine into the muscle.

90° angle
skin
subcutaneous tissue
muscle

Figure 3 – Intramuscular (IM) injection

Source: Immunization Action Coalition (IAC), U.S.A.

- 6.6.7 Withdraw the needle and apply light pressure to the injection site with a piece of dry sterile non-woven ball or gauze to stop bleeding when the injection is completed. Instruct the client or parent/ guardian to apply pressure gently for 1 to 2 minutes over the injection site or till bleeding stops.
- 6.6.8 For conditions of incomplete dose during injection of mRNA vaccine to your clients due to various reasons such as leakage of vaccine from the syringe, please handle according to the following information:

	Action
Less than half of the	A repeat dose should be given immediately at
recommended dose or uncertain	the opposite arm.
amount of vaccine given	
Half of the recommended dose	Another half-volume dose can be administered
given	on the same clinic day, and the 2 doses can
	count as 1 full dose.
More than half of the	No repeat dose is required.
recommended dose given	

Please submit the "Clinical incident notification form" (**Annex IX**) within the same working day upon discovery of incident **AND** submit the "Clinical incident investigation report" (**Annex X**) within 1 week upon discovery of the "incomplete dose" incident.

- 6.6.9 The updated guidance notes on mid-anterolateral thigh injection is at **Annex XI**. The picture of mid-anterolateral thigh injection site is recommended to display in the vaccination booths of PCVS for vaccinators' easy reference.
- 6.6.10 When performing mid-anterolateral thigh injection, VSS doctors have to ensure that;
 - (a) vaccinators have been equipped with the knowledge and skills on thigh injection techniques;
 - (b) the pros and cons of thigh injection have been explained to and understood by the adolescent and their parents / guardians;
 - (c) thigh injection should take place at "thigh booth" (front and back opaque curtains, with top covered depending on the setup of the vaccination venue; air purifier as appropriate for enclosed booth);
 - (d) client's privacy, and chaperon as needed are in place during the whole vaccination procedure;
 - (e) the injection site is documented in eHS(S) "Remarks" field with standard wordings as before (i.e. "Left thigh" or "Right thigh") (For adolescents who optout thigh injection and choose deltoid, there is no need to document the site for deltoid injection).

6.7 Documentation and Medical Exemption Certificate

6.7.1 The vaccination record in eHS(S) and vaccination information for reimbursement claim should be input on the same day of the vaccination to ensure proper record and prevent duplicated dose.

Note on accurate data entry in eHS(S)

1) Correct entry of Service Provider ID / Username / Practice / Outreach Code (if applicable).

- Some doctors may work in more than one vaccination venue on different days and may wrongly use the code of another vaccination venue (e.g. CVC outreach versus VSS outreach, etc).
- VSS doctors should ensure all the relevant staff have inputted them correctly at the start of work every day.

2) Correct input of Lot number

- All your relevant staff should be immediately informed whenever there is a change of Lot number in your clinic/ setting.
- All doctors/ relevant staff should check the Lot number on each vaccine vial or on the printed vaccine label on each pre-filled syringe before inputting each Lot number in eHS(S)
- 6.7.2 Upon saving the vaccination record, vaccination card should be printed directly from eHS(S) (Annex VII). Clinic /PCVS staff should use a printer for printing from eHS(S) and issue the client-held vaccination card to the vaccine recipient after vaccination.
- 6.7.3 The COVID-19 vaccination paper record will contain information: name, date of birth and gender of the vaccine recipient, vaccine name, lot number and the manufacturer, date and place of vaccination.
- 6.7.4 According to the Principle 2 of Schedule 1 of Cap.486 Personal Data (Privacy) Ordinance, all practicable steps shall be taken to ensure that personal data is accurate having regard to the purpose (including any directly related purpose) for which the personal data is or is to be used. Please take all practicable steps to ensure data accuracy of the personal particulars in eHS(S).
- 6.7.5 The VSS doctor/ staff should double-check the personal particulars manually inputted into the eHS(S) and previously stored in eHS(S) before clicking the

"Confirm" or "Next" button. The VSS doctor/ staff must always check the exact age / date of birth on the relevant identity documents carefully before proceed as it may affect the dose required and / or the timing of the dose.

- 6.7.6 Please ask the clients to check carefully the personal particulars on the paper vaccination records (e.g. "name", "document type", "date of birth" and "gender") before leaving the clinic / PCVS.
- 6.7.7 Clinic / PCVS staff should use the "Reprint Vaccination Record" function at eHealth System (Subsidies) to print the paper record (or updated record) when handle requests to reprint the updated vaccination record. Please remind the clients to check carefully the personal information, i.e. "name", "document type", "date of birth" and "gender" in the vaccination record print-out.
- 6.7.8 For amendments of the personal information of vaccination records produced earlier, please notify PMVD via email covid19_vss@dh.gov.hk in case the personal particulars in the print-out are incorrect.
- 6.7.9 All vaccinations given should be clearly documented on a vaccination log to be kept in the doctor's clinic/ medical organisation and the log should include:
 - (a) Name list of all recipients receiving vaccination;
 - (b) Name of vaccine given together with the lot number and expiry date;
 - (c) The date of vaccination; and
 - (d) Names of personnel who administered the vaccine/ the doctor responsible.
- 6.7.10 The Government has announced the arrangement of "Medical Exemption" under "Vaccine Pass" on 27 Jan 2022. The relevant press release can be accessed at: https://www.info.gov.hk/gia/general/202201/27/P2022012700615.htm?fontSize=1 and https://www.info.gov.hk/gia/general/202203/20/P2022032000438.htm?fontSize=3

The government has lifted the Vaccine Pass arrangement since 29 December 2022. However, registered medical practitioners can still issue the "Medical Exemption Certificate" via the eHealth System (Subsidies) (eHS(S)). A Guidance Notes has been prepared to assist doctors in evaluating contraindications or precautions to COVID-19 vaccination that may warrant a medical exemption. The Guidance Notes has been incorporated into the "Interim Guidance Notes On Common Medical Diseases and COVID-19 Vaccination In Primary Care Settings" and can be accessed at:

https://www.chp.gov.hk/files/pdf/guidance_notes.pdf

It is important to emphasize to patients who are issued a Medical Exemption Certificate, that as they are not protected by the vaccine, it is advised to have good personal and environmental hygiene measures, including maintain hand hygiene, go out less and reduce social activities, and maintain appropriate social distance with other people as far as possible. Doctors are also reminded to review their health condition at appropriate interval and advice on the best timing of vaccination.

COVID-19 vaccines may still be administered to the person after exercising clinical judgement by the doctor, clarification of the relevant medical conditions and an informed consent to vaccination is obtained. In such case, the vaccinators should input in the "Remark field" in eHS(S) the brief reason of overriding a "Medical Exemption Certificate". Please see Annex XII "Summary of Remarks for Vaccine Recipients (For mRNA vaccine)" for further details.

6.8 Observation

- 6.8.1 All persons should be observed for 15 minutes after vaccination. Those with a history of immediate allergic reaction of any severity to a vaccine or an injection, and those with a history of anaphylaxis due to any cause should be observed for 30 minutes. Please refer to the Consensus Interim Recommendations on the Use of COVID-19 Vaccines in Hong Kong at https://www.chp.gov.hk/en/static/24008.html.
- 6.8.2 Clients with the following reactions to prior COVID-19 vaccines should also be observed for at least 30 minutes after receiving the next dose:
 - (a) superficial symptoms like rash, itchiness, urticarial, etc. that appear within 1 hour, but without other systemic allergic symptoms such as shortness of breath, wheezing, low blood pressure, etc.;
 - (b) Symptoms that appear later than 1 hour that are self-limiting or resolve by an oral anti-allergy drug.
 - Please refer to the "An Interim Guidance Notes on Common Medical Diseases and COVID-19 Vaccination in Primary Care Settings" for further details. (https://www.chp.gov.hk/files/pdf/guidance_notes.pdf)
- 6.8.3 If vaccine recipient experiences discomfort, clinic/ PCVS staff should give timely intervention, report to the doctor, and provide emergency management along with the

doctor as indicated.

