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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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 https://www.covidvaccine.gov.hk/en/

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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/.

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 residents and staff of RCHs. The Government would reimburse injection fees to VMOs for each dose of vaccination administered to eligible persons.

1.4 For residents and 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, please visit the below link for the latest information:


(a) Indications

- CoronaVac is indicated for active immunization against diseases caused by SARS-CoV-2 virus in individuals aged 18 and above.

(b) 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.

(c) 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.

(d) Contraindications

- 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.

(e) Precautions

i) If a vaccine recipient is with the following condition(s), please consider making referral to specialists in Immunology and Allergy for assessment before vaccination:

- Suspected allergic reaction(s) to prior COVID-19 vaccination
- History of anaphylaxis or at risk of anaphylaxis
- History of severe immediate-type allergic reactions to multiple foods or more than one class of drugs

(Please refer to Clause 2.1.6 for making referral to the Vaccine Allergy Safety Clinic of Hospital Authority)

ii) 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.

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

iv) 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.

v) 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.

vi) 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.

vii) Intramuscular injection of this vaccine may cause bleeding, it should be used with caution in patients with thrombocytopenia or hemorrhagic diseases.

viii) 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.

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

x) 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.

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

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

xiii) 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.

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

xvi) 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.

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

2.1.4 The Scientific Committee on Emerging and Zoonotic Disease and Scientific Committee on Vaccine Preventable Diseases (JSC) 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 (https://www.chp.gov.hk/en/static/24008.html). Some key recommendations on COVID-19 vaccination regime are highlighted below:

   i. According to Sinovac, the vaccination schedule of 2 doses administered at 28 days apart is currently recommended.
   ii. Currently, there is limited information on the safety, immunogenicity and efficacy of receiving vaccine outside the recommended schedule. If more than 28 days have elapsed, the second dose should be given as soon as possible. There is no need to repeat the series.

Individuals are advised to complete both doses of the series with the same product when possible.

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.

COVID-19 vaccination for individuals exposed to SARS-CoV-2

There is currently no evidence on the safety and efficacy of COVID-19 vaccination as post-exposure prophylaxis.

COVID-19 vaccination for persons with previous COVID-19 infection

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.

Please refer to Clause 6.6 for the vaccination arrangement for this group of people.

COVID-19 vaccination for elderly

Elderly is the group with highest risks of complication and death from COVID-19 disease. COVID-19 vaccines are highly recommended for the elderly.

Any elderlies who have received influenza vaccines before can safely receive COVID-19 vaccines. For the frailest elderlies, the benefit versus risk may have to be carefully weighed.

Administration with other vaccines

For the frailest elderlies, the benefit versus risk may have to be carefully weighed.
It is suggested to have an interval of at least 14 days between administration of seasonal influenza vaccine and COVID-19 vaccines.

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.

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

i. persons with allergic reaction after the 1st dose of COVID-19 vaccine;
ii. persons with history of multiple drug allergy; or
iii. persons with History of anaphylaxis or at risk of anaphylaxis

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 are as follows:

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 follows:

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

| Vaccine Allergy Safety Clinic at Queen Mary Hospital |
|-----------------|--------------------------------------------------|
| Address:        | 6/F., S Block, Queen Mary Hospital, 102 Pokfulam Road, Hong Kong |
| Tel. No.:       | 2255 4186                                         |
| Fax No.:        | 2255 3018                                         |
| Service Hours:  | Mon to Fri: 09:00 to 17:00; Sat: 09:00 to 13:00 |

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. 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 are eligible to receive free COVID-19 vaccination under this programme.

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 1st dose or the 2nd dose of COVID-19 Vaccination. No extra payment shall be payable just for the 2nd 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 1st dose or 2nd 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.
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](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

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 in Annex IV before using the Smart ID Card Readers at RCHs.

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 and 25-32mm length needles, should be immediately available for managing anaphylaxis (to be supplied by DH);
(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
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 and 2nd 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 working 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 V).

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.

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 1 – CHP poster of “Hand Hygiene 5 Moments in Hospital or Clinic Settings”):

(a) Before touching a patient
(b) Before clean / aseptic procedure
(c) After body fluid exposure risk
(d) After touching a patient
(e) After touching patient surroundings
5.2.2 Hand hygiene with proper hand rubbing by using soap and water or alcohol-based handrub for at least 20 seconds and 7 steps of hand hygiene techniques should be performed in between each and after last vaccination. (Refer to Figure 2 - CHP poster of “7 steps on hand hygiene”)
5.2.3 Clean hands with liquid soap and water when hands are visibly soiled or likely contaminated with body fluid.

