Doctors’ Guide
for the Coronavirus Disease 2019 (COVID-19) Vaccination Programme at the Residential Care Homes under the Residential Care Home Vaccination Programme (RVP)

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

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Always make sure that you have the latest version by checking the designated COVID-19 vaccine website


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Disclaimer

This Doctors’ Guide provides guidance for Coronavirus Disease 2019 (COVID-19) Vaccination Programme at Residential Care Homes (RCHs) under the Residential Care Home Vaccination Programme (RVP). We welcome doctors’ questions, comments or feedback on this Guide so that we can improve on it. The contents of the Guide will be updated on the designated COVID-19 vaccine website


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1. **Introduction**

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

1.2 This Doctors’ Guide provides guidance for COVID-19 vaccination at residential care home setting. Always make sure that you have the latest version by checking the designated website [https://www.covidvaccine.gov.hk/en/](https://www.covidvaccine.gov.hk/en/).

1.3 The Residential Care Home Vaccination Programme (RVP), administered by the Department of Health (DH), is a programme that provides free COVID-19 vaccination for eligible persons at Residential Care Homes (RCHs). The eligibility of the vaccination recipients shall be determined by the Government, and is being updated from time to time. Enrolled doctors, i.e. Visiting Medical Officers (VMOs), would administer vaccinations to the eligible persons. The Government would reimburse injection fees to VMOs for each dose of vaccination administered to eligible persons.

1.4 For residents/ staff who wish to receive vaccination, they can choose to receive either CoronaVac via RVP or BioNTech via outreach team from Hospital Authority (HA) in RCH setting. They can also arrange their own appointments to receive COVID-19 vaccine in Community Vaccination Centres, private hospitals or clinics etc.
2. Vaccine covered, eligible groups and reimbursement level

2.1 Vaccine covered

2.1.1 COVID-19 vaccines would be provided and delivered to RCHs by the Government. Type of COVID-19 vaccine to be used for the COVID-19 Vaccination Programme under the RVP is introduced in clause 2.1.3.

2.1.2 The COVID-19 vaccine is authorized for use under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) for the specific purpose of preventing COVID-19 infection. The COVID-19 vaccine has not been registered in Hong Kong under the Pharmacy and Poisons Ordinance (Cap. 138).

2.1.3 The COVID-19 Vaccine (Vero cell), Inactivated; is developed by Sinovac Biotech (Brand name: CoronaVac). The fact sheet is attached in Annex I. As the fact sheet might be updated from time to time as necessary, please visit the below link for the latest information:-


(a) Dosage and interval

• CoronaVac is available in single-dose (0.5mL) vial.
• Two doses of CoronaVac should be administered for primary immunisation.
• The second dose is given 28 days after the first dose.
  • **Please refer to section 6.11 for the vaccination arrangement for the third dose.**

(b) Route of administration

• The vaccine is administered intramuscularly in the deltoid muscle of upper arm, preferably on non-dominant arm, after withdrawal from the vial.

(c) Contraindications

i) People with history of allergic reaction to CoronaVac, or other inactivated vaccine, or any component of CoronaVac (active, inactive ingredients, or any material used in manufacturing process)
  (Please refer to the component as listed in the package insert (Annex
II).

ii) People with previous severe allergic reactions to vaccine (e.g. acute anaphylaxis, angioedema, dyspnea, etc.).

iii) People with severe neurological conditions (e.g. transverse myelitis, Guillain-Barré syndrome, demyelinating diseases, etc.).

iv) Patients with uncontrolled severe chronic diseases.

v) Pregnant and lactating women.

(d) Precautions

i) Due to the insufficient data of persistence of protection induced by this vaccine, necessary protective measures should be taken in line with prevention and control of the COVID-19 epidemic.

ii) This vaccine is strictly prohibited for intravenous injection. There is no safety and efficacy data of subcutaneous or intradermal injection.

iii) Treatment for emergency, e.g. epinephrine injection, should be available for use when required. Individuals should be observed for at least 30 minutes on site after vaccination.

iv) Vaccine should be used with caution in patients with acute diseases, acute exacerbation of chronic diseases, severe chronic diseases, atopy and fever. If necessary, delay vaccination after doctor’s evaluation.

v) Vaccine should be used with caution in patients with diabetes or history of convulsions, epilepsy, encephalopathy or mental illness, or family history of those diseases.

vi) Intramuscular injection of this vaccine may cause bleeding, it should be used with caution in patients with thrombocytopenia or haemorrhagic diseases.
vii) The safety and efficacy data of this vaccine on people with impaired immune function (such as malignant tumour, nephrotic syndrome, AIDS patients) have not been obtained, and vaccination should be based on individual considerations.

viii) The injection of human immunoglobulin should be given at least one month before or after the vaccination to avoid affecting the immune effect.

ix) No clinical study has been carried out on the evaluation of immunogenicity when the vaccine product is given before, after or at the same time as other vaccines. Professionals should be consulted when concomitant use.

x) Do not use the vaccine product again if there was any adverse reaction of nervous system after vaccination.

xi) Like other vaccines, the protective effect may not reach 100% for all recipients.

xii) Women of childbearing age: the data collected of women with unexpected pregnancy after vaccination from clinical trials are very limited, which is insufficient to decide the risk of adverse pregnancy outcomes after vaccination.

xiii) Pregnant or lactating women: the clinical data of pregnant and lactating women are not available at present.

xiv) People aged 60 and above: The benefit of using CoronaVac generally exceeds the risk of not using any vaccines in persons aged 60 and above. Phase I and II data on individuals aged 60 and above showed that the vaccine is safe and immunogenic. There is limited phase III efficacy data for individuals aged 60 and above because of small sample size.

xv) Concomitant use with other drugs: immunosuppressive drugs, such as chemotherapy drugs, antimetabolic drugs, alkylating agents, cytotoxic drugs, corticosteroid drugs, etc., may reduce the immune
response to this vaccine.

xvi) Patients undergoing treatment could consult medical professional before use of CoronaVac to avoid possible drug interactions.

(e) To expedite the availability of CoronaVac to Hong Kong, some of the textual information (including but not limited to English name, dosing interval and expiry date of year 2024) in the sales pack/label and the drug insert of the initial shipment of CoronaVac are different from the version provided by the vaccine supplier upon its authorization for emergency use under Cap 599K. In particular, the expiry date of the vaccine is in the year of 2022 instead of 2024. Nevertheless, all the information provided in the information factsheet of CoronaVac are matched with the authorized one. As there might be a chance of the product information updated from time to time, please visit the below link for latest information: https://www.fhb.gov.hk/download/our_work/health/201200/e_evaluation_report_CoronaVac.pdf. The following lot no. and expiry date of the CoronaVac would be printed on the delivery note provided by the distributor:

<table>
<thead>
<tr>
<th>Lot no.</th>
<th>Expiry date</th>
</tr>
</thead>
<tbody>
<tr>
<td>A2021010022</td>
<td>13.01.2022</td>
</tr>
<tr>
<td>A2021010034</td>
<td>19.01.2022</td>
</tr>
<tr>
<td>A2021010037</td>
<td>21.01.2022</td>
</tr>
</tbody>
</table>

2.1.4 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, joined by the Chief Executive’s expert advisory panel (JAC-EAP) jointly provides recommendations on the use of COVID-19 vaccines in Hong Kong VMOs should always refer to latest recommendations of the COVID-19 vaccines at https://www.chp.gov.hk/en/static/24008.html. Some key recommendations on COVID-19 vaccination regime are highlighted below:

(a) Individuals (except for persons recovered from COVID-19 infection, please refer to section 6.6) are advised to complete first and second doses of the series with the same product when possible.
(b) In exceptional situations where the vaccine recipient is unable to complete the series with the same type of vaccine (e.g. due to anaphylaxis after the first dose, or if the vaccine is no longer available / accessible), vaccination with another COVID-19 vaccine may be considered, on a case-by-case basis.

(c) CoronaVac is indicated for susceptible persons aged three years and above. Starting from 21 January 2022, eligible age group to receive the CoronaVac vaccine would be lowered to children of 5 years old. Please see section 6.10.

(d) For individuals aged 18 years and above who had received two doses of CoronaVac vaccine, Comirnaty as the third dose at least 180 days from the second dose is strongly recommended. Personal choice for the vaccines for the third dose is respected (please refer to section 6.11 for details).

(e) Persons who have recovered from previous COVID-19 infection can receive one dose of Comirnaty at least 90 days after hospital discharge or one dose of CoronaVac at least 180 days after discharge for further protection. Comirnaty as the second dose at six months after the first dose is recommended. Personal choice for the vaccines for the second dose is respected (please refer to section 6.6 for the vaccination arrangement).

(f) It is reiterated that elderly is the group with the highest risk of complication and health that any elderly who have received influenza vaccines before can safely receive COVID-19 vaccines. For the frailest elderly, the benefit versus risk may have to be carefully weighed.

2.1.5 The Department of Health has published an Interim Guidance Notes On Common Medical Diseases and COVID-19 Vaccination In Primary Care Settings (https://www.covidvaccine.gov.hk/pdf/Guidance_Notes.pdf). VMOs 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.

(i) Subject to clinical judgement, patients with (a) severe chronic disease not under satisfactory control, especially those with symptoms, (b) acute/ unstable disease requiring treatment/ medical attention, and (c) undergoing treatment adjustment to better control the disease would generally have to defer vaccination. This applies to, for example, diabetes mellitus (control reflected by clinical and relevant blood monitoring) and hypertension (control reflected by
repeated blood pressure monitoring, evidence of end organ damage etc.). Achieving better/ stable control of the disease(s) with appropriate therapy is recommended before considering vaccination. Evidence of clinical disease should be taken into account for assessment when dyslipidaemia alone is encountered. Notwithstanding individual assessment, patients with recent acute myocardial infarction or stroke should defer vaccination for generally 3 to 6 months with good recovery and stable control.

(ii) When patients’ chronic diseases are in better control, the suitability for COVID-19 vaccination should be revisited and, where appropriate, patients should be advised for vaccination for personal protection.

2.2 Eligible persons

2.2.1. The eligibility of the vaccination recipients shall be determined by the Government, and is being updated from time to time. The following groups are eligible to receive free COVID-19 vaccination under this programme:

(a) Residents and staff of Residential Care Homes for the Elderly (RCHEs), Residential Care Homes for Persons with Disabilities (RCHDs), nursing homes and users of day care units attached to the Residential Care Homes
(b) a Person with Intellectual Disability (PID) studying in a school for children with intellectual disability, a school for children with physical disability, a school for children with visual impairment or a school for children with hearing impairment, as listed in the list of aided special schools published in the website of the Education Bureau with the link as follows (https://www.edb.gov.hk/tc/edu-system/special/support-subsidy/special-school/index.html); and
(c) a PID receiving services in a subvented Day Activity Centre, subvented Sheltered Workshop, a subvented Integration Vocational Rehabilitation Services Centre, a subvented Integration Vocational Training Centre, a subvented District Support Centre, as listed in following website (https://www.chp.gov.hk/en/features/41360.html)
The above-mentioned institutions listed in (b) and (c) above are collectively referred to as “Designated Institutions (DIs) serving the PIDs”

2.3 Reimbursement level

2.3.1 The Government will reimburse HK$130 per dose of COVID-19 vaccine given to an Eligible Person under the RVP, regardless of whether it is the 1\textsuperscript{st}, 2\textsuperscript{nd} or 3\textsuperscript{rd} dose of COVID-19 Vaccination. No extra payment shall be payable just for the 2\textsuperscript{nd} dose. An extra Vaccination Fee of HK$50 per dose shall be paid for COVID-19 vaccination to an elderly who has reached or will reach the age of 60 years or above in the calendar year when the vaccination is administered, regardless of whether it is the 1\textsuperscript{st}, 2\textsuperscript{nd} or 3\textsuperscript{rd} dose.

2.3.2 No extra charge of any service fees is allowed. The VMOs and the Associated Organization should not require the recipient to pay any service fee for the vaccination under the COVID-19 Vaccination Programme.

2.3.3 On 25 Oct 2021, the Government announced the payment of an additional allowance of HK$800 per hour and HK$400 for every complete half hour of dedicated one-on-one consultation or health talk at an RCH or a Designated Institution serving the PIDs before the vaccination. The maximum reimbursement allowance to be claimed is determined by the number of residents in the RCH.

<table>
<thead>
<tr>
<th>Number of residents in the RCH</th>
<th>Maximum total hours to be claimed</th>
<th>Maximum allowance* (HK$800/hr, or HK$400/half-an-hour)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 or below</td>
<td>4 hours</td>
<td>HK$ 3,200</td>
</tr>
<tr>
<td>51-100</td>
<td>8 hours</td>
<td>HK$ 6,400</td>
</tr>
<tr>
<td>101-150</td>
<td>12 hours</td>
<td>HK$ 9,600</td>
</tr>
<tr>
<td>151-200</td>
<td>16 hours</td>
<td>HK$ 12,800</td>
</tr>
<tr>
<td>201-300</td>
<td>20 hours</td>
<td>HK$ 16,000</td>
</tr>
<tr>
<td>301 or above</td>
<td>28 hours</td>
<td>HK$ 22,400</td>
</tr>
</tbody>
</table>

VMO should submit the claim form (Annex XIII) to the Department of Health within two weeks.

For more details, please refer to the five new Clauses 51A to 51E of the Agreement
3. Responsibilities of VMOs

As vaccination is invasive in nature and the procedure is performed under non-clinic setting, VMOs should give due consideration to safety and liability issues when providing vaccination service in RCH setting. The following notes aim to highlight areas that VMOs should note when providing vaccination services.

3.1. Requirement for doctors

3.1.1. VMOs 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) Workflow for COVID-19 vaccination in RCH setting (Section 6)
   (d) Clinical waste management (Section 7)
   (e) Reporting of adverse event following immunisation (Section 8)
   (f) Management of clinical incident (Section 9)

3.1.2. Staff of Programme Management and Vaccination Division (PMVD) may conduct random on-site quality assurance activities without prior notice. Please see Annex III for a checklist of items during onsite inspection.

3.1.3. VMOs are required to complete Part I of the online training for the COVID-19 Vaccination Programme offered by the Hong Kong Academy of Medicine before providing vaccination service. Relevant qualified/trained health care personnel who may accompany the VMO in a visit to an RCH are also encouraged to complete the online training before performing vaccination duties. Please find details in the website https://elearn.hkam.org.hk/en. Upon completion of Part I of the online training, an electronic certificate will be issued and should be kept for checking by PMVD on request.

3.1.4. **VMO should be present and oversee the whole vaccination process** in RCHs, ensure that the vaccination duties are performed by qualified/trained health care personnel. Sufficient number of qualified/trained health care personnel must be present to provide support.
3.2. Administrative Procedures

3.2.1. As the computer system for capturing vaccination record, the eHealth System (Subsidies) (eHS(S)), forms an integrated part of the RVP programme, VMOs are advised to familiarise themselves with the eHS(S). For details on using the eHS(S), please refer to the User Manual of using eHS(S) on COVID-19 Vaccination Programme [https://www.ehealth.gov.hk/en/covidvaccine/ehs.html](https://www.ehealth.gov.hk/en/covidvaccine/ehs.html). For quick guide of using eHS(S) for COVID-19 Vaccination Programme in RCHs, please refer to: [https://www.ehealth.gov.hk/en/covidvaccine/doc/quick-guide-for-residential-care-home.pdf](https://www.ehealth.gov.hk/en/covidvaccine/doc/quick-guide-for-residential-care-home.pdf).

3.2.2. The Smart ID Card Reader should be used as far as practicable to upload the accuracy of the vaccine recipients’ personal particulars captured by the eHS(S). Please note that VMOs should download and install the Smart ID Card Reader Software provided by eHS(S) as shown below (Figure 1) before using the Smart ID Card Readers at RCHs.

![Figure 1 - Guidelines for Smart HKID Card Reader Setup](image-url)
3.3. Medical consumables and equipment

3.3.1 The VMOs should ensure all medical consumables and equipment are sufficient and emergency drugs are registered in Hong Kong and not expired.

3.3.2 VMOs should ensure the following medical consumables and equipment required for COVID-19 vaccination are available at RCH on vaccination day:

(i) 70%-80% alcohol-based hand rub;
(ii) Kidney dishes/ containers;
(iii) Alcohol preps/ alcohol swab for skin disinfection before vaccination;
(iv) Dry sterile gauze/ cotton wool balls for post-injection compression to injection site;
(v) Sharps boxes.

3.3.3 VMOs should prepare emergency equipment and medication that must be ready in vaccination venue, including:

(i) Bag valve mask set (with appropriate mask size);
(ii) Adrenaline auto-injector or 1:1000 adrenaline ampoule for IM
injection with 1mL syringes (at least three) and 25-32mm length needles (at least three), should be immediately available for managing anaphylaxis (to be supplied by DH)\(^a\);

(iii) Blood pressure monitor (with appropriate cuff size);

(iv) Protocol for emergency management.

3.3.4 VMO should liaise with RCH ahead of time to ensure the following IT equipment are ready for use on vaccination day:

(i) Smart HKID Card Reader;

(ii) Computer installed with the Smart ID Card Reader Software and access to eHS(S), and the latest version of Internet Explorer for the respective Windows operating system (Internet Explorer 11 in Microsoft Windows 8.1 or later versions)

*In general, VMOs also need to enable the following software items in the browser:
- Javascript
- Cookies
- TLS

(iii) Internet connection;

(iv) Printer

\(^a\) Adrenaline, if needed, can be given in form of adrenaline autoinjector 300 microgram IMI or with reference to the body weight (according to the drug insert, Jext (300microgram) per dose is for adults and children over 30kg). If body weight is not available; dosage of adrenaline can be adjusted according to age.
4. Vaccine ordering, delivery and storage

4.1 Vaccine ordering and delivery
4.1.1. VMOs are responsible for ordering the vaccines with DH for delivery to RCH. VMOs should ensure sufficient vaccines for consented persons and the vaccines ordered are properly stored at RCH.

