Private Clinic COVID-19 Vaccination Station (PCVS) administering mRNA vaccines for children (aged 6 months to 11 years)

Version: 5 **Date of version: 19 August 2024**

Dear Doctors,

Thank you for joining the COVID-19 Vaccination Programme – Private Clinic COVID-19 Vaccination Station (PCVS) and offering mRNA vaccines to clients aged 6 months to 11 years. We would like to highlight the following important points for providing vaccination service at your PCVS.

Please always refer to the Doctors' Guide for the latest information:

- Doctors' Guide for mRNA vaccines: https://www.chp.gov.hk/files/pdf/vssdoctorsguide_covid19_bnt_pilot.pdf

Thank you for your support to the Government's COVID-19 Vaccination Programme.

Programme Management and Vaccination Division
Emergency Response and Programme Management Branch
Centre for Health Protection
Department of Health

Table of Contents

1/ Doctors' Guide

- The Doctors' Guide contains essential information for doctors providing COVID-19 vaccination services and will be updated regularly.

- Please click on the following links for the latest version:
  mRNA vaccines-
  https://www.chp.gov.hk/files/pdf/vssdoctorsguide_covid19_bnt_pilot.pdf

- Useful forms can be found in Annex of the Doctors' Guide:
  - Annex V – Temperature Excursion Incident Report Form
  - Annex V – Vaccine Report Form Relating to Discrepancy/Defective
  - Annex VIIIb – Report on Cases Referred to Hospitals
  - Annex Xb – Clinical Incident Notification Form and Investigation Report

2/ Publicity, package inserts and other useful materials

- Fact sheet for mRNA vaccines:
  https://www.chp.gov.hk/files/pdf/factsheet_covidvaccine_mrna_eng.pdf

- Package inserts :
  For Comirnaty monovalent XBB.1.5 vaccine - toddler formulation (3 mcg):
  https://www.chp.gov.hk/files/pdf/packageinsert_xbb_comirnaty_3mcg.pdf

  For Comirnaty monovalent XBB.1.5 vaccine - paediatric formulation (10mcg):
  https://www.chp.gov.hk/files/pdf/packageinsert_xbb_comirnaty_10mcg.pdf

  For Spikevax monovalent XBB.1.5 vaccine:
  https://www.chp.gov.hk/files/pdf/packageinsert_xbb_spikevax.pdf

- Consent form [applicable to all mRNA / inactivated COVID-19 vaccines under the Government COVID-19 Vaccination Programme]:
  https://www.chp.gov.hk/files/pdf/consent_form_for_covid19_vaccination_eng.pdf

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

- Factsheet on COVID-19 Vaccination for Persons with Prior COVID-19 Infection:
  https://www.chp.gov.hk/files/pdf/factsheet_priorcovid19infection_eng.pdf

- Points to Note and Frequently Asked Questions on COVID-19 vaccination for Children and Adolescents:
  https://www.chp.gov.hk/files/pdf/faq_children_adolescents_eng.pdf

- FAQs on immunocompromised persons:
  https://www.chp.gov.hk/files/pdf/faqs_on_immunocompromised_persons.pdf

- User Manual of eHealth System (Subsidies) [eHS(S)] for COVID-19 Vaccination :
  https://www.ehealth.gov.hk/en/covidvaccine/ehs.html

3/ Updated recommendations on COVID-19 vaccination schedule – the simplified regimen

- With respect to the latest JSC consensus interim recommendation on the use of COVID-19 vaccines, the simplified arrangement for initial doses and the additional booster for 2024/25 under the Government COVID-19 Vaccination Programme has been implemented since 19 August 2024.

- For details, please refer to

  The Concensus Interim Recommendations on the Use of COVID-19 Vaccines by JSC updated on 17 July 2024:
  https://www.chp.gov.hk/files/pdf/consensus_interim_recommendations_on_use_of_covid19_vaccines_in_hong_kong_17jul.pdf

  Press releases:
  Latest COVID-19 vaccination arrangements announced (8 August 2024)
  https://www.info.gov.hk/gia/general/202408/08/P2024080800571.htm?
  Scientific Committees under CHP discuss use of COVID-19 and measles vaccines (17 July 2024)
  https://www.info.gov.hk/gia/general/202407/17/P2024071700598.htm?

A. Initial vaccination schedule

For immunocompetent persons

- Immunocompetent persons aged 6 months to 4 years old need to receive 2 doses of Moderna mRNA vaccine / 3 doses of BioNTech mRNA vaccines or 2 doses of inactivated vaccines for initial vaccination.