5.2.4 When hands are not visibly soiled, 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 setting**

6.1 **Preparation before the day of vaccination**

- **Obtain the summary return** from RCH
  - List of residents consented to receive CoronaVac (Annex VII)
  - List of mentally incapacitated residents who could not give consent (Annex VIII)
  - List of staff consented to receive CoronaVac (Annex IX)

- **Conduct preliminary assessment for residents** to screen for contraindications

- **Confirm with RCH**
  - Number of consented residents and staff eligible for vaccination
  - Vaccination schedule for both 1st and 2nd doses
  - Adequate fridge capacity for storing the vaccines

- **Order vaccines** using the web-based ordering system

- **Liaise with RCH on clinical waste management**

- **Prepare emergency equipment**, and ensure medical consumables are available at RCH for use on the vaccination day
6.2 Vaccination at RCH and Post-vaccination follow up

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

Conduct **pre-vaccination assessment**

**Verify identity** of vaccine recipients

**Confirm/Obtain informed consent from residents/staff**

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, keep the recipients under observation for **30 minutes** and provide emergency management when necessary

Report AEFI(s) and clinical incidents, if any

Update with RCH for the subsequent vaccination schedule e.g. rescheduling for those excluded in the pre-vaccination assessment
6.3 Workflow for vaccination of residents

6.3.1 Obtain the summary return from RCH

6.3.1.1 Information provision and obtaining informed consent

(a) Before vaccination, RCH staff would assist in providing vaccine recipients, guardians and/ or relatives with the fact sheet (Annex I) of the relevant COVID-19 vaccine with information about potential side effect, authorised and not registered status of the vaccines, and vaccine-related adverse events following immunisation (AEFI).

(b) Informed consent should be obtained from the recipient or legal guardian for vaccination, the access and use of recipient’s personal data by the DH, Hospital Authority and relevant organizations collaborated with the Government; for the purpose of continuous monitoring of the safety related to the COVID-19 vaccination for the recipient under the COVID-19 vaccination programme.

(c) RCH staff would collect written consent forms (Annex VI) from residents or legal guardians, and would communicate with relatives to collect their preference on the choice of COVID-19 vaccine for those residents who are mentally incapacitated. A consent form is required for each of the two doses of vaccination.

(d) Based on the above, RCH staff would compile a list of residents consented to receive CoronaVac (Annex VII) and a list of mentally incapacitated persons unable to give consent (Annex VIII).

(e) If the resident has any contraindications to CoronaVac known to the RCH staff, the RCH staff would indicate such on the above lists. The lists would be passed on to the VMO for conducting preliminary assessment.

6.3.2 Conduct preliminary assessment

6.3.2.1 Vaccination history of recipients and their eligibility status should be verified.

(a) 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. VMO cannot make claim for vaccination subsidy if the recipient has previously received the vaccinations;

(b) As residents of RCH 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;
(c) Inspect the vaccination records on vaccination cards (if any);
(d) Ask recipients and/or their relatives for vaccination history.
(e) Should the vaccine recipient already received the first dose of COVID-19 vaccine outside Hong Kong, second 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;

For such cases, vaccinator 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) in Section 6.3.6.6 (j), while the vaccine provided by the vaccinator should be entered as the second dose in eHS(S).

6.3.2.2 VMO should check for any contraindications and precautions, and assess the suitability of residents to receive the COVID-19 vaccine by all means, such as checking the resident’s medical record via Electronic Health Record Sharing System (eHRSS), contacting RCH staff or relatives and conducting onsite assessment. The VMO should allow questions and answer enquiries from residents/legal guardians/relatives.

6.3.2.3 For residents with uncontrolled severe chronic disease, VMO should defer vaccination and reassess when the resident’s chronic disease is in better
6.3.4 **Confirmation with RCH and vaccine ordering**

6.3.4.1 After preliminary assessment, confirm with RCH for the residents eligible for receiving COVID-19 vaccine, vaccination schedule for both the 1st and 2nd dose, adequate fridge capacity for storing the vaccines before placing the order.

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

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

6.3.5 **Medical consumables and emergency equipment**

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

**On the day of vaccination**

6.3.6 **Before vaccination**

6.3.6.1 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.

6.3.6.2 The VMO should conduct pre-vaccination assessment to confirm the eligibility of recipients, with special attention paid to precautions including those residents presented with acute illness on the day of vaccination with assistance from RCH.

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

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

6.3.6.5 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.

