OPERATIONS INSTRUCTION TO VACCINATION PROVIDERS FOR THE CONDUCT OF COVID-19 NUVAXOVID XBB.1.5 VACCINATION FOR INDIVIDUALS AGED 12 YEARS OLD AND ABOVE

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# Documentation Record

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| S/N | Version No. | Date | Description | Author | Approving Authority | Remarks |
| Name, Designation |
| 1 | 1.0 | 28 Dec 2023 | First version | Dom Choong M, OPB | GD(CSOG) |  |
| 2 | 1.1 | 27 Feb 2024 | Para 5:  Updated Clinical Guidance on two-dose baseline, step- down measures for strenuous activity, vaccine co-administration, observation, Anaphylaxis management, revised Guidance document  6.12 b:  Amended 14 days interval between vaccines to can be administered concurrently  Para 6.13:  Updated attachments of documents  Para 6.17 to 6.22:  Deleted Incident Reporting | Tay Lee Hwa  M, VOTG | D(VOTG) |  |
| 3 | 1.2 | 28 Mar 2024 | Para 1.2, 2.1 a, 5.2 & 5.3: Standardised primary series to two initial doses regime  Para 3.1: Deleted PHPCs not to concurrently provide other Covid-19 vaccines  Para 7.4: Deleted outdated reference article | Tay Lee Hwa  M, VOTG | D(VOTG) |  |
| 4 | 1.3 | 23 May 2024 | Para 1.2 & 2.1:  Deleted vaccine as 2nd dose under SAR  Para 3.2:  Added Leverage on HVT  Para 4:  Deleted Operating Parameter  Para 5 renumbered to 4:  Updated clinical guidance on doses and attachments  Para 6:  Deleted requirements of Letter Of Acknowledgement  Para 6. :  Updated parents’ consents for 2 groups  Para 6. a)  Added HAS Appointment  Para 7.15:  Deleted requirement of SAR permit  Para 8.2:  Inserted HAS Booking | Tay Lee Hwa  M, VOTG | D(VOTG) |  |

# General

* 1. This Operations Instruction seeks to inform Vaccination Providers on the instructions to operationalise the COVID-19 Nuvaxovid XBB.1.5 vaccination for individuals aged 12 years old and above.

# Principal Considerations

# The principal considerations are as follows:

# Client safety

# Suitable age of client to receive the COVID-19 Nuvaxovid XBB.1.5 vaccination should be calculated based on the date of birth, not just the birth year, and adhering to the minimum age of 12 years and above.

# Vaccination Providers should pay attention to the minimum interval between the first and second doses according to the vaccine manufacturers’ specifications.

# Minimise vaccine supplies wastage

# Vaccination Providers should avoid holding on to excess vaccine supplies and should trigger re-supply only when necessary.

# Due to the short shelf-life of six hours of the vaccines after puncturing of vials, the vaccination of patients should be scheduled in batches (ideally of five) to reduce vaccine wastage.

# Concept of Operations

# Nuvaxovid XBB.1.5 vaccinations will be administered at designated vaccination sites, such as Public Health Preparedness Clinics (PHPCs), nursing homes, etc.

# Leverage on Home Vaccination Teams

# Home Vaccination Teams may be deployed to conduct vaccinations at individual’s residential home upon request (if client has mobility issues).

# Updates to Clinical Guidance

# Individuals who have not been vaccinated against COVID-19 are recommended to receive two initial vaccine doses.

# The dosage of the Nuvaxovid XBB.1.5 vaccine is as follows:

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| --- | --- | --- |
| **Vaccine** | **Eligible Age** | **Dose(s) and Recommended Intervals** |
| Nuvaxovid XBB.1.5 COVID-19 Vaccine | ≥ 12 years | Two initial doses vaccination regime   * 2 doses of 5mcg (0.5mL) * 8 weeks apart |
| 2024 additional dose   * 1 dose of 5mcg (0.5mL) * 1 year after last dose received |

# Recovered persons are recommended to receive the vaccine dose at least 3 months after the date of COVID-19 infection for better vaccine effectiveness.

