

Interim Guidance Notes On Common Medical Diseases and COVID-19 Vaccination In Primary Care Settings

(As of **January 26, 2024**)

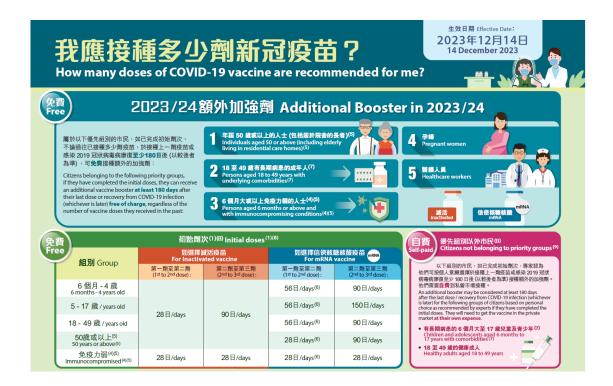
Introduction

Vaccination against COVID-19 is an important public health tool for containing the pandemic and returning to normalcy in Hong Kong. Under the Government Vaccination Programme, over 20 million doses of COVID-19 vaccines have been administered locally to persons aged 6 months to over 100 years old. The protective effect of COVID-19 vaccines is evident, with 87%-98% and 76%-94% reduction in mortality and severe complications respectively among adults who were vaccinated with three doses of vaccines. The local epidemic situation continues to subside. Nevertheless, individuals in particular infants and young children who have not received the first three initial doses of vaccine are strongly advised to get vaccinated as early as possible for self-protection.²

2. Vaccine recipients are recommended to receive age-appropriate vaccine according to the most updated schedule. Please refer to the thematic page on COVID vaccine for the latest recommendations: https://www.chp.gov.hk/en/features/106951.html.



衛生防護中心乃衛生署 轄下執行疾病預防 及控制的專業架構 The Centre for Health Protection is a professional arm of the Department of Health for disease prevention and control



- 3. Persons in the five priority groups* are urged to receive an additional dose of COVID-19 vaccine in 2023/24 at least six months since the last dose or infection as early as possible in view of the potential winter surge, regardless of the number of doses received previously.³ Any of the currently available vaccines (i.e. inactivated / mRNA ancestral vaccines or mRNA bivalent vaccine or XBB mRNA vaccine) should be used as they remain effective in preventing severe disease and death, and can provide timely boosting and protection ahead of the possible winter surge. As monovalent XBB mRNA vaccine confers modestly enhanced protection against circulating strains, experts considered XBB mRNA vaccine the preferred choice in appropriate age groups according to manufacturer's recommendation.³ Co-administration of COVID-19 vaccine and seasonal influenza vaccine is strongly recommended.
- 4. While the Scientific Committee on Emerging and Zoonotic Diseases and Scientific Committee on Vaccine Preventable Diseases and the Chief Executive's Expert Advisory Panel (JSC-EAP) would not make specific recommendation to every single COVID-19 vaccines registered in Hong Kong or overseas, doctors are reminded to make reference to vaccine manufacturers'

^{*} The five Priority Groups include: older adults aged 50 or above including those living in residential care homes, persons aged 18-49 years with underlying comorbidities, persons aged 6 months or above and with immunocompromising conditions, pregnant women and healthcare workers.



衛生署 Department of Health recommendations and conduct clinical assessment when providing any COVID-19 vaccination to their clients under informed consent.

5. For COVID-19 recovered persons, in general, they should take one dose less compared to uninfected persons. Recovered persons should receive the remaining doses according to the interval for the next dose. Details can be accessed at:

https://www.chp.gov.hk/files/pdf/factsheet_priorcovid19infection_eng.pdf

6. In line with the prevailing practice, eligible individuals should complete the initial two doses with the same product whenever possible. In situations where the vaccine recipient is unable to complete with the same type of vaccine (e.g. due to severe side effects, or if the vaccine is no longer available/accessible), vaccination with another COVID-19 vaccine may be considered on a case-by-case basis.

A. Common Medical Diseases and COVID-19 Vaccination

- 7. This part of the Interim Guidance Notes aims to assist primary care and relevant doctors on their assessment and optimization of patients with common medical diseases for the inactivated or mRNA COVID-19 vaccines provided under the Government Vaccination Programme. The information is based on expert opinion on the management of common clinical conditions.
- 8. Persons with contraindications for a type of COVID-19 vaccine should not receive that vaccine. Doctors should always take note of the package insert for the contraindications of COVID-19 vaccines. The package insert of the inactivated and mRNA COVID-19 vaccines provided under the Government Vaccination Programme are available at https://www.chp.gov.hk/en/features/106959.html. The contraindications for mRNA and inactivated COVID-19 vaccines includes:

Do not allow	For mRNA vaccine
vaccination, i.e. with contraindications	Persons who are allergic to its previous dose, or to the active substance or to any of the other ingredients of that mRNA COVID-19 vaccine.
	For inactivated vaccine Persons with: • history of allergic reaction to inactivated COVID- 19 vaccine or other inactivated vaccine; or any





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component of inactivated COVID-19 vaccine
(active or inactive ingredients, or any material used
in the manufacturing process); or
previous severe allergic reactions to vaccine (e.g.
acute anaphylaxis, angioedema, dyspnea, etc.); or
severe neurological conditions (e.g. transverse
myelitis, Guillain-Barré syndrome, demyelinating
diseases, etc.); or
uncontrolled severe chronic diseases

9. Subject to the modification of an individual's condition for suitability of vaccination, health service providers shall exercise clinical judgement to decide the best timing for vaccination with inactivated vaccine as below.

To <u>proceed</u> to vaccination	Persons without contraindications (including persons with stable chronic diseases can proceed to vaccination)
To defer vaccination, until medical condition is in better control	Persons with:

- 10. The **elderly** and individuals with **chronic diseases** have increased risk of morbidity and mortality from COVID-19 infection^{4,5} and are identified as high risk priority group for the 2023/24 additional booster. Unless with contraindications, COVID-19 vaccines are highly recommended for the elderly and individuals with stable medical diseases. Those who have received influenza vaccination before can safely receive COVID-19 vaccination.⁵
- 11. **Pregnant women** are at a higher risk of developing severe adverse outcomes following COVID-19 infection, when compared with non-pregnant population. COVID-19 also increases the risk of preterm birth by 2-fold and extended perinatal mortality by about 50%. Studies have shown that the COVID-19 vaccines are as effective at reducing the risk of hospitalization and deaths in pregnant women as they are in non-pregnant population. Women who are **planning pregnancy**, are pregnant, or are **breastfeeding** should be vaccinated with COVID-19 vaccine, unless contraindicated due to underlying medical reasons. Relevant advice from The Hong Kong College of Obstetricians and Gynaecologists is in the **Appendix 1**. Furthermore, pregnant women are





recommended to receive **another booster dose in 2023/24** at least six months after the last dose or COVID-19 infection (whichever is later).²

- 12. Serious illnesses may occur in **children** infected with influenza and/or COVID-19 who have not completed COVID-19 vaccination. To prevent severe illness, complications and death caused by influenza and/or COVID-19 and minimise subsequent long-term sequelae after infection, infants and young children should receive the recommended number of doses of COVID-19 vaccination as soon as possible and receive seasonal influenza vaccination annually to prevent the simultaneous attack of Influenza and COVID-19 infection. Please refer to **Appendix 1** for details of the Joint Statement endorsed by 13 medical and nursing societies.
- 13. Regarding management of some chronic diseases, health service providers could refer to local^{6,7} and overseas references^{8,9} in making clinical judgement. Some examples of the local references are the Reference Frameworks⁶ published Office by the Primary Healthcare https://www.healthbureau.gov.hk/pho/main/frameworks.html?lang=2 and the Joint Position Statement issued by the Hong Kong College of Paediatricians and Hong Kong Society for Paediatric Immunology Allergy and Infectious Diseases. 10 For conditions requiring specialist care, reference can be made to the advice of respective professional associations (please refer to the **Appendix 1** for details).
- 14. 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 can receive COVID-19 vaccination after 2 to 4 weeks if they are stable after the acute illnesses, or as soon as they are stabilized at a later According to The Hong Kong Neurological Society, COVID-19 vaccination can be considered in stable stroke patients one month or beyond from the stroke onset.





- 15. In particular, the following advice could be referenced for some common medical diseases.⁶ Professional judgement on a patient-by-patient basis has to be exercised as is always in the case of clinical practice.
- a) Diabetes Mellitus: Patients with stable clinical condition can proceed to vaccination. Reference for general management of diabetes mellitus in primary care settings can be available at https://www.healthbureau.gov.hk/pho/rfs/english/pdf_viewer.html?rfs=
 DiabetesCare&file=SummaryCharts. One can consider deferring vaccination, until better control is achieved, having regard to
 - HbA1c, fasting blood sugar, or
 - Adjusting drug dosage for better control, or
 - Newly develop acute symptoms of complications
- b) Hypertension: Patients with stable clinical condition can proceed to vaccination. References for the management of hypertension in primary care settings can be available at https://www.healthbureau.gov.hk/pho/rfs/english/pdf_viewer.html?rfs=HypertensionCare&file=SummaryCharts. One can consider deferring vaccination, until better control is achieved, having regard to
 - Systolic blood pressure, diastolic blood pressure, or
 - Adjusting drug dosage for better control, or
 - Newly develop acute symptoms of complications
- 16. 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.
- 17. COVID-19 vaccines can be co-administered concomitantly, or at any time before or after any other vaccines (including live attenuated vaccines) under informed consent. If clients or parents of children wish to space out COVID-19 vaccine with live attenuated vaccines, an interval of 14 days is sufficient.¹¹

B. Medical Exemption

18. This part of the Interim Guidance Notes[†] (see also **Appendix 3** for details) is intended to assist doctors in evaluating contraindications or precautions to

[†] This part of the document is based on recommendations from Part A of this Interim Guidance Notes, Interim Recommendations for the Use of COVID-19 Vaccines published by the World Health Organization (WHO) and overseas practices. ¹²⁻¹⁴ Reference is also taken from the package inserts of the respective COVID-19 vaccines and expert clinicians' advice.



衛生署 Department of Health COVID-19 vaccination that may warrant a medical exemption. Any registered medical practitioner under Part I and III of the General Register can issue a medical exemption certificate (**Appendix 2**). A contraindication is a situation where a vaccine should not be given as the risks outweigh any potential benefit. A precaution is a condition that may increase the risk of an adverse event following immunization or compromise the ability of the vaccine to produce an immune response, which may result in deferral of immunization. However, there may be circumstances where the benefits of vaccination outweigh the potential risks from vaccination associated with the condition or where reduced immunogenicity still benefits immunocompromised individuals.