4.1.2. VMO should liaise with RCH to confirm the following before placing vaccine order:-
(i) Vaccination date for the 1st, 2nd and 3rd dose
(ii) Number of vaccines required
*Please note each pack of CoronaVac contains 40 vials of vaccines. To minimize the wastage, CoronaVac is also repackaged into 5’s pack by the distributor. Please arrange multiples of 5 people to get vaccinated each time as far as possible. Any remaining vaccines are advised to be kept and stored at refrigerator with temperature (2 °C to 8 °C) for the 2nd dose, given 28 days after the first dose.
(iii) Adequate storage capacity including but not limited to adequate storage space and refrigerators with temperature (2 °C to 8 °C) and cold chain maintained
(iv) Vaccine delivery arrangement (i.e. delivery date, time and designated RCH staff to receive vaccines)

4.1.3. VMOs would order vaccine using the web-based ordering system at least 10 calendar days before the vaccination day. Upon confirmation of vaccine order by the RCH, an acknowledgment email would be sent to the VMO and RCH to inform them about the confirmation.

4.1.4. Vaccines, adrenaline and syringes would be delivered to the RCH and should be received by the designated staff of RCHs.

4.2 Vaccine storage and cold chain management
4.2.1. Purpose-built vaccine refrigerators (PBVR) are the preferred means of storage for vaccines.

4.2.2. Domestic frost-free refrigerators (with or without freezer compartment) can be used if PBVR is not available with the following precautions being made:
(a) Use only the refrigerator compartment for storing vaccines if a domestic combination refrigerator/freezer unit is used.
(b) Modify and stabilize the refrigerator temperature before stocking with vaccine.
(c) Do not store vaccines directly under cooling vents, in drawers, on the floor or door shelves of the refrigerator. The instability of temperatures and air flow in these areas may expose vaccines to inappropriate storage temperatures.
(d) Fill the empty shelves, floor, drawers and the door with plastic bottles or other containers filled with water to maintain temperature stability. Leave a small space between the bottles/containers.
(e) Ensure doors of the refrigerator are closed properly.
(f) The temperature of the vaccine fridge should be monitored by a data logger or maximum-minimum thermometer. The temperatures (min/max if applicable) of the refrigerator would be checked manually 3 times daily each day, probably in the morning, at noon and in the afternoon, and record in the “Daily Fridge Temperature Chart” (Annex IV).

4.2.3. VMOs should follow the requirements and recommendations mentioned in 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.fhb.gov.hk/pho/rfs/tc_chi/pdf_viewer.html?file=download85&title=string105&titletext=string84&htmltext=string84&resources=03_Module_on_Immunisation_Children_chapter3).

4.2.4. 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.

4.2.5. The manufacturers’ recommendation on storage temperature of the vaccine, referencing to the package insert should be strictly followed.

4.2.6. 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.
4.2.7. The refrigerator door should be opened as little 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.

4.2.8. When the temperature of the refrigerator is found to be out of the +2°C to +8°C range, the vaccines that are suspected to have been exposed to temperatures outside the recommended range should remain properly stored in the refrigerator, quarantine them and mark “DO NOT USE” to avoid accidental administration of the possibly compromised vaccines.

4.2.9. In case of temperature excursion (i.e. if the vaccines have been exposed to temperature outside the recommended range), check whether the in-charge of RCH has informed and consulted the PMVD immediately and not later than one working day. The affected vaccines should not be administered until notice from PMVD that advice from vaccine manufacturer confirms the stability and effectiveness of the affected vaccines.

4.3 Management of surplus/ expired vaccines

4.3.1 The vaccines are Government Property and are provided to the doctors solely for the purpose of providing vaccination to eligible recipients. Unused/surplus vaccines should be properly stored in the vaccine-storing refrigerator in the RCH. RCH must return all unused/surplus vaccines at the end of the programme.

4.3.2 VMOs may be liable to costs related to broken or missing vaccines and the Government reserves the right to demand VMOs for payment due to vaccine breakage or missing vaccines.

4.3.3 Regarding the expired vaccines, please note that the expired vaccines should be removed from the refrigerator and labelled "DO NOT USE". The RCH should consider keeping the expired vaccines in a lockable cabinet and wait for the collection by the PMVD at a later time.

4.4 Broken vaccines

4.4.1 If vaccines are found to be broken upon unwrapping or by RCH staff or VMO, take photos of all the broken vaccines and document the lot number and
quantity and inform the PMVD as soon as possible and within one working day. Broken vaccines should be discarded into sharps boxes immediately and disposed of as clinical waste.

4.4.2. Broken vaccines should never be administered.

4.5 Defective vaccines
4.5.1 If vaccine is found to be defective, take photos of the defective vaccine and document the lot number, quantity, and reason of these defective vaccines (e.g. drug label misprinting, presence of foreign particles).

4.5.2 The defective vaccines should be removed from the refrigerator and mark “DO NOT USE” on the outer wrapper of these vaccines. The RCH should keep the defective vaccines in a lockable cabinet.

4.6 Reporting of defective / voided vaccines
4.6.1 The information of defective / voided vaccine should be recorded and provided to PMVD (phone number 2125 2125 during office hour) within one day after the vaccination activity.

4.6.2 Defective or broken vaccines should never be administered.
5. Infection control practice

5.1 Infection Control Practice in RCH setting


5.1.2 VMO and RCH staff are advised to follow the PPE recommendation under Serious Response Level. Please refer to the Recommended Personal Protective Equipment (PPE) in hospitals/clinics under Serious/ Emergency Response Level Coronavirus disease (COVID-19) (Interim) at CHP website (https://www.chp.gov.hk/files/pdf/recommended_ppe_for_nid_eng.pdf).


5.1.4 Surgical masks should be worn at all times during the vaccination activity, and appropriate distancing (i.e. at least 1 metre when surgical masks are worn) shall be kept. In exceptional cases where mask cannot be worn, the participants should be attended separately and kept social distancing of at least 1.5 metres.

5.1.5 Where needed, eye protection (e.g. goggle, face shield) should be used when approaching client who have not worn mask properly within the distance of 1 metre. Eye protection (full face shield or goggles or eye-visors) should be worn at all times during vaccination activity under Serious/ Emergency Response Level.
5.1.6 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.

5.1.7 If gloves have been worn, it should be removed immediately after use for each client, followed by proper hand hygiene.

5.1.8 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.

5.1.9 Cardiopulmonary resuscitation (CPR) is an aerosol-generating procedures with documented increased in risk of respiratory infection transmission, the recommend PPE for CPR included N95 respiratory, eye protection, gown, gloves and cap (optional). (Please refer to the CHP website for details https://www.chp.gov.hk/files/pdf/recommended_ppe_for_nid_eng.pdf).

5.1.10 Clean and disinfect all areas including, but not limited to, the working area inside vaccination areas, with 1 in 49 diluted household bleach (mixing 1 part of household bleach containing 5.25% sodium hypochlorite with 49 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.

5.1.11 For metallic surface, disinfect with 70% alcohol.

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 2 – 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
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 3 - 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, cleaning 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.


5.3 Safe injection practices and sharps handling

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 a patient 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 prevention of 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 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.

5.3.9 Keep clinical waste containers securely in safe and upright position so as to prevent them from being toppled over.

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

5.4 Preventing COVID-19 Vaccine-strain Environmental Contamination

5.4.1 The CoronaVac vaccine contains high concentration of inactivated COVID-19 virus which is not infectious and will not cause COVID-19 infection. Despite its non-infectious nature, the process of vaccine administration and handling may result in environmental contamination which may impact on COVID-19 PCR test.

5.4.2 All healthcare personnel should observe relevant infection control advice for COVID-19 vaccination in all settings. To minimize vaccine-strain environmental contamination, it should be noted that the RNA component of the vaccine, despite being non-infectious, can only be destroyed using diluted bleach but not alcohol. As such, additional measures including but not limited to the following should be taken:

(a) proper environmental cleaning with diluted bleach to areas of vaccine administration and handling,
(b) technique on vaccination preparation procedure,
(c) wash hands thoroughly with liquid detergent and water after handling of vaccines such as after each session of inoculation or whenever changing from inoculation to other tasks,
(d) where applicable and feasible, arrange separate session and/or different staff for vaccine handling and PCR testing with proper infection control measures.
5.4.3 Please refer to the Guideline on Preventing COVID-19 Vaccine-strain Environmental Contamination for details:


6. Workflow for COVID-19 vaccination in RCH / DI setting

6.1 Preparation before the day of vaccination

- **RCH/ DI to provide factsheet to encourage COVID-19 vaccine to residents/ PID who have NOT been vaccinated**
- **RCH/ DI to fill in Annex V & VI, providing details of the unvaccinated residents, e.g. name, ID number, any history of seasonal influenza vaccination**
- **VMO to conduct assessment and provide dedicated one-on-one consultation/ health talk**
- With the help of RCH, collect consent forms from those who are fit and consent for vaccination. **Collect written refusal form from families or legal guardians within specific time.**
- **Verify vaccination history**
- **Confirm with RCH/ DI**
  - Number of residents and staff eligible for vaccination
  - Vaccination schedule for 1st / 2nd / 3rd doses
  - Adequate fridge capacity for storing the vaccines
- **Order vaccines** using the web-based ordering system
- **Liaise with RCH/ DI on clinical waste management**
- **Prepare emergency equipment**, and ensure medical consumables are available at RCH/ DI for use on the vaccination day
6.2 Vaccination at RCH/ DI and Post-vaccination follow up

Cross-check the list of consented residents with the vaccination consent forms

Conduct assessment

Verify identity of vaccine recipients
Confirm/Obtain informed consent from residents/staff/ PID

Insert HKID card to draw up eHS(S),
Check for COVID-19 Vaccination Record, if any,
and document electronic consent in the eHS(S) on the same day

Prepare and administer vaccine

Provide vaccination card printed from eHS(S) to vaccine recipients

With the support of RCH/ DI, keep the recipients under observation for 30 minutes
and provide emergency management when necessary

Report AEFIs and clinical incidents, if any

Update with RCH/ DI for the subsequent vaccination schedule e.g. rescheduling for those excluded due to acute illnesses
6.3 Workflow for vaccination of residents

6.3.1 Information provision, conducting assessment and obtaining informed consent

6.3.1.1 Before vaccination, RCH/ DI staff would assist in providing vaccine recipients, guardians and/or relatives with the fact sheet (Annex I) (as the fact sheet would be updated from time to time as necessary, VMO and RCH staff should use the latest version available at [https://www.covidvaccine.gov.hk/pdf/COVID19VaccinationFactSheet_CoronaVac_CHI.pdf](https://www.covidvaccine.gov.hk/pdf/COVID19VaccinationFactSheet_CoronaVac_CHI.pdf) 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). Starting from 11 November 2021, VMO/ RCH staff should also provide a supplementary sheet (Annex XIV) (as the supplementary sheet would be updated from time to time as necessary, VMO should use the latest version available at [https://www.covidvaccine.gov.hk/pdf/Third_dose_supplementary_sheet_CHI.pdf](https://www.covidvaccine.gov.hk/pdf/Third_dose_supplementary_sheet_CHI.pdf)) to every resident/staff together with the fact sheet, irrespective of whether the resident/staff is having the first, second or third dose. Please make sure you/RCH staff have distributed the latest version of the supplementary sheet to vaccine recipients.

6.3.1.2 RCHs would invite VMO to conduct assessment for residents who have not been vaccinated. RCHs would compile lists of those who have not been vaccinated (Annex V & VI), with resident’s names, ID number, and information on whether they have received seasonal influenza vaccine before, to be handed over to VMOs.

6.3.1.3 Based on the above information, VMOs would conduct assessment to ascertain unvaccinated residents’ fitness to receive both CoronaVac and Comirnaty. Dedicated one-on-one consultation or health talk at the RCH or DI will be provided for these residents and/or their relatives.

6.3.1.4 VMOs could refer to the “An Interim Guidance Notes on Common Medical Diseases and COVID-19 Vaccination in Primary Care Settings” in making clinical judgement on the suitability for COVID-19 vaccination. The Guidance notes will be updated from time to time. Latest version is available at the designated website [https://www.covidvaccine.gov.hk/en/professional](https://www.covidvaccine.gov.hk/en/professional).

6.3.1.5 VMOs may refer the following cases to the Vaccine Allergy Safety Clinic of Hospital Authority for medical consultation/investigation as deemed necessary.
appropriate:

(i) persons with immediate (within an 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 medications.

Clients with allergic rhinitis, asthma, atopic dermatitis, chronic urticaria, drug and food allergies, and anaphylaxis unrelated to COVID-19 vaccines (without other precautions) do **not** 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 **30 minutes** after vaccination:

(i) superficial symptoms like rash, itchiness, urticaria, etc. that appear within an hour, but without other systemic allergic symptoms such as shortness of breath, wheezing, low blood pressure, etc.;

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


(a) To make the referral, VMOs 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 areas 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:

<table>
<thead>
<tr>
<th>Vaccine Allergy Safety Clinic at Grantham Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Address:</strong> Rheumatology and Clinical Immunology Unit, G/F, Block A, Grantham Hospital, 125 Wong Chuk Hang Road, Aberdeen, Hong Kong</td>
</tr>
<tr>
<td><strong>Tel. No.:</strong> 2518 2620</td>
</tr>
<tr>
<td><strong>Fax No.:</strong> 2518 6716</td>
</tr>
<tr>
<td><strong>Service Hours:</strong> Mon to Fri: 08:30 to 17:00; Sat: Closed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vaccine Allergy Safety Clinic at Queen Mary Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Address:</strong> 6/F., S Block, Queen Mary Hospital, 102 Pokfulam Road, Hong Kong</td>
</tr>
<tr>
<td><strong>Tel. No.:</strong> 2255 4186</td>
</tr>
<tr>
<td><strong>Fax No.:</strong> 2255 5018</td>
</tr>
<tr>
<td><strong>Service Hours:</strong> Mon to Fri: 09:00 to 17:00; Sat: 09:00 to 13:00</td>
</tr>
</tbody>
</table>

6.3.1.6 VMOs may also refer adolescents aged 12 to 17 with the following medical history to the Paediatric Allergy Clinics for further allergy assessment:

(i) Immediate and severe allergic reaction to drugs or vaccines containing polyethylene glycol (PEG); or

(ii) History of immediate allergic reaction to the 1st dose of Comirnaty vaccine

(a) VMOs may use the referral form accessible on the website of the Hong Kong Society for Paediatric Immunology Allergy and Infectious Diseases (HKSPIAID) (https://www.hkspiaid.org/download/COVID19 vaccination referral letter 20210804.pdf). It is required to specify the referral reason on the form and to submit it 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:

<table>
<thead>
<tr>
<th>Name of hospital / clinic</th>
<th>Contact number</th>
<th>Fax number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prince of Wales Hospital Paediatric Specialist Out-</td>
<td>3505 4440</td>
<td>3505 4633</td>
</tr>
</tbody>
</table>
6.3.1.7 At the time this Guide is written, since Comirnaty is not available under RVP, VMOs should issue a “Fast Track Service Form” (Annex XIV) for residents who are fit for and wish to receive Comirnaty. Details of Community Vaccination Centres and Hospital COVID-19 Vaccination Stations where they can receive Comirnaty is listed on the second page of the form.

6.3.1.8 With the help of RCH staff, informed consent should be obtained from the residents/ legal guardians/ family members. If the residents/ legal guardians/ family members refuse vaccination, written objection should be submitted to RCHs within a given period of time and this should be documented in either Annex V or Annex VI.

6.3.1.9 The informed consent to be obtained shall allow the access and use of the Vaccination recipient’s personal data for the purpose of (i) creation of eHS(S) account (if it has not been already created), (ii) administration and monitoring of the COVID-19 Vaccination Programme at RCHs and for the purpose of continuously monitoring of the safety and vaccination activities related to the COVID-19 Vaccination; and (iii) all those purposes as set out in the “Statement of Purpose for the collection of Personal Data” at the end of the Consent Form. For any of the aforesaid purposes as mentioned in (i) or (ii) or (iii), transfer of the Vaccination recipient’s personal data (including injection data) may be made to the Government (including the Director of Health and the Immigration Department), the Hospital Authority, the organizations collaborating with the Government for collection and research of data in the manner mentioned in Clauses 36 and 38 of the Agreement (including the University of Hong Kong), relevant private healthcare facilities and healthcare professionals and consultants, advisers and contractors of the Government appointed for any of the aforesaid purposes.

6.3.1.10 RCH/ DI staff would collect written consent forms (Annex VIII) from residents/ PID or legal guardians. A consent form is required for each dose of
vaccination.

6.3.1.11 Relatives of residents/ PID who are mentally incapacitated who wish to opt out from the programme shall be indicated in Annex VI. A written objection form should be submitted to RCHs within a specific time frame.