# Male vaccinees aged 12-29 years should be advised to avoid strenuous physical activity after vaccination for a duration of 1 week.

# COVID-19 vaccines can be administered concurrently with other non-COVID-19 vaccines across all ages eligible for the vaccine.

# There is no longer stipulated period of observation after COVID-19 vaccination, other than for persons at increased risk of anaphylaxis who should be observed for 30 minutes. These individuals include those who had a past history of:

# Allergic reactions (that is, immediate hypersensitivity reactions) to other COVID-19 vaccines, OR,

# Any anaphylaxis

# Emergency drugs / equipment requirements for COVID-19 vaccine providers are now aligned to that required under prevailing regulatory requirements relevant to the licensable healthcare service which the licensee is licensed for and is stipulated in the "Licence Conditions for Providing or Intending to Provide Emergency Life Saving Measures".

# Information on dosage, administration, storage, and handling are included in the vaccine package insert below. Vaccination Providers staff should ensure that they are familiar with the materials before carrying out vaccinations.

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| **Document** | **Purpose of Document** | **Nuvaxovid XBB 1.5** |
| Annex A - Package Insert | Information to vaccination clinics and vaccinators on dosage, administration, storage, and handling |  |

# MOH has provided clinical guidance materials to support Vaccination Providers staff who are carrying out Nuvaxovid vaccinations. Staff of Vaccination Providers staff should ensure that they are familiar with the materials before carrying out vaccinations.

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| **Document** | **Purpose of document** | **Nuvaxovid XBB 1.5** |
| Guidance for Vaccination Providers  (Annex B) | Information to vaccination clinics and vaccinators on dosage, administration, storage and handling |  |
| Accompanying Annexes, Appendices and External References to the Guidance | - |  |

# Operations

# Parent Consent for Vaccination for Persons below 18 Years Old

# Persons below 18 years old are required to have the consent of their parent or legal guardian in order to be administered the vaccine.

# The table below states the requirements for parent’s / legal guardian’s consent, and the in-person presence of the parent / legal guardian during vaccination.

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| --- | --- | --- |
| **Age of Person being Vaccinated (X)** | **Parent / Legal Guardian**  **Consent?** | **Parent / Legal Guardian Presence?** |
| 12 ≤ X <13 | Consent Required. MSP to verify consent onsite with accompanying parent / legal guardian / authorized proxy | Presence Required |
| 13 ≤ X <18 | Consent Required. MSP to verify consent onsite | Presence Not Required |

# Requirements on Granting of Consent and Consent Verification (including in person parent / guardian presence)

# The Vaccination Providers will verify the following before administering the vaccine to the client:

1. HAS Appointment. Verify the HAS appointment status of the client to ensure that he/she has a valid appointment booked for the timeslot when present. If there is a valid HAS appointment, consent was given at the point the appointment was made and there is no need for written consent. If the client does not have any valid appointments, Vaccination Providers shall facilitate the client’s vaccination on site after ensuring consent had been obtained.
2. Verify the identification document of the client to ensure that he / she is the correct person for whom the parent / legal guardian had booked the vaccination appointment.
3. Clients who present the MOE EZ-link as their form of identification document shall be recognized as MOE students. Vaccination Providers shall record the accompanying adult’s relationship with the client in GPConnect-lite / PRPP or vaccination provider’s IT system.

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| Specimen screenshot of MOE EZ-link card |  |