- 19. In general, there are very few actual contraindications to available COVID-19 vaccines that would qualify as medical exemptions and most individuals can safely receive COVID-19 vaccines. Individuals who qualify for medical exemptions should be re-evaluated periodically by their attending doctor as new evidence or vaccine products become available. In many instances, safe administration of subsequent doses of COVID-19 vaccine is possible. True medical exemptions are expected to be infrequent. Examples of conditions that qualify as medical exemptions are outlined in Appendix 3.
- 20. The Department of Health would continue to engage professional input from academic and professional organizations to keep abreast of the latest development and update this guidance notes as need and as appropriate. Please refer to the Centre for Health Protection website (https://www.chp.gov.hk/en/features/106934.html) regularly for the latest updates of this Guidance Notes and other information.

Department of Health January 2024

This Interim Guidance Notes provides basic information and is not intended to provide or take the place of medical advice, diagnosis or treatment, or legal advice. In the event of any conflict between this document and any applicable emergency orders or directives of the HKSAR Government, the order or directives prevails.





This document[‡] is a living document which will be updated from time to time according to the latest development and continuous communication and consultation with relevant specialists, academic and professional organizations.

Date of previous versions
March 15, 2021
April 7, 2021
April 22, 2021
July 15, 2021
September 3, 2021
September 27, 2021
November 22, 2021
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February 14, 2022
February 21, 2022
March 2, 2022
March 9, 2022
March 20, 2022
April 26, 2022
June 22, 2022
August 12, 2022
September 2, 2022
August 9, 2023

[‡] This interim guidance notes should be read together with the documents of Consensus Interim Recommendations on the Use of COVID-19 Vaccines in Hong Kong, issued jointly by the Scientific Committee on Emerging and Zoonotic Diseases and Scientific Committee on Vaccine Preventable Diseases and the Chief Executive's Expert Advisory Panel, accessible via https://www.chp.gov.hk/en/static/24008.html.



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Appendix 1

<u>List of Advice from Respective Professional Associations</u>

Community living older adults. Residential care homes resident 14
The Hong Kong College of Obstetricians and Gynaecologists Pregnant and lactating women
The Hong Kong Society for Paediatric Immunology Allergy and Infectious Diseases, The Hong Kong Paediatric Society, Hong Kong Paediatric and Adolescent Dermatology Society, Hong Kong College of Paediatric Nursing and Hong Kong Paediatric Nurses Association Children and Adolescents 25
The Hong Kong Paediatric Society, the Macau Padiatric Society, The Hong Kong Chinese Medical Association Ltd, The Hong Kong Society for Paediatric Immunology Allergy and Infectious Diseases, The Hong Kong Society for Infectious Diseases, The Obstetrical and Gynaecological Society of Hong Kong, The Hong Kong Paediatric and Adolescent Dermatology Society, The Colleage of Nursing Hong Kong, The Hong Kong College of Paediatric Nursing, The Hong Kong Paediatric Nurses Association, Asian Medical Expert Academy, The Hong Kong Midwives Association, and The Hong Kong School Nurse Association Ltd Appeal to Infants, Children, Pregnant and Breastfeeding Women, Elderly and those with Chronic Diseases
The Hong Kong Institute of Allergy COVID-19 Vaccine Allergy Safety31
The Hong Kong Society of Transplantation Solid organ transplant recipient
The Hong Kong Association for the Study of Liver Diseases Patients with chronic liver disease
The Hong Kong Society of Rheumatology Patients with autoimmune rheumatic disease
Hong Kong Society for Paediatric Rheumatology Children with rheumatic conditions
The Hong Kong Society of Haematology Patients with anemia, thrombocytopenia, on anticoagulants or being immunocompromised
The Hong Kong Cancer Therapy Society Cancer patients or cancers in remission
The Hong Kong Society for Infectious Diseases and Hong Kong Society for HIV Medicine Patients living with HIV





The Hong Kong Lung Foundation, Hong Kong Thoracic Society and CHEST
Delegation Hong Kong and Macau
Patients with asthma or chronic obstructive airway disease
The Hong Kong College of Cardiology
Patients with cardiovascular diseases, or on anti-platelet drugs / anticoagulants







The Hong Kong Geriatrics Society Guidance on COVID-19 Vaccination for the community living older adults and those residing in residential care homes

Community living older adults

1. Why should older people get the vaccine?

According to the figures from the Centers for Disease Control and Prevention in the United States published in September 2021, compared with 18 to 29 years old, the rate of death is 570 times higher in those who are 85 years and older, 220 times higher in 75 to 84 years old and 90 times higher in 65 to 74 years old. [1]

2. Are the vaccines effective in old people?

The currently available COVID-19 vaccines in Hong Kong, BioNTech (Comirnaty) and CoronaVac (Sinovac) are highly effective, up to 85 to 97%, in preventing COVID-19 related hospitalization, critical disease and death among people 60 or above. [2,3]

3. Would the side effect be too much for an old person?

The side-effects of BioNTech, like pain, fatigue and myalgia, are typically mild to moderate, short lasting. These occur less frequently in older adults. Local and systemic side effects of CoronaVac are infrequent and it is well tolerated in older adults. [4 - 6]





4. Would getting the vaccine get my parent killed earlier?

There is no evidence suggestive of any unexpected or untoward increase in fatalities in older people following the use of BioNTech or CoronaVac after millions of doses given. Locally, no excess mortality, stroke or myocardial infarction were observed when compared with previous years, before COVID-19 pandemic. [7-9] The elderly who are fit for seasonal influenza vaccination are fit for COVID-19 vaccination. [10]

Residential care home residents

5. Why is vaccination even more worthwhile for residential care home residents?

Older persons living in residential care homes, being usually older, more frail and with more chronic illnesses, have the highest mortality rate. Among the cases involving residents of RCHEs, the mortality was up to 28%.[11] Vaccination is therefore of the highest life-saving potential in this group.

6. My relative doesn't go out of the care home at all, why should she get vaccinated?

As the environment in care homes also favours COVID-19 transmission, vaccination of individual resident is essential to protect oneself from infection, hospitalization and death.

7. If all the staff and family members have been vaccinated, why should my elderly relative still get the vaccine?

With the emergence of the delta variant, post-vaccination asymptomatic carriage and spread of the virus, and the unlikelihood of an immune barrier, vaccination appears to be one of the most effective means to safeguard individual older persons from hospitalization, critical illness and death. Vaccination is also an important prerequisite for the relaxation of visiting arrangements, which will improve the elderly resident's quality of life.

8. My relative has serious medical illnesses and has been hospitalized a lot in the past year, should he get the vaccine?

Your relative should receive COVID-19 vaccine if he is not having acute illness. [12] For older persons with severe frailty or terminal illness, the attending doctor should specially take note of the recent health condition and discuss with





the patient and relatives on the benefits and risks to attain for an informed decision on vaccination.

Recommendation:

• The benefit of COVID-19 vaccination certainly outweighs the risks of any side effects given the much higher hospitalization and mortality rate of this group. Elderly persons are thus highly recommended to receive COVID-19 vaccine.

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The Hong Kong College of Obstetricians and Gynaecologists advice on COVID-19 vaccination in pregnant and lactating women (interim; updated on 6th May 2022), collated via the Federation of Medical Societies of Hong Kong

(Please refer to the link https://www.hkcog.org.hk/hkcog/news_4_65.html for the latest version)

Data shows that vaccines are effective in protecting people from serious illness from COVID-19. Pregnant women are at a higher risk of developing severe adverse outcomes following SARS-CoV-2 infection, when compared with the non-pregnant population. COVID-19 also increases the risk of preterm birth by 2-fold and the extended perinatal mortality by about 50%.

Women who are planning to conceive, are pregnant, or are breastfeeding should be vaccinated with COVID-19 vaccine as the rest of the population, unless contraindicated due to underlying medical reasons.

Our consensus has been further strengthened by a recent review of studies conducted by the European Medicines Agency, involving around 65,000 pregnancies at different stages. The review has not identified any sign of an increased risk of pregnancy complications, miscarriages, preterm births or adverse effects in the fetuses following mRNA COVID-19 vaccination. Studies have also shown that the COVID-19 vaccines are as effective at reducing the risk of hospitalization and deaths in pregnant women as they are in the non-pregnant population. The most common side effects of the vaccines in pregnant women also match those in the overall vaccinated population. They include pain at the injection site, tiredness, headache, redness and swelling at the site of injection, muscle pain and chills. These effects are usually mild or moderate and improve within a few days of vaccination.

In addition, based on Scottish population-level data on COVID-19 vaccination in pregnancy, partially vaccinated and fully vaccinated pregnant women have a significant reduction in risk of acquiring SARS-CoV-2 infection (unvaccinated 77.4% vs partially vaccinated 11.5% vs fully vaccinated 11.1%), SARS-CoV-2 associated hospitalization (unvaccinated 19.5% vs partially vaccinated 8.3% vs fully vaccinated 5.1%) and SARS-CoV-2 associated critical care admission (unvaccinated 2.7% vs partially vaccinated 0.2% vs fully vaccinated 0.2%). Additional benefits relate to the reduction of preterm birth rate (unvaccinated 16.6% vs vaccinated 8.2%) and extended perinatal mortality rate (unvaccinated 22.6 per 1,000 births vs vaccinated 4.3 per 1,000 births). Pregnant and lactating women should be encouraged to have at least one dose of the COVID-19 vaccine.





Recent studies of COVID-19 vaccination during pregnancy also suggested benefits for the infants. Transplacental transfer of SARS-CoV-2-specific antibodies was documented following maternal vaccination in pregnancy. Between 96-98% of cord blood and all breast milk samples were positive for SARS-CoV-2 specific antibodies. In one longitudinal study, 57% of the infants still had the antibodies at 6 months of age. Recent data from 20 pediatric hospitals in the US demonstrated that completion of a two-dose mRNA COVID-19 vaccination series during pregnancy was associated with reduced risk for COVID-19-associated hospitalization among infants aged <6 months (vaccine effectiveness 61%, 95% CI 31% to 78%). Hence, maternal vaccination during pregnancy might help protect the newborn.