6.3.1.12 For mentally incapacitated residents who have no legal guardians, decision of vaccination is made considering the vaccination is necessary and in the best interest of the vaccine recipient by the VMO. The final responsibility for determining whether the proposed vaccination is necessary and is in the best interests rests with the VMO who will administer the vaccine. However, it is good practice to consult those close to the vaccine recipient (e.g. spouse/partner, legal guardian appointed under Mental Health Ordinance not vested with power to consent to treatment, family and friend, carer) unless you have good reason to believe that the recipient would not have wished particular individuals to be consulted, or unless the urgency of the situation prevents this. “Best interests” go far wider than “best medical interests”, and include factors such as the Patient’s wishes and beliefs when competent, his/her current wishes, his/her general well-being and his/her spiritual and religious welfare.

6.3.2 Verify vaccination history
Vaccination history of recipients and their eligibility status should be verified.

6.3.2.1 Check the vaccine recipient’s vaccination records in the eHS(S) for vaccination history and the type of COVID-19 vaccine that has been given before, if any;

6.3.2.2 As residents/ PID are given the option of receiving BioNTech vaccine, it is important that the eHS(S) be checked for vaccination records created by other medical service providers;

6.3.2.3 Inspect the vaccination records on vaccination cards (if any);

6.3.2.4 Ask recipients and/or their relatives for vaccination history

6.3.2.5 Should the vaccine recipient already received the first dose of COVID-19 vaccine outside Hong Kong, a second or third dose can be offered after the recommended time interval. Vaccine recipient should provide a proof of the first dose vaccination record with date, venue of vaccination and type of vaccine for checking by VMO/ trained personnel under the VMO’s
supervision. Upon checking the first dose vaccination record, the VMO/trained personnel under the VMO’s supervision may consider case-by-case, according to the JSC recommendation as stated in Clause 2.1.4, and assess on the interval between the two doses, the contraindications, and provide second dose vaccination using the COVID-19 vaccines available in HK, as appropriate. For example:

i. if the first dose is an mRNA vaccine (e.g. Moderna) / viral vector vaccine (e.g. Vaxzevria by AstraZeneca), a dose of Comirnaty (BioNTech) may be given at least 28 days apart as the second dose; or

ii. if the first dose is an inactivated vaccine (e.g. SinoPharm), a dose of CoronaVac (Sinovac) may be given at least 28 days apart as the second dose; or

iii. please refer to section 6.11.5 for the updated list of non-local COVID-19 vaccines allowed for mixing with a third dose/ additional dose of local COVID-19 vaccine.

For such cases, VMO should record the details of the first dose received outside Hong Kong including the date, place and type of vaccination under “Remarks” in the eHS(S) while the vaccine provided by the vaccinator should be entered as the second dose in eHS(S).

You may wish to refer to the following List of COVID-19 Vaccines Recognised for Specified Purposes (https://www.coronavirus.gov.hk/pdf/list_of_recognised_covid19_vaccines.pdf). Please note that the number of required doses for different types of vaccines may be different, e.g. Janssen COVID-19 Vaccine requires only one dose.

6.3.3 Confirmation with RCH/ DI and vaccine ordering

6.3.3.1 After receiving the summary return and verifying vaccination records, confirm with RCH/ DI for the residents eligible for receiving COVID-19 vaccine, vaccination schedule for the 1st, 2nd and 3rd dose, and adequate fridge capacity for storing the vaccines before placing the order.

6.3.3.2 Liaise with RCH/ DI ahead of time to make proper management of clinical waste generated in vaccination activity.

6.3.3.3 VMO would use the web-based ordering system to order COVID-19 vaccines
as described in Section 4.

6.3.4 Medical consumables and emergency equipment
6.3.4.1 Prepare emergency equipment and ensure medical consumables and IT equipment are available for use in RCH/ DI on vaccination day. For details, please refer to Section 3.4.

On the day of vaccination
6.3.5 Before vaccination
6.3.5.1 Cross-check the list of consented recipients with the written consent forms to ensure the recipients’ name and the choice of COVID-19 vaccine on the consent form match with the list of consented recipients received earlier.

6.3.5.2 The VMO should conduct assessment to confirm the eligibility of recipients, with special attention paid to contraindications and precautions including those residents/ PIDs presented with acute illness on the day of vaccination with assistance from RCH/ DI.

6.3.5.3 Verify identity of vaccine recipients and confirm informed consent obtained.

6.3.5.4 If the residents are assessed fit for vaccination and no written objections within a given period of time are submitted to the RCHs, for the best interest of the residents, VMOs could decide whether to administer vaccine to these residents based on their professional judgment. For residents to be vaccinated by the principle of ‘best interest’, VMO should enter “vaccinated by best interest” in the “Remarks” field in eHS(S).

6.3.5.5 Insert HKID card to retrieve the vaccine recipient’s personal particulars in the COVID-19 vaccination programme page on eHS(S).

6.3.5.6 To ensure patient safety and assist assessment of vaccine recipient’s suitability for COVID-19 vaccination, VMO should check the vaccine recipient’s 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. Electronic consent should be documented in eHS(S).
6.3.5.7 For other identity document holder, personal information of the vaccine recipient would be keyed-in manually. To upload the accuracy of personal data entered to the system, use the Smart ID Card Reader as far as practicable.

6.3.5.8 The following information would be prefilled or required to be input into the vaccine recipient’s page (Refer to Figure 4):
   (a) Practice
   (b) Name of vaccination scheme (Chosen from pull down menu)
   (c) Injection date
   (d) Category of recipient (Choose Residents)
   (e) RCH/ DI code
   (f) RCH/ DI name
   (g) Vaccine (name and brand)
   (h) Lot number
   (i) Dose sequence
   (j) Remarks

Figure 4 - A Sample of eHS(S) Vaccine Record Creation Page
6.3.5.9 The COVID-19 vaccine is authorized for use under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) for the specific purpose of preventing COVID-19 infection. The requirement related to informed consent is depicted under Section 8 of the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K):

(1) Each person who is responsible for administering an authorized vaccine to a recipient for a specified purpose must ensure that, before the vaccine is so administered—

(a) the following person has been informed that the vaccine is authorized under this Regulation instead of registered and of any other information as may be specified by the Secretary—

(i) the recipient; or

(ii) if the recipient is not legally capable of giving consent to the administration of the vaccine (relevant consent)—a person who is legally capable of giving the relevant consent on the recipient’s behalf; and

(2) For the purposes of this section, a person is responsible for administering an authorized vaccine to a recipient if—

(a) the person administers the vaccine to the recipient; or

(b) the person is a registered medical practitioner who supervises the administration of the vaccine to the recipient.

(3) Subsection (1) does not affect any other duty imposed by law or otherwise on a person who is responsible for administering an authorized vaccine.

6.3.5.10 The VMO/ trained personnel under VMO’s supervision should check the recipient’s personal particulars, vaccine name, type, and duration since last dose to ensure the type and interval of vaccination to be given are correct.

6.3.5.11 The batches of COVID-19 vaccines delivered may have different lot numbers, VMO/ trained personnel under the VMO’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.
6.3.5.12 The VMO/ trained personnel under VMO’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 for COVID-19 vaccine as documented above, including contraindications (and possible adverse events) of COVID-19 vaccination, the vaccine product is authorised under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) for specified purpose for prevention of COVID-19 infection but has not been registered under the Pharmacy and Poisons Ordinance (Cap.138), and agree to receive the documented COVID-19 vaccine. The vaccine recipient have 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);

(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.
6.3.5.13 Should the vaccine recipient consent for joining eHealth, the VMO/ trained personnel under the VMO’s supervision should tick the check box for enrolment. Recipient’s consent to enrol in eHealth is optional.

6.3.6 During vaccination

6.3.6.1 Before administering the vaccine, check the vaccine identification label and ensure the integrity of vaccine for irregularity, e.g. damage, contamination, expiry date and time.

6.3.6.2 Exposing the vaccines to disinfectant should be avoided.

6.3.6.3 The vaccine should not be mixed with other vaccines in the same syringe.

6.3.6.4 Shake well before use. It should be administered immediately after opening.

6.3.6.5 CoronaVac should be administered by intramuscular injection only, preferably into non-dominant deltoid region of the upper arm.

6.3.6.6 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 or diluent;
   - The right time (e.g. correct age, correct interval, 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)
6.3.7 Administration by the Intramuscular (IM) Route

6.3.7.1 The VMO/ trained personnel under the VMO’s supervision should use a new alcohol prep/ alcohol swab for skin disinfection and allow the site to DRY completely before vaccination, and use a new dry clean gauze/cotton wool ball for post vaccination compression of injection site.

6.3.7.2 The VMO/ trained personnel under the VMO’s supervision should wipe the vaccination area from centre outwards, without touching the same area repeatedly.

6.3.7.3 Precautions should be taken to prevent sharps injury. Please refer to section 5.3 for details.

6.3.7.4 The VMO/ trained personnel under the VMO’s supervision should refer to the drug insert for complete vaccine administration information.

6.3.7.5 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.

The information of the voided vaccine should be recorded and provided to PMVD at 2125 2125 during office hour, within one day from the vaccination activity, as stated in Section 4.6.

6.3.7.6 The injection site is swabbed with an alcohol pad (from the centre of deltoid muscle outwards in a circular motion, without going the same area) and allowed to dry before vaccine injection.

6.3.7.7 The skin should be spread between the thumb and forefinger to avoid injection into subcutaneous tissue.

6.3.7.8 Prepare the vaccine and inspect the vaccine vial for any manufacturing defect. Shake vaccines before use according to the drug insert, if necessary.
6.3.7.9 To minimize spillage of CoronaVac vaccine component to environment, the needle should remain inside the vial throughout the whole withdrawal procedure, including during expel of air bubbles from the syringe.

6.3.7.10 The needle at 90-degree angle should be fully inserted into the muscle and inject the vaccine into the muscle.

![Diagram showing injection angle](image)

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

6.3.7.11 Withdraw the needle gently and quickly cover the injection site with a dry clean gauze/cotton wool ball after completion of injection;

6.3.7.12 Instruct the client to gently apply pressure for 1-2 minutes over the injection site or till bleeding stops;

6.3.7.13 Do not recap the needle. The used syringe and uncapped needle should be discarded directly into sharps box; and

6.3.7.14 Perform hand hygiene.

6.3.7.15 The amount of vaccine administered should be made to ascertain at the best estimation. For conditions of incomplete dose during injection of CoronaVac to your clients due to various reasons such as leakage of vaccine from the syringe, please handle according to the following information:

<table>
<thead>
<tr>
<th>Action*</th>
<th>Less than half of the recommended dose or uncertain amount of vaccine given</th>
<th>To give a concomitant dose at the opposite arm on the same day of vaccination</th>
</tr>
</thead>
</table>
More than half of the recommended dose given | No need concomitant dose

*With reference to information provided by CoronaVac Vaccine Manufacturer

Please submit the “Clinical incident notification form” (Annex XI) within the same working day upon discovery of incident AND submit the “Clinical incident investigation report” (Annex XII) within 1 week upon discovery of the "incomplete dose” incident.

6.3.8 After vaccination

6.3.8.1 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. Date back entry is NOT allowed by the computer system.

6.3.8.2 Upon saving the vaccination record, vaccination card containing personal information, date, venue, brand and lot number of vaccines should be printed directly from eHS(S) (Annex IX) and provided to the resident/ PID. If the vaccination card has to be reprinted, please refer to quick guide for reprinting vaccination record at https://www.ehealth.gov.hk/en/covidvaccine/doc/quick-guide-for-reprint-vaccination-record.pdf.

6.3.8.3 VMO should complete relevant parts of the consent form (highlighted with red box in Annex VIII), including Part 3, eHS(S) transaction number, Lot number of the vaccine, vaccination date, time and place, and names of the VMO and vaccinator.

6.3.8.4 The vaccination record should be kept in a database for record in case record tracing or inspection in the future is needed.

6.3.9 Observation

6.3.9.1 All persons should be observed for 30 minutes after vaccination (for CoronaVac).

6.3.9.2 If vaccine recipient experiences discomfort, VMO should give timely intervention and provide emergency management as indicated.

6.3.9.3 For adverse events following immunisation (AEFI), VMO 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).

6.4  Workflow for vaccination of RCH staff

6.4.1  Preparation before the day of vaccination

6.4.1.1 RCH would compile a list of staff consented to receive CoronaVac (Annex VII) and provide the list to VMO.

6.4.1.2 Written consent is NOT required for RCH staff receiving COVID-19 vaccine as electronic consent will be used.

6.4.1.3 Check the vaccine recipient’s vaccination record in the eHS(S) for vaccination history and the type of COVID-19 vaccine that has been given before, if any.

6.4.1.4 Confirm with RCH the number of consented staff (in addition to consented residents) eligible for vaccination for vaccination scheduling and vaccine ordering.

On the day of vaccination

6.4.2  Before vaccination

6.4.2.1 Before vaccination, VMO should ensure the vaccine recipient has read and understood the content of the factsheet of the relevant COVID-19 vaccine with information about potential side effect, authorized and not registered status of the vaccines, and vaccine-related adverse events following immunisation (AEFI).

6.4.2.2 The VMO 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(c) and 2.1.3(d) on the contraindications and precautions of the COVID-19 vaccine.

6.4.2.3 The VMO should check the identity of vaccine recipient, check vaccination history both with the vaccine recipient in-person and against the eHS(S), obtain and document informed consent via eHS(S).

6.4.2.4 The vaccine recipient should insert his/ her Hong Kong Identity Card into the card reader to retrieve the vaccine recipient’s page on eHS(S) and for creating...
the vaccination record and acting as an electronic consent to receive COVID-19 vaccination. For Acknowledgement of Application for an Identity Card and Certificate of Exemption, the document number and other personal information as required should be entered into the eHS(S) manually.

6.4.2.5 For recipients without prior account opened under eHS(S), the VMO has to obtain verbal consent from the recipient and open an eHS(S) account for him/her through insertion of HKID card by the recipient into the card reader.

6.4.2.6 The following information would be prefilled or required to be input into the vaccine recipient’s page (Refer to Figure 5- A Sample of eHS(S) Vaccine Recipient’s Page):
(a) Practice
(b) Name of vaccination scheme
(c) Injection date
(d) Type of recipient (Choose Staff of residential care homes OR Staff of community care service unit)
(e) RCH code
(f) RCH name
(g) Vaccine (name and brand)
(h) Lot number
(i) Dose sequence
(j) Contact No.
(k) Remarks

- If the client has received the first dose of COVID-19 vaccination outside Hong Kong, and after VMO’s assessment as stated in Section 6.3.2.1(e), the client can be offered the second dose under RVP, please put down the Date, Brand, Location of 1st dose, etc in the “Remarks” and choose 2nd dose, after checking the proof of vaccination provided by the client.
- If the client recovered from previous COVID-19 infection but the “COVID-19 Discharge Records” are not shown in eHS(S), please refer to Section 6.7.5

Figure 5- A Sample of eHS(S) Vaccine Recipient’s Page
6.4.2.7 Should the vaccine recipient consent for joining eHealth, the VMO should tick the check box for enrolment. Recipient’s consent to enrol in eHealth is optional.

6.4.2.8 The subsequent workflow is the same as that of vaccinating residents. Please refer to Section 6.3.6.7 to Section 6.3.9.

6.5 Emergency management

6.5.1 VMO should ensure the presence of qualified personnel, who is 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.

6.5.2 VMO should keep training of personnel responsible for emergency management up-to-date and under regular review.

6.5.3 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) Registered adrenaline ampoule (1:1000) with 1mL syringes (at least three) and 25-32mm length needles (at least three) for adrenaline injection; or registered adrenaline auto-injector (150 micrograms and 300 micrograms); (d) AED Defibrillation Pads

6.5.4 Ensure there is sufficient stock of all the emergency equipment, and that the equipment and drugs have not reached expiry.

6.5.5 Keep written protocol and training material in place for quick and convenient reference.

6.5.6 Dosage of Adrenaline required will depend on body weight (BW). The recommended dose for adrenaline is 0.01mg/kg body weight. Please refer to the following Reference Framework is taken from Chapter 5 Monitoring and Management of Adverse Events Following Immunization, Hong Kong Reference Framework for Preventive Care for Children in Primary Care Settings¹. Dosage of Jext: Jext (300 microgram) for persons over 30kg and Jext (150 microgram) for persons with BW 15-30kg.

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

<table>
<thead>
<tr>
<th>Age group</th>
<th>Range of weight (kg)</th>
<th>Range of weight (lb)</th>
<th>Adrenaline dose (1mg/1ml injectable (1:1000 dilution) IM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants and Children</td>
<td>1-6 months</td>
<td>4.8-8.5 kg</td>
<td>9-19 lb</td>
</tr>
<tr>
<td></td>
<td>7-36 months</td>
<td>9-14.5 kg</td>
<td>20-32 lb</td>
</tr>
<tr>
<td></td>
<td>37-59 months</td>
<td>15-17.5 kg</td>
<td>33-39 lb</td>
</tr>
<tr>
<td></td>
<td>5-7 years</td>
<td>18-25.5 kg</td>
<td>40-56 lb</td>
</tr>
<tr>
<td></td>
<td>8-10 years</td>
<td>26-34.5 kg</td>
<td>57-76 lb</td>
</tr>
<tr>
<td></td>
<td>≥ 11 years</td>
<td>35-45 kg</td>
<td>77-99 lb</td>
</tr>
<tr>
<td></td>
<td>≥ 13 years</td>
<td>46+ kg</td>
<td>100+ lb</td>
</tr>
</tbody>
</table>

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.

* Rounded weight at the 50th percentile for each age range
† Maximum dose for children
‡ Maximum 20 or teens

6.5.7 Should anaphylaxis happen after vaccination, RCH staff should take the following actions:
   a. Call ambulance
   b. Inform the VMO immediately, and provide emergency management, e.g. adrenaline injection and airway management as appropriate
   c. Use bag valve mask to assist ventilation (give oxygen if available); and
   d. Monitor blood pressure and pulse every 5 minutes and stay with patient
until ambulance arrives; and

e. If no improvement within 5 minutes, repeat dose(s) of adrenaline injection if appropriate.