6.3.6.6 The following information would be prefilled or required to be input into the vaccine recipient’s page (Refer to Figure 3- Sample of eHS(S) Vaccine Recipient’s Page):

(a) Practice
(b) Name of vaccination scheme (Chosen from pull down menu)
(c) Injection date
(d) Type of recipient (Choose Residents)
(e) RCH code
(f) RCH name
(g) Vaccine (name and brand)
(h) Lot number (The batches of COVID-19 vaccines delivered may have different lot numbers, VMO should check the lot number of vaccines for each vaccine recipient and select a correct lot number from the pull down manual to ensure accuracy of the vaccination record.)
(i) Dose sequence
(j) 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.)
6.3.6.7 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.

6.3.6.8 The VMO/qualified or 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.

6.3.6.9 The VMO/qualified or trained healthcare 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.

6.3.7 During vaccination

6.3.7.1 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.

6.3.7.2 Exposing the vaccines to disinfectant should be avoided.

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

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

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

6.3.7.6 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)

6.3.8 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. Dateback 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 X) and provided to the resident. 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 VI), 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 IX) 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 4- 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.)
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 VMO should have written protocol and training materials in place for quick and convenient reference.

6.5.4 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. Monitor blood pressure and pulse every 5 minutes and stay with patient until ambulance arrives

6.5.5 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).

6.5.6 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 XI) 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 protection. The recommendations can be accessed via https://www.chp.gov.hk/files/pdf/consensus_interim_recommendations_on_the_use_of_covid-19_vaccines_in_hk_may_06_21.pdf.

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_EN)
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 5 when HKID is used to retrieve the vaccine recipient’s page on eHS(S).
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 6 when healthcare personnel try to save the vaccination record.
Figure 6 - 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.

(c) For persons who have recovered from previous COVID-19 infection and have already received one dose of COVID-19 vaccine, a pop-up alert would be displayed as shown in Figure 7 when healthcare personnel try to save the vaccination record. The checkbox under the “Verification Checklist” would also be dimmed and healthcare personnel would not be able to save the vaccination record.
(d) 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.

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.
7. Clinical waste management

7.1.1 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).

7.1.2 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.

7.1.3 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).

7.1.4 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.

7.1.5 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.

7.1.6 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.

7.1.7 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 immunisation

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 Grade 1 (mild), the incidence rate of adverse reactions for Grade 3 and the

\(^1\) Vaccine Safety Basics by WHO (https://vaccine-safety-training.org/classification-of-aefis.html)
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\(^2\) adverse events, even if the adverse event is well known;
(b) Suspected drug interactions including vaccine-drug and vaccine-herb interactions;
(c) Non-serious adverse events but the adverse events are deemed medically significant by the healthcare professional (e.g. increased frequency or unusual presentation of a known adverse event);

\(^2\) 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)
(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

9.1.1 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.

9.1.2 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 residents as soon as possible and make necessary arrangements.

9.1.3 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.

9.1.4 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 XII). 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.

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

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

9.1.7 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

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</tr>
<tr>
<td>Annex III</td>
<td>Checklist of Items during Onsite Inspection</td>
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<td>Annex VI</td>
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<td>Annex VII</td>
<td>List of Residents Consented to Receive CoronaVac</td>
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<td>Annex VIII</td>
<td>List of Mentally Incapacitated Residents Who Could Not Give Consent</td>
</tr>
<tr>
<td>Annex IX</td>
<td>List of Staff Consented to Receive CoronaVac</td>
</tr>
<tr>
<td>Annex X</td>
<td>Sample of a COVID-19 Vaccination Card</td>
</tr>
<tr>
<td>Annex XI</td>
<td>Report on Cases Referred to Hospital</td>
</tr>
<tr>
<td>Annex XII</td>
<td>Clinical Incident Notification Form</td>
</tr>
<tr>
<td>Annex XIII</td>
<td>Clinical Incident Investigation Report</td>
</tr>
</tbody>
</table>
Annex I Fact Sheet on COVID-19 Vaccination (To vaccine recipient)

之克爾來福®

- 本疫苗基礎免疫为2次，間隔28天；每次免疫剂量为0.5 ml。
- 接種後Centre為2次，間隔28天；每次免疫剂量为0.5 ml。
- 接種目標為2次，間隔28天；每次免疫剂量为0.5 ml。

可能出現的副作用

<table>
<thead>
<tr>
<th>副作用</th>
<th>可能影響嚴重比例</th>
</tr>
</thead>
<tbody>
<tr>
<td>十分常見</td>
<td>&gt;10%</td>
</tr>
<tr>
<td>常見</td>
<td>1% - 10%</td>
</tr>
<tr>
<td>少見</td>
<td>&gt;0.1%</td>
</tr>
<tr>
<td>十分少見</td>
<td>&lt;0.01%</td>
</tr>
</tbody>
</table>