The choice of vaccine

Currently, there are two kinds of vaccines available in Hong Kong, namely Comirnaty (BioNTech) and Corona Vac (Sinovac). Comirnaty (BioNTech) is an mRNA vaccine, while CoronaVac (Sinovac) is an inactivated SARS-CoV-2 vaccine. The mRNA vaccine has been widely used worldwide. Hence, published data in pregnant and lactating women in the medical literature are largely based on the mRNA vaccine. There is limited safety data in pregnancy published for CoronaVac (Sinovac). 'Pregnancy and lactation' was previously listed as contraindications for CoronaVac (Sinovac). However, in principle, inactivated whole virus vaccines are considered safe in pregnancy. The World Health Organization has endorsed its use in pregnant and lactating women in their interim recommendations on 5th January 2022. In February 2022, the CoronaVac (Sinovac) company removed 'Pregnancy and lactation' from its 'Contraindications' list. CoronaVac (Sinovac) use in pregnant and lactating women is now authorised by the Hong Kong Government. While the efficacy and safety data of CoronaVac (Sinovac) will likely accumulate following its use, Comirnaty (BioNTech) remains as the preferred choice of vaccine for pregnant and lactating women by the HKCOG, based on the available published data.

Booster dose

Currently, the Royal College of Obstetricians and Gynaecologists (RCOG) in the United Kingdom and the Department of Health in Hong Kong all recommend that pregnant and lactating women receive a booster dose of COVID-19 vaccine 3 months after the second dose of their initial COVID-19 vaccine series.

Such recommendations are based on evidence that neutralizing antibodies against SARS-CoV-2 wane over time after the primary two-dose series. Further, the effectiveness of the COVID-19 vaccines in preventing disease and reducing viral loads of breakthrough infections has decreased, concomitantly with the rise of the Delta variant of SARS-CoV-2. Evidence on mRNA-based COVID-19 vaccines in non-pregnant individuals has demonstrated that a booster dose increases the antibody titers and restores neutralization. The booster dose has also been shown to effectively reduce the risks of symptomatic infection and severe complications including mortality. Booster vaccine efficacy is





consistent irrespective of age, sex, race, ethnicity, and comorbid conditions. The booster doses have adverse events similar to those seen in previous studies with no safety signal identified. These include injection site reactions, fever, vomiting, diarrhea, headache, fatigue, chills, muscle pain and joint pain.

The committee acknowledges that there is so far limited evidence on the efficacy and safety of the booster dose of COVID-19 vaccine in pregnant and lactating women. However, given the established efficacy and safety profile of the primary two-dose series, the efficacy and safety data of the booster dose is therefore expected to be comparable to that observed in non-pregnant women of similar age. We therefore support the recommendation of the Centre of Health Protection, Department of Health on the use of booster dose in pregnant and lactating women.

Pregnant women may wish to discuss the risks and benefits of vaccination with their clinician, including the latest evidence on its safety and which vaccines they should receive. The HKCOG COVID-19 Vaccination Committee will continue to closely monitor the evidence on COVID-19 vaccination in pregnancy and will update its advice as required.





FAQ

- 1. O: Do I need to take a pregnancy test before receiving the vaccine?
 - A: There is no need to take a pregnancy test before receiving the vaccine. However, if you wish to avoid being pregnant while receiving the full course of vaccination then you should consider appropriate contraception. If you are unsure whether you are pregnant, you may wish to wait for your period before receiving the first dose of the vaccine.
- Q: I am trying to become pregnant, can I be vaccinated?
 - A: You are recommended to complete the course of vaccination (2 doses received) before you become pregnant. This will reduce your risk of contracting the virus during pregnancy and therefore severe COVID-19-associated complications such as preterm birth.
- Q: What do I do if I become pregnant after receiving one dose of the vaccine?
 A: You should have the second dose after the recommended interval as scheduled.
 Similarly, we also recommend you to have the booster dose as scheduled during the pregnancy.
- Q: Does COVID-19 vaccine affects fertility?
 - A: There is no evidence to suggest that COVID-19 vaccines will affect fertility.
- 5. Q: After completing the course of vaccination, do I need to wait for a few months before becoming pregnant?
 - A: No, there is no need to wait to try to become pregnant.
- Q: I am pregnant, should I be vaccinated against SARS-CoV-2?
 A: Yes, you are advised to be vaccinated against SARS-CoV-2 at the same time as the rest of the population.
- Q: Which vaccine is recommended for pregnant women?
 - A: Both mRNA vaccine (Comirnaty/BioNTech) and inactivated SARS-CoV-2 vaccine (CoronaVac /Sinovac) are available for use. So far the published data on efficacy and safety for pregnant and lactating women in the medical literature are from the mRNA vaccine but not the inactivated vaccine. Hence, mRNA vaccine is preferred by the HKCOG.
- 8. Q: Do I need extra medical care if I get vaccinated during pregnancy? A: You will be given one day sick leave or attendance for the day you receive the vaccine. If you feel unwell following vaccination, you are advised to seek medical attention.
- Q: Do I need to tell the vaccination center or the attending nurse/ doctor that I am pregnant before the vaccination?
 A: Yes.





10. Q: When should I get vaccinated during pregnancy?

A: You are advised to be vaccinated at the earliest opportunity. As COVID-19 infection in pregnancy is more likely to be associated with severe symptoms and adverse outcome in the later part of pregnancy, vaccination during the first or second trimester is advisable. However, if you are already in your third trimester, you can still be vaccinated to minimise your risk of severe COVID-19.

11. Q: Does COVID-19 vaccine increase the risk of miscarriage?

A: There is no evidence to suggest that COVID-19 vaccine increases the risk of miscarriage. If you are concerned about the baby's development during the first 12 weeks of pregnancy, you may wish to be vaccinated after 12 weeks' gestation.

12. Q: What are the side effects from the vaccine?

A: Non-pregnant specific side effects from the vaccine are common, such as injection site reactions, headache, muscle pain, fever, chills, fatigue and joint pain. You are advised to seek medical attention if you feel unwell following vaccination in order to rule out other causes of your symptoms.

- 13. Q: Do I need to stop breastfeeding in order to be vaccinated?
 - A: There is no need to stop breastfeeding while being vaccinated.
- 14. Q: Are there any contraindications with maternal Pertussis vaccination or flu vaccination?

A: COVID-19 vaccines can be administered at the same time as other vaccines, including the Pertussis (DTaP) and flu vaccination.

15. Q: Can I receive a booster dose of the COVID-19 vaccine if I am pregnant?

A: If you have completed your initial COVID-19 vaccine series (either mRNA or inactivated vaccine) and did not have any serious side effects, you should get a booster dose of vaccine at the recommended interval.





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Joint Statement by The Hong Kong Society for Paediatric Immunology Allergy and Infectious Diseases, The Hong Kong Paediatric Society, Hong Kong Paediatric and Adolescent Dermatology Society, Hong Kong College of Paediatric Nursing and Hong Kong Paediatric Nurses Association on COVID-19 Vaccination for Children and Adolescents

"Recommendations in Relation to COVID-19 Vaccination Allergy"

Recent studies demonstrated that COVID-19 vaccines are immunogenic, highly effective and safe against COVID-19 for 6 months- to 17-year-old recipients. ¹⁻¹⁰ It is evident that the personal and societal benefits of COVID-19 vaccination to prevent severe illness, death and long-term complications outweigh the risks from serious allergic reactions to vaccines.

The conditions below are <u>not a contraindication</u> to COVID-19 vaccination and the individual would not require referral to a College-accredited PIAID Fellow for assessment before receiving vaccine:

- 1) Allergic history not to COVID-19 vaccines or their components, such as:
 - -unrelated vaccines/drugs,
 - -food.
 - -insect venoms,
 - -inhalant allergens (e.g., house dust mites, pollens, animal dander, moulds)
- 2) Asthma
- 3) Allergic rhinitis
- 4) Eczema
- 5) Chronic spontaneous urticaria

Referral of children and adolescents to evaluate for fitness to receive either BioNTech or CoronaVac vaccine by College-accredited PIAID fellow is recommended if they have the following conditions:

- 1. <u>For BioNTech</u>: Allergy (*immediate* and *severe**) to the active substance or any of the other ingredients of this medicine as stated in the fact sheet.
- For CoronaVac: History of allergic reaction (immediate and severe*) to other
 inactivated vaccine, or any component of CoronaVac (active or inactive ingredients,
 or any material used in manufacturing process as stated on the factsheet); previous
 severe allergic reactions to other vaccine (e.g., acute anaphylaxis, angioedema,
 dyspnea, etc.).





3. History of *immediate* and *severe* allergic reaction to the previous dose of BioNTech or CoronaVac vaccine.

* allergic reactions that are *immediate* and *severe*: "*immediate*" means within 1 hour; "*severe*" means occurrence of non-cutaneous adverse reactions (e.g., respiratory, cardiovascular or severe gastrointestinal);

Referrals for children and adolescents who fulfil the above criteria will be screened, possibly followed by further evaluation and diagnostic assessment, such as drug provocative / challenge test (by full dose or graded), by a College-accredited PIAID Fellow knowledgeable and equipped to provide full management in case of severe anaphylaxis. Children and adolescents who are diagnosed by a College-accredited PIAID Fellow to have highly suspected or confirmed COVID-19 vaccine allergy will be advised to receive the other type of COVID-19 vaccine, unless the child/adolescent and parent (or legally authorised representative) insist on receiving the same type of vaccine after full counselling and understanding of the risks and benefits, in which case a College-accredited PIAID Fellow would consider drug desensitisation to the vaccine.

We recommend that the following subjects require a 30-minute observation period after vaccination: 12

- Children with an allergic contraindication to a different type of COVID-19 vaccine (for example, people with an allergic contraindication to the BioNTech vaccine who receive CoronaVac vaccine should be observed for 30 minutes following CoronaVac vaccination);
- 2. Children with a history of drug or vaccine allergies unrelated to the COVID-19 vaccine or its component(s);
- 3. Children with a history of anaphylaxis due to any cause;
- 4. Mastocytosis

Clinicians administering COVID-19 vaccines should be prepared to recognise the signs and symptoms of allergic reactions as early as possible, promptly manage such allergic reactions and activate further emergency medical services while continuing to care for the patient. 13-17

18th February 2022

12th August 2022 (updated version)





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Pediatric Society, The Hong Kong Chinese Medical Association Ltd., The Hong
Kong Society for Paediatric Immunology Allergy and Infectious Diseases, The
Hong Kong Society for Infectious Diseases, The Obstetrical and Gynaecological
Society of Hong Kong, The Hong Kong Paediatric and Adolescent Dermatology
Society, The College of Nursing Hong Kong, The Hong Kong College of
Paediatric Nursing, The Hong Kong Paediatric Nurses Association, Asian
Medical Expert Academy, The Hong Kong Midwives Association and The Hong
Kong School Nurse Association Ltd.