6.8.4 For adverse events following immunisation (AEFI), VSS doctor should conduct medical assessment and report to the Drug Office online at https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html (Please see section 8).

6.9 Emergency management

- 6.9.1 The doctor should arrange qualified personnel, who are trained in emergency management of severe immediate reactions, with qualification such as Basic Life Support, to standby for emergency management and give timely intervention as indicated.
- 6.9.2 Emergency equipment (with age-appropriate parts) is highly recommended and should include, but is not limited to:
 - (a) Age-appropriate sized Bag Valve Mask
 - (b) BP monitor with Age-appropriate size cuff.
 - (c) AED Defibrillation Pad and age-appropriate pad (if applicable)

The clinic/PCVS should be equipped with registered adrenaline ampoule [1:1000] (at least three) with 1mL syringes (at least three, for intramuscular injection) and 25-32mm length needles (at least three) for adrenaline injection; or registered age-appropriate adrenaline auto-injector (at least three) for management of anaphylaxis.

- 6.9.3 The doctor should keep training of personnel responsible for emergency management up-to-date and under regular review.
- 6.9.4 Clinic / PCVS staff should have written protocol and training materials in place for quick and convenient reference.
- 6.9.5 Adrenaline, if needed, could be given in form of adrenaline autoinjectors of 300 microgram IMI or Adrenaline in ampoules, with reference to the bodyweight. In cases when adrenaline autoinjectors are not available, the dosage of adrenaline should be adjusted according to body weight and age, with reference to the following extracted from the Chapter 5 Monitoring and Management of Adverse Events Following Immunisation of the Hong Kong Reference Framework for Preventive

Care for Children in Primary Care Settings¹:

Table 22. Quick reference for dosage of adrenaline (The recommended dose for adrenaline is 0.01mg/kg body weight) (Adopted from Immunization Action Coalition)

o.ormg/kg oody	Age group		Range of weight (lb)	Adrenaline dose
	1-6 months	4-8.5 kg	9-19 lb	0.05 ml (or mg)
Infants and Children	7-36 months	9-14.5 kg	20-32 lb	0.1 ml (or mg)
	37-59 months	15-17.5 kg	33-39 lb	0.15 ml (or mg)
	5-7 years	18-25.5 kg	40-56 lb	0.2-0.25 ml (or mg)
	8-10 years	26-34.5 kg	57-76 lb	0.25-0.3 ml (or mg)†
Teens	11-12 years	35-45 kg	77-99 lb	0.35-0.4 ml (or mg)
	≥ 13 years	46+ kg	100+1b	0.5 ml (or mg);

Note: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

- 6.9.6 Should anaphylaxis happen after vaccination, clinic /PCVS staff should take the following actions:
 - (a) Call ambulance
 - (b) Inform the doctor-in-charge immediately, and provide emergency management, e.g. adrenaline injection and airway management as appropriate
 - (c) Monitor blood pressure and pulse every 5 minutes and stay with patient until ambulance arrives
- 6.9.7 For details of management of anaphylaxis, please refer to section 9 of the Online Training for COVID-19 Vaccination Programme provided by HKAM (https://elearn.hkam.org.hk/en).
- 6.9.8 Please refer to **Section 6.14** for the management for adolescents in case of emergency.
- 6.9.9 Should there be cases with anaphylaxis or severe adverse reaction after vaccination requiring **on-site transferral to hospital via ambulance**, VSS doctors should report these cases to the Central Medical Team of the Department of Health, after immediate management, by phone (Tel: 3975 4859); followed by submitting the Report on Cases Referred to Hospitals (**Annex VIII**) to the Central Medical Team by email (email addresses listed in the form) with password protection of the file, or fax (Fax: 2544 3908) within the same day of occurrence of the incident.

^{*}Rounded weight at the 50th percentile for each age range

[†]Maximum dose for children

[‡]Maxim20or teens

¹ Chapter 5 Monitoring and Management of Adverse Events Following Immunisation, Hong Kong Reference Framework for Preventive Care for Children in Primary Care Settings – Module on Immunisation (https://www.healthbureau.gov.hk/pho/rfs/english/pdf_viewer.html?rfs=PreventiveCareForChildren&file=ModuleOnImmunisation_Chapter5).

6.10 Vaccination arrangement for persons recovered from previous COVID-19 infection

6.10.1 Persons aged 6 months or above with prior COVID-19 infection would ever need to receive one dose of mRNA COVID-19 to complete the initial vaccination. No delay for initial doses vaccination for recovered persons, as recommended by vaccine manufacturers.

For free additional boosters applicable to persons belonging to high-risk priority groups who had completed initial doses, a booster dose is recommended to be given at least 180 days after the last dose or COVID-19 infection (whichever is later), regardless of the number of doses received previously.

For further information, please refer to the factsheet on COVID-19 Vaccination for Persons with Prior COVID-19 Infection:

(https://www.chp.gov.hk/files/pdf/factsheet_priorcovid19infection_eng.pdf) and "How many doses of COVID-19 vaccine are recommended for me": (https://www.chp.gov.hk/en/features/106951.html)

6.10.2 To facilitate the checking of previous COVID-19 history and the relevant interval between discharge and vaccination **BEFORE vaccination**, the eHS(S) has been enhanced with the following new feature:

For persons who have used HKID as the identity document for admission to hospitals under the Hospital Authority and on the day of vaccination, previous COVID-19 discharge record, if any, would also be displayed when HKID is used to retrieve the vaccine recipient's page on eHS(S).

6.11 Documentary proof for assessing clients with prior COVID-19 infection

- 6.11.1 The Green box of "COVID-19 Discharge Record" will be displayed only for locally infected client using HK Identify Card (HKIC) as identity document and was admitted to a HA hospital. Recipients' positive nucleic acid test results or reported positive rapid antigen test results since the fifth wave of COVID-19 would also be displayed. The Green box will not be shown for recovered patients who:
 - (a) did not use HKIC as identity document during HA's hospital admission, e.g foreign passports, two-way permits, etc
 - (b) had COVID-19 infection outside HK
 - (c) had not reported his/her local COVID-19 infection to Department of Health

The screen cap of the "green box" is attached for your easy reference.



6.11.2 The eHealth System (Subsidies) is enhanced to capture the "prior COVID-19 infection status" by adding a tick-box.

Please refer to the following User Manual and Quick Guide for more information: User Manual on COVID-19 Vaccination Programme:

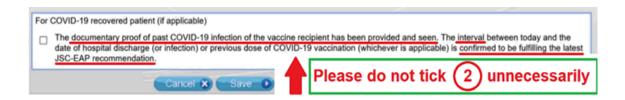
https://www.ehealth.gov.hk/en/covidvaccine/ehs.html

Quick Guide for Private Clinics:

https://www.ehealth.gov.hk/en/covidvaccine/doc/quick-guide-for-private-clinics.pdf

6.11.3 The tick-box have to be ticked by the vaccinators whenever the proof of past

COVID-19 infection has been shown by the client to the vaccinator and the recommended interval is fulfilled. If the Green box of "COVID-19 Discharge Record" is already displayed, there is no need to tick the tick-box. The screen cap is attached for your easy reference.



6.11.4 The proof of past COVID-19 infection in paper or electronic format are equally acceptable. For the accepted supporting document types, please refer to

https://www.chp.gov.hk/files/pdf/factsheet_priorcovid19infection_eng.pdf
If the proof is not in English or Chinese, it should be presented together with a written confirmation in English or Chinese, bearing all the relevant information with the client's identity particulars matched.

- 6.11.5 When the tick-box is ticked, please enter the following information in the "Remark" field:
 - (a) Recovered from COVID-19 infection
 - (b) Date of discharge (or infection)
 - (c) Place of discharge (or infection) (e.g. HK, Chinese Mainland, country/region name, etc)

Example: "Recovered from COVID-19 infection, 1 May 2021, UK"

Please see Annex XII "Summary of Remarks for Vaccine Recipients (For mRNA vaccines)" for further details.

