Guidance Notes on COVID-19 Vaccination for People (Adults) with HIV (February 2022, SCAS)

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 CME / CNE / PEM point accreditation (please refer to the attached test paper for the number of credit points awarded)

Introduction

The emergence of Coronavirus Disease (COVID-19) caused by SARS-CoV-2 has seeded a pandemic since late 2019. Different SARS-CoV-2 Variants of Concern (VOCs) have evolved with different phenotypic characteristics leading to differences in terms of transmissibility, disease severity, risk of reinfection, and impacts on diagnostic and therapeutic options, vaccine efficacy, or other public health and social measures¹.

2. Despite initial smaller scale studies showing contradictory findings, subsequent data from larger observational studies indicate that a subset of people with HIV are at increased risk of severe COVID-19 outcomes, such as hospitalisations, admissions to intensive care units, and in-hospital mortality²⁻⁸. Age above 60, and the presence of comorbidities have been identified as the most consistent factors that are associated with increased severity of COVID-19 in the general population⁹. Many people with HIV have one or more comorbidities that may put them at increased risk for a more severe course of COVID-19. Those with advanced HIV disease or AIDS with uncontrolled viraemia and low CD4 count or CD4 nadir are also demonstrated to be at increased risk for developing severe disease¹⁰.

3. At both individual and population level, COVID-19 vaccination is the most critical prevention measure to lower the risk of infection, and the risk of severe COVID-19 outcomes even if infected. Two COVID-19 vaccines have been authorised for emergency use in Hong Kong: i) inactivated virus technology platform: CoronaVac by Sinovac Biotech (Hong Kong) Limited; and ii) mRNA technology platform: Comirnaty by Fosun Pharma/BioNTech. The first two doses of vaccine are to be given at least 28 days apart for CoronaVac and at least 21 days apart for Comirnaty.

4. This Guidance Notes aim to provide information for healthcare professionals and other stakeholders in the field on the recommended use of locally available COVID-19 vaccines for people with HIV. The Guidance notes are based on the interpretation of data available at the time of its preparation, while acknowledging the limitations of studies on vaccine effectiveness against the rapidly evolving viral strains. It would be kept under review and be subjected to further revision with a growing body of scientific information.

Recommendations on vaccination

(I) Vaccination against COVID-19 (SARS-CoV-2) is strongly recommended for all people with HIV, regardless of CD4 count or viral load

(a) Safety

• Available data and extensive experience following vaccine administration suggest that

current COVID-19 vaccines validated for use by World Health Organization (WHO) are safe for people with HIV. There are no reported interactions between COVID-19 vaccines with antiretroviral medications, and people with HIV should be advised to continue with their treatment while receiving COVID-19 vaccination¹¹.

- (b) Vaccine effectiveness and choice of COVID-19 vaccines
 - All WHO approved COVID-19 vaccines, including both Comirnaty and CoronaVac, when fully administered, are effective at preventing serious illness, hospitalisation and death from COVID-19¹². People with HIV should be encouraged to get vaccinated to protect themselves and those around them.
 - Small studies of people with well-controlled HIV showed comparable immune responses to mRNA vaccines and adenovirus-vectored vaccine compared to the general population¹³⁻¹⁴. A local study of people with HIV after receiving Comirnaty and CoronaVac showed that inactivated vaccine gave a generally lower peak and shorter duration of surrogate viral neutralisation test responses compared to mRNA vaccine.
 - For those who have received two doses of CoronaVac, a local study has shown that a third dose of Comirnaty elicits a better immune response than CoronaVac in the general population¹⁵. Upon the emergence of Omicron, another local study examining the protection of COVID-19 vaccines against infection by SARS-CoV-2 showed markedly reduced serum antibody titres against the Omicron variant as compared to wild-type SARS-CoV-2 after two doses of either Comirnaty or CoronaVac vaccines. Booster dose with Comirnaty in people who received two doses of Comirnaty or CoronaVac has been shown to elicit better response that those vaccinated with three doses of CoronaVac, thus offering better protection in response to the spread of Omicron in the community¹⁶.
 - Health service providers should provide relevant information to their clients to facilitate decision making regarding their choice of COVID-19 vaccines.
- (c) Contraindications
 - There are very few conditions that would exclude an individual from being vaccinated. As HIV infection is being identified as one of the risk factors for severe COVID-19 outcomes, people with HIV are in fact more indicated to receive COVID-19 vaccine, unless with contraindications (same as other people) as listed in **Table 1**.