6.5.8 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).

6.5.9 Should there be cases with anaphylaxis or severe adverse reaction during the 30 minutes observation period after vaccination requiring on-site transferral to hospital via ambulance, VMO should report these cases to the Central Medical Team of the Department of Health, after immediate management, by phone (Tel: 2104 5233); followed by submitting the Report on Cases Referred to Hospitals (Annex X) to the Central Medical Team by email (email addresses listed in the form) with password protection of the file, or fax (Fax: 2217 3078) within the same day of occurrence of the incident.
6.6 Vaccination arrangement for persons recovered from previous COVID-19 infection

6.6.1 With reference to the recommendations from the JSC, persons who have recovered from previous COVID-19 infection can receive one dose of Comirnaty at least 90 days after hospital discharge or one dose of CoronaVac at least 180 days after discharge for further personal protection. A second dose of Comirnaty at 180 days after the first dose is recommended, but individuals could also choose CoronaVac as the second dose. The latest recommendations made by JSC-EAP can be accessed via https://www.chp.gov.hk/en/static/24008.html.

6.6.2 Upon discharge from hospitals under the Hospital Authority, persons recovered from previous COVID-19 infection would be given a fact sheet (https://www.covidvaccine.gov.hk/pdf/factsheet_priorCOVID19infection_ENG.pdf).

6.6.3 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 features:

(a) 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 as shown in Figure 6 when HKID is used to retrieve the vaccine recipient’s page on eHS(S).
Figure 6 - A sample of eHS(S) vaccine recipient’s page with COVID-19 discharge record

(b) If the recommended interval between discharge date and vaccination appointment date has not been reached (i.e. 90 days for Comirnaty and 180 days for CoronaVac), a pop-up alert would be displayed as shown in Figure 7 when healthcare personnel try to save the vaccination record.
Figure 7 - A sample of pop-up alert on eHS(S) when the recommended interval between discharge date and vaccination appointment date has not been reached for persons recovered from previous COVID-19 infection.

To reflect the status of having completed the vaccination regimen with one dose of COVID-19 vaccine for persons who have recovered from previous COVID-19 infection, both the electronic and paper vaccination records have been amended as shown in Figure 8 with the second dose being marked as “Not applicable”:
Figure 8 – A sample of revised vaccination certificate for persons recovered from previous COVID-19 infection who have already received one dose of COVID-19 vaccine

(d) SMS messages were sent to persons who have recovered from previous COVID-19 infection and have already received one dose of COVID-19 vaccine to remind them to approach their previous vaccination service provider to obtain a revised vaccination certificate as shown in Figure 8. VMO/ trained personnel under the VMO’s supervision could retrieve
vaccine recipient’s page on eHS(S) and print out the updated vaccination certificate for this group of vaccine recipients.

6.6.4 Starting from 26 November 2021, VMOs would be able to input the second dose vaccination for COVID-19 recovered patients. An interval of 180 days between the two doses is recommended. The eHS(S) have been enhanced and VMOs are required to provide reason(s) for second dose vaccination on the pop-up alert as shown in Figure 9. A verbal confirmation from the client (e.g. higher risk groups, to travel to high risk areas, or advised by family doctor) would be acceptable for proceeding with the second dose.

Figure 9 – A sample of pop-up alert on eHS(S) for inputting the reason(s) for second dose vaccination for persons recovered from previous COVID-19 infection

6.6.5 If the “COIVD-19 discharge Records” are not shown in eHS(S), please enter the following information in the “Remarks” field:
1. Recovered from COVID-19 infection
2. Date of discharge (or infection)
3. Place of discharge (or infection) [e.g. mainland China, country name, etc]

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

It is required to enter the above words, especially “Recovered from COVID-19 infection”, because this would facilitate the future updating of the vaccination records for these clients.
6.7 Documentary proof for assessing clients with prior COVID-19 infection

6.7.1 The Green box of “COVID-19 Discharge Record” (in Figure 9) will be displayed only for locally infected clients using HK Identify Card (HKIC) as identity document. 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

6.7.2 The eHealth System (Subsidies) is enhanced to capture the “prior COVID-19 infection status” by adding a tick-box (Figure 10).

For details on vaccination to COVID recovered patients, please refer to “Quick Guide for Recovered Patients”
Figure 10 – A sample of eHealth System (Subsidies) screen enhanced to capture the “prior COVID-19 infection status” by adding a tick-box

For patients recovered from COVID-19 infection (if applicable)
[Tick box] The documentary proof of past COVID-19 infection of the vaccine recipient has been provided and seen. The interval between date of hospital discharge (or infection) is confirmed to be more than 90 days from today (if Comirnaty is to be administered) or more than 180 days from today (if CoronaVac is to be administered).

6.7.3 In assessments of clients with previous COVID-19 infection, the acceptable documentary proof of previous COVID-19 infection includes supporting documents such as a doctor's certification letter or hospital's discharge summary (in English/Chinese, with the client's identity particulars matched).

6.7.4 The new 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 of 90 days or 180 days is fulfilled, in hard copy or in electronic format, in order to print out a full vaccination record with 2nd dose showing “Not Applicable”. If the Green box of “COVID-19 Discharge Record” is already displayed (i.e. prior local COVID-19 infection history is already stored in eHS(S)), there is no need to tick the new tick-box.

6.7.5 The proof of past COVID-19 infection in paper or electronic format are equally acceptable. There is no need to keep a copy of the proof of previous overseas COVID-19 infection. 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.

6.7.6 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, mainland China, country name, etc)
Example: "Recovered from COVID-19 infection, 1 May 2021, UK"

6.7.7 If clients cannot provide documentary proof of previous COVID-19 infection, documentary proof of past COVID-19 infection should be provided for assessment by the on-site healthcare professionals (please see sections 6.7.3 to 6.7.6). If documentary proof cannot be provided, the provision of second dose (CoronaVac or Comirnaty) as in general public can be acceded to.

6.7.8 The name on the documentary proof, if not an exact match with HKID/ travel document presented for vaccination, should be identical to that in the client's relevant valid identity document or travel document. Any valid identity document or travel document that the client presented with name identical to the one shown on the documentary proof will be regarded acceptable. 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. If the proof is assessed to be incompatible with the client's identity, the previous COVID-19 infection status of the client might not be ascertained.
6.8 Co-administration of COVID-19 vaccines with other vaccines
6.8.1 According to the Consensus Interim Recommendations on the Use of COVID-19 Vaccines in Hong Kong of Scientific Committee on Emerging and Zoonotic Diseases and Scientific Committee on Vaccine Preventable Diseases (As of 27 October 2021), it is suggested to maintain the minimal interval of at least 14 days between the administration of COVID-19 vaccine (Comirnaty or CoronaVac) and any other vaccines including seasonal influenza vaccine. There are circumstances when shortening the interval between the administrations of these vaccines are justified. These include:

(a) situations when there are increased risk of COVID-19 and other vaccine preventable disease;
(b) when another vaccine is required for post-exposure prophylaxis, such as tetanus and rabies.

6.9 Non-local Vaccination Declaration
6.9.1 Individuals can register the non-local vaccination records with the Government by voluntary declaration for obtaining a local vaccination record QR code (https://www.info.gov.hk/gia/general/202109/14/P2021091400572.htm?font Size= 1). The arrangement will facilitate these persons to carry and view the records in electronic format in fulfilling relevant requirements under the local vaccine bubble.

6.9.2 This QR code generated for vaccine bubble CANNOT replace the original non-local vaccination record as a proof of vaccination. Thus, for arrangement of 2nd dose, recipients have to show the original non-local vaccination record, instead of this QR code, to the doctors for assessment.

6.9.3 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.
6.10 Vaccination arrangement for adolescents and children

6.10.1 Starting from 21 January 2022, the eligible age group to receive the CoronaVac vaccine is lowered to 5 years old. Consensus Interim Recommendations on the Use of COVID-19 Vaccines in Children in Hong Kong (As of 17 January 2022):
Press release:
https://www.info.gov.hk/gia/general/202201/20/P2022012000242.htm

6.10.2 Paper consent (Annex VIII) should be completed and signed by parent/guardian before vaccination. RCH staff should assist to collect the signed consent form.

(a) VMOs should check if the signed consent form has been filled in completely and correctly: including identity document type (only when the child has no HKID, then other identity document type should be used), and contact no. of parent/guardian.
(b) Please check the validity period of the identity document, if applicable.
(c) If the identity document has no photo, e.g. birth certificate, please cross-check the child's identity with the child's documents with photos.
(d) Please be reminded to check if the child has any non-local recovery or recent local and overseas vaccination history, as usual.
(e) Please ensure the parent/guardian who sign the consent forms understand the latest factsheet of Sinovac especially the contraindications.

6.10.3 Children aged below 12 years must be accompanied by an adult (e.g. parent, grandparent, adult relative, helper, RCH staff).

6.10.4 Parental accompany is not mandatory for the first and second dose of CoronaVac vaccination for adolescents aged 12 to 17 years, but it is mandatory for the third dose. For adolescents aged 12 to 17, only those with immunocompromised conditions are recommended to receive a third dose at least 28 days from the second dose (Please refer to section 6.15 for the vaccination arrangement).

6.10.5 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.

6.10.6 Please use smart card reader for HKID holders as the first choice of identity document, and manually input into eHS(S) for any other identity document types. The following additional types of identity documents for children have been enabled in eHS(S)

- HK Birth Certificate
- HKSAR Re-entry Permit
- HKSAR Document of Identity
- Permit to Remain in HKSAR (ID 235B)
- Non-HK Travel Document (e.g. Foreign passports)
- Certificate issued by the Births Registry for adopted children

6.10.7 For samples of the above identity documents, please refer to: https://www.chp.gov.hk/files/pdf/doctors_guide_rvp202122.pdf (Annex A)

For information on the input of these document types in eHS(S), please refer to the Quick Guide: https://www.ehealth.gov.hk/en/covidvaccine/doc/quick-guide-for-using-manual-input-of-other-document.pdf (Slides 16 to 26)

6.10.8 Please check if the child has any non-local recovery or recent local and overseas vaccination history, as in adults.

6.10.9 Some infographics have been prepared for vaccination for adolescents which are available at https://www.covidvaccine.gov.hk/pdf/FAQ_aged_12_to_17_full_ENG.pdf. They are designed for parent/guardian and adolescents, as well as to assist the VMO and RCH staff to give appropriate advice to parents on COVID-19 vaccination.

6.10.10 For adolescents aged 12 to 17, only those with immunocompromised conditions are recommended to receive a third dose at least 28 days from the second dose (Please refer to section 6.15 for vaccination arrangement). A doctor’s letter to certify the immunocompromised status is mandatory. VMO should enter “Doctor’s letter for 3rd dose seen” in the “Remarks” field in eHS(S).
6.10.11 Emergency management

Vaccination may cause untoward reactions. Some recipients may even develop allergic reactions to the vaccine(s). Failure to give timely intervention may result in serious consequences. Please refer to section 6.5 for management of emergency conditions.

6.11 Vaccination arrangement for third dose of COVID-19 vaccine

6.11.1 The Government announced that starting from 11 November 2021, according to the JSC-EAP recommendations, immunocompromised individuals and individuals who have received two doses of CoronaVac or Comirnaty (aged 18 or above who are in certain higher risk groups) are recommended to receive a third dose of COVID-19 vaccine. Please refer to the following documents for details

(a) JSC-EAP recommendation:

(b) Press release at
https://www.info.gov.hk/gia/general/202111/03/P2021110300536.htm and
https://www.info.gov.hk/gia/general/202111/18/P2021111800310.htm

(c) A poster on the recommendation of third dose vaccination (Figure 11) As the poster would be updated from time to time as necessary, VMO/RCH staff should use the latest version available at
6.11.2 The poster in Figure 11 could assist RCH staff or residents to check whether they are eligible for a third dose of COVID-19 vaccine. Please make sure you have used the latest version of the poster.

6.11.3 The vaccination arrangement for the third dose are as follows:
(a) Immunocompromised persons

- The third dose should be administered at least 28 days after the second dose.
- A medical proof of immunocompromised status (or doctor’s letters in other formats with valid contents) signed by a registered medical practitioner, must be presented for inspection by the vaccinator before administering the third dose of COVID-19 vaccine. The proof or doctor’s letter should be returned to the client after inspection. A sample template of the medical certificate could be found at https://www.covidvaccine.gov.hk/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 3rd dose seen”
- Adolescents aged 12-17 who are eligible (i.e. only those with immunocompromised conditions) for the 3rd dose (CoronaVac or Comirnaty) have to attend the vaccination with their parents/guardians with filled-in consent form for the 3rd dose.

(b) Other persons aged 18 and above who have received two doses of CoronaVac or Comirnaty

- The third dose should be administered at least 180 days after the second dose.
- The minimal interval between the second and third doses could be shortened from 180 days to 90 days for recipients with personal needs, e.g. travel outside Hong Kong, high risk occupation.

6.11.4 A third dose of Comirnaty vaccine may elicit a better immune response than CoronaVac vaccine. Comirnaty vaccine offers greater protection but CoronaVac vaccine is also allowed to respect personal preference.

6.11.5 The table below shows the list of non-local COVID-19 vaccines that are allowed for mixing with a 3rd dose/ additional dose of local COVID-19 vaccine. Please note that the combinations are allowed only if the client is a Hong Kong resident.

<table>
<thead>
<tr>
<th>Vaccine platform</th>
<th>Primary series</th>
<th>3rd dose / additional dose</th>
<th>Medical eligibility</th>
<th>Interval of 3rd dose / additional dose from preceding</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>(No history of)</td>
<td></td>
</tr>
</tbody>
</table>
### COVID-19 vaccination dose

<table>
<thead>
<tr>
<th>Type</th>
<th>Brands</th>
<th>Persons Eligible</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inactivated</td>
<td>Sinopharm, Sinovac OR BioNTech</td>
<td>All persons ≥ 18 years old</td>
<td>At least 28 days after the second dose for immunocompromised persons</td>
</tr>
<tr>
<td>mRNA</td>
<td>Moderna, BioNTech</td>
<td>≥ 12 Years Old</td>
<td>For other eligible mRNA vaccines</td>
</tr>
<tr>
<td>Viral vector</td>
<td>AstraZeneca, BioNTech</td>
<td>For immunocompromised persons</td>
<td>At least 28 days after the second dose for immunocompromised persons</td>
</tr>
<tr>
<td></td>
<td>Janssen, BioNTech</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Effective from 1 Jan 2022 onwards

6.11.6 The eHS(S) has been enhanced to allow capturing information of the third dose vaccination. Different prompt messages would be shown as reminders for clinic staff to re-check or confirm (Figure 12).

Figure 12 - A sample of eHS(S) screen enhanced to capture the third dose information
6.11.7 The paper vaccination records for third dose have been amended as shown in Figure 13.

Figure 13 - A sample of vaccination certificate for persons who have received a third dose of COVID-19 vaccine
7. Clinical waste management

7.1 Regulation of clinical waste handling is under the purview of Environmental Protection Department (EPD). Please find details in the website: (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 Management of Clinical Waste (Small Clinical Waste Producers) (http://www.epd.gov.hk/epd/clinicalwaste/file/doc06_en.pdf).

7.2 Clinical waste generated (mainly needles, syringes, ampoules and cotton wool 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 cotton wool 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 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 used vaccine package boxes and package inserts should not be given to recipients and should be kept at the RCH for arrangement of collection by the Department of Health.

7.6 Unused/ surplus vaccines should be properly stored in the vaccine-storing refrigerator in the RCH. RCH must return all unused/ surplus vaccines at the end of the programme.

7.7 Regarding the expired vaccines, please note that the expired vaccines should be removed from the refrigerator and labelled "DO NOT USE". The RCH should consider keeping the expired vaccines in a lockable cabinet and wait for the collection by the PMVD at a later time.
8. Reporting of adverse events following immunization

8.1 Adverse events following immunisation (AEFIs)

8.1.1 Adverse events following immunisation (AEFIs)\(^1\) 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 According to the grading standard of adverse reaction incidence from Council for International Organizations of Medical Sciences (CIOMS), i.e. very common (\(\geq 10\%\)), common (1\%-10\%, 1\% was inclusive), uncommon (0.1\%-1\%, 0.1\% was inclusive), rare (0.01\%-0.1\%, 0.01\% was inclusive) and very rare (<0.01\%), all adverse reactions revealed in clinical trials were summarized and described as follows.

8.1.3 Adverse reactions at injection site:
(a) Very common: pain
(b) Common: swelling, pruritus, erythema, induration
(c) Uncommon: burn at injection site

8.1.4 Systemic adverse reactions:
(a) Very common: headache, fatigue
(b) Common: myalgia, nausea, diarrhea, arthralgia, cough, chills, pruritus, loss of appetite, rhinorrhea, sore throat, nasal congestion, abdominal pain
(c) Uncommon: vomit, hypersensitivity, abnormal skin and mucosa, fever, tremor, flushing, edema, dizziness, drowsiness
(d) Rare: muscle spasms, eyelid edema, nosebleeds, abdominal distension, constipation, hyposmia, ocular congestion, hot flashes, hiccup, conjunctival congestion

8.1.5 Severity of adverse reactions:
(a) The severity of adverse reactions observed in these clinical trials is mainly

\(^1\) Vaccine Safety Basics by WHO (https://vaccine-safety-training.org/classification-of-aefis.html)
Grade 1 (mild), the incidence rate of adverse reactions for Grade 3 and the above was 1.31%. Grade 3 and above adverse reactions includes pain at injection site, cough, fever, headache, sore throat, abdominal pain, dizziness and drowsiness.