- 6.11.6 If documentary proof cannot be provided, the provision of next as in general public can be acceded to.
- 6.11.7 If the name on the documentary proof is not an exact match with the client's available identity document, passport and travel document, then the documentary proof has to be assessed by the on-site healthcare professionals on a case-by-case approach.

6.12 Co-administration of COVID-19 vaccines with other vaccines

6.12.1 COVID-19 vaccines can be co-administered with, or at any time before or after, any other vaccines# including live attenuated vaccines under informed consent. If clients/ parents of children wish to space out COVID-19 vaccine with live attenuated vaccines (e.g. Measles, Mumps, Rubella & Varicella (MMRV), Live Attenuated Influenza Vaccine (LAIV)), an interval of 14 days is sufficient.

#Remark: If individuals at high risk of exposure of Mpox (also known as monkeypox) need to arrange for pre-exposure Mpox vaccination, it is recommended an interval of at least 4 weeks before or after mRNA COVID-19 vaccine (e.g. BioNTech, Moderna)

The above recommendation is also updated in FAQ#8 (https://www.chp.gov.hk/en/features/106953.html) and FAQ#11 (https://www.chp.gov.hk/files/pdf/faq children adolescents eng.pdf) accordingly.

*The latest updates and implementation schedule will also be communicated to the responsible staff of PCVSs by means of email. The responsible staff of PCVSs should check their registered email account for the latest updates. VSS doctors and other staff may also refer to the Government's thematic webpage for the latest updates (https://www.chp.gov.hk/en/features/106934.html)

For co-administration of SIV and COVID-19 vaccine in PCVS

6.12.2 Please refer to the thematic webpage:

(https://www.chp.gov.hk/en/features/106096.html) and the Vaccination Guide for Co-Administration of Seasonal Influenza

Vaccine and COVID-19 Vaccines at Same Visit: (https://www.chp.gov.hk/files/pdf/vssdg ch5 appendix h.pdf)

6.12.3 PCVS are encouraged to actively offer co-administration of seasonal influenza vaccine (SIV) and COVID-19 vaccine to eligible Hong Kong residents for both vaccination at the <u>same visit</u>.

Starting from 2025-26 season, PCVS should not charge the eligible Hong Kong residents for co-administration. The Government would reimburse to the enrolled doctor a subsidy of \$260 for each PCVS self-procured dose administered to the eligible persons (as announced by the Government) under the Vaccination Subsidy Scheme (VSS).

Please be reminded that PCVS can provide mRNA vaccine to appropriate clients of age ≥ 12 years old only, except the designated PCVSs.

For the details of Seasonal Influenza Vaccination Subsidy Scheme (VSS), please visit: https://www.chp.gov.hk/en/features/17980.html

- 6.12.4 To allow more flexibility in PCVS, online booking will not be made available to the public.
- 6.12.5 If the 2 vaccines are administered at <u>different days</u> for VSS eligible groups, extra charge is allowed. These extra charges would be shown in the online directory (https://apps.hcv.gov.hk/public/en/SPS/Search) as transparent information for the public.
- 6.12.6 To ensure clients receive correct information on the fee charged, please state clearly the extra charge on the price poster and give clear explanation by clinic staff whether your PCVS has stocked SIV for provision to the public, which types of clients are offered free SIV and which are not.
- 6.12.7 PCVS should obtain informed consent for both COVID-19 and SIV vaccines. Please use the relevant IT system to claim subsidy for vaccinations.

6.13 Non-local Vaccination Declaration

6.13.1 Individuals could register the non-local vaccination records with the Government by voluntary declaration for obtaining a local vaccination record QR code before 2 November 2023 via online system.

(https://www.info.gov.hk/gia/general/202109/14/P2021091400572.htm?fontSize=1)

- . The arrangement facilitates these persons to carry and view the records in electronic format.
- 6.13.2 This QR code CANNOT replace the original non-local vaccination record as a proof of vaccination. Thus, for arrangement of subsequent dose, recipients have to show the original non-local vaccination record, instead of this QR code, to the doctors for assessment. The vaccinator should input the non-local COVID-19 vaccination history [date, place and type of vaccination] under "Remarks" in the eHealth System. Please see Annex XII "Summary of Remarks for Vaccine Recipients (For mRNA vaccines)" for further details.
- 6.13.3 Also, recipients' self-declaration via this declaration channel **would NOT be** reflected in eHS(S). Doctors should check with the recipients their COVID-19 vaccination history, including those given outside Hong Kong before vaccination.
- 6.13.4 If clients have declared his/her non-local vaccination record to the Government, and then received vaccination in Hong Kong as well as registered with eHealth by the same identity document, they can use the "Vaccines" function on the eHealth app to view both the local and non-local electronic vaccination records. They can also input their non-local vaccination record to the eHealth app for uploading to the eHealth system.

6.14 Vaccination arrangement for adolescents

6.14.1 Please refer to the latest COVID-19 vaccination recommendation for individuals with previous COVID-19 infection by the JSC via

https://www.chp.gov.hk/en/static/24008.html.

Please refer to "How many doses of COVID-19 vaccine recommended for me?" for reference: https://www.chp.gov.hk/en/features/106951.html

*The latest updates and implementation schedule will also be communicated to the responsible staff of PCVS by means of email. The responsible staff of PCVS should check their registered email account for the latest updates. VSS doctors and other

staff may also refer to the Government's thematic webpage for the latest updates (https://www.chp.gov.hk/en/features/106934.html).

- 6.14.2 Immunocompromised persons have to bring with the relevant doctor's letter. An updated doctor's template can be downloaded here:

 https://www.chp.gov.hk/files/pdf/medical_certificate_of_third_dose_eligibility_for_immunocompromised_persons.pdf
- 6.14.3 For all clients below age of 18 years, paper consent (**Annex VI**) should be completed and signed by parent/guardian before vaccination. The recipient should bring the signed consent to the PCVS on the day of vaccination, otherwise, PCVS staff should provide a blank consent form for parent/guardian to sign before vaccination.
- 6.14.4 Similar to the vaccination arrangement for adults, a smart card reader should also be used for adolescents aged 12 to 17 years to capture their personal identifiers for HKID holders.
- 6.14.5 In order to ensure the unique identifier to be used in different COVID-19 vaccination systems, please remind the recipient/ parent/ guardian to use the same identity document for vaccination.
- 6.14.6 Please also see the Points to Note and FAQs on COVID-19 vaccination for Children and Adolescents:

https://www.chp.gov.hk/files/pdf/faq_children_adolescents_chi.pdf https://www.chp.gov.hk/files/pdf/faq_children_adolescents_eng.pdf

- 6.14.7 Mid-anterolateral thigh injection **should be offered to all adolescents** (both male and female) aged 12 17 as the site of vaccination. Adolescents aged 12 17 could make an informed choice to opt-out from thigh injection and receive vaccination in deltoid. Please refer to **section 6.6** for the technique of mid-anterolateral thigh injection.
- 6.14.8 For vaccination for persons of age 12-17 years old, in case of emergency, age appropriate measures should be taken including the use of age-appropriate blood pressure cuffs for measuring blood pressure, age-appropriate bag-valve masks for airway protection. Please see section 6.9 for emergency equipment and management.

6.14.9 Other process of vaccination, including information provision, verification of informed consent, vaccine preparation and administration and resting, should follow section 6.

6.15 Immunocompromised person

Immunocompromised person would need to take more dose(s) for completing initial dose(s) compared to others. For further details, please refers to the FAQs on Immunocompromised persons at:

(https://www.chp.gov.hk/files/pdf/faqs_on_immunocompromised_persons.pdf)

Immunocompromised persons should bring the relevant medical certificate to the designated vaccination venue on the day of the vaccination in order to confirm their eligibility to receive the COVID-19 vaccination in accordance with the schedule for immunocompromised persons. A sample template of the medical certificate could be found at

https://www.chp.gov.hk/files/pdf/medical certificate of third dose eligibility for immunocompromised persons.pdf.

Please enter the following standard wordings in the "Remark" field in eHS(S): "Doctor's letter for additional booster seen". Please see Annex XII "Summary of Remarks for Vaccine Recipients (For mRNA vaccines)" for further details.