接種疫苗後的異常事件報告

若在接種24小時後注射部位的腫紅或腫脹增加，或若你的副作用使你擔心，又或副作用似乎不會在幾天內消失，請聯繫你的醫生。

編輯人員的提示：

如您認為在接種疫苗後出現嚴重的異常事件，請將反饋轉介到醫院。

更多有關疫苗及副作用資訊，請瀏覽網站：
https://www.gov.hk/covid-19/vaccination/
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 ("AEI") 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 AEI to the DH if they consider that the AEIs may be associated with the vaccination.

For continuously monitoring 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 AEI that is deemed medically significant to DH for further action and assessment.

Please allow the healthcare professional to report the AEI, 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 AEI 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/epdo/ehc/healthcare_providers/aei_reporting/index.html

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

For further information on the vaccines and side effects, please visit the website at

www.covidvaccine.gov.hk

☐ I have read and understood all information as provided in the factsheet and the Statement of Purpose 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 (a) my / my child / my ward* personal data contained herein and (b) my / my child / my wards 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

Version date: 12 July 2021 Please refer to online version for most updated information.
COVID-19 Vaccine (Vero Cell), Inactivated

This is the Conditional Marketing Authorization, please refer to the instruction and use under the doctor guidance.

Annex II Package Insert of CoronaVac (detailed edition)
59
COVID-19 Vaccine (Vero Cell), Inactivated (Brief Edition)

This is the Conditional Marketing Authorization, please refer to the instruction and use under the doctor guidance.

[NAME OF THE MEDICAL PRODUCT]
Generic Name: COVID-19 Vaccine (Vero Cell), Inactivated
Trade Name: CoronaVac
Chinese Phonetic Alphabet: Xinxiang Guanzhong Bingdu Miehuyimin (Vero Xibao)

[COMPOSITION]
Active ingredient: Inactivated SARS-CoV-2 Virus (CZ02 strain)
Adjuvant: Aluminium hydroxide
Excipients: disodium hydrogen phosphate dodecahydrate, sodium dihydrogen phosphate monohydrate, sodium chloride,

[DESCRIPTION]
CoronaVac is a milky-white suspension. Stratifed precipitate may form which can be dispersed by shaking.

[TARGET GROUPS FOR VACCINATION]
Susceptible people aged 18 and above.
In Brazil, phase III clinical trials (only 5,10% participants enrolled was 60 years and above, hence, the efficacy evidence of people aged 60 and above is insufficient). The subsequent clinical trials will be carried out for further evaluation of efficacy in this population. Data from conducted clinical trials showed that neutralizing antibodies would be induced after vaccination. When use CoronaVac among people aged 60 and above by relevant institutions, the health status and exposure risk of people aged 60 and above shall be considered.

[THERAPEUTIC INDICATION]
CoronaVac is indicated for active immunization against diseases caused by SARS-CoV-2 virus. Based on the efficacy results for two months from overseas phase III clinical trial, a conditional marketing authorization (CMA) for CoronaVac has been issued. The final efficacy data are not yet available; hence, the efficacy and safety results need to be further confirmed.

[PRESENTATION]
Each vial (syringe) contains 0.5 mL. Single dose of 0.5 mL contains 600S.U. 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, 0.5 mL per dose. CoronaVac should be administered by intramuscular injection in the deltoid region of the upper arm, Shake well before use.

[ADVERSE REACTIONS]
The safety of CoronaVac was evaluated in 4 clinical trials conducted domestic and overseas, including randomized, double-blind, placebo-controlled phase III clinical trials in people aged 18-69 years and in elderly aged 60 years and above, a phase II clinical efficacy trial in Brazilian health professionals aged 18 years and above, and a phase III bridging trial in different production scales and different trials. Systematic safety observation was carried out within 7 days after each vaccination, and adverse events were collected by voluntary report of subjects and regular follow-up of investigators on 14/28 days. Long-term of serious adverse events within 12 months after the full vaccination is still ongoing.

General description of adverse reactions in clinical trials and post-authorization experience of this product
A total of 14,527 patients aged 18 and above were enrolled in a series of clinical trials conducted domestic and overseas, of which 7,658 subjects received at least one dose, all subjects have completed at least 28 days follow-up after full immunization, and long-term safety visits are ongoing.