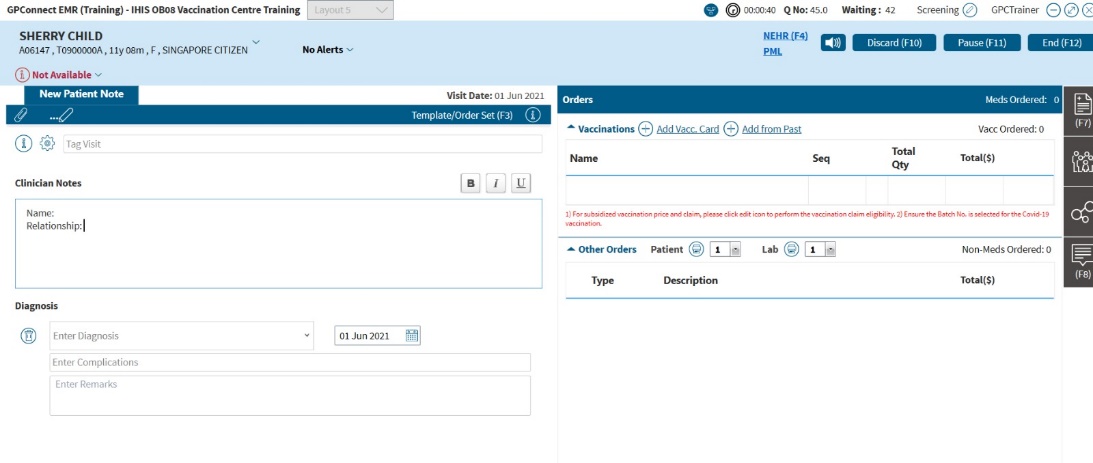
1. If the client presents other forms of identification documents (e.g., birth certificate or other valid identification documents), Vaccination Providers shall verify the parent’s / legal guardian’s signed letter of consent in hardcopy or softcopy form (Annex C) which is produced by the client. If the client is unable to produce the signed letter of consent either in hardcopy or softcopy form, the Vaccination Providers will verbally verify consent with the parent / legal guardian whose presence is required in person and record the consent in GPConnect lite / PRPP or vaccination provider’s IT system.

For foreign clients with foreign identification documents or whose birth certificates indicate they are not Singaporean at birth, Vaccination Providers shall register the clients with their FIN number.

1. Vaccination Providers are not required to retain the hardcopy of the signed Letter of Consent and Authorisation. However, the Vaccination Providers should document the parent’s/legal guardian’s consent in their IT system by capturing the following details for every client whose parent/legal guardian consent needs to be verified:
2. Name of the parent/legal guardian
3. Contact number of the parent/legal guardian
4. Consent obtained from parent/legal guardian
5. <Mode of consent obtained> from parent/legal guardian
6. Relationship between parent/legal guardian and client

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| **Document** | **Attachment** |
| Annex C – Letter of Consent and Authorisation |  |

1. For the second and additional dose appointments, the Vaccination Providers onsite will again verify that the client has the required parent consent and capture the same details in GPConnect / PRPP for each appointment, before administering any subsequent dose.
2. The Vaccination Providers will capture the required data under the “Clinical Notes” area and in accordance with the template shown below.



1. Hospitals and other healthcare institutions that provide vaccination services to their existing clients should obtain consent from a parent/legal guardian for their clients who are below 18 years old, using the hospital/institution’s existing processes. Hospitals/institutions should document the parent/legal guardian’s consent obtained in an appropriate EMR system/IT System.

**Consent for Vaccination**

* 1. Consent for vaccination is implied when a person registers for vaccination, shows up for vaccination, offers medical information to the vaccination provider if asked, and presents his/her arm to receive the vaccine without raising any verbal objection. Sector Leads/Agencies may choose to adopt a higher standard of consent-taking (e.g., written consent) in line with the agency’s existing processes. As part of the process in booking a vaccination appointment via the Health Appointment Booking System (HAS), the person will be asked for his/her consent to be vaccinated.
  2. For persons who may be unable to provide consent for vaccination (including persons with dementia or others lacking mental capacity), consent from next-of-kin (NOK) / donee / deputy if no NOK is available, is required.

**Consent for Vaccination of Persons Lacking in Mental Capacity with / without Next-Of-Kin (NOK)**

* 1. The following section will cover the requirement for consent for persons lacking mental capacity with / without NOK.