6.16 Vaccination for pregnant and lactating women

Pregnant women are at high risk of developing complications from COVID-19 infections. COVID-19 vaccine can be safely given at any time during pregnancy. The World Health Organization(WHO) recommended that COVID-19 vaccination in mid-second trimester is preferred to optimize protection of the pregnant women, the foetus and the infant.

WHO doses not recommend discontinuing breastfeeding because of vaccination. As an mRNA COVID-19 vaccine is not a live vaccine, the mRNA does not enter the nucleus of the cell and is degraded quickly. It is biologically and clinically unlikely to pose a risk to the breastfeeding child.

7 Waste management

- 7.1 Regulation of clinical waste handling is under the purview of Environmental Protection Department details (EPD). Please find the (https://www.epd.gov.hk/epd/clinicalwaste/en/information.html). All clinical waste generated should be properly handled and disposed (including proper package, storage and disposal) in accordance with the Waste Disposal (Clinical Waste) (General) Regulation. For details, please refer to the EPD's Code of Practice (CoP) for the Clinical Management of Waste (Small Clinical Waste Producers) (http://www.epd.gov.hk/epd/clinicalwaste/file/doc06 en.pdf).
- 7.2 Clinical waste generated (mainly used needles, syringes, ampoules and non-woven balls fully soaked with blood) should be disposed of directly into sharps box with cover. Clinical waste must not be collected or disposed of as municipal solid waste or other types of wastes.
- 7.3 Alcohol swabs and non-woven balls slightly stained with blood, which are not clinical waste by definition, should also be properly handled and disposed of as general refuse. For details, please refer to the CoP published by the EPD (http://www.epd.gov.hk/epd/clinicalwaste/file/doc06_en.pdf).
- 7.4 Discard the used vials and expired vials after punctured in the sharp boxes and be handled as clinical waste, or to discard as chemical waste and handled in accordance with EPD guidelines.
- 7.5 The specifications of a typical sharps box are given in Annex B of Code of Practice for the Management of Clinical Waste (Small Clinical Waste Producers) (the CoP) published by the EPD (http://www.epd.gov.hk/epd/clinicalwaste/file/doc06 en.pdf).
- 7.6 Every container of clinical waste must bear a label. Please find details in Annex B of Code of Practice for the Management of Clinical Waste (Small Clinical Waste Producers) (the CoP) published by the EPD (http://www.epd.gov.hk/epd/clinicalwaste/file/doc06 en.pdf).
- 7.7 Clinic /PCVS staff should provide suitable area for temporary storage of clinical waste. Please find details in the Code of Practice for the Management of Clinical Waste (Small Clinical Waste Producers) (the CoP) published by the EPD (http://www.epd.gov.hk/epd/clinicalwaste/file/doc06_en.pdf)

- 7.8 When the licensed collector comes to collect clinical waste stored on-site, the clinic staff should sign on the Clinical Waste Trip Ticket.
- 7.9 The Waste Producer Copy (pink copy) of the Clinical Waste Trip Ticket should be forwarded to the doctor / medical organization (of the venue) representative for record.

8 Reporting of adverse events following immunisation

8.1 Adverse events following immunisation (AEFIs)

- 8.1.1 Adverse events following immunisation (AEFIs) ² are any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. The early detection will decrease the negative impact of these events on the health of individuals.
- 8.1.2 Like all vaccines, the mRNA COVID-19 vaccine can cause side effects, although not everybody gets them. Please refer to relevant Package insert or consult healthcare providers for details.
- 8.1.3 There are reports of allergic reactions occurred with mRNA vaccine, including a very small number of cases of severe allergic reactions (anaphylaxis) which have occurred when mRNA vaccine has been used in vaccination campaigns. As for all vaccines, mRNA vaccine should be given under close supervision with appropriate medical treatment available.
- 8.1.4 For more information on the possible side effects of COVID-19 vaccines, please refer to the website at https://www.chp.gov.hk/en/features/106934.html.

8.2 Reporting of AEFIs

8.2.1 PCVS staff should inform the vaccine recipients what to expect after receiving the vaccine (common side effects) and advise them to read the fact sheet in **Annex I** (as the fact sheet would be updated from time to time as necessary, PCVS staff should use the latest version available at https://www.chp.gov.hk/files/pdf/covid19vaccinationfactsheet_comirnaty_chi.pdf for the relevant information.) PCVS staff should also encourage vaccine recipients to tell healthcare professionals such as doctors and pharmacists of the suspected adverse event occurred after immunisation so that they can report to DH the suspected adverse event after vaccination. Informed consent should also be obtained from the recipient that the DH would continue to access the relevant information and medical records for

² Vaccine Safety Basics by WHO (https://apps.who.int/iris/handle/10665/340576)

continue monitoring of the medical outcome of the vaccination.

- 8.2.2 VSS Doctors are encouraged to report the following AEFIs:
 - (a) All suspected serious³ adverse events, even if the adverse event is well known;
 - (b) Suspected drug interactions including vaccine-drug and vaccine-herb interactions;
 - (c) Non-serious adverse events but the adverse events are deemed medically significant by the healthcare professional (e.g. increased frequency or unusual presentation of a known adverse event);
 - (d) Unexpected adverse events, i.e. the adverse events are not found in the product information or labelling (e.g. an unknown side effect).
- 8.2.3 Please conduct medical assessment and report to the Drug Office online at https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.h tml.

• is life-threatening,

- results in persistent or significant disability/incapacity,
- is a congenital anomaly/birth defect,
- requires intervention to prevent one of the outcomes above (medically important)

³ An AEFI will be considered serious, if it:

[•] results in death,

[•] requires in-patient hospitalization or prolongation of existing hospitalization,

9 Management of clinical incident

- 9.1.1 Clinical incident is defined as any events or circumstances that caused injury to vaccine recipients or posed risk of harm to vaccine recipients in the course of provision of clinical service.
- 9.1.2 VSS doctor should have plans to handle clinical incidents (e.g. incorrect vaccine administered). Appropriate actions should be taken, including inform the recipients/ parents/ guardians as appropriate, attend to the concerned clients as soon as possible and make necessary arrangements.
- 9.1.3 VSS doctor should attend all clinical incident immediately and provide appropriate interventions. Clear documentation of clinical assessment and interventions, including but not limited to medications used, should be done according to the practice of VSS doctor.
- 9.1.4 Following all necessary immediate interventions, the doctor in private clinic should inform the PMVD and the doctor in PCVS should inform Central Medical Team (CMT) at the earliest possible by phone, followed by the Clinical Incident Notification Form (**Annex IX**). The form should be returned to the PMVD or CMT by fax or email with password protection of the file within the same day of occurrence of the incident.
- 9.1.5 Summary of the incident, with preliminary assessment and immediate remedial actions should be included in the notification form.
- 9.1.6 The doctor should conduct a full investigation of the medical incident and submit the Clinical Incident Investigation Report (Annex X) to the PMVD or CMT within 7 days from the occurrence of the incident.