- Immunocompetent persons aged 5 years or above need to receive 1 dose of mRNA vaccine or 2 doses of inactivated vaccines to complete the initial vaccination.

For immunocompetent persons with prior COVID-19 infection

- Immunocompetent persons aged 6 months or above with prior COVID-19 infection should follow the vaccination schedule as immunocompetent persons aged 5 years or above (i.e. 1 dose of mRNA vaccine or 2 doses of inactivated vaccines, regardless of history of infection)

- No delay for initial doses vaccination for recovered persons, as recommended by vaccine manufacturers

- For details, please refer to “Factsheet on COVID-19 Vaccination For Persons with Prior COVID-19 Infection” at
  https://www.chp.gov.hk/files/pdf/factsheet_priorcovid19infection_eng.pdf

For immunocompromised person

- Persons with immunocompromising conditions need to receive more dose(s) for completing initial doses compared to immunocompetent persons. Immunocompromised persons should follow the same vaccination schedule to complete the initial vaccination regardless of history of infection.

- For details, please refer to " FAQs on Immunocompromised Persons: at : https://www.chp.gov.hk/files/pdf/faqs_on_immunocompromised_persons.pdf

B. Additional booster vaccination schedule

- Eligible high-risk priority groups can receive booster dose 180 days after their COVID-19 infection instead of recovery

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 the vaccination schedule of initial dose(s) and additional booster dose(s).

Please also refer to the Points to Note and Frequently Asked Questions on COVID-19 vaccination for Children and Adolescents at: https://www.chp.gov.hk/files/pdf/faq_children_adolescents_eng.pdf

C. Transition vaccination arrangement for children aged 4 turning into 5

For children who have not yet completed the mRNA initial doses and transited from age 4 years to 5, they are allowed to continue receive the remaining initial doses as 4 years old persons, via walk-in at the vaccination venues providing COVID-19 vaccine for children.

4/ Vaccine Ordering and Training Material on Vaccine Management (as of 9 August 2024)

- For vaccine ordering, PCVS operators and related staff should go through the following training material:

Presentation in Notes for PCVS ad

(For PCVS providing mRNA vaccines to children and adolescents, please refer to the attachment in the email)

- Any discrepancy or defective vaccines should be reported to the Department of Health as soon as possible.

- For lost/ discrepancy / defective mRNA vaccines, please report to the Department of Health via the online Day End Report. After that, please complete the following form and return the following form to the Department of Health.

(For PCVS providing mRNA vaccines to children and adolescents, please refer to the attachment in the email)

5/ Information related to Comirnaty monovalent XBB.1.5 vaccine [paediatrics and toddler formulations] and Spikevax monovalent XBB.1.5 vaccine

A. Dosage and interval

- Comirnaty monovalent XBB.1.5 vaccine [paediatric and toddler formulations] are available in multi-dose vial containing up to 10 doses (*1) and require dilution before use.
- Spikevax monovalent XBB.1.5 vaccine is available in multi-dose vial containing up to 10 doses of 0.25 ml and **NO DILUTION IS REQUIRED**.

B. Eligibility

PCVSs can provide monovalent XBB.1.5 mRNA vaccine to eligible clients of age ≥ 6 months as the initial dose and to priority groups as the booster dose.

For further details, please refers to the poster:
https://www.chp.gov.hk/en/features/106951.html

PCVSs should refer to the prevailing recommendation announced by the Government and offer XBB vaccines to clients belonging to announced priority group.

C. Route and site of administration

- The vaccine is administered intramuscularly in the deltoid muscle of non-dominant arm. Mid- anterolateral thigh injection **should** be offered to all adolescents, children and toddler (both male and female) aged 17 and below as the site of vaccination.

- The picture of proper position of holding a child during injection is recommended to display in the vaccination booths of PCVS for vaccinators' and accompanying adults' easy reference.