According to the grading standard of adverse reaction incidence from Council for International Organizations of Medical Sciences (CIOMS), i.e., very common (≥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 were summarized and described as follows,

1. Adverse reactions at injection site
   Very common: pain
   Common: swelling, pruritus, erythema, induration
   Uncommon: burn at injection site

2. Systemic adverse reactions
   Very common: headache, fatigue
   Common: myalgia, nausea, diarrhea, arthralgia, cough, chills, pruritus, loss of appetite, rhinorrhea, sore throat, nasal congestion, abdominal pain
   Uncommon: vomiting, hypersensitivity, abnormal skin and mucosa, fever, tremor, flushing, edema, dizziness, drowsiness
   Rare: muscle spasms, edema, edema, nose [nose] epistaxis, abdominal distension, constipation, hyposmia, ocular congestion, hot flashes, hiccups, conjunctivitis
   Very rare: Bell’s palsy
   + Adverse reaction observed post-approval in Hong Kong

3. Severity of adverse reactions
   The severity of adverse reactions observed in these clinical trials is mainly Grade 1 (mild). The incidence rate of adverse reactions for Grade 3 and above was 1.21%.
   Grade 3 and above adverse reactions includes pain at injection site, cough, fever, headache, sore throat, abdominal pain, dizziness and drowsiness,

4. Serious adverse event (SAE)
   No serious adverse event related to vaccination was identified up to February 3, 2021.
   For detailed information of adverse reactions among these clinical trials, please refer to the complete version of the product.

[CONTRAINDICATIONS]
1. People with history of allergic reaction to CoronaVac or other inactivated vaccine, or any component of CoronaVac (active or inactive ingredients, or any material used in the process);
2. Previous severe allergic reactions to the vaccine (e.g., acute anaphylaxis, anaphylactoid, dyspnea, etc.);
3. People with severe neurological conditions (e.g., transverse myelitis, Guillain-Barré syndrome, demyelinating diseases, etc.).

SINOVAC
4. Patients with uncontrolled severe chronic diseases;
5. Pregnant and lactating women.

[PRECAUTIONS]
1. Due to the insufficient data of protection persistence, necessary protective measures should be taken in line with the COVID-19 pandemic.
2. Due to the insufficient data of efficacy in people aged 60 and above. When use CoronaVac among people aged 60 and above by relevant institutions, the health status and exposure risk of people aged 60 and above shall be considered.
3. This vaccine is strictly prohibited for intravenous injection. There is no safety and efficacy data of subcutaneous or intradermal injection.
4. Before use, check whether the packaging container, label, 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 expose CoronaVac to the disinfectant during use.
6. This product should be stored at places out of reach of children.
7. Adequate treatment provisions, including epinephrine injection and emergency treatment, should be available for immediate use. Individuals should be observed for at least 30 minutes on site after vaccination.
8. Do not mix with other vaccines in the same syringe.
9. Do not freeze, it shall be administered immediately after open.
10. Patients with acute diseases, acute exacerbation of chronic diseases, severe chronic diseases, atopy and fever should be used with caution, if necessary, delay vaccination after doctor's evaluation.
11. Patients with diabetes, or history of convulsions, epilepsy, encephalopathy or mental illness, or family history of those diseases should be used with caution.
12. Patients with thrombocytopenia or hemorrhagic diseases, intramuscular injection of this product may cause bleeding, so it should be used with caution.
13. 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.
14. The injection of human immunoglobulin in children should be given at least one month interval to avoid affecting the immune effect.
15. 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). Professionals should be consulted when concomitant use.
16. Do not use if there is any adverse reaction of nervous system after inoculation.
17. Like other vaccines, the protective effect may not reach 100% for all recipients.

[SPECIAL POPULATION MEDICATION]
1. Women of childbearing age, the data collected 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.
2. Pregnant or lactating women: the clinical data of pregnant and lactating women are not available at present.
3. Children 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]
1. 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).
2. Concomitant use with other drugs: immunosuppressive drugs, such as immunosuppressive drugs, chemotherapy drugs, antimitabolic drugs, all the antiviral drugs, corticosteroid drugs, etc., may reduce the immune response to this product.
3. 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 +2~8°C, and protect from light.

[ SHELF LIFE] The shelf life of the vaccine is tentatively scheduled as 12 months.

[PACKAGE] This product is packaged into vials, 40 vials per box.