Comirnaty	Persons with:	
	i) hypersensitivity to previous dose of Comirnaty, or to the	
	active substance or to any of the excipients	
CoronaVac	Persons with:	
	 i) history of allergic reaction to CoronaVac or other inactivated vaccine; or any component of CoronaVac (active or inactive ingredients, or any material used in the manufacturing process); or 	
	ii) previous severe allergic reactions to vaccine (e.g. acute anaphylaxis, angioedema, dyspnea, etc.); or	
	 iii) severe neurological conditions (e.g. transverse myelitis, Guillain-Barré syndrome, demyelinating disease, etc.); or 	
	iv) uncontrolled severe chronic diseases	

Table 1. Contraindications to receiving COVID-19 vaccines¹⁷

- (*d*) Timing of COVID-19 vaccination
 - In general, for people with HIV who have acute/unstable disease who are undergoing treatment to achieve immune reconstitution, it may be preferable to defer COVID-19 vaccination until the clinical condition is more stable in order to maximise the vaccine effectiveness. However, health service providers shall exercise clinical judgement to decide the best timing for vaccination on individual basis. Factors to consider include HIV status (e.g. CD4 count, HIV viral load, presence of concurrent acute conditions including opportunistic infections), other comorbidities, one's potential risk of exposure and the extent of local COVID-19 transmission etc.
- (e) Booster (third dose) vaccination
 - Except for those with advanced or untreated HIV who are recommended for a 3-dose primary series as listed in Recommendation (II), people with HIV who are otherwise stable with antiretroviral treatment should receive booster vaccination as in the recommendations for the general adult population. Booster dose (third dose) should be administered as soon as threemonths after the second dose ^{18,19}.

(II) People who have advanced or untreated HIV should receive an additional dose of COVID-19 vaccine (i.e. a 3-dose primary series) for better protection against COVID-19

- Immunocompromised individuals, including people with HIV with CD4 count less than 200 cells/uL, evidence of an opportunistic infection, not on HIV treatment, and/or those with a detectable viral load, may have suboptimal response to a 2-dose primary series. They are recommended to receive the third dose at least 28 days from the second dose²⁰.
- Those who have received a 3-dose primary series are strongly recommended to receive the fourth dose of COVID-19 vaccine three months after the third dose to offer better protection¹⁹.

(III) Confidentiality of HIV status should be ensured during vaccine administration

• Health service providers and vaccination facilities should ensure that the confidentiality about one's HIV status or other underlying conditions be preserved during the vaccine administration procedures.

(IV) Antibody testing is not a standard post-vaccination

• It should also be noted that SARS-CoV-2 antibody tests does not need to be routinely performed to evaluate an HIV patient's level of immunity or protection from COVID-19, especially after receiving COVID-19 vaccination²¹. Unless in research setting and when appropriate advice is offered by health care providers familiar with the use and limitations of the test to aid interpretation, there is a potential risk that the vaccinee may interpret the antibody test results incorrectly and results in taking suboptimal precautions against SARS-CoV-2 exposure undesirably.

Other recommendations

(I) Other precautionary measures should be continued to mitigate the risk of exposure to SARS-CoV-2

• Although COVID-19 vaccines are highly effective against severe outcomes, hospitalisations and death, they are, however, less effective in preventing non-severe infections. The effect of vaccination on reducing transmissibility and preventing onward transmission has shown to be mild and transient. Vaccine effectiveness in terms of prevention of infection and transmission also differs with different strains of SARS-CoV-2¹². Therefore, regardless of HIV status, it remains important for everyone to continue exercising infection control measures to mitigate the risk of exposure to SARS-CoV-2, such as wearing masks, practicing hand hygiene, and following guidance on social distancing.

(II) People with HIV should not switch their antiretroviral regimens for the purpose of preventing or treating COVID-19

• Some antiretroviral agents, e.g. lopinavir/ritonavir, booster darunavir, and tenofovir disoproxil fumarate/emtricitabine, have been evaluated in clinical trials or have once been prescribed for off-label use to treat or prevent COVID-19 during the early pandemic. To-date, no antiretroviral agents have been shown to be effective in these settings. There is no role to consider prescribing specific antiretrovirals for the prevention or treatment of COVID-19 per se.