D. Ordering, delivery and storage

(1) Comparison of shelf-life of different formulations of mRNA vaccines for person aged 6 months to 11 years

	Comirnaty XBB.1.5 - toddler formulation (3mcg/dose)	**Comirnaty XBB.1.5 - paediatric formulation (10mcg/dose)**	**Spikevax XBB.1.5 0.1 mg/mL**
Plastic cap color	**Maroon**	**Orange**	**Blue**
Dilution	**Required**	**Required**	**DO NOT DILUTE**
Frozen vial	**18 months (-90 to -60°C)**	**18 months (-90 to -60°C)**	**9 months (-50°C to -15°C)**
Thawed vial	**10 weeks (70 days) (2 to 8°C)**	**10 weeks (70 days) (2 to 8°C)**	**30 days (2 to 8°C)**
Unopened vial prior to use	**12 hours (8°C to 30°C)**	**12 hours (8°C to 30°C)**	**12 hours(8°C to 25°C)**
Opened vial (2 to 30°C)	**12 hours (after dilution with sodium chloride 0.9% solution for injection) (2°C to 30°C)**	**12 hours (after dilution with sodium chloride 0.9% solution for injection) (2°C to 30°C)**	**12 hours (2°C to 25°C)**

(2) Wastage reduction

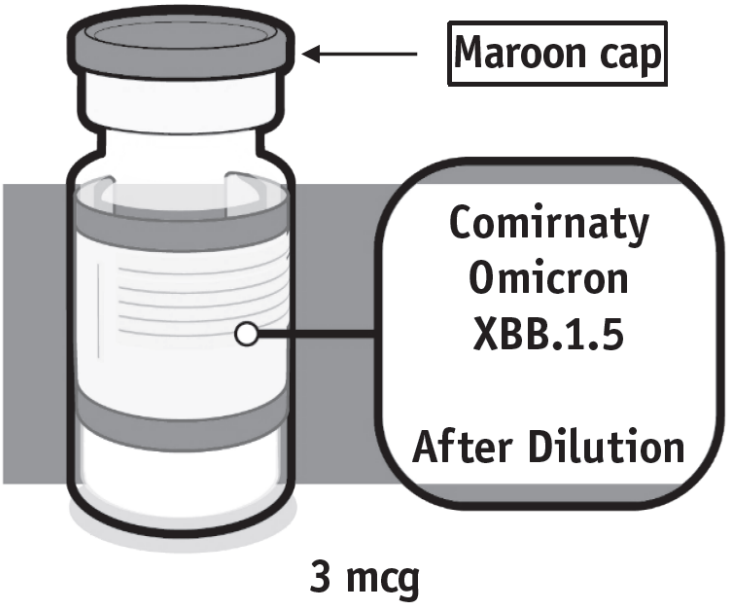
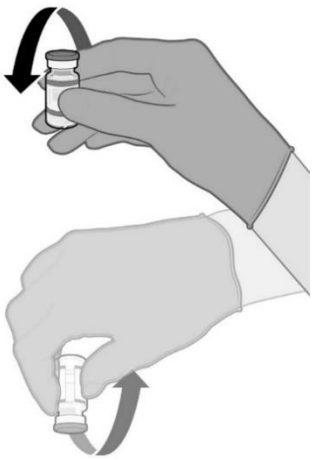
- Preventative measures should be in place to avoid unnecessary vaccine wastage.
- You are strongly recommended to avoid following scenarios that may lead to unnecessary vaccine wastage, including:
  (a) High rate of absenteeism
  (b) Substandard dilution technique
  (c) Violation of vaccine storage condition
  (d) Vaccine exposed to room temperature beyond allowed duration (please see above table for shelf life of different vaccines under various circumstances)
- Wastage rate will be reviewed by the PMVD periodically.