8.1.6 Serious adverse event (SAE):
(a) No serious adverse event related to vaccination was identified up to February 3, 2021.

8.1.7 For more information on the possible side effects of COVID-19 vaccines, please refer to the website at https://www.covidvaccine.gov.hk/.

8.2 Reporting of AEFIs
8.2.1 VMO should inform the vaccine recipients and RCH staff on what to expect after receiving the vaccine (common side effects) and advise them to read the fact sheet in Annex I for the relevant information. VMO 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 continue monitoring of the medical outcome of the vaccination.

8.2.2 VMOs are encouraged to report the following AEFIs:
(a) All suspected serious 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

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2 An AEFI will be considered serious, if it:
● results in death,
● is life-threatening,
● requires in-patient hospitalization or prolongation of existing hospitalization,
● results in persistent or significant disability/incapacity,
● is a congenital anomaly/birth defect,
● requires intervention to prevent one of the outcomes above (medically important)
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).

9. Management of Clinical Incident

9.1 Clinical incident is defined as any events or circumstances\(^3\) that caused injury to vaccine recipients or posed risk of harm to vaccine recipients in the course of provision of clinical service.

9.2 VMO 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 vaccine recipient as soon as possible and make necessary arrangements.

9.3 VMO 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 VMO.

9.4 Following all necessary immediate interventions, the VMO should inform the PMVD at the earliest possible by phone, followed by the Clinical Incident Notification Form (Annex XI). The form should be returned to the PMVD by fax or email with password protection of the file within the same day of occurrence of the incident.

9.5 Summary of the incident, with preliminary assessment and immediate remedial actions should be included in the notification form.

9.6 The VMO should conduct a full investigation of the medical incident and submit the Clinical Incident Investigation Report (Annex XII) to the PMVD within 7 days from the occurrence of the incident.

9.7 Depending on the severity of the incidents, disclosure to the public may be needed. In such cases, the VMO should work closely with the Central Medical Team to investigate, provide necessary information, and get prepared for press announcements or other actions as necessary.

\(^3\) Any events or circumstances refer to those with any deviation from usual medical care.
10. List of Annexes

Annex I  Fact Sheet on COVID-19 Vaccination (To Vaccine recipients)
Annex II  Package Insert of CoronaVac
Annex III  Checklist of Items during Onsite Inspection
Annex IV  Daily Fridge Temperature Chart
Annex V   List of Residents/ Mentally Incapacitated Persons (MIPs) with Legal Guardians Consented to Receive CoronaVac
Annex VI  List of MIPs without Legal Guardians who are unable to give consent
Annex VII  List of Staff Consented to Receive CoronaVac
Annex VIII Consent Form
Annex IX   Sample of a COVID-19 Vaccination Card
Annex X   Report on Cases Referred to Hospital
Annex XI  Clinical Incident Notification Form
Annex XII  Clinical Incident Investigation Report
Annex XIII Claim form for additional allowance
Annex XIV Supplementary sheet on the recommendation for third dose COVID-19 vaccination
Annex XV  Fast Track Service Form
Annex I Fact Sheet on COVID-19 Vaccination (To vaccine recipient)
As the fact sheet would be updated from time to time as necessary, VMO should refer to the latest version available at
What is CoronaVac and what it is used for:

CoronaVac is a recombinant DNA vaccine against COVID-19, specifically targeting the Spike S protein of SARS-CoV-2. It is designed to stimulate the immune system to produce antibodies against this protein.

Precautions:

- Due to the insufficient data of persistence of protection induced by this vaccine, regular post-vaccination measures should be taken. In line with prevention and control of the COVID-19 pandemic.
- For patients with acute diseases, acute exacerbation of chronic diseases, severe chronic diseases, atopy, and allergy, the vaccine should be used with caution if necessary, delay vaccination after doctor's evaluation.
- For patients with diabetes, history of cardiovascular disease, hypertension, diabetes, cerebrovascular disease, and aggressive, uncontrolled, or unmanaged neurological disease, the vaccine should be used with caution.
- For patients with thrombocytopenia or other hematologic disorders, intramuscular injection of this product may cause bleeding, so it should be used with caution.
- The safety and efficacy data of this product on people with impaired immune function (such as in immunocompromised states, patients with severe acute respiratory disease syndrome COVID-19) have not been obtained, and the vaccination of this product should be based on individual considerations.
- People who have a history of severe reactions to previous vaccines should not receive this vaccine unless careful observation is made for at least one month following vaccination.

Women of childbearing age:

The data collected from clinical trials on women with unexpected pregnancy after vaccination are very limited, and it is insufficient to declare the risk of adverse pregnancy outcomes after vaccination.

Pregnant or lactating women:

The clinical data on pregnant and lactating women are not available at present.

Children and Adolescents:

Phase 1 and 2 trials on children in China showed that CoronaVac is immunogenic, safe, and well-tolerated in children. In addition, ongoing phase 3 trials also showed that CoronaVac is well-tolerated in this age group.

Possible side effects:

Some possible side effects for 18 years or above:

- Injection site pain
- Headache
- Fatigue
- Nausea
- Myalgia
- Chills
- Hot flashes
- Rash
- Fatigue
- Abnormal liver function
- Anemia
- Transaminitis
- Reversible posterior leukoencephalopathy syndrome
- Hemolytic anemia
- Anaphylaxis
- Acute hemorrhagic necrotizing encephalopathy
- Other rare side effects:

  - Allergic reactions
  - Hypersensitivity reactions
  - Anaphylaxis
  - Guillain-Barre syndrome

Very rare side effects:

- Hypersensitivity reactions
- Anaphylaxis
- Guillain-Barre syndrome
- Transaminitis
- Transient post-vaccination headache

Note:

- People should be advised to report any adverse reactions to the local health authorities.
- People should be advised to seek medical attention if they experience any severe adverse reactions.
- People should be advised to seek medical attention if they experience any severe adverse reactions.

Source:

### Possible side effects for children and adolescents aged 3 to 17 years

<table>
<thead>
<tr>
<th>Side effects</th>
<th>may affect</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Very common</strong></td>
<td>2/10% people</td>
</tr>
<tr>
<td>Injection site pain</td>
<td></td>
</tr>
<tr>
<td>Abdominal pain</td>
<td></td>
</tr>
<tr>
<td>Abdominal discomfort</td>
<td></td>
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<tr>
<td>Nausea</td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td></td>
</tr>
</tbody>
</table>

| **common** | 1%-10% people |
| Injection site induration, swelling | |
| Abdominal skin and mucous membrane rash | |
| Rash | |
| Cough | |
| Rhinorrhea | |

| **Uncommon** | 0.3%-1% people |
| Injection site pruritus | |
| Urticaria | |
| Myalgia | |
| Polyarthralgia | |
| Abdominal pain | |
| Abdominal distension | |
| Lymphadenitis | |
| Otorrhea | |

| **Serious** | |
| No serious adverse event related to vaccination was identified up to November 2021. |

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### Reporting of adverse events after immunization

The Department of Health ("DH") has an adverse drug reaction ("ADR") reporting system which receives adverse events following immunization ("AEFI") reports to monitor the safety of COVID-19 vaccines.

If you have any suspected adverse event occurred after immunization, please alert healthcare professionals (e.g. doctors, dentists, pharmacists, nurses and Chinese medicine practitioners), when seeking their advice, to report the AEFI to the DH if they consider that the AEFI may be associated with the vaccination.

For continuously monitoring of the safety and clinical events associated with COVID-19 vaccination, your personal data collected for vaccination and your clinical data held by the Hospital Authority and the relevant private healthcare facilities and healthcare professionals, may be accessed and used by DH and relevant organizations collaborated with the Government (including the University of Hong Kong) to ensure such information is necessary for the monitoring.

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**Message to the healthcare professionals:**

Please conduct medical assessment and if you consider the AEFI associated with the vaccine is deemed medically significant, please report it to the Drug Office of the Department of Health via online reporting at the webpage https://www.drugoffice.gov.hk/epss/en/healthcare_providers/aei_reporting/index.html

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**For further information on the vaccines and side effects, please visit the websites at www.covidvaccine.gov.hk**

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**Version date: 24 December 2021** Please refer to online version for most updated information.
復星醫藥/德國藥廠BioNTech

信使核糖核酸新冠疫苗
COVID-19 mRNA Vaccine

Comirnaty「復必泰」

接種須知
Vaccination Fact Sheet

1. 「復必泰」及其用途

「復必泰」是通過預防由SARS-CoV-2病毒引起的COVID-19的有效。

成人和12歲及以上的青少年可接種「復必泰」。

本疫苗可使免疫系統（人體的天然防護系統）產生對SARS-CoV-2病毒的抗體和細胞免疫，從而預防COVID-19。

由於「復必泰」不含產生免疫力的病毒，故不會導致COVID-19。

此產品由荷蘭根據「預防及控制疾病（使用疫苗）條例」（第599章）獲准可使用，它尚未根據《藥物及毒藥條例》第138章在香港註冊。

2. 在使用「復必泰」前，需要了解哪些事項

不應給予「復必泰」

- 如果您曾對「復必泰」或其活性物質或其他成分有過敏反應

- 11-15歲（第三劑）：爲第4B型及第5B型（375-380見下）

- 15歲以上（第三劑）：項3-4型（370-380見下）

警告和注意事項

如果您有以下情況，使用本疫苗前，請諮詢您的醫生、藥劑師或護士：

- 以往接受「復必泰」或任何其他疫苗後，曾經出現過嚴重過敏反應或呼吸問題。

- 您在接種過程感到焦慮，或在任何針頭插入前使用。

- 患有嚴重疾病或伴隨著發熱感染，如出現急性情況，請延後接種。

- 由於COVID-19感染症狀或注射部位的發炎反應，可能使您的免疫系統減弱。

- 根據藥物提供商資料

「復必泰」含有鈣和納

本疫苗每劑含<1 mmol（39 mg）的鈣，約基於上「無鈣」。

本疫苗每劑含<1 mmol（23 mg）的納，約基於上「無鈉」。
### 如何给予「速必泰」

- 在您上臂内侧注射0.3 mL已稀释好的「速必泰」。
- 联合科学委员会正在审查药物或施肥剂使用情况，可能导致患者或患者家属的副作用。
- 应避免在老人、重病患者、个别敏感的人群中使用。
- 您将接受2次注射，至少相隔21天。
- 接种第1剂「速必泰」后，
  - 应在21天内接种第2剂相同的疫苗，以完成疫苗接种。

### 禁忌症

- 无法确定成分。
- 孕妇和哺乳期妇女。
- 对药物有明显反应。

### 副作用

<table>
<thead>
<tr>
<th>副作用</th>
<th>可能影响患者比例</th>
</tr>
</thead>
<tbody>
<tr>
<td>发热</td>
<td>≤1/1000</td>
</tr>
<tr>
<td>疼痛</td>
<td>不适</td>
</tr>
</tbody>
</table>

### 接种疫苗后的异常事件报告

- 行政单位有规定，按时报告。
- 未出现异常的事件。
- 若出现异常的事件，请在60天内报告。
- 若出现异常的事件，应及时就医。

### 给醫護人員的信息：

- 请报告副作用。
- 副作用包括发热、疼痛、红肿。
- 若出现严重副作用，应立即就医。

### 疫苗接种注意事项

- 请阅读产品说明书。
- 请确认接种部位。
- 请确认接种间隔。
- 请确认接种者的健康状况。
- 请确认接种者的过敏史。

### 可能出现的副作用

- 可能出现的副作用。
- 若出现副作用，应立即就医。
- 若出现严重副作用，应立即就医。

### 另外的副作用

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3 How Comirnaty is given
- Comirnaty is given after dilution as an injection of 0.3 mL into a muscle of your upper arm.
- The JSC-EAP recommended intramuscular injection of the Comirnaty vaccine at mid-outer deltoid, especially for male children and male adolescents.
- You will receive 2 injections
given at least 21 days apart.
- After the first dose of Comirnaty, you should receive a second dose of the same vaccine after 21 days to complete the vaccination course.

If you have any further questions on the use of Comirnaty, ask your doctor, pharmacist or nurse.

4 Possible side effects
Like all vaccines, Comirnaty can cause side effects, although not everybody gets them.

5 Reporting of adverse events after immunization
The Department of Health ("DH") has an adverse drug reaction ("ADR") reporting system which receives adverse events following immunization ("AEFIs") reports to monitor the safety of COVID-19 vaccines. If you have any suspected adverse event occurred after immunization, please alert healthcare professionals (e.g. doctors, dentists, pharmacists, nurses and Chinese Medicine Practitioners), when seeking their advice, to report the AEFIs to the DH if they consider that the AEFIs may be associated with the vaccination.

For continuously monitoring of the safety and clinical events associated with COVID-19 vaccination, your personal data collected for vaccination and your clinical data held by the Hospital Authority and the relevant private healthcare facilities and healthcare professionals, may be accessed and used by DH and relevant organizations collaborated with the Government (including the University of Hong Kong) insofar as such information is necessary for the monitoring.

⚠️ In situations when pain or redness at the injection site increases after 24 hours from injection; or your side effects are worrying you or do not seem to be going away in a few days, please contact your doctor.

If you do seek medical attention, make sure you tell the healthcare professionals about your vaccination details and show them your vaccination record card if available. Healthcare professionals will then make proper assessment and, if necessary, report any AEFI that is deemed medically significant to DH for further action and assessment.

Please allow the healthcare professional to report the AEFI with your consent to passing the adverse event case information, personal and clinical data to DH for continuous monitoring the safety and clinical events associated with COVID-19 vaccination.

Message to the healthcare professionals:
Please conduct medical assessment and if you consider the AEFI associated with the vaccine is deemed medically significant, please report it to the Drug Office of the Department of Health via online reporting at the webpage [https://www.drug.gov.hk/epi/docs/healthcare_providers/adr_reporting/index.html](https://www.drug.gov.hk/epi/docs/healthcare_providers/adr_reporting/index.html)

If the vaccine recipient experiences serious adverse event following immunization, please refer the recipient to hospital.

☐ I have read and understood all information as provided in the factsheet and the Statement of Purposes of Collection of Personal Data, and I consent to the administration of COVID-19 Vaccination to me / my child / my ward under the COVID-19 Vaccination Programme and the Department of Health and the relevant organizations collaborated with the Government (including the University of Hong Kong)’s access to and use of (i) my / my child / my ward’s personal data contained herein and (ii) my / my child / my ward’s 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.

*Please delete as appropriate
Annex II  Package Insert of CoronaVac (detailed edition)  
(Table 2) Incidence of Selected Adverse Reactions in Table 3 (Clinical Trial in Brazil) %

<table>
<thead>
<tr>
<th>Name of Adverse Reaction</th>
<th>Vaccine (N=1929) (%)</th>
<th>Placebo (N=1916) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal reactions</td>
<td>41/53 (2.2)</td>
<td>27/16 (1.7)</td>
</tr>
<tr>
<td>Nausea</td>
<td>14/76 (7.9)</td>
<td>19/78 (2.6)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>17/76 (11.7)</td>
<td>20/78 (2.6)</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>12/76 (15.8)</td>
<td>14/78 (17.9)</td>
</tr>
<tr>
<td>Headache</td>
<td>2/76 (2.6)</td>
<td>10/78 (17.9)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>4/76 (5.3)</td>
<td>1/78 (1.3)</td>
</tr>
<tr>
<td>Myalgia</td>
<td>3/76 (4.0)</td>
<td>1/78 (1.3)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>2/76 (2.6)</td>
<td>1/78 (1.3)</td>
</tr>
<tr>
<td>Rash</td>
<td>2/76 (2.6)</td>
<td>1/78 (1.3)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>1/76 (1.3)</td>
<td>1/78 (1.3)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>1/76 (1.3)</td>
<td>1/78 (1.3)</td>
</tr>
</tbody>
</table>

Post Authorization Experience

According to a case series and review of noncontrolled study reported in the period between February 23, 2021 and May 4, 2021 conducted in Hong Kong, 38 cases of clinically confirmed COVID-19 following Covaxin vaccination were admitted to the Department of Health of Hong Kong. The age-adjusted incidence rate was 6.68 cases per 1,000 population (95% confidence interval: 3.67, 10.94) per 100,000 people vaccinated.

The age-standardized rate ratios were 2.26±3.68, higher than the background population rate equivalent to an additional 48 cases per 1,000 people vaccinated. In the nested case-control studies, 298 cases were matched to 1,064 controls. The adjusted odds ratio was 2.1 (95% CI 0.7-5.8) for Covaxin. The findings in Hong Kong described a signal of risk of COVID-19 infection in vaccinated persons and additional studies are needed in other regions to confirm the risk.

Children

The safety of Covaxin in children was evaluated in a clinical trial conducted in China, including the phase I and phase II clinical trial in children aged >1 year. Immunization schedule of day 0/28 was selected in both studies, systematic safety evaluation was carried out within 7 days after each vaccination and adverse events were recorded. A primary report of adverse events and regular follow-up of investigators on day 28 long-term of serious adverse events within 12 months after the 1st vaccination is still ongoing.
1. General description of adverse reactions in clinical trials

A total of 1,002 subjects aged 18-79 years were enrolled in the clinical trials of which 963 subjects received the vaccine (500 mg/10 mL) and 39 subjects received placebo. The treatment was administered in two doses of 200 mg/5 mL or 700 mg/35 mL, respectively, with a 21-day interval. The incidence of adverse reactions was evaluated by the investigators and reported.