1. Those with mental capacity: Client’s consent needs to be obtained and documented.
2. Those with no mental capacity: To obtain consent from the donee / deputy, if there is one, or the NOK who makes decisions on behalf of the client.
3. Those with no mental capacity and no donee / deputy / NOK: The doctor may proceed with the vaccination according to his/her best judgment of the client’s best interests.
   1. The vaccination will generally follow the processes below:
4. Pre-vaccination – client will make appointment for vaccination.
5. On-Site Registration and Triaging – Upon the client’s arrival at the vaccination site, the client will be triaged and screened based on the client’s updated information and age. For organisations with access to NEHR, the Doctor / Nurse shall also access the client’s NEHR via GPConnect Lite / Staff Surveillance System (S3) / Electronic Medical Record (EMR) / Patient Risk Profile Portal (PRPP) or vaccination provider’s IT system to verify the client’s medical history. COVID-19 vaccines can now be administered concurrently with other non-COVID-19 vaccines across all ages eligible for the vaccine. The Doctor / Nurse shall also check the client’s COVID-19 vaccination records, if any, via GPConnect Lite / S3 / EMR / PRPP or vaccination provider’s IT system.
6. Vaccination - Vaccination and data capture.
7. Post-vaccination – Monitoring and reporting of adverse effects, if necessary.
   1. The following documents are required during the vaccination process:

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| **Document** | **Purpose of document** | **Nuvaxovid XBB 1.5** |
| Vaccination Information Sheet (VIS)  (Annex D) | Vaccine information and post-vaccination advice for client, if necessary.  VIS is available on MOH website |  |
| Vaccination Screening Form  (Annex E) | Reference of the minimum dataset for various uses, including registration, declaration of contraindications, indication of consent, medical record documentation, and vaccination procedure medical record documentation |  |
| Vaccination Card  (Annex F) | Vaccination record for client and appointment reminder for subsequent doses, if necessary.  To be issued to client after the vaccination is administered, if required. |  |

**Vaccination Screening**

* 1. If a client has been assessed to be ineligible or has to be deferred for vaccination, the screening Doctor / Nurse should reflect the associated reason / medical conditions on the GPConnect / S3 / EMR / PRPP, or vaccination provider’s IT system as follows:

1. The reasons / medical conditions[[1]](#footnote-1) should be aligned to the latest “MOH Guidance for Vaccination Providers” under Annex B.
2. The screening Doctor / Nurse should clearly communicate the said reasons to the client.
   1. Vaccination Providers should continue to exercise due diligence to assess clients during screening / triaging. This includes questioning clients as to whether they had experienced anaphylaxis following previous doses. The Vaccination Batch Number should continue to be recorded.
3. **Daily Reporting Requirements**

Vaccination Providers are required to submit daily reports to MOH. The reporting requirements are as follows:

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| **Document** | **Attachment** |
| Daily reporting requirements  (Annex G) |  |

1. **Logistics**

**Vaccine Handling and Storage**

* 1. Vaccination Providers shall adhere to the following vaccine storage guidelines.
  2. Unused vaccine vials should be stored in a refrigerator with the temperature maintained between 2°C and 8°C and must be monitored. For refrigerators that do not have a temperature data logger, the internal temperature of the refrigerator where vaccine vials are stored should be recorded twice daily, e.g., in the morning and evening.
  3. Care should be taken to protect the vaccine vials from light if the refrigerator door / window panel is transparent.
  4. Adopt a first-expire-first-out system when retrieving vaccine vials from the refrigerator.
  5. Vaccination Providers shall adhere to the following vaccine handling guidelines.
  6. Vaccine vials must always be protected from light when not being handled. Unopened vaccine should be kept within the outer box to protect from light. Handling refers to the process of preparation (pre-filling the syringe) and administration of the vaccine.
  7. Vaccines vials should be visually inspected for discolouration or particulates before each syringe is filled during preparation.
  8. When filling the syringe, the dose in each syringe should be visually inspected by lifting up each syringe to check for (i) the correct final dosing volume, (ii) no discolouration and no particulates, and (iii) no air bubbles.