List of Annexes

Annex I	Fact sheet
Annex II	Package insert of mRNA vaccine
Annex III	Checklist of items during onsite inspection
Annex IV	Daily Fridge Temperature Chart
Annex V	Temperature Excursion Incident Report Form (COVID-19)
Annex VI	Consent Form
Annex VII	Sample of a COVID-19 Vaccination Card
Annex VIII	Report on Cases Referred to Hospitals
Annex IX	Clinical Incident Notification Form
Annex X	Clinical Incident Investigation Report
Annex XI	Interim Operation Workflow and Guidance Notes on Intramuscular mid-
	anterolateral thigh injection (mRNA vaccines)
Annex XII	Summary of Remarks For Vaccine Recipients (For mRNA vaccines)
Annex XIII	Useful link of the document about the vaccination programme

Annex I

Fact sheet on COVID-19 Vaccination (To Vaccine recipients)

Please download the latest version available at

https://www.chp.gov.hk/files/pdf/factsheet_covidvaccine_mrna_chi.pdf https://www.chp.gov.hk/files/pdf/factsheet_covidvaccine_mrna_eng.pdf (Factsheet - Chinese)

(Factsheet - English)

Annex II

Package Insert of mRNA vaccines

Please download the latest version at https://www.chp.gov.hk/en/features/106959.html

Checklist of items during onsite inspection for COVID-19 Vaccination Programme under the \overline{VSS}

A)	Booking/ appointment system
	Should provide vaccine information before confirmation of appointment
	Venue setting Segregation of vaccine storage/ handling and workflow if different type or brand of vaccines are provided in the same hospital/ clinic Display poster/ factsheet to indicate the type of vaccine (mRNA vaccines) to be provided Venue disinfection Have the Doctors' Guide in place for easy reference
	Certificate of online training for COVID-19 Vaccination Programme offered by the Hong Kong Academy of Medicine
E)	Medical consumables and equipment Adrenaline auto-injector or 1:1000 adrenaline ampoule for injection and 1mL syringes and 25-32mm needles
	70%-80% alcohol-based hand rub
	Alcohol preps/ alcohol swab for skin disinfection before vaccination
	Dry sterile gauzes/ non-woven balls for post-injection compression
	Sharps boxes/ clinical waste containers
	Card reader
	Printer
F)	Vaccine/ Vaccines storage Use of purpose-built vaccine refrigerators
	Maintain cold chain of the vaccines (+2°C to +8°C)
	Check and record temperature on the Daily Fridge Temperature Chart.
	Stock level vs consumption record of vaccines

Doctors' Guide for the COVID-19 Vaccination Programme at Clinics under VSS /PCVSs Daily log to monitor the utilization and stock balance Label and appearance of vaccines Disposal of vaccine vials and packaging materials Wastage reporting and preventive measures to avoid unnecessary vaccine wastage G) Administrative procedures before vaccination Check identity of recipient ☐ Check vaccination record in eHealth System (Subsidies) [eHS(S)]. H) Obtaining informed consent Provide factsheet of the COVID-19 vaccine to recipients and go through the contents ☐ Handle enquiries about COVID-19 vaccination ☐ Verify the verification checklist and tick the check box I) Vaccine preparation Assign a designated area and dedicated person-in-charge for vaccine preparation Label each prepared vaccine syringe with "name of vaccine", "use before date and time" and "Lot number" Use within 12 hours for Comirnaty monovalent JN.1 vaccine after first puncture Discard unused vaccines that are prepared longer than the labeled time J) Checking before vaccine administration Check for contraindications and assess suitability to receive vaccine. 3 checks when taking out the vaccine from storage

before preparing the vaccine

before administering the vaccine

•	7 rights
	The right patient
	The right vaccine
	The right time (e.g. correct age, correct interval, vaccine not expired)
	The right dosage
	The right route, needle length and technique
	The right site
	The right documentation (e.g. Document the name, DOB and gender of recipient, vaccine provider, vaccine type/ name, name of manufacturer and date of vaccination on the vaccination card.)
K)	Observation and reminder to recipients after vaccine administration
	Arrange recipients to have rest for at least 15 minutes before leaving the clinic.
	Remind recipients to attend the appointment for the next dose if applicable.
L)	Vaccination record Issue vaccination card to recipient

M) Clinical waste management

The above checklists are by no means exhaustive. Please refer to the Doctors' Guide for more information on details of the guidelines.

Annex IV

Daily Fridge Temperature Chart

The acceptable temperature range is +2°C to +8°C but Strive for five! (+5°C). Should check the current, the maximum and the minimum temperatures inside the refrigerator three times daily (once in am, once at noon and once in pm) and record in the form. Please reset the maximum/minimum temperature thermometer after recording

Fri	Fridge Model:					Serial no.: Location:										
	MONTH YEAR															
Date	M	fornin	5	Comments,	Initia	ıls		Noon		Comments,	Initials	Af	ternoo	n	Comments,	Initials
	(Fri	idge ter	mp.)	if any*			(Fri	idge ter	np)	if any*		(Fri	idge te	mp)	if any*	
	Current	Min.	Max.	1		Cur	rent	Min.	Max.	1		Current	Min.	Max.	1	
1						\top							V			
2						十										
3																
4																
5						\perp										
6																
7																
8																
9																
10						_										
11							4									
12						_	_					_				
13							L									
14						\perp	_									
15			_							_						
16						Æ										
17							h	4					_			
18	-		-			+	F					_	_			
19	-				-	1	_	_				_	_			
20						$\overline{}$		<u> </u>				_	<u> </u>			
21						+										
22						+							-			
-						+		\vdash				_	\vdash			
24 25						+										
26				_		+										
27	 		\vdash			+		\vdash			_	\vdash	\vdash		-	
28			\vdash			+		\vdash								
29			\vdash			+		\vdash					\vdash			
30						+							\vdash			
31						+										

^{*} If the fridge temperature is abnormal during checking, please fill the relevant code in the comments column and inform PMVD.

DO	Door opened for extended time	TTD	Thermostat turned down	PF	Power failure
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Annex V

Temperature Excursion Incident Report Form (COVID-19)

To:	Pharmacist (Department of Health) Email: pharm_cmt@dh.gov.hk	Ref. No.:	
<u>Part</u>	<u>[</u>		
Name	e of Doctor:		
Name	e of Clinic:		
	ess of Clinic:		
	hone Number: Email Address:		
Fridg	e Location: Fridge Model Number:		
<u>Part</u>	<u>II</u>		
Repo	rt when the temperature on refrigerator is read <i>outside the recommended range</i>	(2°C-8°C)	
Date	of Occurrence: Time of Occurrence:		
1.	What was the temperature inside the refrigerator at the time the problem was	Current:	°C
	discovered?	Min.:	°C
		Max.:	°C
2.	How long had the vaccines been exposed to the inappropriate storage temperatures ⁴ ?		
3.	Has an inventory check of the vaccines within the refrigerator been conducted? (Please refer to Part III for details)	☐ Yes	□ No
4.	Did the refrigerator resume normal after electricity supply resumed or plugged to another functioning power supply?	☐ Yes	□ No
5.	Have all the affected vaccines been labelled with "DO NOT USE" (quarantined)?	☐ Yes	□ No
6.	Could the affected vaccines be transferred and be stored in another refrigerator?	☐ Yes	□ No

⁴ Please provide the total amount of time by calculating the difference between the time of discovery and the time of the last temperature check

Part III

List of COVID-19 vaccines affected:

Vaccine name	Lot no.	Quantity

Part	IV
------	----

Probable causes(s) for the temperature excursion:

		Power not plugged in or not turned on						
		Power failure						
		Prolonged opening of refrigerator door						
		Refrigerator door cannot be properly closed						
		Unit's temperature knob setting is incorrect						
		Other:						
	Part V Remedial action taken to restore the cold chain to the recommended range (2°C-8°C)							
Part VI (To be completed by the Department of Health) Consideration for affected vaccines to be released or disposed:								

Vaccine Report Form Relating to Discrepancy/Defective

To:	Pharmacist (Department of Health)	Email: pharm_cmt@dh.gov.hk	Ref. No.:
<u>Part</u>	<u>I</u>		
Na	ame of Doctor:		
Na	ame of Clinic:	Telephone Number:	
Ad	ldress of Clinic:		
<u>Part</u>	<u>II</u>		
Da	ate & Time of Occurrence:		
Br	and of Vaccine:		
Ba	atch Number (and/or BPR):		
Ex	spiry Date (and/or Use by date):		
Qυ	uantity:		
Kou	ason:		
Da	ate of Reporting:	Signature:	
		Position:	
		Name of Contact:	
==== *For	Department of Health to fill in		
Da	nte:	Signature:	
Re	eference Number:	Position:	
		Name of Contact:	

Annex VI

Vaccination Consent Form under the Government Programme

English: https://www.chp.gov.hk/files/pdf/consent_form_for_covid19_vaccination_eng.pdf

Traditional Chinese: https://www.chp.gov.hk/files/pdf/consent_form_for_covid19_vaccination_chi.pdf