"Sincere Appeal to Infants, Children, Pregnant and Breastfeeding Women, The Elderly and Those with Chronic Diseases to Receive The 2023/24 Seasonal Influenza Vaccine Before Christmas. They Should Also Complete / Update Their COVID-19 Vaccination And Maintain Good Personal and Environmental Hygiene to Prevent Severe Diseases, Acute Complications, Hospitalisation, Death, and Medium and Long-term Sequelae Caused by the Simultaneous Attack of "Mycoplasma Pneumoniae" and "Respiratory Viruses"

A series of anti-epidemic measures in response to the COVID-19 epidemic, such as wearing face masks, frequent hand washing and maintaining social distance, have greatly reduced influenza and other respiratory virus infections. The antibodies and immunity against respiratory viruses among people of all ages have also correspondingly much decreased. This "Immunity Debt" situation is very serious. In fact, this can explain the phenomenon of sequential infections in the population by various and numerous types of respiratory viruses, such as seasonal influenza, respiratory syncytial virus, adenovirus, parainfluenza virus, etc.

Mycoplasma pneumoniae infections have been on the rise recently. Because of its unique biological characteristics and long replication time, a delayed emergence is observed in different parts of the world after countries lifted their COVID-19 prevention measures. Although the problem of mycoplasma pneumoniae antibiotics resistance in neighboring regions is a concern, and there is currently no vaccine against mycoplasma pneumoniae, the public can rest assured that doctors in Hong Kong and Macau have mastered the diagnosis and treatment of mycoplasma pneumoniae. If the public maintains good personal and environmental hygiene (Reference 1.), mycoplasma pneumoniae infection outbreaks can be controlled (Reference 2. – 4.). On the other hand, the "Twindemic" and / or "Tridemic" caused by "seasonal influenza", "COVID-19" and other respiratory viruses (such as respiratory syncytial virus, etc.) are even more worrying today.

There is enough scientific evidence to show that simultaneous infection with influenza virus and COVID-19 will lead to more severe illnesses (Reference 5.). Members of the





public must not underestimate the risk of being infected with multiple respiratory viruses at the same time. High-risk groups, such as pregnant women, infants and young children, the elderly or people with chronic diseases, are more likely to suffer from severe illness, acute complications and death if they are infected with influenza and COVID-19 at the same time.

Influenza vaccines and COVID-19 vaccines are clinically very effective, and serious adverse vaccine reactions are quite rare, so parents and caregivers need not to worry. Parents and caregivers should no longer hesitate and should vaccinate infants and young children with the 2023/24 seasonal influenza vaccine and complete the COVID-19 vaccine* as soon as possible to prevent the simultaneous attack of Influenza and COVID-19 infection in the coming Winter. The flu vaccine and the COVID-19 vaccine can be given at the same time. (Reference 6.) Elderly people and individuals with chronic illnesses should also receive the 2023/24 seasonal influenza vaccine and complete the COVID-19 vaccine* at the same time as soon as possible.

Antibodies in the mother's body can be transferred to the fetus and infant through the placenta and breast milk. Therefore, pregnant, and breastfeeding women should also be vaccinated against influenza and COVID-19 as to protect themselves, their fetuses and newborn babies from the serious consequences of influenza and COVID-19 virus infections.

Children, adolescents, and adults recovered from COVID-19 should complete COVID-19 vaccination* to prevent severe illnesses and complications.

The Hong Kong Paediatric Society, The Macau Pediatric Society, The Hong Kong Chinese Medical Association Ltd, The Hong Kong Society for Paediatric Immunology Allergy and Infectious Diseases, The Hong Kong Society for Infectious Diseases, The Obstetrical and Gynaecological Society of Hong Kong, The Hong Kong Paediatric and Adolescent Dermatology Society, The College of Nursing Hong Kong, The Hong Kong College of Paediatric Nursing, The Hong Kong Paediatric Nurses Association, Asian Medical Expert Academy, The Hong Kong Midwives Association and The Hong Kong School Nurse Association Ltd. jointly issue this "Sincere Appeal to Infants, Children, Pregnant and Breastfeeding Women, The Elderly and Those with Chronic Diseases to Receive The 2023/24 Seasonal Influenza Vaccine Before Christmas . They Should Also Complete / Update Their COVID-19 Vaccination* And Maintain Good Personal and Environmental Hygiene to Prevent Severe Diseases, Acute Complications, Hospitalization, Death, and Medium and Long-term Sequelae Caused by the Simultaneous Attack of "Mycoplasma Pneumoniae" and "Respiratory Viruses"

*Complete COVID-19 vaccination = To receive the number of doses of COVID-19 vaccination as recommended by the Scientific Committee on Vaccine Preventable Diseases, Centre for Health Protection, Department of Health, Hong Kong SAR Government (Reference 7.- 10.).

18th December 2023





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Kong (As of 6th June 2023)

https://www.chp.gov.hk/files/pdf/consensus_interim_recommendations_on_the_use_of_covid19_vaccine s_in_hong_kong_6iun.pdf





The Consensus Statements on COVID-19 Vaccine Allergy Safety (VAS) from the Hong Kong Institute of Allergy

The consensus statements is available at

https://www.allergy.org.hk/doc/Consensus%20Statements%20Updates%20on%20COVID19%20VAS%20(2021.08).pdf



Updated Consensus Statements on COVID-19 Vaccine Allergy Safety in Hong Kong



Valerie Chiang, Agnes S. Y. Leung, Elaine Y. L. Au, Marco H. K. Ho, Tak Hong Lee, Adrian Y. Y. Wu, Gary W. K. Wong and Philip H. Li



- People with a history of immediate-type allergic reaction with systemic symptoms to prior COVID-19 vaccination should not receive further COVID-19 vaccination until Allergist evaluation.
- People with a history of non-immediate type allergic reaction to prior COVID-19 vaccination which required medical attention should seek Allergist advice prior to further COVID-19 vaccination.
- People with a history of severe immediate-type allergy to multiple classes of drugs may have an undiagnosed excipient (such as polyethylene glycol (PEG)) allergy and they may be vaccinated with a non-PEG-containing vaccine[^].
- Allergy testing with PEG or PEG-containing surrogates appear to be poorly predictive and should not be routinely performed. In cases where these tests are used, results should be interpreted in the context of a detailed clinical history by an Allergist.



- Patients with allergic rhinitis, asthma, atopic dermatitis, chronic urticaria, drug and food allergies, and anaphylaxis unrelated to COVID-19 vaccines (without other precautions) do not need to see an Allergist for evaluation of COVID-19 vaccine allergy risk.
- Healthcare providers should be sufficiently prepared to recognize and treat allergic reactions properly, with adrenaline and antihistamines available.
- When an immediate-type allergic reaction following COVID-19 vaccination is suspected, blood for serum tryptase should be saved from 30 minutes to 4 hours (preferably within 2 hours) of symptom onset.



People should be routinely observed for at least 15 minutes after COVID-19 vaccination. Those at higher risk of COVID-19 vaccine associated allergic reactions should be observed for at least 30 minutes after vaccination.

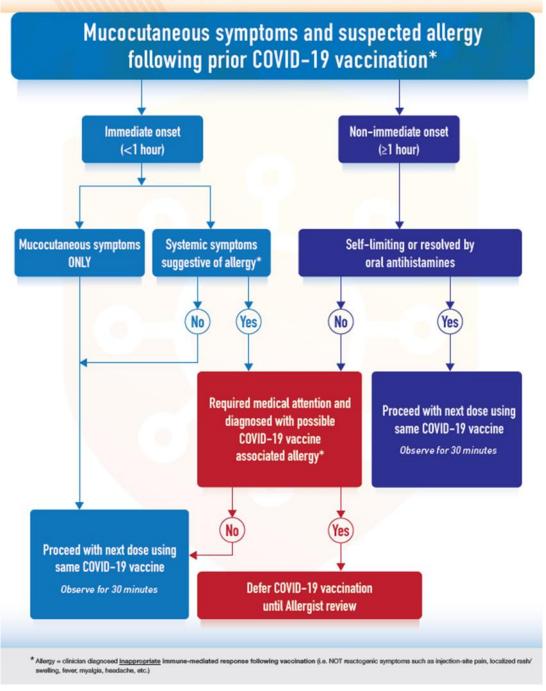


- Full excipient lists should be mandated and made available in all product inserts of registered drugs.
- ^ Individuals with strong preference to receive PEG-containing vaccines may consider referral to an Allergist. Children, for whom non-PEG-containing vaccines are ourrently unavailable, may follow advice of a Paediatric Allergist.





Updated Consensus Statements on COVID-19 Vaccine Allergy Safety in Hong Kong









Statement from Hong Kong Society of Transplantation on COVID-19 vaccine in solid organ transplant recipients, collated via the Federation of Medical Societies of Hong Kong

Solid organ transplant (SOT) recipients are vulnerable and they are prone to develop complications when having COVI-19 infection.

COVID-19 vaccination in solid organ transplant recipients

Vaccination is a highly effective means to prevent COVID-19 infection and reduce risk of developing complications and death. Based on current evidence, we recommend SOT recipients to receive COVID-19 vaccine. However, the immune responses to COVID-19 vaccine in immunocompromised individuals, such as SOT recipients, are diminished compared with the general population.

Shall SOT recipients receive booster vaccination?

The protection from primary COVID-19 vaccine series can wane in around 4-6 months. Based on current evidence, we recommend SOT recipients to receive booster vaccination. <u>The advisory Panel on COVID-19 Vaccines recommends persons with immunocompromising conditions aged six months who have completed the initial doses of COVID-19 vaccine, to receive another booster in 2023, at least 6 months after the last dose or COVID-19 infection (whichever is later).</u>

Shall SOT recipients receive bivalent vaccine?

Bivalent vaccine is designed against both the original strain and the more contagious omicron variant of virus. SOT recipients can consider receiving bivalent vaccine.

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Guidance notes from the Hong Kong Association for the Study of Liver Diseases, collated via the Federation of Medical Societies of Hong Kong

Scenario: What if I have chronic liver diseases?

- Patients with chronic liver diseases (CLD) like cirrhosis, hepatocellular carcinoma
 are at risk of severe COVID-19 infection. However, patients with advanced CLD,
 receiving immunosuppressive therapy and liver transplant recipients have not been
 included in most of the vaccine studies and as such data on effectiveness and safety
 are lacking in these populations. Therefore, there are large knowledge gaps in
 various areas related to liver disease and vaccination that require further studies for
 clarification.
- Based on current knowledge, there is no evidence to contradict the safety and immunogenicity of currently approved vaccines in patients with CLD and hepatobiliary cancer. Adult persons with stable CLD should consider receiving COVID-19 vaccine unless they are having the contraindications as stated by the pharmaceutical companies or the Department of Health.
- Currently, there are insufficient data to recommend one vaccine over the other in patients with CLD.
- Patients with CLD who are receiving antiviral therapy for HBV or HCV or medical therapy for primary biliary cholangitis or autoimmune hepatitis should continue these medications for their liver disease as usual and NOT withhold their medications while receiving the COVID-19 vaccines. Patients with hepatocellular carcinoma undergoing locoregional or systemic therapy should also be considered for vaccination without interruption of their treatment. However, patients with recent infections or fever should not receive the COVID-19 vaccine until they are medically stable.
- All patients with CLD, including vaccine recipients, should continue to mitigate their risk of SARS-CoV-2 exposure, such as masking, social distancing and hand washing.
- COVID vaccination is a rapidly evolving area and the recommendation in patients with CLD may also change with time. If in doubt, please discuss with your doctor before vaccination.