The incidence of adverse reactions in clinical trials is shown in Table 5. The incidence of adverse reactions in clinical trials is shown in Table 6.

2. Common adverse reactions

Common adverse reactions include:

- Mild and transient fever
- Soreness and tenderness at the injection site
- Headache
- Myalgia
- Nausea
- Diarrhea
- Studied adverse reactions

Studied adverse reactions are:

- Headache
- Fever
- Myalgia
- Fatigue
- Chills
- Nausea
- Diarrhea
- Cough
- Photophobia
- Myalgia
- Soreness at the injection site

In addition, adverse reactions that were observed during the clinical trials include:

- Rash
- Pruritus
- Urticaria

3. Adverse reactions to vaccination

Adverse reactions to vaccination include:

- Fever
- Soreness at the injection site
- Headache
- Myalgia
- Nausea
- Dizziness

4. Common adverse reactions

Common adverse reactions include:

- Headache
- Dizziness
- Nausea
- Fatigue
- Myalgia
- Soreness at the injection site

These adverse reactions were also observed in clinical trials of the placebo group.

5. Severe adverse reactions

Severe adverse reactions were observed in clinical trials of the placebo group.

6. Laboratory tests

Laboratory tests were performed before and after vaccination.

7. Body weight

Body weight was measured before and after vaccination.

8. Blood pressure

Blood pressure was measured before and after vaccination.

9. Heart rate

Heart rate was measured before and after vaccination.

10. Electrocardiogram

Electrocardiogram was performed before and after vaccination.

11. Chest X-ray

Chest X-ray was performed before and after vaccination.

12. Ultrasonography

Ultrasonography was performed before and after vaccination.

13. CT scan

CT scan was performed before and after vaccination.

14. MRI

MRI was performed before and after vaccination.

15. Bone density measurement

Bone density measurement was performed before and after vaccination.

16. Blood tests

Blood tests were performed before and after vaccination.

17. Urine tests

Urine tests were performed before and after vaccination.

18. Liver function tests

Liver function tests were performed before and after vaccination.

19. Kidney function tests

Kidney function tests were performed before and after vaccination.

20. Hematological tests

Hematological tests were performed before and after vaccination.

21. Immunological tests

Immunological tests were performed before and after vaccination.

22. Tumor marker tests

Tumor marker tests were performed before and after vaccination.

23. Other tests

Other tests were performed before and after vaccination.

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COVID-19 Vaccine (Vero Cell), Inactivated (Brief Edition)

This is the Conditional Marketing Authorization. Please refer to the instruction and use under the doctor's guidance.

Name of the Medical Product: COVID-19 Vaccine (Vero Cell), Inactivated

Trade Name: CoronaVac

Chinese: 克尔来福

Latin: Coronavac

CoronaVac is a lyophilized, suspensoid vaccine which may be dispersed by shaking.

Target Group for Vaccination: People aged 3 years and above.

Clinical Trials: A 0-1-2 regimen was used in the clinical trials, where 50% of participants were given 3 doses of CoronaVac at 0, 1, and 2 months.

Effectiveness: The efficacy of CoronaVac was evaluated in a randomized, double-blind, placebo-controlled phase III clinical trial. The primary efficacy endpoint was the proportion of subjects who experienced a confirmed COVID-19 infection within 28 days after the first dose of the vaccine.

Adverse Reactions:

1. Adverse reactions at injection site
   - Common: pain, redness, swelling, bruising, itching
   - Uncommon: urticaria, injection site abscess

2. Systemic adverse reactions
   - Common: headache, fatigue
   - Uncommon: fever, chills, myalgia, arthralgia, nausea, vomiting, diarrhea, abdominal pain

3. Adverse reactions observed post-vaccination in Hong Kong
   - Common: pain, redness, swelling

4. Serious adverse events (SAE)
   - No serious adverse event related to vaccination was identified up to February 3, 2021.

CoronaVac is a lyophilized, suspensoid vaccine which may be dispersed by shaking.

Therapeutic Indication:

CoronaVac is indicated for active immunization against diseases caused by SARS-CoV-2 virus.

Presentation:

Each vial containing 0.5 mL of single dose of 0.5 mL contains 6000IU of inactivated SARS-CoV-2 virus as antigen.

Administration and Schedule:

Two doses should be administered for primary immunization. The second dose is preferably given 28 days after the first dose.

The safety of CoronaVac in adults was evaluated in 4 clinical trials conducted in China, including randomized, double-blind, placebo-controlled phase III clinical trials. The primary efficacy endpoint was the proportion of subjects who experienced a confirmed COVID-19 infection within 28 days after the first dose.

According to the January 24, 2021, median of 363 effective COVID-19 infections in a total of 8838 subjects, the efficacy rate was 79.3% (95% CI: 70.9%, 85.8%).

The adverse reaction rate of the vaccine was low, with no serious adverse events related to vaccination identified up to February 3, 2021.
Uncommon hypersensitivity, diarrhoea, vomiting, myalgia, arthralgia, ear, pharyngitis, upper respiratory tract infection, abdominal pain, upper abdominal pain, abdominal distension, dizziness, lymphadenitis, chest discomfort, headache

3. Severity of adverse reactions
   The severity of adverse reactions observed in these clinical trials is similar to that in clinical trials of other vaccines. In general, the incidence rate of adverse reactions for grade 1 was 0-24% and for grade 2 was 0-26% and no grade 3 or above reactions were reported. The severity of adverse reactions is low.

4. Serious adverse events (SAE)
   No serious adverse events related to vaccination were identified up to November, 2021. For detailed information of recommendations, immunizations should be administered at the earliest stage of the illness.

CONTRAINDICATIONS
   1. People with a history of allergic reaction to CoronaVac or other inactivated vaccines, or any component of CoronaVac, including any of its ingredients, or any material used in the vaccine preparation.
   2. People who have had a severe allergic reaction to the vaccine (e.g., anaphylaxis, angioedema, dyspnoea, etc.);
   3. People with severe neurological conditions (e.g., transverse myelitis, Guillain-Barré syndrome, demyelinating diseases, etc.);
   4. Patients with uncontrolled severe chronic diseases;
   5. Pregnant and lactating women.

CAUTIONS
   1. Due to the insufficient data on protection persistence, necessary protective measures should be taken in line with the COVID-19 pandemic.
   2. Due to the insufficient data on the efficacy of the vaccine in people aged 60 and above. When using CoronaVac among people aged 60 and above, the health status and exposure risk of people aged 60 and above should be considered.
   3. This vaccine is strictly prohibited for intradermal injection. There is no safety and efficacy data of subcutaneous or intradermal injection.
   4. Before use, check whether the packaging container is intact, appearance and validity period meet the requirements or not. Do not use if there are cracks in the vial, spots, stains and scratches on the outer surface of the vial label is not clear or more than the expiration date and abnormal appearance.
   5. Avoid exposure to the patient during use.
   6. This product should be stored at or below the room temperature between 2°C and 8°C.

ADVERSE TREATMENT: In case of anaphylaxis reaction and emergency treatment, should be available for first aid in case of anaphylaxis reaction. Individuals should be observed for at least 30 minutes after vaccination.

Do not mix with other vaccines in the same syringe.

If not needed, it should be administered immediately after opening.

Patients with acute diseases, acute exacerbation of chronic diseases, severe chronic diseases, atopy and fever should be used with caution. In patients with a history of atopy or allergy, vaccination should be given after doctor's evaluation.

Patients with diabetes or a history of convulsions, epilepsy, encephalopathy, mental disorder, or family history of these diseases should be used with caution.

Patients with thrombocytopenia or hemolytic diseases, intramuscular injection of this product may cause bleeding, so it shall be used with caution.

The safety and efficacy data of this product on people with impaired immune function (such as malignant tumor, nephrotic syndrome, AIDS patients) have not been obtained, and the vaccination of this product should be based on individual considerations.

The injection of human immunoglobulin should be given at least 1 month before or after the vaccination to avoid affecting the immune effect.

The clinical study has been carried out on the evaluation of immune response with other vaccines on the immunogenicity at the same time (before, after or at the same time). Professionals should be consulted when concomitant use.

Do not use if there is any adverse reaction of nervous system after inoculation.

Like other vaccines, the protective effect may not reach 100% for all recipients.

Based on the findings of 19-21 COVID-19 cases due to contamination by non-targeted virus vaccine published in the Clinical Infectious Diseases, and the immunogenicity study conducted by SinoVac, the adaptive outcomes (as showed by a-kh-1 genome sequencing) on the spike protein of inactivated SARS-CoV-2 Virus (C02 strain) of CoronaVac do not change its safety, efficacy and immunogenicity.

SPECIFIC POPULATION MEDICATION

Information on the clinical trials of women with unexpected pregnancy after vaccination from clinical trials are very limited which is not enough to decide the risk of adverse pregnancy outcomes after vaccination.

Pregnant or lactating women, the clinical data of pregnant and lactating women are not available at present.

If patients aged 60 and above, the immunogenicity and safety data from conducted clinical trials have been obtained, while the efficacy data from phase III clinical trial is insufficient.

[Drug-drug interactions]

Concomitant use with other vaccines, no clinical study has been carried out on the evaluation of immune response with other vaccines on the immunogenicity at the same time (before, after or at the same time).

Concomitant use with other drugs, immunosuppressive drugs, such as immunosuppressive drugs, chemotherapy drugs, antihypertensive drugs, antiinflammatory drugs, anti-cancer drugs, etc., may reduce the immune response to this product.

Patients undergoing treatment: For patients undergoing treatment, please consult the professional doctors before use CoronaVac to avoid possible drug interactions.

STORAGE

Store and transport between -2°C and 8°C, and protect from light.

SHELF LIFE

The shelf life of the vaccine is 18 months as of the date of manufacture.

PACKAGING

This product is packaged into 10 vials per box.

MANUFACTURER

Name: SinoVac Life Sciences Co., Ltd.
Address: No. 21, Tianfu Street, Daxing Biodmedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing, Beijing, China.

MARKETING AUTHORIZATION HOLDER

Name: SinoVac Life Sciences Co., Ltd.
Address: No. 21, Tianfu Street, Daxing Biodmedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing, Beijing, China.

Website: www.sinovac.com
E-mail: info@sinovac.com

Post code: 100193
Tel: 86-10-56697188
Fax: 86-10-56697173

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Annex III Checklist of Items during Onsite Inspection

A) Sufficient number and qualification of on-site staff throughout vaccination activity
   - Presence of Visiting Medical Officer (VMO) (completed Part I of online training for COVID-19 Vaccination Programme by the HK Academy of Medicine) for overall supervision of the whole vaccination process
   - VMO or qualified /trained health care personnel to perform vaccine administration
   - Presence of qualified personnel who is trained in emergency management of severe immediate reactions

B) Infection Control Measures
   - Social distancing if applicable
   - Hand hygiene
   - Use of PPE if applicable
   - Environmental disinfection

C) Liaison with RCH
   - Preliminary assessment to screen for contraindications
   - Cold chain management of vaccine storage
   - Preparation of emergency equipment, vaccination equipment and medical consumables and IT equipment (e.g. printer, computer with internet access, Smart ID Card Reader)

D) Vaccines and Vaccination procedures
   1. Administrative procedure
      - Cross-check list of consented recipients with vaccination consent forms
      - Conduct pre-vaccination assessment
      - eHS(S) record (Identity verification)
      - Checking of previous vaccination record
      - Record informed consent
      - Issue Vaccination Record
   2. Safe vaccine handling and administration practice (Three checks and seven rights)
   3. Sharps Management
   4. Infection Control Practice
   5. Keep recipients under observation for 30 minutes
   6. Update RCH for subsequent vaccination schedule
   7. Proper documentation
   8. Proper storage of used vaccine package boxes and package inserts for collection by DH

E) Others
   1. Management of voided/defective vaccines
2. Clinical Waste Management
3. Chemical Waste Management (if applicable)
4. Clinical Incident Management
5. Management and report of AEFI
6. Summary Reports to Central Command Centre of COVID-19 Vaccination Programme

The above checklists are by no means exhaustive. Please refer to the Doctor’s Guide for more information.
Annex IV  Daily Fridge Temperature Chart

<table>
<thead>
<tr>
<th>疫苗名稱</th>
<th>接收數量</th>
<th>接收日期</th>
<th>送貨單上的有效日期</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>圖1/2</td>
</tr>
</tbody>
</table>

*第一劑／第二劑

<table>
<thead>
<tr>
<th>日期</th>
<th>檢查雪櫃時間</th>
<th>雪櫃內溫度（攝氏℃）</th>
<th>雪櫃溫度（攝氏℃）</th>
<th>疫苗數量</th>
<th>檢查及記錄人員</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. 請於接收疫苗前連續七天（每天上午、中午和下午各一次）檢查及記錄雪櫃溫度。
2. 所有疫苗須保存於攝氏2至8度雪櫃內備用（請參考運送疫苗及儲存須知）
3. 請於記錄雪櫃最高及最低溫度後，重置最高/最低溫度計。
4. 請保留此記錄至少一年，以便有需要時作參考。
5. 所有疫苗屬政府公物，即使過期亦必須妥善保存及交回衛生署處理。

註：如雪櫃溫度低於攝氏+2度或高於攝氏+8度
1. 請暫勿使用受影響的疫苗，並應將疫苗立即存放於攝氏2至8度的雪櫃
2. 請聯絡衛生署疫苗管理及疫苗計劃科

*請刪去不適用者
（如不敷應用，請自行黏貼）
### Annex V

**List of Residents/ MIPs with Legal Guardian Consented to Receive CoronaVac**

(2022 年 01 月 28 日更新版)

致：已聯繫的院舍防疫注射計劃到診註冊醫生
（傳真號碼：__________）
院舍名稱：__________________________
院舍地址：__________________________

### 2019 冠狀病毒病疫苗接種計劃 — 院舍外院接種安排
院友接種「新冠疫苗」名單
（第 ___ 頁 ／ 共 ___ 頁）

**根據聯合科學委員會聯同專家顧問團建議，所有曾接種流感疫苗的長者均可安全地接種 2019 冠狀病毒病疫苗**

**甲部：同意接種「新冠疫苗」院友資料**
[不用再填寫已接種的院友資料]

<table>
<thead>
<tr>
<th>院友資料 [由院舍填寫]</th>
<th>到診註冊醫生評估為</th>
<th>此欄於接種當日填寫</th>
</tr>
</thead>
<tbody>
<tr>
<td>姓名</td>
<td>身份證明</td>
<td>是否接種或</td>
</tr>
<tr>
<td></td>
<td>文件號碼</td>
<td>將接種「新冠疫苗」</td>
</tr>
<tr>
<td></td>
<td>[例：A12345678]</td>
<td>否</td>
</tr>
</tbody>
</table>

1. 2.

| | 1. | 2. | 3. |
| | 第一劑 | 第二劑 | 第三劑 |
| (日期) | (日期) | (日期) |

- 包括所有 18 歲或以上具備健康能力或有法定監護人的院友。
- 疫苗可預防醫學科學委員會及新發現及動物傳染病科學委員會（聯合科學委員會）聯同行政長官專家顧問團（專家顧問團）。
- 對於最差劣的長者，可考慮作考課相關的權益與風險，詳情請參閱聯合科學委員會於 2021 年 6 月 9 日發出的建議。
- 包括所有已出院友或獲法定監護人簽署同意接種新冠疫苗的院友（包括老人院、殘疾人士院舍及獲實施院友接種的院舍）。接種疫苗者可享有院友接種科興或科興疫苗的護理服務及福利。
- 請院舍於接種當日填寫此欄並保存有關記錄，以便衛生署及衛生署有關資料。
<table>
<thead>
<tr>
<th>姓名</th>
<th>身份證明文件號碼 (例如: A12345678)</th>
<th>是否曾接種或將會接種流感疫苗？(是/否)</th>
<th>合並接種</th>
<th>合並接種</th>
<th>有否接種新冠疫苗(如是,請填疫苗名稱及日期;如否,請填“X”)</th>
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<tbody>
<tr>
<td></td>
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<td>第一劑</td>
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<td>第三劑</td>
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<td>4</td>
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<td>17</td>
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</tbody>
</table>

(如不適用,請自行影印)
附件五
(2022年01月28日更新版)

乙部：未表達同意接種「新冠疫苗」院友資料（包括反對接種「新冠疫苗」的院友）

| 院友資料[由院企廣宣] | 註冊護理人員評定為 [請於黑格填上“√”或“×”] 合格接種「科興疫苗」 | 院友自己反對或法定監護人在指定時間內以書面形式表示反對接種 [已提交・請填“√”] | 此欄於接種當日填寫
|-----------------|----------------------------------------|-------------------------------------------------|-------------------|
| 姓名 | 身份證明文件號碼 [例如 A123456(X)] | 是否曾接種或將會接種其他疫苗？ [如是，請填“√”；如否，請填“×”] | 院友自己反對或法定監護人在指定時間內以書面形式表示反對接種 [已提交・請填“√”] | 有否接種該款「新冠疫苗」

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※包括所有18歲或以上而精神上有行為能力或有法定監護人的院友。
※請院友於接種當日填寫此欄並保存有關記錄，以便衛生署日後索取有關資料。
| 姓名 | 身份證明文件號碼 | 是否曾接種或將會接種 seasonal vaccines? [是，請選 "✓"； 否，請選 "×"] | 合適接種「科興疫苗」 | 合適接種「復必泰疫苗」 | 院友自己反對或法定監護人在指定時間內以書面形式表示反對接種 [已提交，請選 "✓"] | 附件五، 2022年01月28日更新版

| 第一劑 (日期) | 第二劑 (日期) | 第三劑 (日期) |
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（如不敷應用，請自行影印）