Annex VII

Sample of a COVID-19 Vaccination Card

Please refer the sample of vaccination card:

https://www.chp.gov.hk/files/pdf/sample_covidvaccinationrecord.pdf

NOTIFICATION TO CENTRAL MEDICAL TEAM REPORT ON CASES REFERRED TO HOSPITAL

PCVS

(RESTRICTED)

Annex VIII From:_____PCVS Email: nurse_cmt@dh.gov.hk Name:_____(Doctor / Nurse) duty_ro_cmt@dh.gov.hk Date: Report on Cases Referred to Hospital (To be completed by PCVS) **Points to Note:** For all cases which required medical attention and referral to hospital, PCVS should inform (For medical the Central Medical Team after immediate management by phone (3975 4859); followed by team) this written Report on Cases Referred to Hospital. The completed form should be returned to the Central Medical Team by email (nurse cmt@dh.gov.hk and duty ro cmt@dh.gov.hk) or fax (2544 3908) as soon as possible and within the same day after the incident. I. Particulars of the person who was referred to hospital Sex:_____ ID number: _____ Name: Age: Date sent to hospital (dd/mm/yyyy): Time (24 hr format): ____:___: Hospital (if known): Reason(s)/ Preliminary Diagnosis: П. COVID-19 vaccine given to the person on the day Vaccine Not given Vaccine given Name of COVID-19 vaccine: Dose sequence: _____ dose Time given: _____:____ am / pm* III. **Details Details of event:**

NOTIFICATION TO CENTRAL MEDICAL TEAM REPORT ON CASES REFERRED TO HOSPITAL

(RESTRICTED)

Symptoms & Time of onset:				
IV. Management provided at PCVS				
V. Condition of the patient on leaving PCVS				
Awake / Verbal / Pain / Unresponsive *	Vita	l Signs : BP	/Pulse	SaO2
VI. Information given to relatives (if applicable)				
VII. Other information if applicable				
VII. Other mormation if applicable				
VIII. Reporter's Information				
Name (in Full): Mr / Ms	Pos	: Please tick the appro	priate box below	· •
Phone:		Doctor		
Email:		Nurse		
		Pharmacist/ dispense	r	
		Clerk		
		Other healthcare pro	fessionals, please	e specify:
N. CRCVO				<u>-</u>
Name of PCVS:				
Name of enrolled doctor:		Car (24 har form of).		_
Date:(dd/mm/yyyy)	J	Cime (24 hr format):	:	_

Annex IX

Private Clinic Vaccination Station CLINICAL INCIDENT NOTIFICATION FORM (RESTRICTED)

Case Number (assigned by Central Medical Team):_____

Notification Form for Suspected Clinical Incident								
(To be completed by organisation / service provider)								
Points to Note - Clinical Incident is defined as any events or circumstances (i.e. with any								
(for Medical operator): deviation from usual medical care) that caused injury to client or posed risk of								
harm to client in the course of direct patient care or provision of clinical serv								
- Clinical incident could be notified by any staff of any rank								
- It is not required to get all details confirmed to make a notification								
- Notification should be made as soon as possible (by phone to the Central Medica								
Team at 3975 4859) And followed by this written Clinical Incident Notification Fo								
- The completed from should be returned to the Central Medical Team by email								
(<u>nurse_cmt@dh.gov.hk</u> and <u>duty_ro_cmt@dh.gov.hk</u> and <u>mo_cmt@dh.gov.hk</u>) or so (2544 3908) as soon as possible and within the same day after the incident.								
								- A follow up full inv
	submitted to the Cer	ntral Medical Team by email within 1 week upon discovery of						
	(suspected) incident	t.						
IX. Brief Facts								
Name of Private Clinic Vac	ccination Station involved	d:						
Date of discovery (dd/mn	m/yyyy):	Time (24 hr format):						
• `								
Date of occurrence (dd/mn	n/yyyy):	Time (24 hr format):						
2 400 01 00041101100 (44/1111								
Place of occurrence:		At the private clinic vaccination station						
		Others, please specify:						
Stage of care when		Pre-vaccination						
incident occur		During vaccination						
		Post-vaccination						
Number of vaccine recipier	nt(s) affected:							
Demographics of clients af	ffected:							
L								

Person	Gender	Age	Type of	Level	of injury		Consequence	Name and batch of
(1, 2,	(M/F)		harm/ injury	as pe	er initial	(e	.g. referred to AED/	vaccine involved
3)				assess	sment by	oth	er specialties/ repeat	
					ical team		additional procedure	
				(M,	1, 2, 3)		d investigation, etc.)	
					Annex II)		, ,	
				(
	<u> </u>							
Summary o	of the incid	ent: (inc	luding what hap	pened.	how it hap	pene	d, and what actions we	re taken etc. Do
not put in a	ny persona	l inform	ation of the perso	ons affe	ected in the	inci	dent; And Do not put i	n any name, post or
rank of staf	f involved i	in the inc	rident.)					
Any proper	ty damage	e?			Yes, detai	ls:		
					No			
X. Re	porter's In	ıformatio	n					
						Post	: Please tick the approp	riate box below:
Name (in F	ull) : Mr/	Ms			_		Doctor	
							Nurse	
Phone:				_			Pharmacist/ dispenser	•
							Clerk	
Email:							Other healthcare prof	essionals, please specify:
Name of or	ganisation	/ service	provider:					
Name of en	rolled doc	tor:						
Date:			(dd/	mm/yy	yy)	Time	e (24 hr format):	

Classification of level of Injury

Level of	The level of injury is defined as follows,
Injury	Level M Near miss OR incidents that caused no or minor injury, which may or may not
	require repeat of investigation, treatment or procedure, or additional monitoring (including
	telephone follow-up).
	Level 1 No or minor injury was resulted AND additional investigation or referral to other
	specialty (including AED) was required for the client.
	Level 2 Significant injury was resulted AND additional investigation or referral to other
	specialty (including AED) was required for the client.
	Level 3 Significant injury was resulted AND resulted in death or arrest or requiring
	resuscitation or permanent loss of function was resulted or expected.

Private Clinic Vaccination Station CLINICAL INCIDENT INVESTIGATION REPORT (RESTRICTED)

Case Number (assigned by Central Medical Team):

	cuse runner (useigned by central receiver ream).					
Clinical Incident Investigation Report						
(To be completed	by th	e Doctor in-charge of the PCVS))				
Points to Note:	-	Report should be made within 1 week upon discovery of the incident				
	-	Do not put in any personal information of the persons / staff affected involved in the incident				
	-	The completed form should be returned to the Central Medical Team by email				
		(nurse_cmt@dh.gov.hk and duty_ro_cmt@dh.gov.hk and mo_cmt@dh.gov.hk) fax (2544				
		3908)				

XI. Br	rief Facts							
Name of Private Clinic Vaccination Station involved:								
Date of discovery (dd/mm/yyyy):			_	Time (24 hr format):				
Date of occ	urrence (d	d/mm/y	ууу):		_	Time (24 hr format):		
Place of occ	currence:				At the pr	ivate clinic vaccination station		
					Others, p	lease specify:		
Stage of car	re when				Pre-vaccination			
incident oc	cur				During vaccination			
					Post-vaco	cination		
Number of	vaccine re	cipient(s	affected:					
Demograph	hics of clier	nts affec	ted:					
Person	Gender	Age	Type of	Level of	injury as	Consequence	Name and batch	
(1, 2,	(M/F)		harm/	per i	nitial	(e.g. referred to AED/ other	of vaccine	
3)			injury	assessr	nent by	specialties/ repeat or	involved	
				medica	al team	additional procedure and		
				(M, 1	, 2, 3)	investigation, etc.)		
				(See A	nnex II)			

Commence of the Control of the contr	
Summary of the incident: (including what happened. how it happened	
A stions to how for this incident.	
Actions taken for this incident:	
Dome diel messenne te museut fetune similar communes	
Remedial measures to prevent future similar occurrences:	

Other recommendations and comments:						
D. A. A. F. G. at						
Reporter's Information		T				
Name (in Full) : Dr	_					
Phone:						
Email:	_					
Date:	<u> </u>					

Interim operation workflow and guidance notes on Intramuscular midanterolateral thigh injection (mRNA COVID-19 vaccine)

Background for Intramuscular Injection at Mid-anterolateral Thigh

Over 17 million doses of the Comirnaty vaccines have been administered to children and adolescents in multiple countries since May 2021. Myopericarditis is a known side effect of the Comirnaty vaccine reported in both overseas and locally, with the majority occurred following the second dose in adolescents.