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Guidance Notes from the Hong Kong Society of Rheumatology, collated via the Federation of Medical Societies of Hong Kong

General comments regarding COVID-19 vaccination

- Patients with autoimmune diseases may have weakened immune systems due to their illnesses or medication, and they might be at increased risk for severe COVID-19.
- There is no absolute contraindication for vaccination in patients with autoimmune rheumatic diseases, though the current data regarding safety and efficacy is limited.
- In general, patients with autoimmune rheumatic diseases should be encouraged to receive COVID-19 vaccination, as the benefit from protection exceeds the potential risk of adverse reactions to vaccines.
- It is preferable to give the vaccination when the disease is stable (i.e. in a quiescent phase).
- Please follow the precautions/ guidelines accordingly if you have other co-existing medical conditions.
- If you have specific questions on your personal conditions or drugs that you are using, please consult your rheumatologist.
- Patients with autoimmune rheumatic diseases should continue current guidance and precautions to protect themselves against COVID-19 after vaccination as they may have reduced immune response to the vaccine.









Hong Kong Society for Paediatric Rheumatology Consensus Statement on BNT162B2 mRNA Vaccine in Children with Rheumatic Conditions in Hong Kong, collated via the Federation of Medical Societies of Hong Kong

Background:

On 10 May 2021, the U.S. Food and Drug Administration (FDA) amended the emergency use authorization for the Pfizer COVID-19 vaccine, allowing it to be given to children between 12 and 15. Before this, the vaccine could be administered only to individuals aged 16 or above. Emergency use authorization (EUA) is not the same as FDA approval, which typically takes much longer to obtain. A EUA is used to make treatments like vaccines available during public health emergencies, such as the COVID-19 pandemic.

Consensuses are obtained among local paediatricians taking care of rheumatology patients. The statements made are based on the most recent researches available and from the consensus or recommendations from various international bodies of the rheumatology societies. Because of the heterogeneity of paediatric rheumatic diseases and treatment options, these consensus statements are not intended to replace or supersede individual clinical judgement. Furthermore, the statements are not to override the values and perspectives of the rheumatology patients or their parents. Paediatricians are encouraged to engage their patients and discuss the COVID 19 vaccination through a shared-decision making process.

Statement 1: Rheumatic diseases alone are not observed to post children a higher risk of developing COVID 19 infection or having a more severe disease course.

So far, since the start of the pandemic, most children with COVID 19 infection exhibit only mild to moderate symptoms. In general, children with rheumatic diseases are not at a higher risk of contracting COVID 19 or developing a more severe disease ^{1,2,3,4}.





Statement 2: Children are at risk of developing Multisystem Inflammatory Syndrome (MIS) associated with COVID 19 infection.

There are reports of previously healthy children who developed multisystem inflammatory syndrome related to prior COVID 19 infection. It could be severe and even fatal ⁵.

Statement 3: COVID 19 is best prevented by vaccination in addition to stringent infection control measures.

It is now clear that infection control measures alone, namely social distancing, hand hygiene and wearing a face mask, is not enough to prevent one from acquiring the infection.

Statement 4: The BNT162B2 mRNA vaccine is effective and safe in adolescent aged 12 or older.

It was demonstrated in a clinical trial that the use of the BNT162B2 mRNA vaccine in adolescent aged 12 or above is both safe and effective in preventing COVID 19 infection⁶. Apart from offering protection against COVID 19 infection and its potential complications, it can also contribute to the herd immunity necessary to eliminate the pandemic.

Statement 5: Children with stable rheumatic diseases and currently not taking any medications are recommended to receive the vaccine as usual, provided there is no contradiction as stated by the vaccine manufacturer ^{7,8,9,10}.

Statement 6: Children with a stable rheumatic condition and currently under treatment, including NSAIDs, corticosteroid, Disease-Modifying Anti-Rheumatic Drugs (DMARDs), biological DMARDs, or immunosuppressants, are <u>not</u> contraindicated for receiving this vaccine ^{7,8,9,10}.

Given the concomitant immunomodulating or immunosuppressing agents, there are concerns that the efficacy of the vaccines might be compromised. Current data shows that the mRNA vaccine in the adult with rheumatic diseases is safe and can elicit an immune response. The use of medication including DMARDs, biological DMARDs or immunosuppressants did not lead to particular safety concern ^{7,8,9,10}.





Statement 7: Children currently taking multiple DMARDS, including corticosteroid, are encouraged to discuss the vaccination with their rheumatology health care providers. An adjustment to the medication schedule may be considered in individual patient.

Theoretically, the level of immune response to a vaccine may be diminished in those receiving immunosuppressive treatment. There are also recent reports that the immune response after COVID 19 vaccination may be lower in patients with inflammatory conditions, and the use of some immunosuppressive drugs may further influence that^{7,9}. Therefore, there are recommendations on rescheduling the timing of specific immunosuppressive agents. However, a lower antibody response may not be equivalent to lower vaccine efficacy. The practice of withholding treatment temporarily before or after the COVID 19 vaccine has not been fully investigated. We are not sure whether this can boost the immune response to the COVID vaccine. On the contrary, people with unstable disease may have a theoretical risk of flare. Hence, patients need to discuss with their rheumatology care providers for advice before vaccination^{7,8,9,10}.

Statement 8: A flare of rheumatic disease or an increase in vaccine-related side effects were not observed excessively in stable rheumatic patients who received the vaccine.

Given that worldwide mass vaccination is only rolled out for less than a year, despite flare or excessive side effects were not observed in the rheumatology patient cohorts, we have to be cautious about the long-term safety data. This watchful attitude, however, does not undermine our recommendation for COVID 19 vaccination during this pandemic⁷. The beneficial effect has outgrown the theoretical risk.

Statement 9: It remains vital to continue stringent infection control measures whether or not one has been vaccinated against COVID 19, as the protection may not be perfect.

Statement 10: Household members or carers in close contact with rheumatic patients should consider taking the COVID 19 vaccine to facilitate the cocooning effect that may help to protect the patients.





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Draft at 24 June 2021







Guidance notes from the Hong Kong Society of Haematology, collated via the Federation of Medical Societies of Hong Kong

Scenario: Can I receive COVID-19 vaccine if I have anaemia?

There is no contraindication for patients with chronic anaemia to receive COVID-19 vaccine.

The adult thalassemia patients with iron overload, sickle cell diseases are encouraged to receive COVID-19 vaccine because these patients are prone to the complications of SARS-CoV-2 infection.

Scenario: Can I receive COVID-19 vaccine if I am on warfarin or direct oral anticoagulant?

Individuals receiving warfarin in therapeutic range or direct oral anticoagulant (dabigatran, apixaban, rivaroxaban and edoxaban) or heparin can receive the COVID-19 vaccine.

After the intramuscular injection of the COVID-19 vaccine, prolonged direct pressure lasting for 5 minutes or more should be applied to the injection site to reduce bleeding or bruising.

Scenario: Should immunocompromised patients receive COVID-19 vaccine?

Immunocompromised patients are recommended to receive COVID-19 vaccine. The benefits far outweigh the potential side effects of vaccine.

If the patient is receiving or has received immunosuppressive therapy of B-cell depletion, consider vaccination 3-6 months after the patient has been taken off therapy to increase the likelihood of developing immunity.





If patients has undergone hematopoietic stem cell transplantation (HSCT), inactivated vaccines are generally started after 3-6 months after HSCT.

Scenario: Can I receive COVID-19 vaccine if I have thrombocytopenia?

COVID-19 vaccination is recommended to patients with platelet count more than $30 \times 109 / L$. In patients with platelet count less than $30 \times 109 / L$, the attending physician can consider increasing the platelet count with medications, especially non-immunosuppressive agents before vaccination.

Similar to other vaccines, COVID-19 vaccine could potentially cause recurrence or worsening of immune thrombocytopenia in rare instances, but the benefits of vaccination outweighs the risks.

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Latest Update of COVID-19 Vaccination for Patients Living with Cancer & FAQ (April, 2022 Edition) by The Hong Kong Cancer Therapy Society, collated via the Federation of Medical Societies of Hong Kong

Latest Update of COVID-19 Vaccination for Patients Living with Cancer & FAQ (April, 2022 Edition)

By The Hong Kong Cancer Therapy Society (HKCTS)

Since our last update of the COVID-19 vaccination dated 28th February, 2022 in the midst of high waves of the 5th wave of the COVID-19, and the HKCTS Council has been closely monitoring the progress and evolution of the COVID-19 situation as well as updates of the COVID-19 vaccination from the Centre for Health Protection.