[SPECIFICATION IMPLEMENTED] YB00152021

[MARKETING AUTHORIZATION HOLDER]
Name: Sinovac Life Sciences Co., Ltd.
Registered address: Building 1, No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing, P.R., China

[MANUFACTURER]
Name: Sinovac Life Sciences Co., Ltd.
Address: No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing, P.R., China
Postal code: 102601
Tel: 86-10-56897188
Fax: 86-10-56897123
Website: www.sinovac.com
E-mail: sinovac@sinovac.com

SINOVAC
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 Guidelines for Smart HKID Card Reader Setup

Then, this popup page will show for doctors to download the guide and software:

Guide to install new software for reading Smart ID Card

Steps:
1. Please click the link to download the installation guide and software. Please follow the guide to install.
2. After installation, please login the eHealth System (Subsidies) again to run the new software.
# Annex V Daily Fridge Temperature Chart

## 2019 冠狀病毒病疫苗接種計劃 — 院舍外展接種安排

貯存疫苗的雪櫃溫度檢查表

1. 請於接種前連續七天（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（請參考運送疫苗及貯存須知）。
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。

注：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，並應將疫苗立刻存放在攝氏+2至+8度的雪櫃。
2. 請聯絡衛生署項目管理及疫苗計劃科。

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

*第一劑／第二劑 (科興疫苗)  1/2

<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>最高</td>
<td>最低</td>
<td></td>
<td>姓名</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>職級</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>簽署</td>
</tr>
</tbody>
</table>

*請列明不適用者 (如不適用，请自行印签)
Annex VI Consent Form

2019 冠状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在適當位置加上“√”號及* 刪去不適用者。

第一部份：疫苗接種者個人資料 (以身份證明文件所載者為準)

姓名：
(英文) (姓氏) (名字)
(中文) (姓氏) (名字)
出生日期： 年/月/日 (日/月/年)

聯絡電話號碼：
香港居民身份證號碼：

身份證號號碼標記： □ A □ B □ C □ D □ E

簽發日期： 年/月/日 (日/月/年)
或 其他身份證明文件：
證件類別：
證件號碼：

第二部份：接種 2019 冠状病毒病疫苗同意書

接種 2019 冠状病毒病疫苗種類及劑次 (請在適當位置加上“√”號)

□ 信使核糖核酸疫苗 (復星醫藥／德國藥廠 BioNTech)
□ 滅活病毒疫苗 (科興控股 (香港) 有限公司)

接種劑次 (請在適當位置加上“√”號)

□ 第一劑 □ 第二劑

注意：接種疫苗種類只可選擇一類：接種兩劑疫苗須於接種每一劑疫苗填寫一份同意書。

□ 本人同意 (a) 政府為本人／本人的子女／受監護者 * 接種在 2019 冠状病毒病疫苗接種計劃下提供的 2019 冠状病毒病疫苗(詳情載於第二部)；及 (b) 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、相關醫療機構及醫務人員持有屬於本人／本人的子女／受監護者 * 的臨牀資料，以便衛生署根據有關透政及接種 2019 冠状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可查閱及使用。
### 第三部：2019 冠狀病毒病疫苗詳情

<table>
<thead>
<tr>
<th>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)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ 信使核糖核酸疫苗 (復星醫藥／德國藥廠 BioNTech)</td>
</tr>
<tr>
<td>□ 第一劑</td>
</tr>
</tbody>
</table>

### 第四部：聲明及簽署

<table>
<thead>
<tr>
<th>供年滿 18 歲或以上的疫苗接種者填寫</th>
</tr>
</thead>
</table>

本人已閱讀及明白有關詳列於第二部的 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 599 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[同意]接種上述 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。本人也完全理解本同意書和收集個人資料目的聲明中的義務和責任。

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（詳情載於第二部）；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）獲取及使用由醫院管理局、相關醫療機構及醫護人員持有關於本人的臨牀資料，以便衛生署持續監測接種 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獲取及使用的情況下才可獲取及使用。

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「收集個人資料目的聲明」所述的用途，本人備妥政府或會與我聯絡，以核實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：本人同意授權醫護人員及公職人員讀取儲存在本人香港特別行政區智能身份證晶片內的個人資料(只限香港身份證號碼、中英文姓名、出生成日期和香港身份證發行日期)，以供政府作「收集個人資料目的聲明」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（如不會讀寫，請印上指模）：

日期：


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二部的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599F章）第119條規定使用，並未根據《藥物管理條例》第138條在香港註冊及代表人士／受監護者／同行接種上述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。本人也完全理解本同意書和收集個人資料目的聲明中的義務和責任。

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／同行接種2019冠狀病毒病疫苗接種計劃下提供的2019冠狀病毒病疫苗（詳情載於第二部）；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、相關醫療機構及護理人員持有關於本人的子女／受監護者／同行的臨牀資料，以便衛生署持續監測與接種2019冠狀病毒病疫苗有關的健康狀況及臨牀事件，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／本人子女／受監護者的個人資料供政府用於「收集個人資料目的聲明」所述的用途。本人備悉政府或會與我聯絡，以核實有關資料及有關接種疫苗的安排。