**Disposal of Used / Empty Vaccine Vials, Syringes and Needles**

* 1. Used / empty vaccines vials are considered pharmaceutical waste. They must be collected in containers that are non-reactive, tamper-proof and designed to resist impact rupture and labelled with the proper colour code and symbol before disposal by a licensed biohazard waste collector.
  2. As COVID-19 vaccines delivered to vaccination sites are considered controlled consumables, used / empty vials should be properly accounted for and stored in a controlled environment before disposal to prevent unauthorised possession.
  3. Vaccination Providers must adhere to the following guidelines to prevent needle-stick injuries.
  4. Used needles and syringes must be disposed as one single unit into a Sharps Disposal Container immediately after they have been used.
  5. Used needles must not be removed from the syringe, bent or broken by hand manipulation / removal device / port to prevent accidental needle sticks which may cause serious infections.
  6. Used needles and syringes should not be left protruding from Sharps Disposal Containers, and Sharps Disposal Containers should not be more than full.
  7. Sharps Disposal Containers should be located in a safe and secure position such that they cannot be easily tipped over. Sharps Disposal Containers should not be stored on the floor or above shoulder level.
  8. There should not be any form of crossing over of hands / persons when disposing used needles and syringes into Sharps Disposal Containers.
  9. When Sharps Disposal Containers are not in use, the temporary closure mechanism must be used.
  10. If recapping of needles is necessary or required as part of the vaccine preparation workflow, the needle should be recapped with the aid of a pair of forceps, using a cap-holding device, or using a “one-handed scoop” technique to scoop the cap.
  11. Vaccination Providers should ensure that Sharps Disposal Containers used are properly secured and safely stored in a controlled area that is not accessible to any unauthorised personnel. Proper storage and handling of Sharps Disposal Containers before disposal **must be adhered to** as part of workplace safety management (i.e., Sharps Disposal Containers must not be stacked hazardously.)
  12. Please refer to the National Infection Prevention and Control Guidelines for more information:



**Inventory Management**

* 1. Vaccination Providers need to have a system to account for the vaccines issued. Proper recording of vaccine inventory and stock movement (e.g., stock balance / usage / received / transferred / wastage / disposed) should be maintained. Vaccination service providers are recommended to adopt the good practice of counting empty / used / damaged vaccine vials before disposal, to ensure that quantity discarded tally with that taken out of fridge.
  2. Vaccination Providers must have a system to monitor the stock expiry and transfer any excess stock to fellow vaccination providers at the first instance, to reduce wastage. If necessary, Vaccination Providers may seek assistance from your operations lead[[2]](#footnote-2) at least 2 weeks before expiry for MOH redistribution of the excess stock, subject to availability of vaccination sites that are able to consume it before expiry.
  3. Vaccination Providers are recommended to hold sufficient supply for 5 to 7 days to keep the vaccine fresh, and to manage the supply and re-supply properly to keep wastage to a minimum.

**Nuvaxovid XBB.1.5**

* 1. The vaccine will be delivered to Vaccination Providers at a temperature range of 2 to 8 degrees Celsius. The expiry date of the vaccine is labelled on the vaccine vial.
  2. Each Nuvaxovid XBB.1.5 vial is a multi-dose vial sufficient for **five** clients to be vaccinated.
  3. Nuvaxovid XBB.1.5 vaccine **does not require dilution** and must be used **within six hours** after first puncture of vial. Store the opened vial at 2°C to 8°C for up to twelve hours after first puncture of vial or six hours at room temperature (maximum 25°C) from the time of first needle puncture to administration.
  4. Vaccination Providers are recommended to hold sufficient supplies for 5 to 7 days’ requirements so as to keep the vaccine fresh, and to manage the supply and re-supply properly to keep wastage to a minimum.
  5. Vaccination Providers should note the order cut-off time, and the expected delivery when requesting for top-up of vaccines.

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| **Order Placed on Working Day** | **Vaccine Delivery** |
| Day 1; Before 10am | By Day 4; Within 3 working days |
| Day 1; After 10am  (Processed as next working day; Day 2) | By Day 5; Within 4 working days |
| Orders placed on Friday or eve of public holiday (Before 10am) | Next 3 working days |
| *Note: No order processing on weekends and public holidays* | |

* 1. Please refer to Annexes H and I for detailed work instructions for the requisition of vaccine and medical supplies.