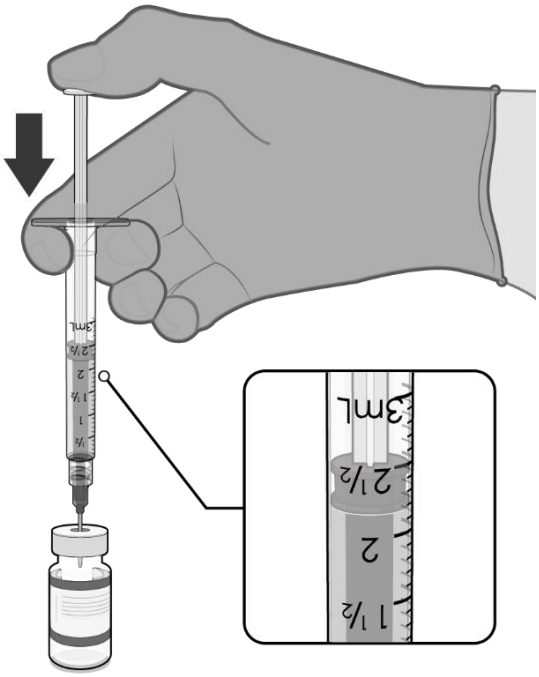
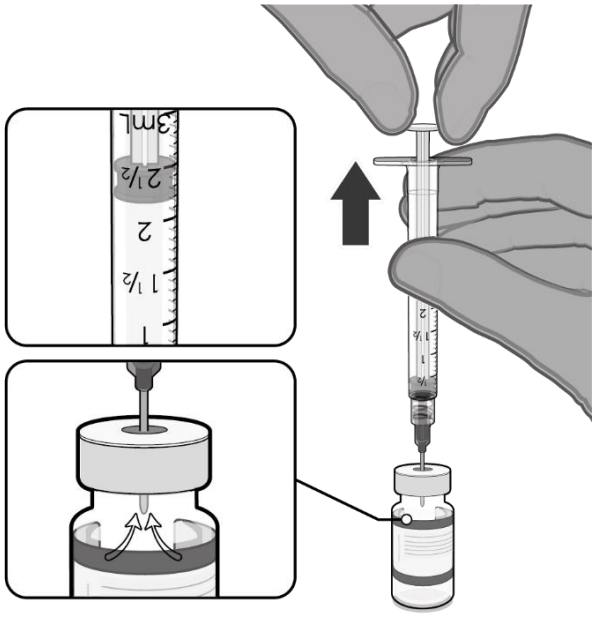
For further details, please refers to Section 4 " Vaccine ordering, delivery and storage" of Doctors' Guide for mRNA vaccines.

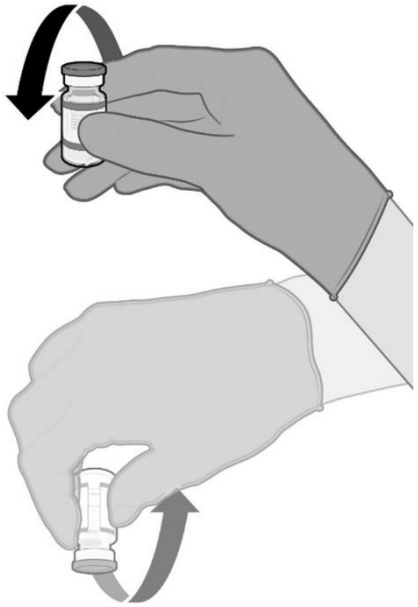
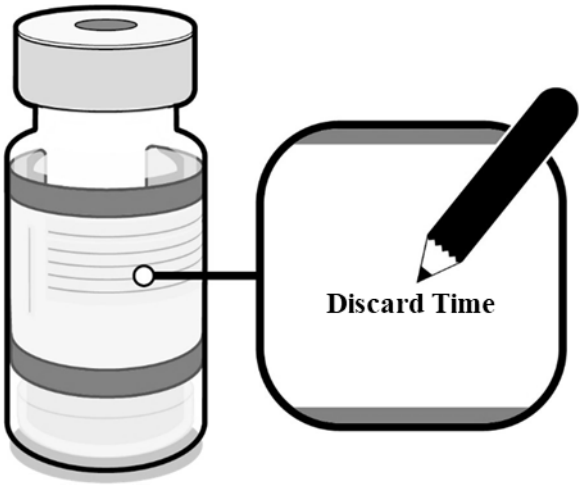
E. Dilution and preparation procedure

- It is suggested that Comirnaty monovalent XBB.1.5 vaccine [paediatric and toddler formulations] should be diluted immediately after withdrawal from the refrigerator. Expiry of undiluted vaccine at room temperature is 12 hours. After dilution, the diluted vaccines should be used within 12 hours.
- Please see the procedure for the dilution of Comirnaty monovalent XBB.1.5 vaccine [paediatric and toddler formulations].