As we enter the month of April, the COVID-19 local situation is coming under much better control with the concerted effort of everyone. By reviewing the latest data and knowledge available with regular review and updates, and in response to the latest update from the "Consensus Interim Recommendations on the Use of COVID-19 Vaccines in Hong Kong" by the Scientific Committee on Vaccine Preventable Diseases (SCVPD) and the Scientific Committee on Emerging and Zoonotic Diseases (SCEZD) under the Centre for Health Protection of the Department of Health (JSC) joined by the Chief Executive's expert advisory panel (EAP) dated 6th April, 2022 with the Press Release dated 7th April, the HKCTS would like to update the current issues and concerns on COVID-19 vaccination for patients living with cancer. While the World Health Organization (WHO) has been approving vaccines against COVID-19 with more vaccines under clinical development and are being assessed for efficacy and safety, the currently available COVID-19 vaccines in Hong Kong include 1) CoronaVac – an inactivated vaccine and 2) BioNTech - mRNA vaccine and updated information highlighted:

- 1. Effective mass vaccination programmes are key for preventing severe COVID-19 and the emergency of variants especially for high-risk patients such as cancer patients.
- Patients living with cancer are at invariably higher risk of severe COVID-19 as opposed to the general population(1-3).
- 3. For patients living with cancer, those living with haematological or lung malignancies, male sex, geriatric oncology patients, those with progressive or advanced disease such as metastatic disease, poor performance status, and co-existing multiple co-morbidities, particular those with visceral crises and deranged blood parameters, as well as those with recent cytotoxic treatment or B-cell-depleting therapies, are associated with a persistently increased risk for COVID-19 severity and mortality(3-6).
- 4. Ongoing scientific evidence supports the efficacy and safety of vaccination against COVID-19 and to reduce potential complications, morbidity and mortality from COVID-19 infection. Local data have shown that 3 doses of COVID-19 vaccines (i.e. Comirnaty vaccine or CoronaVac vaccine) are highly effective in reducing hospitalizations and death across all age groups in the adult population (15-16).
- 5. The current "global strategy" of early vaccination and vaccine booster dose should be considered for all patients living with cancer based on the current international and local guidelines in accordance to the available vaccines in the local community. As the majority of local fatal cases in the fifth wave of the COVID-19 epidemic have been persons aged 60 or above, the JSC-EAP thus recommended persons aged 60 years or above to receive an additional dose (i.e. fourth dose) of either Comirnaty vaccine or CoronaVac vaccine at least three months after their last dose for better protection. The same principle would also be applied to recovered persons from COVID-19 in those aged 60 or above. The experts concurred that COVID-19 vaccination should be offered to persons who are unsure if they had previous COVID-19 infection as if they have not been infected. COVID-19 vaccine is safe in persons with evidence





of previous SARS-CoV-2 infection, and prior COVID-19 screening before administration of COVID-19 vaccine is not required. (15-16).

- Family members and other caregivers including healthcare workers who take care of patients with cancer should be prioritized in receiving COVID-19 vaccination to minimize any potential risk of transmission.
- Social distancing measures including wearing masks, hand hygiene and any other infection control
 measures should be continued with local governance.

Frequently Asked Questions (FAQ)

e.g. 1. What if I have cancer or on cancer treatment?

Patients with cancer are generally eligible for coronavirus disease 2019 (COVID-19) vaccination.

- Cancer patients receiving immunosuppressive therapy (e.g. chemotherapy, immunotherapy, targeted therapy or radiotherapy) should NOT receive live attenuated vaccine. Live-attenuated vaccines are, usually contraindicated in patients undergoing immunosuppressive therapy (7-8). The currently available COVID-19 vaccines in Hong Kong (CoronaVac an inactivated vaccine, or BioNTech mRNA vaccine) are generally considered safe in cancer patients.
- Although the efficacy of COVID-19 vaccine is expected to be lower in patients receiving immunosuppressive therapy, the protection is still high and clinically relevant.
- All cancer patients who have not yet received the first dose of COVID-19 vaccines are strongly
 advised to get vaccinated as soon as possible and be fully vaccinated.
- If you are receiving any active cancer treatment, you should discuss with your oncology specialist (Specialist in Clinical Oncology or Specialist in Medical Oncology) about the best timing to receive COVID-19 vaccine in relation to your cancer treatment. For patients receiving cytotoxic chemotherapy, it is generally recommended to separate the vaccination and chemotherapy dose by 1-2 weeks to avoid overlapping side effects and increase the potential for the immune system to mount a response. For those with anticipated extra high risk of COVID-19 infection, individual personalized discussion could be conducted between the patients and their oncologists for special consideration to receive the 3rd dose booster at an earlier time. It is indeed strongly advised that patients discuss their own concerns and issues with their caring oncologists9. The JSC-EAP also recommended an additional dose (i.e. the 4th dose) of COVID-19 vaccine for immunocompromised individuals who have received three doses for better protection.
- Given the potential for a blunted immune response to vaccination in cancer patients, it is important to maintain adequate personal protective measures. Thus, we should continue to observe hand hygiene, social distancing and follow all the public health and infection control measures.





 Open discussion between patients and families and the healthcare professionals should be uphold to clear any potential misunderstanding or pre-conception of COVID-19 vaccine.

According to the latest update of the "Consensus Interim Recommendations on the Use of COVID-19 Vaccines in Hong Kong" by the JSC-EAP recommendation, for those who have been exposed to COVID-19 infection (15-16):

- · For any adult cancer patients especially those on active treatment, who are unvaccinated before the COVID-19 infection including those who are aged 60 years old or above, those residents for residential care homes dedicated for elderly or persons with disability, they are recommended to receive dose 1 of the COVID-19 vaccine at about 1 month from recovery from COVID-19 irrespective of choice of the COVID-19 vaccine. Yet for the dose 2, for those who have opted for CoronaVac, dose 2 should be given at 3 months' interval from dose 1 for adult patients, and dose 2 of CoronaVac should be given at 1-3 months' interval for those aged 60 years old or above, or those residents of residential care home dedicated for elderly or persons with disability. For those adult patients or those aged 60 years old or above, or those residents of residential care home dedicated for elderly or persons with disability who have opted for Cormirnaty, dose 2 of Cormirnaty should be given at 3 months' interval from dose 1. Any specific cancer patients deemed by the parent oncology team to be immunocompromised should receive dose 2 at 1 month's interval from dose 1 irrespective of the choice of COVID-19 vaccine. With regard to dose 3 booster, irrespective of the choice of COVID-19 vaccine, for those aged 60 years old or above, residential care home residents as stated above, or those specific cancer patients deemed by the parent oncology team to be immunocompromised should receive dose 3 at 3 months' interval from dose 2.
- For any adult cancer patients especially those on active treatment, who have received 1 dose of COVID-19 vaccine before the COVID-19 infection including those aged 60 years old or above, and those residing in residential care home for the elderly or residential care home for persons with disability, they are recommended to receive dose 1 of the COVID-19 vaccine at about 3 months from recovery from COVID-19. For those specific cancer patients deemed immunocompromised by the parent oncology team, they should receive dose 1 of COVID-19 vaccine at about 1 month from recovery from COVID-19. For those aged 60 years old or above, residential care home residents as stated above, or those specific cancer patients deemed by the parent oncology team to be immunocompromised should receive dose 2 at 3 months' interval from dose 1.
- For any adult cancer patients especially those on active treatment, who have received 2 doses
 of COVID-19 vaccine before the COVID-19 infection, not all need to have "dose 3 booster"
 unless for those aged 60 years old or above, or those residing in residential care home for the
 elderly or residential care home for persons with disability, or those specific cancer patients
 deemed by the parent oncology team to be immunocompromised should receive dose 1 at 3
 months' interval from recovery from COVID-19.





e.g.2. What if I beat cancer 10 years ago?

If your cancer is in remission and you are not receiving active cancer treatment, your eligibility to receive COVID vaccine is the same as for other people without cancer provided you have no other uncontrolled active medical illnesses such as diabetes, unstable cardiovascular disease and no known history of severe allergy history.

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Guidance notes from the Hong Kong Society for Infectious Diseases and Hong Kong Society for HIV Medicine, collated via the Federation of Medical Societies of Hong Kong

COVID-19 Vaccination in People Living with HIV

People living with HIV (PLHIV) appear to be at increased risk for severe outcomes with COVID-19 compared with people without HIV. PLHIV with stable diseases have been included in the COVID-19 vaccine clinical trials but safety and efficacy data specific to PLHIV are yet to be available. Nonetheless, based on the safety profiles to date and the nature of the vaccines (non-live vaccines), there is no reason for additional concern at present. Given that the potential benefits of COVID-19 vaccines outweigh the potential risks, it is recommended PLHIV, unless with contraindications, to receive COVID-19 vaccination for personal protection. PLHIV shall always discuss with his/her HIV physicians for advice whenever needed.

Scenario: Should PLHIV receive COVID-19 vaccines?

- Unless with contraindications, PLHIV, regardless of their CD4 count, are recommended to receive COVID-19 vaccination for personal protection from COVID-19 infection as the potential benefits outweigh the potential risks.
- It is possible that the level of protection from COVID-19 vaccines may vary among PLHIV. It is advised that infection control practice in the COVID-19 pandemic such as wearing masks, hand hygiene, and social distancing shall continue with COVID-19 vaccination at the moment.

Scenario: Are COVID-19 vaccines safe for PLHIV?

• The COVID-19 vaccines § currently provided by the Government's vaccination programme do not contain live or attenuated SARS-CoV-2 viruses thus cannot cause COVID-19. There is currently no evidence for increased side effects in PLHIV.

[§] For more information about the COVID-19 vaccines, please refer to the designated website of the COVID-19 Vaccination Programme at https://www.covidvaccine.gov.hk/en/vaccine.



衞生署 Department of Health

• PLHIV should take into consideration factors including (1) contraindications such as allergic history and comorbidities, (2) vaccine efficacy, (3) personal choice, etc., when opting for vaccination. If PLHIV carry other co-existing medical conditions that are not under control, they shall discuss with their doctors first to see if deferral of vaccination is necessary.

Scenario: Will COVID-19 vaccines affect antiretroviral therapy?

• There is no known interaction between antiretroviral therapy and the COVID-19 vaccines so far. Thus antiretroviral therapy should be continued without interruption during the course of vaccination.

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Guidance notes from the Hong Kong Lung Foundation, Hong Kong Thoracic Society and CHEST Delegation Hong Kong and Macau, collated via the Federation of Medical Societies of Hong Kong

(18 May 2021)

General comments regarding COVID-19 vaccination for patients with asthma and chronic obstructive airway disease (COPD)

If I have asthma or COPD, should I receive COVID-19 vaccine?

People with asthma or COPD should have COVID-19 vaccination unless you have the conditions listed below for which you should take precautions and consult a medical professional. You should continue your usual inhaled and oral medications for your asthma or COPD when you plan for vaccination. COPD patients are at higher risk of developing severe COVID-19. 2,3

Conditions requiring special precaution for patients with asthma or COPD for COVID-19 vaccine:

- 1. If you are currently having worsening of asthma or COPD <u>symptoms despite taking</u> <u>the usual medications regularly</u>, you should wait for this worsening to settle before receiving the vaccination. You should consult a medical professional for appropriate treatment and seek advice on when you are ready to receive the vaccine.
- 2. If you have a *fever or any acute illness*, delay vaccination until you are fully recovered.
- 3. If you are currently on *biologic therapy for asthma*, COVID-19 vaccine and biologic therapy should not be given on the same day so that adverse effects of either can be more easily distinguished.¹
- 4. If you have a history of <u>allergic reaction</u> to prior COVID-19 vaccine or its components, you should not receive the vaccine concerned. Evaluation by a specialist in allergy may help determine if a different COVID-19 vaccine can be administered.⁴ A history of severe allergic reaction to other medications or foods is not a contraindication for COVID-19 vaccine, but caution should be exercised (particularly for people with previous anaphylaxis to multiple, different drug classes,





which evaluation by a specialist in allergy may be considered) and you should be observed for 30 minutes following vaccination.⁵⁻⁷

5. <u>Other medical conditions</u> that are considered to have contraindications for COVID-19 vaccination.