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Test paper - Guidance Notes on COVID-19 Vaccination for People (Adults) with HIV (February 2022, SCAS)

Validity Period:29August 2022 - 28 August 2023CME point # / CNE point: 1 / PEM point: 0 (Midwifery related)

Please:

- choose the best option
- answer on the answer sheet and submit **by email** (<u>**rrc@dh.gov.hk**</u>) to Special Preventive Programme, Department of Health within the validity period.

Accreditors	CME Point
Department of Health / HKMA/ HKAM / HKDU (for practising doctors who are not taking CME programme for specialists)	1
Anaesthesiologists	1
Community Medicine	1
Dental Surgeons	1
Emergency Medicine	1
Family Physicians	N/A
Obstetricians and Gynaecologists	1
Ophthalmologists	1
Orthopaedic Surgeons	1
Otorhinolaryngologists	0.5
Paediatricians	1
Pathologists	1
Physicians	1
Psychiatrists	1
Radiologists	N/A
Surgeons	1

#Please contact respective authorities directly for CME/CPD accreditation if it is not on listed above.

- 1. Which of the following is not a general account of COVID vaccination for people with HIV?
 - a. People with HIV is more indicated to receive COVID vaccine than the general population
 - b. COVID vaccine is safe for people with HIV
 - c. COVID vaccine can prevent serious illness and death from COVID in people with HIV
 - d. Antibody testing is advisable after vaccination in people with HIV
 - e. None of the above
- 2. Which of the following is not true about the COVID vaccination programme in Hong Kong?
 - a. Two vaccines with different technology platform are deployed
 - b. A live attenuated vaccine is used
 - c. The second dose of CoronaVac is to be administered at least 28 days after the first dose
 - d. The second dose of Comirnaty is to be administered at least 21 days after the first dose
 - e. None of the above

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- 3. Which of the following is not generally correct about the contraindications of COVID vaccines?
 - a. People with severe hypersensitivity to the first dose should not be given a second dose
 - b. CoronaVac has more listed contraindications than Comirnaty
 - c. HIV per se is not a contraindication to receive COVID vaccine
 - d. Severe neurological condition is a contraindication to CoronaVac
 - e. None of the above
- 4. Which of the following is not true about the potential difference in characteristics of SARS-CoV-2 variants?
 - a. Transmissibility
 - b. Pathogenicity
 - c. Impact on diagnostics
 - d. Impact on treatment/vaccine efficacy
 - e. None of the above
- 5. Which of the following is not true about HIV antiretroviral and COVID?
 - a. It has been shown that HIV antiretroviral interacts with COVID vaccine
 - b. Some HIV antiretroviral is effective in preventing or treating COVID
 - c. The antiretroviral regimen sometimes require adjustment to receive COVID vaccine
 - d. HIV status has to be clarified if HIV antiretroviral is to be prescribed in COVID patients
 - e. All of the above
- 6. Which of the following is not a risk factor for severe disease after COVID infection?
 - a. Age above 60
 - b. Presence of chronic medical illnesses
 - c. Low CD4 in people with HIV
 - d. Uncontrolled viraemia in advanced HIV disease
 - e. None of the above
- 7. Which of the following is not true about the scientific findings of vaccine response?
 - a. People with HIV have comparable immune response to mRNA and adenovirus-vectored vaccine as the general population
 - b. Both Comirnaty and CoronaVac elicited reduced antibody titres towards Omicron variant as compared to wild-type virus after two doses in the general population
 - c. CoronaVac induced higher antibody level which also lasted longer as gauged by surrogate viral neturalisation test than Comirnaty in people with HIV
 - d. A third dose with Comirnaty resulted in better immune response in people who received two doses of Comirnaty or CoronaVac than people who received three doses of CoronaVac
 - e. None of the above
- 8. Which of the following is not true in considering COVID vaccine in people with HIV?
 - a. It may be preferred to defer vaccination in people with acute/unstable HIV disease
 - b. Current CD4 count, HIV viral load, potential risk of exposure, vaccine effectiveness are factors affecting consideration of the timing of vaccination
 - c. Advanced disease patients are recommended to receive a third dose 3 weeks after the second dose
 - d. A fourth dose is expected to offer better protection in patients with advanced or untreated HIV
 - e. None of the above