適用於香港特別行政區居民身份證持有人：本人同意授權護理人員及公職人員讀取儲存在本人／本人子女／受監護者／香港特別行政區居民身份證晶片內的個人資料[只限香港身份證號碼／中英文姓名／出生日期和香港身份證發行日期]，以供政府作「收集個人資料目的聲明」所述的用途。

此同意書受香港特別行政區法律管限，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／簽署：

父母／監護人／姓名（中文）：

關係：

父母／監護人／香港居民身份證號碼：

聯絡電話號碼：

日期：

如疫苗接種者不是精神上無行為能力但不會讀寫，見證人須填寫以下資料

本人見證此同意書已在本人面前向疫苗接種者讀出及解釋。疫苗接種者有提出問題的機會。

見證人／簽署：

見證人姓名（中文）：

香港居民身份證號碼：
（只限英文及首3個數字）

聯絡電話號碼：

日期：

X X X
收集個人資料的目的的聲明

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。

收集個人資料的目的

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，以及執行和監督2019冠狀病毒病疫苗接種計劃，包括但不限於透過電子程式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) 作法律規定、授權或條例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。衛生署應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
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: ____________________________
(English) (surname) (given name)

Date of Birth: _______/_______/______ (DD/MM/YYYY) Gender: _______

Contact number: __________________ (mobile)

Hong Kong Identity Card No.: ___________ (HKIC)
HKIC Symbol: □ A □ C □ R □ U

OR Other identity document:
Document type: __________________
Document number: ________________

Part 2: Consent to Administration of COVID-19 Vaccination

Type and Dose Sequence of COVID-19 vaccination (Put a “✓” in the most appropriate box)

☐ mRNA Vaccine (Fosun Pharma/German drug manufacturer BioNTech)
☐ Inactivated Virus Vaccine (Sinovac Biotech (Hong Kong) Limited)

Dose Sequence of vaccination (Put a “✓” in the most appropriate box)

☐ First dose ☐ Second dose

Note: You can only choose one type of COVID-19 vaccine; a consent form is required for each of the two doses of 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 2); 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 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.
### 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)

<table>
<thead>
<tr>
<th>Type</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRNA Vaccine (Fosun Pharma/German drug manufacturer BioNTech)</td>
<td>First dose</td>
</tr>
<tr>
<td>Inactivated Virus Vaccine (Sinovac Biotech (Hong Kong) Limited)</td>
<td>Second dose</td>
</tr>
</tbody>
</table>

Category of vaccine recipient: ________________
Part 4  Declaration and Signature

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 2, 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 COVID-19 vaccine particularised in Part 2. 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 2); 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 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 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 finger print if illiterate#): __________________________________________

Date: __________________________________________
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 2, 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 2. 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 2); 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/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/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/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 no. of Parent/Guardian*:

Contact Telephone No.:

Date:
Witness should complete the following if the vaccine recipient is not mentally incapacitated but is illiterate:

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.

Signature of Witness: _____________________________
Name of Witness (in English): _____________________________
Hong Kong Identity Card No.: _____________________________
(only the alphabet and the first three digits are required)
Contact Telephone No.: _____________________________ Date: _____________________________

To be completed by Healthcare Provider

<table>
<thead>
<tr>
<th>eHS(S) Transaction No.</th>
<th>ONE Transaction Number ONLY</th>
</tr>
</thead>
<tbody>
<tr>
<td>T - - - - - - - - -</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vaccine log number</th>
<th>Date of Vaccination</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Place of Vaccination</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Name of Doctor</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Name of Vaccination Staff</th>
</tr>
</thead>
</table>
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 eHealth (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
Annex VII List of Residents 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新冠病毒病疫苗接種計劃」— 院舍外展接種安排
同意接種名單及摘要（科興疫苗）
接種疫苗名稱：科興控股（香港）有限公司 - 滅活病毒疫苗（下稱：科興疫苗）
科興疫苗（第__頁／共__頁）