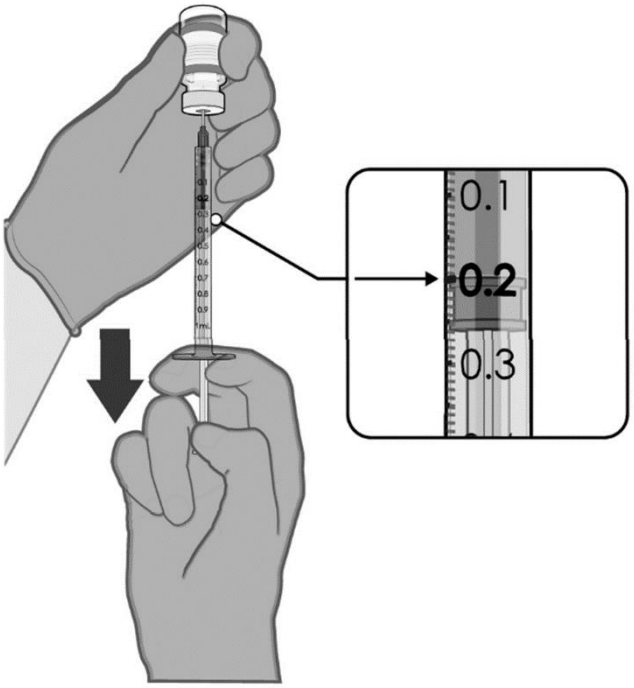
(1) For **Comirnaty monovalent XBB.1.5 vaccine [toddler formulation]**, the procedure for vaccine dilution should be carried out according to the drug insert as illustrated below:

<table>
<tr><th colspan="2">VIAL VERIFICATION - Comirnaty monovalent XBB.1.5 vaccine [toddler formulation]</th></tr>
<tr><td> 
</td><td>• Verify that the vial has a maroon plastic cap.
• PLEASE CHECK AND ENSURE THAT THE NAME OF THE VACCINE SHOULD BE <u>“Comirnaty Omicron XBB.1.5 3 micrograms/dose concentrate for dispersion for injection.”</u>.</td></tr>
<tr><th colspan="2">PRIOR TO DILUTION- Comirnaty monovalent XBB.1.5 vaccine [toddler formulation]</th></tr>
<tr><td> 
Gently × 10</td><td>• Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.
• Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.</td></tr>
</table>

DILUTION- Comirnaty monovalent XBB.1.5 vaccine [toddler formulation]	
 **2.2 mL of sodium chloride 9 mg/mL (0.9%) solution for injection**	• The thawed vaccine must be diluted in its original vial with 2.2 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.
 **Pull back plunger to 2.2 mL to remove air from vial.**	• Equalise vial pressure before removing the needle from the vial stopper by withdrawing 2.2 mL air into the empty diluent syringe.

 **Gently × 10**	• Gently invert the diluted dispersion 10 times. Do not shake. • The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.
 **Record appropriate date and time.** **Use within 12 hours after dilution.**	• The diluted vials should be marked with the appropriate date and time. • After dilution, store at 2 ºC to 30 ºC and use within 12 hours. • Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

The preparation of each 0.2 mL dose using a new sterile 1mL low dead-volume (LDV) syringe after dilution is illustrated below:

<table>
<tr><th colspan="2">PREPARATION OF INDIVIDUAL 0.2 mL DOSES- Comirnaty monovalent XBB.1.5 [toddler formulation]</th></tr>
<tr>
<td> 

0.2 mL diluted vaccine</td>
<td>

After dilution, the vial contains 2.6 mL from which 10 doses of 0.2 mL can be extracted.
Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
Withdraw 0.2 mL of diluted vaccine

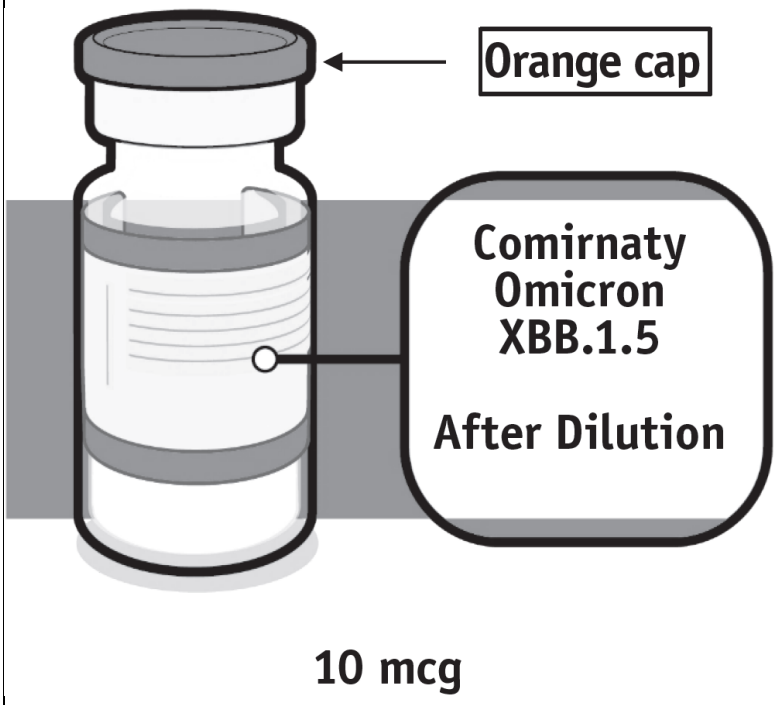
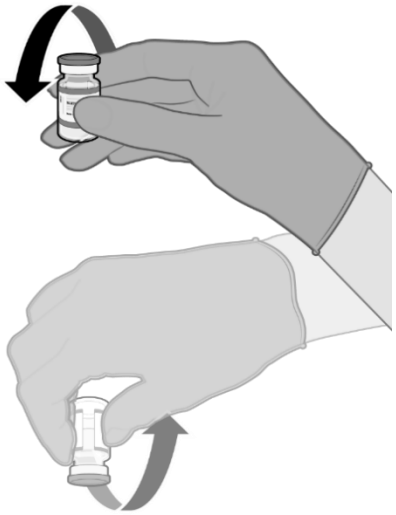
Low dead-volume syringes and/or needles should be used in order to extract 10 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.