院舍經營者／營辦人／主管簽署：
院舍經營者／營辦人／主管姓名：
院舍經營者／營辦人／主管職位：
日期：

（院舍印章）
### Annex VI  List of MIPs without Legal Guardians who are unable to give consent

附件六  2019冠狀病毒病疫苗接種安排

**致：**

已聯繫的院舍防護注射計劃及註冊醫生（傳真號碼：

院舍名稱：

院舍地址：

「2019冠狀病毒病疫苗接種安排」

未能表達接種意願名單

（第 貳 / 共 貳 頁）

**根據聯合科學委員會聯合專家顧問團建議，所有接種流感疫苗的長者均可安全地接種2019冠狀病毒病疫苗**

相關院友資料：

<table>
<thead>
<tr>
<th>院友資料</th>
<th>到院註冊醫生評估為</th>
<th>家屬在指定時間內以書面形式表示反對接種</th>
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<tr>
<td>姓名</td>
<td>身份證號碼</td>
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1. 有否咳嗽發燒
2. 有否接種疫苗
3. 有否健康問題
4. 有否發燒或咳嗽
5. 有否接種疫苗
6. 有否健康問題
7. 有否發燒或咳嗽
8. 有否接種疫苗
9. 有否健康問題
10. 有否發燒或咳嗽

(2022年01月28日更新版)
### Annex VII

<table>
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<tr>
<th>姓名</th>
<th>身份證號碼 [例 A12345678]</th>
<th>性別 (F/M)</th>
<th>年齡</th>
<th>是否曾接種或將會接種新冠疫苗？ [如有，請填 &quot;✓&quot;；如否，請填 &quot;×&quot;]</th>
<th>合適接種 &quot;科興疫苗&quot;</th>
<th>合適接種 &quot;復必泰疫苗&quot;</th>
<th>家屬在指定時間內以書面形式表示是否接種 [已提交，請填 &quot;✓&quot;；未提交，請填 &quot;×&quot;]</th>
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（如不需使用，請自行塗改）

院舍經營者／營辦人／主管簽署：____________________

院舍經營者／營辦人／主管姓名：____________________

院舍經營者／營辦人／主管職位：____________________

日期：____________________ (院舍印章)
Annex VIII List of Staff Consented to Receive CoronaVac

致：已聯繫的院舍防疫注射計劃到診註冊醫生（傳真號碼：____________）
院舍名稱：____________________________
院舍地址：________________________________

「2019冠狀病毒病疫苗接種動員
院舍員工外展接種安排
院舍同意接種名單
接種疫苗名稱：「科興疫苗」
（第 ___ 頁／共 ___ 頁）

同意接種「科興疫苗」員工名單2

<table>
<thead>
<tr>
<th>員工姓名</th>
<th>身份證明文件號碼</th>
<th>此欄於接種當日填寫^</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>有否接種該劑「科興疫苗」（如無，請填寫原因）（✓/×）</td>
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（如不敷應用，請自行另印）

院舍經理／營辦人／主管簽署：________________________
院舍經理／營辦人／主管姓名：________________________
院舍經理／營辦人／主管職位：________________________
日期：________________________（院舍印章）

^ 包括安老院、殘疾人士院舍及護養院及附設於院舍的日間服務單位的員工。
2 請院舍先取得員工同意將其個人資料按需要交予相關診註冊醫生，以安排有關員工接種新冠疫苗事宜。
3 請院舍於接種當日填寫此欄以保存有關紀錄，以便準確掌握接種情況。
Annex IX  Consent Form

2019 冠狀病毒病疫苗接種同意書

注意: 請用黑色或藍色筆以正楷填寫本同意書並並適當位置加上“✓” 號及* 刪去不適用者。

第一部分：疫苗接種者個人資料 (以身份證明文件所載者為準)

姓名：_________________________(姓氏) __________________________ (名字)
(中文) __________________________ (英文)
出生日期：_____/_____/_______(日/月/年年年年) 性別：________
聯絡電話號碼：________________________ (流動電話)
香港居民身份證號碼：

或 其他身份證明文件:

證件類別：________________________
證件號碼：________________________

第二部分：接種 2019 冠狀病毒病疫苗同意書

☐ 本人同意 (a) 政府為本人／本人的子女／受監護者 * 接種在 2019 冠狀病毒病疫苗接種計劃下提供的 2019 冠狀病毒病疫苗（詳情載於第三部）；及 (b) 醫療機構及與政府合作的相關機構（包括香港大學）查閱及使用

注意: 本表接種每一劑疫苗填寫一份同意書。

第三部分：2019 冠狀病毒病疫苗詳情

2019 冠狀病毒病疫苗種類及劑次 *(供護理人員填寫) (請在適當位置加上～ “✓” 號)

☐ 復必泰—信使核糖核酸疫苗 (BNT 162b2)
(復星醫藥／德國藥廠 BioNTech)
☐ 克爾來福—滅活疫苗 (Vero 細胞)
(科興)

☐ 第一劑 ☐ 第二劑 ☐ 其他，請註明：______________________ 剤

Rev: 11/2021
第四部：聲明及簽署

甲. 供年滿18歲或以上的疫苗接種者填寫

本人已閱讀及明白有關詳列於第三部的2019冠狀病毒病疫苗的接種須知，當中包括接種2019冠狀病毒病疫苗的禁忌症及可能的副作用，上述疫苗是根據《預防及控制疾病（使用疫苗）規例》（第599K章）指明目的為預防2019冠狀病毒病獲認可使用，它並未根據《藥劑業及毒藥規例》（第138章）在香港註冊及／或遞續上述2019冠狀病毒病疫苗。本人有提出問題的機會，所有問題都得到本人認為滿意的答覆。本人也完全理解並同意書中所收集個人資料的聲明中的義務及責任。

本人在下方簽署確認，本人同意(a)政府為本人接種在2019冠狀病毒病疫苗接種計劃下提供的2019冠狀病毒病疫苗（詳情載於第三部）；及(b)本人亦同意衛生署及與政府合作的相關機構（包括香港大學）查閱及使用由醫院管理局、相關醫療機構及醫護人員持有屬於本人的臨時資料，以便衛生署持續監測及接種2019冠狀病毒病疫苗有關的安全及臨時事件，而該等資料只可在為此目的而必須查閱及使用的情況下才能查閱及使用。

本人特此聲明，本人在此同意書中所提供的一切資料，全屬真確。

本人同意把此同意書中本人的個人資料供政府用於「收集個人資料資料的聲明」所述的用途。本人悉知政府會與我聯絡，以審視有關資料及有關接種疫苗的安排。

適用於香港特別行政區智能身份證持有者：本人同意授權醫院護理人員及公職人員讀取及存在本人香港特別行政區智能身份證芯片內的個人資料[只限香港身份證號碼、中文姓名、出生日期及香港身份證發放日期]，以供政府作「收集個人資料資料的聲明」所述的用途。

此同意書受香港特別行政區法律管轄，並須按照香港特別行政區法律解釋；本人須不可撤銷地接受香港特別行政區法院的專屬司法管轄權管轄。

疫苗接種者簽署（如不會書寫，請印上指模）：

日期：

乙. 如疫苗接種者未滿18歲或精神上無行為能力，只供父母／監護人填寫以下資料

本人已閱讀及明白有關詳列於第三部的2019冠狀病毒病疫苗的接種須知，當中包括接種2019冠狀病毒病疫苗的禁忌症及可能的副作用，上述疫苗是根據《預防及控制疾病（使用疫苗）規例》（第599K章）指明目的為預防2019冠狀病毒病獲認可使用，它並未根據《藥劑業及毒藥規例》（第138章）在香港註冊及代表本人的子女／受監護者／同住／無配偶／同住，本人有提出問題的機會，所有問題都得到本人認為滿意的答覆。本人也完全理解並同意書中所收集個人資料的聲明中的義務及責任。

本人在下方簽署確認，本人同意(a)政府為本人的子女／受監護者／同住／無配偶／同住接種在2019冠狀病毒病疫苗接種計劃下提供的2019冠狀病毒病疫苗（詳情載於第三部）；及(b)本人亦同意衛生署及與政府合作的相關機構（包括香港大學）查閱及使用由醫院管理局、相關醫療機構及醫護人員持有屬於
本人的子女／受監護人*的臨時資料，以便衛生署持續監測與接種 2019 冠狀病毒病疫苗有關的安全及臨牀事件，而該等資料只可在為此目的而必須查閱及使用的情況下才能查閱及使用。

本人特此聲明，本人在此同意書中所提供之一切資料，全部正確。

（本人同意）把此同意書中本人／本人子女／受監護人*的個人資料供政府或其有關機構用作收集個人資料的目的之用途。本人願意見面或會與我聯繫，以核實有關個人資料及有關接種疫苗的安排。

適用於香港特別行政區公民身份證持有者：本人同意授權醫療護理人員及政府人員讀取儲存在本人／本人子女／受監護人*的香港特別行政區公民身份證內的個人資料[只限香港身份證號碼、中文姓名、出生日期和香港身份證簽發日期]，以供政府作「收集個人資料的目的聲明」所述的用途。

此同意書受香港特別行政區法律規定，並須按照香港特別行政區法律解釋，本人須不可撤銷地接受香港特別行政區法院的專屬司法管轄權管轄。

父母／監護人*署名：

父母／監護人*姓名（中文）：

關係：

父母／監護人*的香港居民身份證或
其他身份證明文件·證件類別·證件號碼：

聯絡電話號碼：

日期：

如已填寫第四部，則無需填寫此部

見證人署名：

見證人姓名（中文）：

香港居民身份證號碼：
（只限英文母及首3個數字）

或  其他身份證明文件：

證件類別：

證件號碼：

聯絡電話號碼：

日期：

以下資料只由護理人員填寫（如接種場地是社區疫苗接種中心，則無需填寫此部）

醫療通(資助)交易號碼：

只可填寫一個交易號碼（如適用）：

轉帳日期：

負責護理姓名：

Rev. 11/2021
收集個人資料目的聲明

提供個人資料乃屬自願性質，如果你不提供充分的資料，可能無法接種疫苗。

收集個人資料目的

1. 所提供的個人資料，會供政府作下列一項或多項用途：
   (a) 與有關政府部門和組織核對接受2019冠狀病毒病疫苗的狀況；
   (b) 通知有關政策局或政府部門及組織安排疫苗接種事宜以及接種後的跟進事宜；
   (c) 開設、處理及管理醫健通（資助）戶口，以及執行和監察2019冠狀病毒病疫苗接種計劃，包括但不限於通過電子程序與入境事務處的資料核對；
   (d) 轉交衛生署及與政府合作的相關機構（包括香港大學）作持續監測與2019冠狀病毒病疫苗接種計劃下接種2019冠狀病毒病疫苗有關的安全及臨牀事件；
   (e) 作統計和研究用途；以及
   (f) 作法例規定，授權或准許的任何其他合法用途。

接受轉介人的類別

2. 你所提供的個人資料，主要是供政府內部使用，但政府亦可能於有需要時，因以上第1段所列收集資料的目的而向其他機構和第三者披露。

查閱個人資料

3. 根據《個人資料(私隱)條例》（香港法例第 486 章）第 18 條和第 22 條以及附表 1 保障資料原則第 6 原則所述，你有權查閱及修正你的個人資料。衛生署會查閱資料要求而提供資料時，可能要徵收費用。

查詢

4. 如欲查閱或修改有關提供的個人資料，請聯絡:
   行政主任(項目管理及疫苗計劃科)
   地址：九龍亞皆老街 147C 衛生防護中心二樓 A 座
   電話: 2125 2045

Rev: 11/2021

第49頁，英譯本
Consent Form for COVID-19 Vaccination

Note: Please complete this form in BLOCK letters using black or blue pen and put a “✓” in appropriate boxes and *delete as appropriate.

Part 1: Personal Details of Vaccine Recipient (as indicated on identity document)

Name: ____________________________
Surname: ____________________________
Given name: ____________________________
(Chinese) (Surname) (Given name)
Date of Birth: __________/________/________ (DD/MM/YYYY) Gender: ______
Contact number: ____________________________ (mobile)
Hong Kong Identity Card No: ________ ________ ________ ________ ________ ( )
HKID Symbol: □ A □ C □ E □ U
Date of Issue: __________/________/________ (dd/mm/yyyy)
OR Other identity document:
Document type: ____________________________
Document number: ____________________________

Part 2: Consent to Administration of COVID-19 Vaccination

☐ I consent to (a) the administration of COVID-19 Vaccination to me / my child / my ward * under the COVID-19 Vaccination Programme (see particulars in Part 3); and (b) the access and use by the Department of Health and the relevant organisations collaborated with the Government (including the University of Hong Kong) of my/ my child/ my ward’s * 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.

Note: A consent form is required for each dose of vaccination.

Part 3: Particulars of COVID-19 Vaccination

Type and Dose Sequence of COVID-19 Vaccination* (Filled in by Healthcare Provider) (Put a “✓” in the most appropriate box)

☐ Comirnaty – mRNA Vaccine (BNT 162b2) (Pfizer-BioNTech Deckle)
☐ CoronaVac – Inactivated Vaccine (Vero Cell) (Sinovac)
☐ First dose  ☐ Second dose  ☐ Others, please specify: ___________ dose
Part 4  Declaration and Signature

A. To be completed by vaccine recipient who is aged 18 or above

I have read and I understood the information in the Vaccination Fact Sheet for the COVID-19 vaccine particularised in Part 3, including contraindications (and possible adverse events) of COVID-19 vaccination, the vaccine product is authorised under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599B) for specified purpose for prevention of COVID-19 infection but has not been registered under the Pharmacy and Poisons Ordinance (Cap. 138), and [agree] to receive the COVID-19 vaccine particularised in Part 3. I have had the opportunity to ask questions and all of my questions were answered to my satisfaction. I also fully understood my obligation and liability under this consent form and the Statement(s) of Purpose of Collection of Personal Data.

I confirm that by signing underneath, I consent to (a) the administration of COVID-19 Vaccination under the COVID-19 Vaccination Programme (see particulars in Part 3); and (b) the access and use by the Department of Health and the relevant organisations collaborated with the Government (including the University of Hong Kong) of my 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.

I declare the information provided in this form is correct.

I agree to provide my personal data in this form for the use by the Government for the purposes set out in the “Statement of Purpose of Collection of Personal Data”. I understand that the Government may contact me to verify the information and the arrangement of the vaccination.

For Smart Identity Card holder: I agree to authorise the Healthcare Providers / public officers to read my personal data [limited to Hong Kong Identity Card No., Name (in English and Chinese), date of birth and date of issue of Hong Kong Identity Card] saved in the chip embodied in my Smart Identity Card for the use by the Government for the purposes as set out in the “Statement of Purpose of Collection of Personal Data”.

This consent form shall be governed by and construed in accordance with the laws of Hong Kong Special Administrative Region and I shall irrevocably submit to the exclusive jurisdiction of the Courts of Hong Kong Special Administrative Region.

Signature of vaccine recipient (or fingerprint if illiterate): __________________________

Date: __________________________

Rev. 11/2021
B. To be completed by parent / guardian only if vaccine recipient is aged below 18 / mentally incapacitated

I have read and I understood the information in the Vaccination Fact Sheet for the COVID-19 vaccine particularised in Part 3, including contraindications (and possible adverse events) of COVID-19 vaccination, the vaccine product is authorised under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) for specified purpose for prevention of COVID-19 infection but has not been registered under the Pharmacy and Poisons Ordinance (Cap. 138), and agree on behalf of my child / ward* to receive the COVID-19 vaccine particularised in Part 3. I have had the opportunity to ask questions and all of my questions were answered to my satisfaction. I also fully understood my obligation and liability under this consent form and the Statement(s) of Purpose of Collection of Personal Data.

I confirm that by signing underneath, I consent to (a) the administration of COVID-19 Vaccination to my child / my ward* under the COVID-19 Vaccination Programme (see particulars in Part 3); and (b) the access and use by the Department of Health and the relevant organisations collaborated with the Government (including the University of Hong Kong) of my child / my ward*’s clinical data held by the Hospital Authority and the relevant private healthcare facilities and healthcare professionals for the purpose of continuously monitoring of 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.

I declare the information provided in this form is correct.

I agree to provide my child / my ward*’s personal data in this form for the use by the Government for the purposes as set out in the “Statement of Purpose of Collection of Personal Data”. I understand that the Government may contact me to verify the information and the arrangement of the vaccination.

For Smart Identity Card holder: I agree to authorise the Healthcare Providers / public officers to read my child / my ward*’s personal data [limited to Hong Kong Identity Card No., Name (in English and Chinese), date of birth and date of issue of Hong Kong Identity Card] saved in the chip embodied in my child / my ward*’s Smart Identity Card for the use by the Government for the purposes as set out in the “Statement of Purpose of Collection of Personal Data”.

This consent form shall be governed by and construed in accordance with the laws of Hong Kong Special Administrative Region and I shall irrevocably submit to the exclusive jurisdiction of the Courts of Hong Kong Special Administrative Region.

Signature of Parent / Guardian*:

Name of Parent / Guardian* (in English):

Relationship:

HKID/ Other Identity Document Type and Document No. of Parent/ Guardian*:

Contact Telephone No.:

Date:

Rev. 11/2021
**C. Witness should complete the following if the vaccine recipient is illiterate**
(Obtain this Part if Part 4(B) has been completed)

This document has been read and explained to the vaccine recipient in my presence. The vaccine recipient has been given an opportunity to ask questions.