On 15 September 2021, to balance the risk and benefit in the local setting, the Joint Scientific Committee on Vaccine Preventable Diseases and the Scientific Committee on Emerging and Zoonotic Diseases and the Chief Executive's Expert Advisory Panel (JSC-EAP) recommend persons aged 12 to 17 years to receive one dose of the Comirnaty vaccine, instead of two doses. The JSC-EAP also noted the study results of intravenous injection of COVID-19 mRNA vaccine and acute myocarditis in mouse model and the hypothesis regarding providing intramuscular injection of the Comirnaty vaccine at mid-anterolateral thigh to minimise the potential side effects of the vaccine.

On 23 December 2021, the JSC-EAP presented that emerging data suggest that two doses of Comirnaty vaccine with a longer interval would result in better immune response. The risk of myocarditis and/or pericarditis is also lowered when compared with a shorter interval. In view of the emergence of the Omicron variant, the JSC-EAP recommended persons aged 12 to 17 years to receive the second dose of the Comirnaty vaccine, at least 12 weeks between the two doses. The JSC-EAP also recommends intramuscular injection of the Comirnaty vaccine at midanterolateral thigh, especially for male children and adolescents.

This consensus interim recommendations provided an update on top of the previous JSC-EAP interim recommendation dated 15 September 2021.

Currently, the risk of myocarditis or pericarditis from mRNA vaccine injection was unknown and could not be estimated from the available data.

While the prevailing requirements on COVID-19 vaccination should be followed, the following additional information and workflow should be implemented.

At Info Zone and injection booths:

Confirm choice of injection site with client by medical team:

For those aged 12 to 17 years adolescents (male or female):

- Offer mid-anterolateral thigh injection as the site of injection.
- Those who made an informed choice to opt-out from midanterolateral thigh injection, can choose to receive the vaccine in deltoid muscle.

For those aged 18 years or above:

- The workflow is unchanged at the moment and deltoid muscle remains the default site of injection.
- The clients can still choose to receive the mRNA vaccine in their mid-anterolateral thigh on-demand basis.

Advice to clients for mid-anterolateral thigh injection

- For injection of mRNA vaccine at the mid-anterolateral thigh (大腿前外側中段部位 i.e. vastus lateralis muscle or 'thigh'), the clients should be explained the pros and cons of thigh injection (i.e. the background of this paper), local side effects and how to relieve injection site pain, etc.
- Those who have made an <u>informed choice</u> to receive the vaccine at their thigh should be brought to the special '<u>Thigh Booth</u>' for injection. 'Thigh Booths' should be available at every mRNA vaccine providing venue. The 'Thigh Booth' has front and back opaque curtain, +/- top covered depending on the setup of venue.

Precautions for thigh injection

Clients with below conditions may not be suitable for thigh injection

- Thigh muscle atrophy/ myopathy
- Infection/ inflammation/ swelling/ presence of wounds or scar tissues/ moles at site of injection
- Other clinical conditions as deemed necessary

Additional workflow inside injection booth for clients for injection at thigh muscle

Confirm age of and injection site with clients:

Confirm the age of clients

- Confirm with clients that they will have the injection at thigh muscle and have understood the pros and cons without further question.
- Enquire whether they want the injection to be done on the thigh
 of the left or right lower limb.

Input of injection site to eHS(S) (Additional input):

 If the client chooses to be vaccinated at thigh, this should be documented clearly in the Remarks field of eHS(S);

e.g. "Left thigh" or "Right thigh"

Roll up pants/ Undress client for thigh injection in "Thigh booth" only:

- Ensure the privacy of clients at all times. Curtains at the thigh booth, both front and back, should be closed before the client undresses.
- Chaperon should be present if deemed appropriate and necessary.
 Parents / guardians are not chaperons.
- The two curtains should be left open in between clients for better ventilation.

Choice of needle:

- A 1-inch or 1.5-inch needle with needle gauge 22-25G can be used for mid-anterolateral thigh injection for teenagers or adults¹.
- Please NOTE the LDV syringes with 1" fixed needle, which are currently provided for mRNA vaccination, are suitable for intramuscular vaccine administration at mid-anterolateral thigh.
- In case the client is of larger build or obese, it is suggested to use
 a longer needle (i.e. 1.5" needle) to avoid inadvertent
 subcutaneous injection. For reference, ACIP guideline¹ suggests a
 1.5" needle should be used for Men >118kg (260lbs) or Women
 >90kg (200lbs) for deltoid injection in adults.

¹ACIP Guideline (General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices) (https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html)

 The 1" needle of a standard 1-ml syringe can be replaced by a 1.5" needle when necessary. The preparation of vaccine using this special syringe should be performed in the dilution booth on-site.

Dilution of mRNA vaccine if 1.5" needle is used

- NO change to dilution method and syringe labelling procedure, only replace a LDV 1-ml syringe with a standard 1-ml syringe and a CHANGED 1.5" needle.
- Prepare only when inoculator makes a request to the dispensary/ dilution booth on-site when the use of 1.5" needle is required.
- For dilution/ reconstitution, GET READY a standard 1-ml syringe with a CHANGED 1.5" needle to be used to draw the required dose of vaccine. The remaining vaccine content in the same vial would be drawn using LDV syringes for a total of 6 doses/vial.
- In occasional circumstances when more than one standard 1-ml syringe with a CHANGED 1.5" needle is needed, it is suggested each vial can be drawn by a <u>maximum of 3 standard 1-ml syringes</u> and 3 LDV syringes.
- Content should not be transferred from withdrawn syringe back to vials for withdrawal into syringe with 1.5 inch needle.

Locate the mid-anterolateral thigh muscle for injection

Please refer to Figures 1 & 2 for injection site illustration and slides for step-by- step instructions.

- · Arrange client in sitting position. This can help relax the client.
- Visually divide area between greater trochanter of femur and lateral femoral condyle into thirds and select the middle third.
- Estimate the anatomical position of the injection site which is around one hand's width above the knee to one hand's width below the greater trochanter of femur. The outer middle third of the muscle is used for injections. The width of the muscle extends from the mid-line of the thigh to mid-line of the outer thigh.²

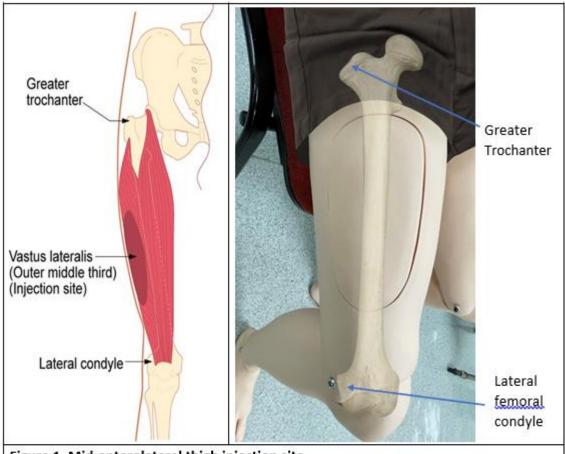


Figure 1. Mid-anterolateral thigh injection site

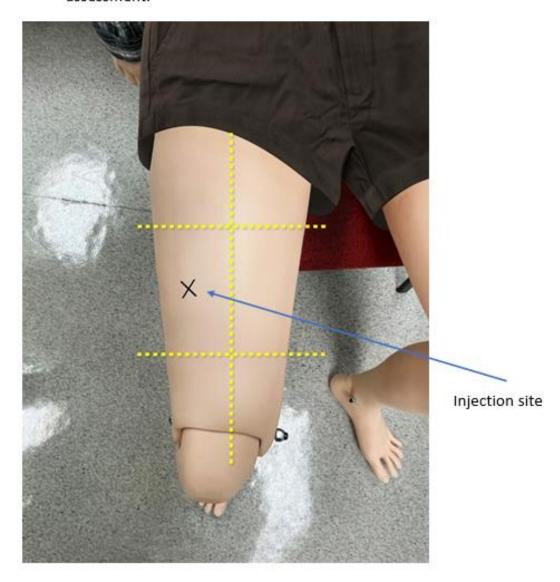
² 7.4 Intramuscular injections. Clinical Procedures for safer patient care. https://opentextbc.ca/clinicalskills/chapter/6-8-iv-push-medications-and-saline-lock-flush/