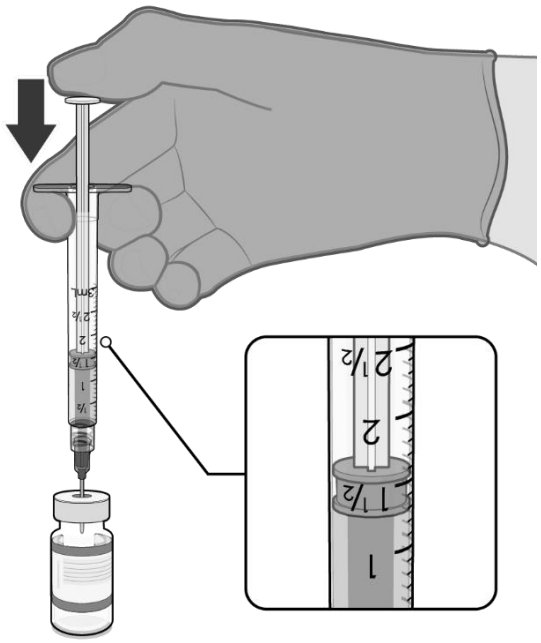
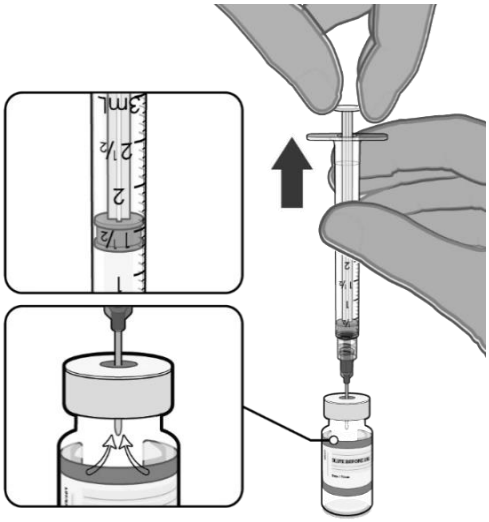
If standard syringes and needles are used, there may not be sufficient volume to extract ten doses from a single vial.
Each dose must contain 0.2 mL of vaccine.
If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.
Discard any unused vaccine within 12 hours after dilution.

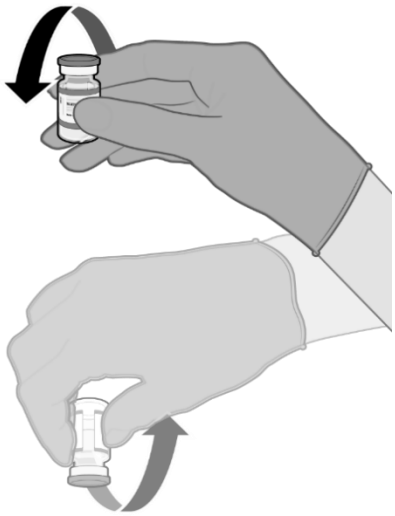
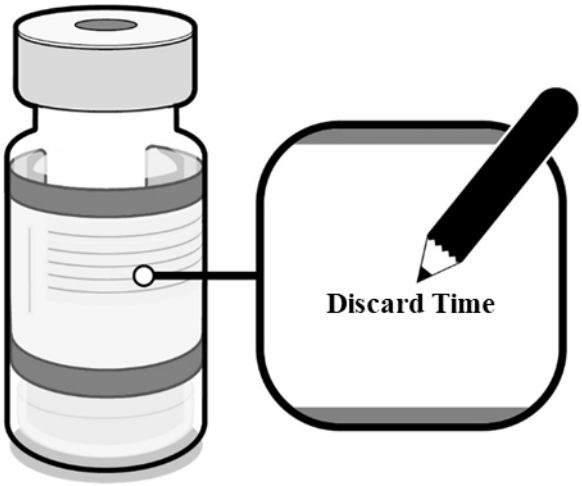
</td>
</tr>
</table>