<table>
<thead>
<tr>
<th>Signature of Witness:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Witness (in English):</td>
</tr>
<tr>
<td>Hong Kong Identity Card No.:</td>
</tr>
<tr>
<td>(only the alphabet and the first three digits are required)</td>
</tr>
<tr>
<td>OR. Other Identity Document</td>
</tr>
<tr>
<td>Document type:</td>
</tr>
<tr>
<td>Document number:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Contact Telephone No.:</th>
<th>Date:</th>
</tr>
</thead>
</table>

---

**To be completed by Healthcare Provider (Not required for Community Vaccination Centre)**

<table>
<thead>
<tr>
<th>eHS(S) Transaction No.</th>
<th>T <strong><strong><strong>-</strong>__-</strong></strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>ONE TRANSACTION NUMBER ONLY (if applicable)</td>
<td></td>
</tr>
<tr>
<td>Date of Vaccination</td>
<td></td>
</tr>
<tr>
<td>Name of Doctor</td>
<td></td>
</tr>
</tbody>
</table>

Rev. 11/2021
Statement of Purpose of Collection of Personal Data

The provision of personal data is voluntary. If you do not provide sufficient information, you may not be able to receive vaccination.

Purpose of Collection

1. The personal data provided will be used by the Government for one or more of the following purposes:
   (a) checking with relevant government departments and organisations on the status of receiving COVID-19 vaccine;
   (b) informing relevant government bureaux or departments and organisations for arranging vaccination and follow up after the vaccination;
   (c) for creation, processing and maintenance of an "Health (Subsidies)" account, and the administration and monitoring of the COVID-19 vaccination programme, including but not limited to, a verification procedure by electronic means with the data kept by the Immigration Department;
   (d) transferring to the Department of Health and relevant organisations collaborated with the Government (including the University of Hong Kong) for continuous monitoring of the safety and clinical events associated with COVID-19 Vaccination under the COVID-19 Vaccination Programme;
   (e) for statistical and research purposes; and
   (f) any other legitimate purposes as may be required, authorised or permitted by law.

Classes of Transferees

2. The personal data you provided will be transferred to the Government and may also be disclosed by the Government to its agents, other organisations, and third parties for the purposes stated in paragraph 1 above, if required.

Access to Personal Data

3. You have the right to request access to and correction of your personal data under sections 18 and 22 and principle 6, schedule 1 of the Personal Data (Privacy) Ordinance (Cap. 486). The Department of Health may impose a fee for complying with a data access request.

Enquiries

4. Enquiries concerning the personal data provided, including the request for access and correction, should be addressed to:
   Executive Officer (Programme Management and Vaccination Division)
   Address: Centre for Health Protection, Block A, 2/F, 147C Argyle Street, Kowloon
   Telephone No.: 2125 2045

Rev. 11/2021
Annex X  Sample of a COVID-19 Vaccination Record

**First Dose**

![COVID-19 Vaccination Record](image-url)
<table>
<thead>
<tr>
<th>第一針 1st Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>疫苗名稱 Vaccine Name</td>
</tr>
<tr>
<td>生產商 / 批號 Manufacturer / Lot No.</td>
</tr>
<tr>
<td>灌藥日期 Injection Date</td>
</tr>
<tr>
<td>灌藥地點 Injection Premises</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>第二針 2nd Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>疫苗名稱 Vaccine Name</td>
</tr>
<tr>
<td>生產商 / 批號 Manufacturer / Lot No.</td>
</tr>
<tr>
<td>灌藥日期 Injection Date</td>
</tr>
<tr>
<td>灌藥地點 Injection Premises</td>
</tr>
</tbody>
</table>

Ref: TC21A13-1766-1 請妥善保存 Keep this record properly Printed on 13-Oct-2021 14:17
<table>
<thead>
<tr>
<th>第一針 1st Dose</th>
<th>2019冠狀病毒病疫苗 (克爾來福)</th>
<th>CoronaVac COVID-19 Vaccine (Vero Cell), Inactivated</th>
</tr>
</thead>
<tbody>
<tr>
<td>名稱</td>
<td>Vaccine Name</td>
<td>Sinovac / A2021010022</td>
</tr>
<tr>
<td>生產商 / 批號</td>
<td>Manufacturer / Lot No.</td>
<td></td>
</tr>
<tr>
<td>接種日期</td>
<td>Vaccination Date</td>
<td>2021年10月13日 / 13-Oct-2021</td>
</tr>
<tr>
<td>接種地點</td>
<td>Vaccination Premises</td>
<td>Community Vaccination Centre, Hong Kong Central Library (Exhibition Gallery)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>第二針 2nd Dose</th>
<th>2019冠狀病毒病疫苗 (克爾來福)</th>
<th>CoronaVac COVID-19 Vaccine (Vero Cell), Inactivated</th>
</tr>
</thead>
<tbody>
<tr>
<td>名稱</td>
<td>Vaccine Name</td>
<td>Sinovac / A2021010022</td>
</tr>
<tr>
<td>生產商 / 批號</td>
<td>Manufacturer / Lot No.</td>
<td></td>
</tr>
<tr>
<td>接種日期</td>
<td>Vaccination Date</td>
<td>2021年10月13日 / 13-Oct-2021</td>
</tr>
<tr>
<td>接種地點</td>
<td>Vaccination Premises</td>
<td>Community Vaccination Centre, Hong Kong Central Library (Exhibition Gallery)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>第三針 3rd Dose</th>
<th>2019冠狀病毒病疫苗 (復必泰)</th>
<th>Comirnaty COVID-19 mRNA Vaccine (BNT162b2) Concentrate for Dispersion for Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>名稱</td>
<td>Vaccine Name</td>
<td>BioNTech / BNT202000001</td>
</tr>
<tr>
<td>生產商 / 批號</td>
<td>Manufacturer / Lot No.</td>
<td></td>
</tr>
<tr>
<td>接種日期</td>
<td>Vaccination Date</td>
<td>2021年10月13日 / 13-Oct-2021</td>
</tr>
<tr>
<td>接種地點</td>
<td>Vaccination Premises</td>
<td>Community Vaccination Centre, Hong Kong Central Library (Exhibition Gallery)</td>
</tr>
</tbody>
</table>

Ref: TC21A13-1767-3 請妥善保存 Keep this record properly Printed on 13-Oct-2021 14:23
Annex XI  Report on Cases Referred to Hospital

NOTIFICATION TO CENTRAL MEDICAL TEAM
REPORT ON CASES REFERRED TO HOSPITAL

(RESTRICTED)

To: Central Medical Team
From: __________________________ (RCH)

Email: duty_smo_cmt@cshb.gov.hk

Name: ________________________ (Doctor/RCH staff)

Tel: __________________________

CVP_CC_Dean_Department@cshb.gov.hk

Date: ________________________

Report on Cases Referred to Hospital  (To be completed by Visiting Medical Officer)

Points to Note:
- For all cases which required medical attention and referral to hospital, VMO should inform
  the Central Medical Team after immediate management by phone (2104 5233); followed by
  this written Report on Cases Referred to Hospital.
- The completed form should be returned to the Central Medical Team by email
  (duty_smo_cmt@cshb.gov.hk and duty_nurse_cmt@cshb.gov.hk) and
  CVP_CC_Dean_Department@cshb.gov.hk) or fax (2217 3079) as soon as possible and within
  the same day after the incident.

I. Particulars of the person who was referred to hospital

Name: _______________________ Sex: _____ Age: _______ ID number: ____________

Date sent to hospital (dd/mm/yyyy): _______________ Time (24 hr format): ____________

Hospital (if known): __________________________________________________________

Reason(s)/Preliminary Diagnosis:

II. COVID-19 vaccine given to the person on the day

☐ Vaccine Not given

☐ Vaccine given
  • Name of COVID-19 vaccine: ___________________________ (☐ First dose  ☐ Second dose)
  • Time given: ___________________________ am/pm

III. Details

Details of event:

Symptoms & Time of onset:
NOTIFICATION TO CENTRAL MEDICAL TEAM
REPORT ON CASES REFERRED TO HOSPITAL
(RESTRICTED)

Others:

<table>
<thead>
<tr>
<th>IV. Management provided at Residential Care Home</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>V. Condition of the patient on leaving Residential Care Home</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awake / Verbal / Pain / Unresponsive *</td>
</tr>
<tr>
<td>-----------------------------------------</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>VI. Information given to relatives (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>VII. Other information if applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>VIII. Reporter’s Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name (in Full): Mr / Ms_________</td>
</tr>
<tr>
<td>Phone:_________________________</td>
</tr>
<tr>
<td>Email:_________________________</td>
</tr>
<tr>
<td>Port: Please tick the appropriate box below:</td>
</tr>
<tr>
<td>☐ Doctor</td>
</tr>
<tr>
<td>☐ Nurse</td>
</tr>
<tr>
<td>☐ Pharmacist / dispenser</td>
</tr>
<tr>
<td>☐ Clerk</td>
</tr>
<tr>
<td>☐ Other healthcare professionals; please specify:</td>
</tr>
</tbody>
</table>

Name of Residential Care Home: ____________________________
Name of Visiting Medical Officer: ___________________________
Date: ___________________________ (dd/mm/yyyy) Time (24 hr format): ______ : _______
Annex XII  Clinical Incident Notification Form

COVID-19 Vaccination at Residential Care Home under RVP
CLINICAL INCIDENT NOTIFICATION FORM

(RESTRICTED)

Case Number (assigned by PMVD):  

<table>
<thead>
<tr>
<th>Points to Note:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Clinical Incident is defined as any events or circumstances (i.e. with any 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 service</td>
</tr>
<tr>
<td></td>
<td>Clinical incident could be notified by any staff</td>
</tr>
<tr>
<td></td>
<td>It is not required to get all details confirmed to make a notification</td>
</tr>
<tr>
<td></td>
<td>Notification should be made as soon as possible (by phone to PMVD at 21252125) and followed by fax (Fax Number: 27136916) or email in form of with password encrypted file (Email: <a href="mailto:coxwi20_rvp@dh.gov.hk">coxwi20_rvp@dh.gov.hk</a>) after completion of this form, within the same working day upon discovery of (suspected) incident</td>
</tr>
<tr>
<td></td>
<td>A follow up full investigation report by the Visiting Medical Officer should be submitted within 1 week upon discovery of (suspected) incident</td>
</tr>
</tbody>
</table>

I. Brief Facts

Name of RCH involved:  

Date of discovery (dd/mm/yyyy):  

Time (24 hr format):  

Date of occurrence (dd/mm/yyyy):  

Time (24 hr format):  

Place of occurrence:  

- At the residential care home  
- Others, please specify:  

Stage of care when incident occur:  

- Pre-vaccination  
- During vaccination  
- Post-vaccination  

Number of vaccine recipient(s) affected:  

Demographics of clients affected:

<table>
<thead>
<tr>
<th>Person (1, 2, 3 …)</th>
<th>Gender (M/F)</th>
<th>Age</th>
<th>Type of harm/ injury</th>
<th>Level of injury as per initial assessment by medical team (M, 1, 2, 3) (See Annex II)</th>
<th>Consequence (e.g. referred to AED/ other specialties/ repeat or additional procedure and investigation, etc.)</th>
<th>Name and batch of vaccine involved</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>


1
COVID-19 Vaccination at Residential Care Home under KVP
CLINICAL INCIDENT NOTIFICATION FORM

(RESTRICTED)

Summary of the incident: (including what happened, how it happened, and what actions were taken etc. Do not put in any personal information of the persons affected in the incident. And Do not put in any name, post or rank of staff involved in the incident.)

Any property damage?  □ Yes, details: __________________________
  □ No

II. Reporter’s Information

Name (in Full): Mr / Ms: __________________________  □ Doctor
                                                     □ Nurse
Phone: __________________________  □ Pharmacist/ dispenser
Email: __________________________  □ Clerk
                                             □ Other healthcare professionals, please specify:

Name of organisation/ service provider: __________________________________________________________

Name of VMO: __________________________________________________

Date: __________________________ (dd/mm/yyyy)  Time (24 hr format): __________

Classification of level of injury

<table>
<thead>
<tr>
<th>Level of Injury</th>
<th>The level of injury is defined as follows</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level M</td>
<td>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).</td>
</tr>
<tr>
<td>Level 1</td>
<td>No or minor injury was resulted AND additional investigation or referral to other specialty (including AED) was required for the client.</td>
</tr>
<tr>
<td>Level 2</td>
<td>Significant injury was resulted AND additional investigation or referral to other specialty (including AED) was required for the client.</td>
</tr>
<tr>
<td>Level 3</td>
<td>Significant injury was resulted AND resulted in death or arrest or requiring resuscitation or permanent loss of function was resulted or expected.</td>
</tr>
</tbody>
</table>
Annex XIII Clinical Incident Investigation Report

COVID-19 Vaccination at Residential Care Home under RVP
CLINICAL INCIDENT INVESTIGATION REPORT
(RESTRICTED)

Case Number (assigned by PMVD): 

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 affected / staff involved in the incident

I. Brief Fact:

Name of RCH involved: 

Date of discovery (dd/mm/yyyy): 

Time (24 hr format): 

Date of occurrence (dd/mm/yyyy): 

Time (24 hr format): 

Place of occurrence: 
- At the residential care home
- Others, please specify 

Stage of care when incident occur: 
- Pre-vaccination
- During vaccination
- Post-vaccination

Number of vaccine recipient(s) affected: 

Demographics of clients affected:

<table>
<thead>
<tr>
<th>Person (1, 2, 3 ...)</th>
<th>Gender (M/F)</th>
<th>Age</th>
<th>Type of harm/injury</th>
<th>Level of injury as per initial assessment by medical team (1, 2, 3) (See Annex II)</th>
<th>Consequence (e.g., referred to AED/ other specialities/ repeat or additional procedure and investigation, etc.)</th>
<th>Name and batch of vaccine involved</th>
</tr>
</thead>
</table>

Summary of the incident: (including what happened, how it happened)
**COVID-19 Vaccination at Residential Care Home under RVP**

**CLINICAL INCIDENT INVESTIGATION REPORT**

(RESTRICTED)

<table>
<thead>
<tr>
<th>Actions taken for this incident:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Remedial measures to prevent future similar occurrences:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other recommendations and comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Reporter’s Information**

Name (in Full): Dr _______________________
Phone: _________________________________
Email: _________________________________
Date: _______________________________________________________________________

---

2
Annex XIII Claim form for additional allowance

<table>
<thead>
<tr>
<th>摘要</th>
<th>数目</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 院内於最後完成講座／諮詢當日的入院人數：</td>
<td>(人)</td>
</tr>
<tr>
<td>(ii) 提供健康講座／諮詢服務的詳情如下：</td>
<td></td>
</tr>
<tr>
<td></td>
<td>服務日期</td>
</tr>
<tr>
<td>提供服務日期</td>
<td>提供健康講座／諮詢服務的詳情如下：</td>
</tr>
<tr>
<td></td>
<td>健康講座（可包括檢視醫療／健康紀錄）</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>(iii) 為院友及／或其家屬提供服務總時數 2</td>
<td>小時</td>
</tr>
<tr>
<td>(iv) 申報津貼總額（每小時港幣 $800 元）</td>
<td>合計港幣 元</td>
</tr>
</tbody>
</table>

| 列診時醫生聲明： |  |
| 本人在此申領表填報的所有資料均屬真實及正確，並明白及同意此文件會交予衞生署批閱及發放津貼。 |  |
| 醫生姓名： | 醫生簽署： |
| 醫生註冊編號： | 電話號碼： |
| 日期： |  |

| 院舍經辦者／主管聲明： |  |
| 本人已審視上述資料均屬正確，並明白及同意此文件會交予衞生署批閱及發放津貼。 |  |
| 姓名： | 簽署： |
| 職位： | 電話號碼： |
| 查核日期： | 院舍印制： |

1. 為院友及／或其家屬免費提供有關康健飲食的健康講座／諮詢服務。講座／諮詢可以小組或一對一形式並透過電話或電郵處理。

2. 為服務時數以實際提供健康講座／諮詢服務的時間計算，惟不能超過「講座／諮詢津貼」指引第 3(b)項的指定上限，服務時數最少每 30 分鐘為單位，如逾 30 分鐘則以港幣 400 元計算。
Annex XIV Supplementary sheet on the recommendation for third
dose COVID-19 Vaccination
To encourage fellow citizens to receive COVID-19 vaccination, eligible persons with valid Hong Kong identity cards may bring along this leaflet to one of the listed Community Vaccination Centres or Hospital COVID-19 Vaccination Stations for BioNTech vaccination. No prior booking is required*.

This is to certify the following resident is considered suitable to receive BioNTech vaccination.

<table>
<thead>
<tr>
<th>Name</th>
<th>Date of Birth</th>
<th>Sex</th>
</tr>
</thead>
</table>

*It is recommended to have a minimal interval of at least 14 days between administration of BioNTech vaccine and any other vaccine.

Signature of Visiting Medical Officer

Name of Visiting Medical Officer

Date
<table>
<thead>
<tr>
<th>Center Name</th>
<th>Address</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioTech Community Vaccination Center*</td>
<td>Address</td>
<td>Contact Information</td>
</tr>
<tr>
<td>BioTech Hospital COVID-19 Vaccination Unit*</td>
<td>Address</td>
<td>Contact Information</td>
</tr>
</tbody>
</table>

*Address and contact information provided for vaccination centers located in Hong Kong. Each center may have specific operating hours and requirements. For the most up-to-date information, please visit the official website or contact the vaccination center directly.