甲部：同意接種科興疫苗院友名單 1

<table>
<thead>
<tr>
<th>院友姓名</th>
<th>身份證明文件號碼 A12345678X</th>
<th>如院舍知情院友有下列情況，請在適當位置加上“✓”號</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 包括安老院、殘疾人士院舍及護養院院友及附設於院舍的日間服務單位的服務使用者。
2 請院舍先取得院友同意將其個人資料按需要交予衛生署／相關的診療註冊醫生／管轄社區疫苗接種中心及其外展團隊／醫院管理局／社會福利署，以安排有關院友接種新冠疫苗事宜。
3 請院舍於接種當日填寫此欄並保存有關紀錄，以便衛生署及衛生署接種有關資料；須於2021年3月22日遞交此欄資料。
Annex VIII  List of Mentally Incapacitated Residents Who Could Not Give Consent
Annex IX List of Staff Consented to Receive CoronaVac

致：已聯繫的院舍防護注射計劃到診註冊醫生（專業號碼：___________）
院舍名稱：__________________________________________
院舍地址：__________________________________________

「2019冠狀病毒病疫苗接種計劃」－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

<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>
<td></td>
<td>有否接種該款「科興疫苗」（是/否）請註明原因。</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>第一劑（日期__________） 第二劑（日期__________）</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
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<td>9</td>
<td></td>
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<tr>
<td>10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

（如不敷應用，請自行影印）

院舍經理／營辦／主管簽署：______________
院舍經理／營辦／主管姓名：______________
院舍經理／營辦／主管職位：______________

日期：______________ （院舍印章）

---

1. 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. 請院舍在接種當日填寫此欄並保存有關記錄，以作為有關員工接種新冠疫苗的資料。
3. 請院舍在接種當日填寫此欄並保存有關記錄，以作為有關員工接種新冠疫苗的資料。
Annex X Sample of a COVID-19 Vaccination Record

First Dose
<table>
<thead>
<tr>
<th>Vaccine Name / Lot No.</th>
<th>COVID-19 vaccine (CoronaVac)</th>
<th>Lot No.: SNV2021000001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccination Date</td>
<td>21-01-2021</td>
<td></td>
</tr>
<tr>
<td>Vaccination Premises</td>
<td>Healthy Clinic</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaccine Name / Lot No.</td>
<td>COVID-19 vaccine (CoronaVac)</td>
<td>Lot No.: SNV2021000001</td>
</tr>
<tr>
<td>Vaccination Date</td>
<td>18-02-2021</td>
<td></td>
</tr>
<tr>
<td>Vaccination Premises</td>
<td>Healthy Clinic</td>
<td></td>
</tr>
</tbody>
</table>
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@csb.gov.hk
duty Nurse_cmt@csb.gov.hk
CVP CC Deputy Controller@csb.gov.hk

Name: ____________ (Doctor/ RCH staff)
Tel: __________________ 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 (2304 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@csb.gov.hk and duty nurse cmt@csb.gov.hk and
  CVP CC Deputy Controller@csb.gov.hk) or fax (2217 3978) 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:**

### IV. Management provided at Residential Care Home

### V. Condition of the patient on leaving Residential Care Home

<table>
<thead>
<tr>
<th>Awake / Verbal / Pain / Unresponsive *</th>
<th>Vital Signs: BP</th>
<th>Pulse</th>
<th>SaO2</th>
</tr>
</thead>
</table>

### VI. Information given to relatives (if applicable)

### VII. Other information if applicable

## VIII. Reporter’s Information

- **Name (in Full):** Mr./Ms. __________________________
- **Post:** Please tick the appropriate box below:
  - Doctor
  - Nurse
  - Pharmacist/Dispenser
  - Clerk
  - Other healthcare professionals; please specify: __________________________
- **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):

Notification Form for Suspected Clinical Incident

Points to Note:
- 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.
- Clinical incident could be notified by any staff.
- It is not required to get all details confirmed to make a notification.
- 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: covid19_rvp@dh.gov.uk) after completion of this form, within the same working day upon discovery of (suspected) incident.
- A follow up full investigation report by the Visiting Medical Officer should be submitted within 1 week upon discovery of (suspected) incident.

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>
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</tbody>
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COVID-19 Vaccination at Residential Care Home under RVP
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. ____________________________

Post: Please tick the appropriate box below:

□ Doctor

□ Nurse

□ Pharmacist/ dispenser

□ Clerk

□ Other healthcare professionals, please specify:

Email: ____________________________

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>
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</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>
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 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:

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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>
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<tr>
<th>Actions taken for this incident:</th>
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<tr>
<th>Remedial measures to prevent future similar occurrences:</th>
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</table>

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<tr>
<th>Other recommendations and comments:</th>
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</table>

<table>
<thead>
<tr>
<th>Reporter’s Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name (in Full): Dr __________________</td>
</tr>
<tr>
<td>Phone: ____________________</td>
</tr>
<tr>
<td>Email: ____________________</td>
</tr>
<tr>
<td>Date: ____________________</td>
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