Each dose must contain 0.2 mL of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

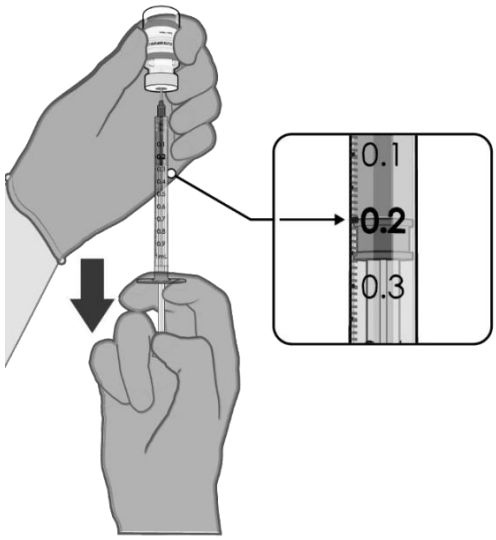
(2) For **Comirnaty monovalent XBB.1.5 vaccine [paediatric formulation]**, the procedure for vaccine dilution should be carried out according to the drug insert as illustrated below:

<table>
<tr><td colspan="2">VIAL VERIFICATION - Comirnaty monovalent XBB.1.5 vaccine [paediatric formulation]</td></tr>
<tr><td> 
</td><td>• Verify that the vial has an orange plastic cap.
• PLEASE CHECK AND ENSURE THAT THE NAME OF THE VACCINE SHOULD BE <u>“Comirnaty Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection”</u>.</td></tr>
<tr><td colspan="2">PRIOR TO DILUTION - Comirnaty monovalent XBB.1.5 vaccine [paediatric formulation]</td></tr>
<tr><td> 
Gently × 10</td><td>• Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.
• Prior to dilution, the thawed dispersion may contain white to off- white opaque amorphous particles.</td></tr>
</table>

DILUTION- Comirnaty monovalent XBB.1.5 vaccine [paediatric formulation]	
 **1.3 mL of sodium chloride 9 mg/mL (0.9%) solution for injection**	• The thawed vaccine must be diluted in its original vial with 1.3 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.
 **Pull back plunger to 1.3 mL to remove air from vial.**	• Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.3 mL air into the empty diluent syringe.

 **Gently × 10**	• Gently invert the diluted dispersion 10 times. Do not shake. • The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.
 **Record appropriate date and time.** **Use within 12 hours after dilution.**	• The diluted vials should be marked with the appropriate date and time. • After dilution, store at 2 ºC to 30 ºC and use within 12 hours. • Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

The preparation of each 0.2 mL dose using a new sterile 1mL low dead-volume (LDV) syringe after dilution is illustrated below:

<table>
<tr><th colspan="2">PREPARATION OF INDIVIDUAL 0.2 mL DOSES - Comirnaty monovalent XBB.1.5 vaccine [paediatric formulation]</th></tr>
<tr>
<td> 

0.2 mL diluted vaccine</td>
<td>

After dilution, the vial contains 2.6 mL from which 10 doses of 0.2 mL can be extracted.
Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
Withdraw 0.2 mL of diluted vaccine.

Low dead-volume syringes and/or needles should be used in order to extract 10 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 ten doses from a single vial.

Each dose must contain 0.2 mL of vaccine.
If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.
Discard any unused vaccine within 12 hours after dilution.

</td>
</tr>
</table>

Each dose must contain 0.2 mL of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

- For Spikevax monovalent XBB.1.5 vaccine, the dose in the syringe should be prepared as single dose **immediately before vaccination inside the vaccination booth/room**. DO NOT prepare the vaccine doses in advance. After first puncture of the multidose vial, the vaccines should be used within 12 hours.