References

- 1. GINA guidance about COVID-19 and asthma (Updated 26 April 2021). https://ginasthma.org/wp-content/uploads/2021/04/21_04_26-GINA-COVID-19-and-asthma.pdf.
- 2. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2021 report). https://goldcopd.org/wp-content/uploads/2020/11/GOLD-REPORT-2021-v1.1-25Nov20 WMV.pdf.
- 3. Alqahtani JS, Oyelade T, Aldhahir AM, Alghamdi SM, Almehmadi M, Alqahtani AS, Quaderi S, Mandal S, Hurst JR. Prevalence, Severity and Mortality associated with COPD and Smoking in patients with COVID-19: A Rapid Systematic Review and Meta-Analysis. PLoS One. 2020 May 11;15(5):e0233147.
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Guidance Notes from the Hong Kong College of Cardiology, collated via the Federation of Medical Societies of Hong Kong (May 2022)

- Pre-existing cardiovascular diseases significantly increase the risk of severe complications from COVID-19 infection.
- The benefit from COVID-19 vaccine in patients with stable cardiovascular diseases or stable cardiovascular risk factors exceeds the risk of severe adverse reaction to the vaccine. Therefore, patients with stable cardiovascular diseases or stable cardiovascular risk factors, and without other contraindications, should receive COVID-19 vaccination.
- Patients experiencing unstable symptoms like chest pain, shortness of breath, syncope or palpitations should seek medical attention before COVID-19 vaccination.
- 4. In general, patients having undergone elective percutaneous coronary intervention or coronary artery bypass graft surgery can have COVID-19 vaccination 2 to 4 weeks after the procedure. For patients after acute myocardial infarction, they can receive COVID-19 vaccination after 2 to 4 weeks if they are stable after the acute illnesses, or as soon as they are stabilized at a later time. Variation in the period is expected in some patients and should be recommended by the attending cardiologist or cardiac surgeon on an individualized approach.
- 5. Antiplatelet drugs, e.g. Aspirin, Clopidogrel, Prasugrel and Ticagrelor and oral anticoagulants, e.g. Warfarin, Dabigatran, Rivaroxaban, Apixaban and Edoxaban, should be continued during COVID-19 vaccination. Prolonged direct pressure lasting for 5 to 10 minutes should be applied to the injection site to reduce bleeding or bruising.





Appendix 2

Review the **Guidance for COVID-19 Vaccination Medical Exemption Certificate** prior to certifying a medical exemption to ensure all criteria are met.

[發出日期 Date of issue of letter]

敬啟者

To whom it may concern

新冠疫苗接種醫學豁免證明書

COVID-19 Vaccination Medical Exemption Certificate

兹證明以下人士

This is to certify that the following person

姓名 Name (如身分證明文件) (as in identification document)	:	
證件種類及號碼 Document Type & Number	:	□ 香港身份證號碼 HKID number
出生日期 Date of Birth	:	(DD/MM/YYYY)
性別 Gender	:	
核糖核酸疫苗)。 is considered not suitable to rec	eive an	王何一款本港現行提供的 2019 冠狀病毒病疫苗 (滅活疫苗/信使 ny one of the currently available COVID-19 vaccines) in Hong Kong Special Administrative Region due to the
此證明書的有效期直至 This certification remains valid	 until ₋	[日期]*]。 [Date]*。
長有效期亦應只限於六個月。 * In general, the validity period of this	s certif	明書的有效期不應長於三個月。如果有特殊醫學原因,本證明書的最 ication should not be more than 3 months, unless there are special medical the maximum validity period of this certification should not be more than
		() 註冊醫生簽署及姓名
		註冊對土競者及姓石 Signature and Name of Registered Medical Practitioner

Review the Guidance for COVID-19 Vaccination Medical Exemption Certificate prior to certifying a medical exemption to ensure all criteria are met.

第一部分:新冠信使核糖核酸疫苗或新冠滅活疫苗的禁忌症

Part I: Contraindications to mRNA or inactivated COVID-19 vaccines

請在適當 位置加上√。 Please $\sqrt{}$ the appropriate box(es).

請注意,必須選填新冠信使核糖核酸疫苗及新冠滅活疫苗適當 位置。

Please note that you must $\sqrt{\text{at least one box for both mRNA}}$ and inactivated COVID-19 vaccines.

如以上條件不適用,請選填第二部分。 If the above criteria is not applicable, please proceed to Part II.

醫學原因 Medical Reason(s)			
新冠信使核糖核酸疫苗	新冠滅活疫苗		
mRNA COVID-19 vaccine	Inactivated COVID-19 vaccine		
□ 曾對如接種須知所述新冠信使核糖核酸疫苗活性物質或其他成分有過敏反應Allergy to the active substance or any of the other ingredients of this medicine as stated on the fact sheet	□對其他滅活疫苗*;或如接種須知所述新冠滅活疫苗中的任何成分(活性或非活性成分,或生產工序中使用的任何物質)有過敏史;過往發生過疫苗嚴重過敏反應(如急性過敏反應、血管神經性水腫、呼吸困難等) History of allergic reaction to other inactivated vaccine*, or any component of inactivated COVID-19 vaccine (active or inactive		
口於接種信使核糖核酸2019 冠狀病毒病疫苗後患有心肌炎或心包炎 Myocarditis or Pericarditis following a mRNA COVID-19 vaccine	ingredients, or any material used in manufacturing process as stated on the factsheet); previous severe allergic reactions to other vaccine (e.g. acute anaphylaxis, angioedema, dyspnea, etc.)		
	□患有嚴重神經系統疾病(如橫貫性脊髓炎、格林巴利綜合症、脫髓鞘疾病等) Severe neurological conditions (e.g. transverse myelitis, Guillain-Barré syndrome, demyelinating diseases, etc.)		
滅活疫苗如滅活小兒麻痺疫苗、滅活流感疫苗等	口未控制的嚴重慢性病患 Uncontrolled severe chronic diseases		

Inactivated vaccines such as inactivated polio vaccine, inactivated influenza vaccine etc.

第二部分:既有身體狀況/新冠疫苗接種異常事件

Part II: Pre-existing condition/ Adverse event following COVID-19 immunisation

請在適當 位置加上√。請注意,必須選填一個 位置,以符合醫學豁免要求。

Please $\sqrt{}$ the appropriate box(es). Please note that you must $\sqrt{}$ at least one box in order to fulfill the medical exemption requirement.

醫學原因 Medical Reason(s)

1對所有本港現行提供的 2019 冠狀病毒病疫苗曾出現嚴重過敏反應或過敏反應
Severe allergic reaction or anaphylaxis to all currently available COVID-19 vaccines

□特定醫學原因(讀	青註明):
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Specific medical condition(s) (please specify): _____

Guidance for COVID-19 Vaccination Medical Exemption Certificate

This Interim Guidance Notes is intended to assist registered medical practitioners in evaluating contraindications or precautions to COVID-19 vaccination that may warrant a medical exemption. Any registered medical practitioner under Part I and III of the General Register can issue a Medical Exemption Certificate (Appendix 2). A contraindication is a situation where a vaccine should not be given as the risks outweigh any potential benefit. A precaution is a condition that may increase the risk of an adverse event following immunization or compromise the ability of the vaccine to produce an immune response, which may result in deferral of immunization. However, there may be circumstances where the benefits of vaccination outweigh the potential risks from vaccination associated with the condition or where reduced immunogenicity still benefits immunocompromised individuals.

2. In general, there are very few actual contraindications to available COVID-19 vaccines that would qualify as medical exemptions and most individuals can safety receive COVID-19 vaccines. Individuals who qualify for medical exemptions should be re-evaluated periodically by their attending doctor as new evidence or vaccine products become available.

Reasons for Medical Exemption

- 3. Individuals who have experienced serious Adverse Events Following COVID-19 Immunization (AEFIs) and those with certain medical conditions which may affect their response to immunization should be assessed by a registered medical practitioner. Referral to a specialist for further assessment may be necessary depending on the nature of the adverse events or medical conditions. Such assessment should include a detailed patient's history, assessment of the adverse event or medical condition, further investigations and diagnosis necessary. individualized risk-benefit analysis, recommendations or options for immunization. Where appropriate, assessment from the Expert Committee on Clinical Events following COVID-19 immunization should also be taken into consideration.
- 4. In many instances, safe administration of subsequent doses of COVID-19 vaccine is possible. True medical exemptions are expected to be infrequent. The following conditions are some reasons for medical exemption:
 - a) <u>Pre-existing condition / AEFIs</u>
 - i) Severe allergic reaction or anaphylaxis to all currently available COVID-19 vaccines





According to the Updated Consensus Statements on COVID-19 Vaccine Allergy Safety in Hong Kong (Appendix 1), individuals who have had a history of immediate-type allergic reaction with systemic symptoms or non-immediate type allergic reaction which required medical attention are contraindicated to receive further COVID-19 vaccination until an allergist's evaluation. Upon assessment, the physician may determine whether the individual can be vaccinated with the same vaccine or should be vaccinated with an alternative vaccine of a different platform. A medical exemption may be issued after discussion on potential options for vaccination with the same or alternative COVID-19 vaccine, and the physician has determined that the individual is unable to receive any COVID-19 vaccine available in Hong Kong.

Persons who are contraindicated for a type of COVID-19 vaccine should not receive that vaccine, but may instead consider an alternative vaccine. People with a history of severe immediate-type allergy to multiple classes of drugs may have an undiagnosed excipient (such as polyethylene glycol (PEG)) allergy and they may be vaccinated with a non-PEG containing vaccine (i.e. inactivated vaccine).

Please see Section 5b(i) & (ii) on allergy to previous dose of mRNA and inactivated COVID-19 vaccines, or to the active substance or any of the other ingredients of the respective vaccines as stated in the fact sheet for more details.

ii) <u>Specific medical conditions</u> (Please find below a list of examples of specific medical conditions where the client may be exempted temporarily from vaccination. The list is non-exhaustive.)

Active cancer on treatment

According to the guidance notes from the Hong Kong Cancer Therapy Society (Appendix 1), patients with cancer are generally eligible for COVID-19 vaccination. Cancer patients receiving immunosuppressive therapy (e.g. chemotherapy, immunotherapy, targeted therapy or radiotherapy) should not receive a live-attenuated vaccine but the currently available COVID-19 vaccines in Hong Kong (inactiviated and mRNA vaccines) are generally considered safe in cancer patients. Although the efficacy of COVID-19 vaccine is expected to be lower in patients receiving immunosuppressive therapy, the protection is still high and clinically relevant.