Figures 2. Procedures of mid-anterolateral thigh injection

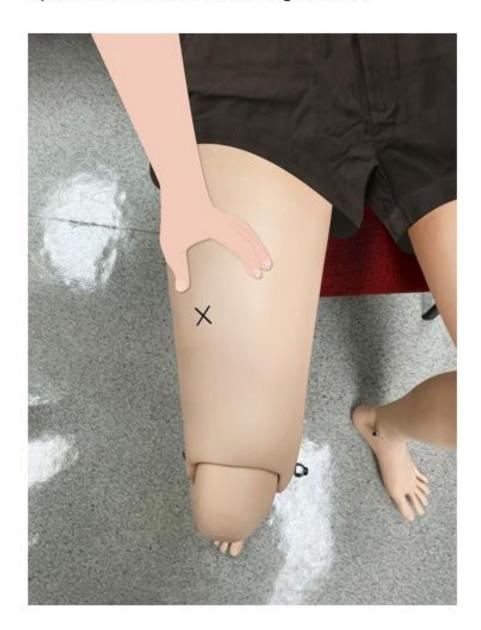
- Visually divide area between greater trochanter of femur and lateral femoral condyle into thirds and select the middle third.
- The top border of the vastus lateralis muscle can be visually determined about a hand-width below the greater trochanter.
- Visually estimate the bottom border of the vastus lateralis muscle which is about a hand-width above the knee



- 2. Identify the side borders of vastus lateralis muscle
- The side borders are from the mid anterior thigh to the mid lateral thigh
- The midpoint of the middle segment is the ideal site for injection
- The chosen site should be based on individualised client assessment.



Spread the skin to isolate the muscle to avoid injection into subcutaneous tissue. For clients with little muscle mass, squeeze the muscle to avoid hitting the bone.



- 6. Disinfect the injection site properly before injection
- 7. The needle should be injected at 90 degrees angle.
- Aspirate before injection. Remove the needle and discard it if blood is aspirated.



Common local side effects

Common local side effects on the leg where client received the mid-anterolateral thigh injection include but are not limited to the following:

- Pain
- Numbness
- Redness
- Swelling

Post-vaccination advice

The advice is similar to intramuscular injection to deltoid. The following measures can help to relieve possible mid-anterolateral thigh injection site pain:

- Placing a clean, cool, and wet towel over the area
- Taking paracetamol to relieve pain if not contraindicated

Prepared by PMVD, CHP Version 3.0 10 December 2023

Annex XII

Summary of Remarks For Vaccine Recipients (For mRNA vaccines)

Type of recipients	Scenarios	Input in "Remark" in eHS(s)		
HK residents	Recipients use solely HKSAR	HKID number as listed in the HKSAR passport.		
	passport as the identity document for			
	the 1st dose	E.g. HKID: G1234567.		
Persons with different	Different identity documents	State the identity document used in the previous vaccination		
identity document	registered in the previous vaccination			
		E.g. HKSAR passport was used for the 1 st dose.		
Persons with Medical	Administer to recipients before the	Brief reason of overriding a "Medical Exemption Certificate".		
Exemption Certificate	expiry of a Medical Exemption			
	Certificate	E.g. The recipient is suitable for vaccination after assessment by the		
		Allergy Clinic.		
Persons with thigh	-	"Left thigh" or "Right thigh"		
injection				
		E.g. Right thigh		
COVID-19 recovered	With history of COVID-19 infection	Recovered from COVID-19 infection, Date of discharge (or infection),		
persons	(local and non-local)	Place of discharge (or infection) [e.g. HK, Chinese Mainland,		
		country/region name, etc)		
		E.g. Recovered from COVID-19 infection, 1 May 2021, UK.		
	Recipients denied COVID-19	E.g. No prior COVID-19 infection according to the recipient. Explained to		
	infection but eHealth displays the	the recipient and consent obtained.		
	history			

Type of recipients	Scenarios	Input in "Remark" in eHS(s)
Persons with non-	-	Date, place and type of vaccination
local vaccination		
record		E.g. Last dose (5th) Pifizer on 1 Jan 2023 in USA
Immunocompromised	Immunocompromised persons who	"Doctor's letter for x dose seen"
persons	request to vaccinate	
		E.g. Doctor's letter for additional booster seen.

Annex XIII
Useful links of the document about the vaccination programme

Document type	Document name	C	R code of the lin	k
		(car	can)	
		ENG	СНІ	SChi
Webpage	COVID-19 Thematic website			
	About the Vaccines			
	About the Programme			
	FAQs			
Eligibility for receiving vaccination	Persons eligible for receiving vaccination			
	Samples of identity documents (Annex A of "Quick Guide to joining RVP")			

Document type	Document name	QR code of the link				
		(can either click or scan)				
		ENG	СНІ	SChi		
Package Insert of vaccines	BioNTech XBB.1.5 (Pediatrics formulation / 10mcg)					
	BioNTech XBB.1.5 (Toddler formulation / 3 mcg)					
	BioNTech monovalent JN.1					
	Spikevax monovalent JN.1					
Vaccination fact sheet	mRNA COVID-19 vaccine					
Consent form	Applicable to all mRNA / inactivated COVID-19 vaccines under the Government COVID-19 Vaccination Programme					
Expert Opinion	Expert Opinion					
	Recommendations from the Scientific Committee on Emerging and Zoonotic Disease and Scientific Committee on Vaccine Preventable Diseases					
Recommendation on number of doses and interval	How many doses of COVID-19 vaccine recommended for me?					

Document type	Document name	QR code of the link			
		(can either click or scan)			
		ENG	СНІ	SChi	
Information for children and adolescents	COVID-19 Resources from the Hong Kong Society for Paediatric Immunology Allergy and Infectious Diseases				
	Referral letter for Paediatric COVID-19 Vaccine Allergy Safety Assessment				
	FAQ - children and adolescents				
Information for persons with diseases or allergy	Interim Guidance Notes On Common Medical Diseases and COVID-19 Vaccination in Primary Care Settings				
	3 Important Considerations for individuals with chronic diseases				
	Examples of Chronic Diseases				
	FAQ – Immunocompromised person				
	Certification for Immunocompromised Persons				
Information for recovered persons	Factsheet on COVID-19 Vaccination For Persons with Prior COVID-19 Infection				

Document type	Document name	QR code of the link (can either click or scan)			
		ENG	СНІ	SChi	
eHealth	User Manual of eHealth System (Subsidies) for COVID-19 Vaccination Programme				
	Quick Guide of Manual Input of Other Documents in the eHealth System (Subsidies) for COVID-19 Vaccination Programme				
	Consent form for eHealth	□ \$2; \$1,000			
	Register eHealth for your child				
Infection control	ICB Infection Control Guidelines				
	Recommendations on Hand Hygiene and Use of Gloves in Health Care Settings				
	Recommendations on the Management and Postexposure Prophylaxis of Needlestick Injury or Mucosal Contact to HBV, HCV and HIV				
	Prevention of Sharps Injury and Mucocutaneous Exposure to Blood and Body Fluids in Healthcare Settings				

Document type	Document name	QR code of the link		
		(can either click or scan)		
		ENG	СНІ	SChi
	Code of Practice for the		E2//83E3	
	Management of Clinical			
	Waste			
Others	COVID-19 Vaccination			
	Online Training Platform			
	Reporting Adverse Drug			
	Reactions			