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| **Document** | **Site Provider** | **Attachment** |
| Detailed Work instructions for the requisition of vaccine and medical supplies (Annex H – Nuvaxovid XBB 1.5) | PHPCs, JTVCs and Hospitals |  |
| Detailed Work instructions for the requisition of vaccine and medical supplies (Annex I – Nuvaxovid XBB 1.5) | Public Healthcare Institutions without eZRx access |  |

* 1. Medical supplies for vaccination may also be ordered from MOH via MOH-appointed logistics partner if medical service provider is unable to get from their usual sources.

**Low Dead Volume (LDV) Syringes and Needles**

* 1. Vaccination sites can order the MICSAFE NIPRO Slip Tip 1cc LDS syringe and NIPRO Hypodermic 25G needle (as a set). Users are to attempt to extract 5 doses from the Nuvaxovid XBB.1.5 vaccine vial.

# 8 IT Systems

* 1. The broad approach for IT systems is to provide a unified and integrated system to complement MOH vaccination sites with administrative and clinical functions to handle operational requirements.

**Health Appointment Booking System (HAS)**

* 1. The COVID-19 vaccination appointment booking function had been incorporated into the HAS to enable MOPs to book their COVID-19 vaccination appointments at the respective vaccination sites. This system will enable notifications and reminder functions to facilitate appointment attendance.

**Vaccination Operations EMR System**

* 1. GP Connect Lite (GPC Lite), Vaccination Care System (VCS) and Patient Risk Profile Portal (PRPP) have been identified to be the EMR Systems to manage the vaccination sites’ operations. Deployment of GPC Lite, VCS or PRPP to specific vaccination sites is at MOH’s discretion.

**Updating of COVID-19 Vaccination Records into National Immunisation Registry (NIR)**

* 1. Updating of vaccination records into NIR will be done via GPC Lite / VCS / PRPP automatically. Vaccination sites are to ensure that all clients’ vaccination records accumulated within each operational day are entered into GPC Lite / VCS / PRPP by **2200H** on the same day.

**Manual Updating of Vaccination Records into NIR**

* 1. There are currently 2 main methods to manually update vaccination records into the NIR Web Portal. Operators performing the updating of vaccination records via this route are to login using their CorpPass account using this internet link: <https://www.nir.hpb.gov.sg/nird/ens/enslogin>.
  2. *Data Entry Method*: Operators may choose one of the following relevant modes to perform the data entry function on the NIR Web Portal. ‘*Individual Record Entry (12 Years Old and Above)*’, ‘*Individual Record Entry (Below 12 Years Old)*’ and “*Multiple Record Entry*”.
  3. *Batch (Excel) Upload Method*: Operators may choose to batch vaccination records and pre-populate them into the .xls excel template provided on the NIR Web Portal. The completed templates are to be uploaded into the NIR Web Portal within the daily stipulated timing. **Operators should adhere to this template and not develop one of their own.**
  4. To perform the operations specified in this section efficiently, operators are advised to apply for an appropriate number of NIR “User” accounts within their respective organisations to assist with the updating requirements.
  5. The collective instructions for manual updating of vaccination records into NIR are prescribed in the following document.

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| **Document** | **Attachment** |
| NIR User Guide for COVID Notification  (Annex L) |  |

# 9 Conclusion

* 1. MOH seeks Vaccination Providers’ support and adherence to the requirements when carrying out vaccination service to members of public.

# 10 MOH Contact Information

* 1. MOH Vaccination Operations Centre (VOC): [COVID\_Vaccination\_Ops@moh.gov.sg](mailto:COVID_Vaccination_Ops@moh.gov.sg)

# Issued by:

**S. Vijakumar**

**Director, Vaccination Operations Task Group**

**Ministry of Health**

# On behalf of:

## Group Director, Crisis Strategy and Operations Group

**Ministry of Health**

Dated: 23 May 2024

1. The reasons/medical conditions are codified in GPC as: fever, acute respiratory infections, general unwell, immunosuppression, platelet count abnormality, allergy to vaccine product, history of drug-induced anaphylaxis, others, cancer treatment. [↑](#footnote-ref-1)
2. PHPC to contact AIC account manager. [↑](#footnote-ref-2)