All cancer patients who have not yet received the first dose of COVID-19 vaccines are strongly advised to get vaccinated as soon as possible and be fully vaccinated. It is strongly advised that the





physician should discuss with their patients about the best timing to receive COVID-19 vaccine in relation to the cancer treatment. For patients receiving cytotoxic chemotherapy, it is generally recommended to separate the vaccination and chemotherapy dose by 1-2 weeks to avoid overlapping side effects and increase the potential for the immune system to mount a response.

Receiving aggressive immunotherapy

According to the guidance notes from the Hong Kong Society of Haematology (Appendix 1), immunocompromised patients are recommended to receive COVID-19 vaccine. The benefits far outweigh the potential side effects of vaccine. If the patient is receiving or has received immunosuppressive therapy of B-cell depletion, consider vaccination 3-6 months after the patient has been taken off therapy to increase the likelihood of developing immunity.

<u>Receiving monoclonal antibody or convalescent plasma treatment</u> for COVID-19

According to WHO, vaccination does not need to be delayed in people who have previously received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Although some reduction in vaccine-induced antibody titres was observed in people who previously received antibody products, the clinical significance of this reduction is unknown, and the balance of benefits vs. risks favours proceeding with vaccination, even when considering the possibility of diminished vaccine effectiveness in this situation.

Transplant recipient

According to the statement from Hong Kong Society of Transplantation (Appendix 1) on COVID-19 vaccine in solid organ transplant recipients, vaccination is a highly effective means to prevent COVID-19 infection and reduce risk of developing complications and death. However, the immune responses to COVID-19 vaccine in immunocompromised individuals, such as solid organ transplant recipients, are diminished compared with the general population. According to the Guidance notes from the Hong Kong Society of Haematology, if patients have undergone hematopoietic stem cell transplantation (HSCT), inactivated vaccines can generally be started 3-6 months after HSCT.

<u>Other serious adverse events following COVID-19 vaccination (e.g. resulting in hospitalisation, persistent or significant disability/incapacity)</u>

Individuals who experience a serious adverse event following immunization (AEFI) (e.g. hospitalization, persistent or significant





disability/incapacity) with a COVID-19 vaccine should be medically assessed by a registered medical practitioner, and the event should be reported to Drug Office of the Department of Health. A list of Serious or Unexpected AEFI of COVID-19 vaccines can be accessed here: https://www.drugoffice.gov.hk/eps/do/en/doc/Lists_of_AEFIs_and_AESIs_for_COVID19_Vaccines_Eng.pdf.

The individual qualifies for a medical exemption if the relevant registered medical practitioner determines that the individual is unable to receive any COVID-19 vaccine after the event has been medically evaluated AND a discussion has occurred on the individual's risks and benefits of potential options for immunization with the same or alternative COVID-19 vaccine.

Recent COVID-19 infection

Currently, JSC-EAP recommended persons recovered from COVID-19 to wait for a minimum interval after recovery before receiving a dose of COVID-19 vaccine. Please refer to the "Factsheet on COVID-19 Vaccination For Persons with Prior COVID-19 Infection" for details:

https://www.chp.gov.hk/files/pdf/factsheet_priorcovid19infection_e ng.pdf.

b) <u>Contraindications to mRNA or inactivated COVID-19 vaccines</u>

i) Contraindications to mRNA COVID-19 vaccine

For persons who have contraindications to mRNA COVID-19 vaccine, they should consider receiving inactivated COVID-19 vaccine if they have no contraindication to the inactivated COVID-19 vaccine or any of its components/ingredients and vice versa.

Allergy to active substance or any of the other ingredients of this medicine as stated on the fact sheet

According to updated Consensus Statements on COVID-19 Vaccine Allergy Safety (Appendix 1) in Hong Kong, people with a history of immediate-type allergic reaction with systemic symptoms to prior COVID-19 vaccination or a history of non-immediate type allergic reaction to prior COVID-19 vaccination which required medical attention should not receive further COVID-19 vaccination until allergist's evaluation.

People with a history of severe immediate-type allergy to multiple classes of drugs may have an undiagnosed excipient (such as





polyethylene glycol (PEG) allergy and they may be vaccinated with a non-PEG containing vaccine.

In addition, allergy testing with PEG or PEG-containing surrogates appear to be poorly predictive and should not be routinely performed. In cases where these test are used, results should be interpreted in the context of a detailed clinical history by an allergist.

People at higher risk of COVID-19 vaccine associated allergic reactions should be observed for at least 30 minutes after vaccination.

Myocarditis or Pericarditis following mRNA COVID-19 vaccine

Individuals with a diagnosed episode of myocarditis and/or pericarditis after receipt of their first dose of an mRNA COVID-19 vaccine should defer their second dose in the vaccination series until more information and guidance is available. A medical exemption may be issued if myocarditis/pericarditis was diagnosed after medical evaluation by a medical practitioner. In situations where there is uncertainty regarding myocarditis/pericarditis diagnosis, discussion should occur with a relevant specialist on potential options for reimmunization with the same or alternative COVID-19 vaccine, balancing the risks and benefits for the individual. The individual qualifies for a medical exemption if the specialist has determined that the individual is unable to receive any COVID-19 vaccine.

ii) Contraindications to inactivated COVID-19 vaccine

For persons who have contraindications to inactivated COVID-19 vaccine, they should consider receiving mRNA COVID-19 vaccine if they have no contraindication to mRNA COVID-19 vaccine or any of its components/ingredients and vice versa.

History of allergic reaction to other inactivated vaccine, or any component of inactivated COVID-19 vaccine (active or inactive ingredients, or any material used in manufacturing process as stated in the fact sheet); previous severe allergic reactions to other vaccine (e.g. acute anaphylaxis, angioedema, dyspnea, etc.)

A history of anaphylaxis to any component of an inactivated COVID-19 vaccine is a contraindication to vaccination using that inactivated COVID-19 vaccine. People who have an anaphylactic reaction following the first dose of an inactivated COVID-19 vaccine should not receive a second dose of the same vaccine.¹

The updated Consensus Statements on COVID-19 Vaccine Allergy Safety in Hong Kong (Appendix 1) further detailed that people with





a history of immediate-type allergic reaction with systemic symptoms to prior COVID-19 vaccination or a history of non-immediate type allergic reaction to prior COVID-19 vaccination which required medical attention should not receive further COVID-19 vaccination until allergist's evaluation.

Severe neurological conditions (e.g., transverse myelitis, Guillain-Barré syndrome, demyelinating diseases, etc.)

Patients with history of convulsions, epilepsy, encephalopathy, mental illness, or family history of those diseases, inactivated COVID-19 vaccine should be used with caution. In addition, it is recommended not to use inactivated COVID-19 vaccine if there is any adverse reaction of nervous system after inoculation.

Uncontrolled severe chronic diseases and acute/unstable disease

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.). Evidence of clinical disease should be taken into account for assessment when dyslipidemia alone is encountered.

Achieving better/ stable control of the disease(s) with appropriate therapy is recommended before considering vaccination. 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.

Notwithstanding individual assessment, patients with recent acute myocardial infarction can receive COVID-19 vaccination after 2 to 4 weeks if they are stable after the acute illnesses, or as soon as they are stabilized at a later time. COVID-19 vaccination can be considered in stable stroke patients one month or beyond from the stroke onset. In particular, please refer to Reference Frameworks published by the Primary Healthcare Office of the Health Bureau for advice on some common medical diseases.² Professional judgement on a patient-bypatient basis has to be exercised as is always in the case of clinical practice.





c) <u>Conditions not considered as contraindications to COVID-19</u> <u>vaccination</u>

Allergic reactions (including severe allergic reactions) not related to vaccines (COVID-19 or other vaccines) or injectable therapies, such as allergic reactions related to food, pet, venom, or environmental allergies, or allergies to oral medications (including the oral equivalents of injectable medications), are not a contraindication to COVID-19 vaccination.

The vial stoppers of COVID-19 vaccines are not made with natural rubber latex, and there is no contraindication to vaccination for people with a latex allergy.

In addition, because the COVID-19 vaccines do not contain eggs or gelatin, people with allergies to these substances do not have a contraindication to vaccination.

Delayed-onset local reactions have been reported after mRNA vaccination in some individuals beginning a few days through the second week after the first dose and could sometimes be quite large. People with only a delayed-onset local reaction (e.g., erythema, induration, pruritus) around the injection site area after the first vaccine dose do not have a contraindication to a subsequent dose. For the mRNA primary vaccine series, these individuals can receive the subsequent dose(s) using the same vaccine product as the first dose at the recommended interval, preferably in the opposite arm.

Pregnancy and lactating women

Pregnant women are at a higher risk of developing severe adverse outcomes following COVID-19 infection, when compared with non-pregnant population. COVID-19 also increases the risk of preterm birth by 2-fold and extended perinatal mortality by about 50%. Studies have shown that the COVID-19 vaccines are as effective at reducing the risk of hospitalization and deaths in pregnant women as they are in non-pregnant population. Pregnant women should be offered COVID-19 vaccine. Women who are planning pregnancy, are pregnant, or are breastfeeding should be vaccinated with COVID-19 vaccine, unless contraindicated due to underlying medical reasons.

Documentation

5. The medical exemption must be assessed and clearly documented by a Registered Medical Practitioner under Part I and III of the General Register.



What to include in the Medical Exemption Certificate?

The information is complete by including:

- a) Full name of registered medical practitioner;
- b) Statement that there is a medical reason as outlined in this Guidance Notes from receiving all of the currently available COVID-19 vaccines; and
- c) The issue date and validity period of this Exemption Certificate, which should not be more than 3 months (90 days, both days inclusive, e.g. 1 Feb 2022 to 1 May 2022), unless there are special medical reasons. Even with the special medical reasons, the maximum validity period of this certification should not be more than 6 months (180 days, both days inclusive). Individuals who qualify for medical exemptions should be re-evaluated periodically as new evidence or vaccine products become available.

How to document the required information?

The basis on which the medical exemption for COVID-19 vaccination is made for an individual must be clearly indicated as part of the clients' medical record. The aforementioned information should be recorded electronically via the IT system of eHealth System (Subsidies) (eHS(S)) which is the same IT system supporting COVID-19 vaccination or Hospital Authority's Clinical Management System (CMS).

The electronically created Medical Exemption Certificate bearing a QR code should then be printed out to the client for record.

References

- World Health Organization. Interim recommendations for use of the inactivated COVID-19 vaccine, CoronaVac, developed by Sinovac (version as at 15 March 2022). Available at https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-Sinovac-CoronaVac-2021.1
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