  For Spikevax monovalent XBB.1.5 vaccine, the procedure for vaccine handling and preparation should be carried out according to the drug insert as below:

  (a) Vial verification
  - Verify that the vial has a blue flip-off cap and the product name is Spikevax 2023-2024 Formula (XBB.1.5) Suspension for Intramuscular Injection.

  (b) Prior to use
  - Do not shake or dilute. Swirl the vial gently after thawing and before each withdrawal.
  - The vaccine should be inspected visually for particulate matter and discolouration prior to administration.
  - Spikevax monovalent XBB.1.5 vaccine 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

  (c) Preparation
  - Use a new sterile needle and syringe to pierce the stopper preferably at a different site each time. 10 doses (of 0.25 mL each) can be withdrawn from each multidose vial.
  - Verify syringe volume after withdrawing the dose (i.e. 0.25ml per dose).
  - **Record the use before date and time, along with any other relevant information mentioned in section 6.5.12 of Doctors' Guide for mRNA vaccine on the vial label. Discard any punctured vial 12 hours after first puncture.**
  - **The dose in the syringe should be used immediately. DO NOT prepare the vaccine doses in advance.**

For further details, please refers to Section 6 "Vaccination procedures" of Doctors' Guide for mRNA vaccine.

6/ Recommendations on segregation

- For those venues providing more than one type of COVID-19 vaccines, there should be clear segregation for different type of vaccines at the venue. The logistics of storage and administration for each type of vaccine should be followed accordingly.

  For details, please refers to section 6 of Doctors' guide.

- The identification photos of vaccines may be adopted to facilitate confirmation on choice of vaccine with the parents or guardians.

Vaccine Identification_202

(For PCVS providing mRNA vaccines to children and adolescents, please refer to the attachment in the email)

7/ Recommendations for usage of Spikevax monovalent XBB.1.5 vaccine for BOTH adults and children in same venue

- Spikevax monovalent XBB.1.5 vaccine have the SAME FORMULATION but DIFFERENT DOSAGE for adult (aged ≥12 years) and children (aged 6 months to 11 years). Please see the comparison table of Spikevax monovalent XBB.1.5 vaccine offering to different age group.

	Spikevax XBB.1.5 0.1 mg/mL dispersion for injection (2.5mL per vial)	
Age group	Adult (aged ≥ 12 years)	Children (aged 6 months to 11 years)
Volume of each dose	0.5mL **(full dose)** (50 micrograms of andusomeran)	0.25mL **(half dose)** (25 micrograms of andusomeran)
Number of doses per vial	5 doses	10 doses

- PCVSs should provide adequate training to frontline staff on the dosage and other relevant information of Spikevax XBB.1.5 vaccine. The vaccinators should

familiarize themselves with the dosage indicated for different age groups and administer accordingly.

- Use of identification photos of vaccines to facilitate confirmation on choice and dosage of vaccine with the parents or guardians before administration is strongly recommended.
- The vaccinators are also recommended to keep a record (e.g. log sheet) to monitor the administration of children and adult dose.
- The vaccinator should select the correct dosage in the computer system for vaccination record creation.
- Other measures may also be adopted to segregate different age group of PBVs (e.g. set up designated booth, use of different colour chits etc).

ANNEX 1 – Useful Contacts

Central Medical Team (CMT)	Tel: 3975 4859 (Operating hours: **Weekdays (Non-PH)** from 0900-1745**)** Email: nurse_cmt@dh.gov.hk (Medical issues) adm_cmt@dh.gov.hk (Administrative support)
Vaccination Subsidy Scheme Team	Tel: 3975 4806 / 2125 2299 (Operating hours: **Weekdays (Non-PH)** from 0900-1730) Email: covid19_vss@dh.gov.hk
CMT Pharmacist	Tel: 5394 3508 (Operating hours: **Weekdays (Non-PH)** from 0900 - 1745**)** Email: pharm_cmt@dh.gov.hk

ANNEX 2 – Useful links of the document about the vaccination programme

Document type	Document name	QR code of the link (can either click or scan)		
		ENG	CHI	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”)			

Package Insert of vaccines	BioNTech monovalent XBB.1.5 (Pediatrics formulation / 10mcg)			
	BioNTech monovalent XBB.1.5 (Toddler formulation / 3 mcg)			
	Spikevax monovalent XBB.1.5			
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?			

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			

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			
	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			

	Code of Practice for the Management of Clinical Waste			
Others	COVID-19 Vaccination Online Training Platform			
	Reporting Adverse Drug Reactions			