Standards for COVID-19 Vaccination Centres

Version 3.1

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Health Policies and Standards Department

Health Regulation Sector (2022)

INTRODUCTION

Health Regulation Sector (HRS) forms an integral part of Dubai Health Authority (DHA) and is mandated by DHA Law No. (6) of 2018 to undertake several functions including but not limited to:

- Developing regulation, policy, standards, guidelines to improve quality and patient safety and promote the growth and development of the health sector.
- Licensure and inspection of health facilities as well as healthcare professionals and ensuring compliance to best practice.
- Managing patient complaints and assuring patient and physician rights are upheld.
- Governing the use of Narcotics, Controlled and Semi-Controlled Medications.
- Strengthening health tourism and assuring ongoing growth.
- Assuring management of health informatics, e-health and promoting innovation.

The Standards for COVID-19 Vaccination Centers aims to fulfil the following overarching DHA Strategic Priorities (2022-2026):

- Pioneering Human-centered health system to promote trust, safety, quality and care for patients and their families.
- Make Dubai a lighthouse for healthcare governance, integration and regulation.
- Leading global efforts to combat epidemics and infectious diseases and prepare for disasters.
- Pioneering prevention efforts against non-communicable diseases.

ACKNOWLEDGMENT

The Health Policy and Standards Department (HPSD) developed this Standard in collaboration with Subject Matter Experts. HPSD would like to acknowledge and thank these healthcare professionals for their dedication toward improving quality and safety of healthcare services in the Emirate of Dubai.

Health Regulation Sector

Dubai Health Authority

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EXECUTIVE SUMMARY

This is the Third edition of the Standards for COVID-19 Vaccination Centres in Dubai. This document is based on current knowledge of the situation in the UAE and across the globe; it is aligned with current international guidelines and circulars issued by DHA related to the subject. The document aims to ensure public and patient health protection and to ensure efficiency and integrity of the vaccination services provided for the public, in all DHA licensed health facilities providing COVID-19 vaccination services. This document outlines the facility and professional requirements to provide the service, as well outlines information on the currently available vaccines storage, preparation and administration. DHA will update these Standards as new information becomes available.

Updates in Version 3.1:

- Health Facility Requirements, page 11.
- Drive-through vaccination centres, page 13.
- Appendix 4. Evaluation Checklist for Drive-Through Vaccination Centres, page 52.
- References and appendices, page no 42-60.

DEFINITIONS

Adverse reaction: Any unintended and unwanted effect or presentation that appears on the user of the medical product within the doses documented in the internal leaflet and the authorized uses within the marketing approval that occurs as a result of separate effects from those essential effects of the medical product.

Batch number: a distinctive combination of numbers, symbols and/or letters which specifically identifies a batch.

Beyond-use-date: the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based the date or time the preparation is compounded, its chemical stability, and the sterility limits.

Health Facility: Any facility, owned and managed by natural or corporate body, provides medical services for individuals, including preventive, therapeutic and convalescent care services.

Healthcare Professional: a natural person who is authorized and licensed by the DHA to practice any of the healthcare professions in the Emirate.

Immediate allergic reaction: a reaction within 4 hours of being vaccinated, including symptoms such as hives, swelling, or wheezing (respiratory distress).

Legal guardian: a person appointed by the law to consent in place of an incompetent patient based on UAE federal laws and/ or local regulation, when the patient is unable to provide Informed Consent due to an illness or incompetency.

Medical Director: is a DHA licensed healthcare professional who holds responsibility and oversight of medical services and clinical operations within a DHA licensed health facility.

Person In-charge: Is a qualified and trained DHA licensed healthcare professional as the person designated site responsible in-charge to be responsible for the safe and secure handling, management accountable, monitoring, tracking, reporting, and operational responsibility of the vaccines within the site.

Serious adverse reaction: is one that requires inpatient hospitalization or prolongation of existing hospitalization, causes congenital malformation, result in persistent or significant disability or incapacity, is life threatening or result in death.

Temperature excursion: is any temperature reading outside of the recommended range for vaccine storage as defined in the manufacturer's package insert.

ABBREVIATIONS

ACIP	:	Advisory Committee on Immunization Practices
ACOG	:	American College of Obstetrics & Gynaecology
ADRs	:	Adverse Drug Reactions
AEFI	:	Adverse Event Following Immunization
AFI	:	Acute febrile illness
COVID	:	Corona Virus Disease
DHA	:	Dubai Health Authority
DOB	:	Date of Birth
HPSD	:	Health Policies and Standards Department
HRS	:	Health Regulation Sector
IM	:	Intramuscular
MOHAP	:	Ministry of Health and Prevention
Purple vial cap	:	Pfizer-BioNTech vaccine vial for 12 years of age and older
Orange vial cap	:	Pfizer-BioNTech vaccine vial for 5 - 11 years of age
PPE	:	Personal Protective Equipment
SOPs	:	Standard operating procedures
WHO	:	World Health Organization

1. BACKGROUND

Coronavirus Disease (COVID-19) is a disease caused by new strain of coronavirus (SARS-CoV2) that has not been previously identified. Cases were registered initially in the Republic of China, but COVID-19 has spread to several countries around the world. It is very contagious and the infection can vary from mild to severe symptoms.

Vaccines protect individuals from some infectious diseases and their serious complications, which can lead to a healthier community free from these infectious diseases and epidemics. The COVID-19 vaccine will reduce the chance of being infected with COVID-19 virus and its spread. When many individuals are vaccinated, COVID-19 virus is less likely to spread in the community. The current available COVID-19 vaccines in the country are:

- mRNA COVID-19 (BNT162b2) COVID-19 Vaccine (Pfizer-BioNTech).
- ChAdOx1 nCoV- 19 (Recombinant) COVID-19 Vaccine (AstraZeneca).
- Inactivated SARS-CoV-2 (BBIBP-CorV) COVID-19 Vaccine (Sinopharm).
- Gam-COVID-Vac Vaccine (Sputnik).
- SARS-COV-2 (Vero Cell), Inactivated Vaccine (Hayat-Vax).

Some of the available vaccines can be given to everyone starting from the age of 5 years. However, it is recommended to give the priority for vaccination to those at highest risk of contracting the infection and those who are at risk of serious complications of infection when being infected, including the following priorities: Individuals aged 60 years and above, front liners, individuals of determination and individuals with chronic condition/s such as:

- Heart diseases.

- Diabetes.
- Chronic lung diseases.
- Kidney diseases.
- Liver diseases.
- Immunocompromised conditions.
- Cancer.

2. SCOPE

2.1. COVID-19 Vaccination services under DHA's jurisdiction.

3. PURPOSE

3.1. To standardise the requirements and eligibility for the establishment of COVID-19 vaccination programs by DHA Licensed Health Facilities in the Emirate of Dubai.

4. APPLICABILITY

4.1. DHA licensed health facilities providing COVID-19 Vaccination services.

4.2. DHA licensed health facilities approved to provide mRNA COVID-19 vaccine for children.

5. STANDARD ONE: HEALTH FACILITY REQUIREMENTS

5.1. All DHA licensed health facilities should obtain approval from HRS before providing COVID-19 Vaccination services.

5.2. DHA licensed health facilities should obtain approval to provide mRNA COVID-19 vaccine for children.

5.3. Health facilities should adhere to all the requirements outlined in these standards, updates and circulars related to it thereafter.

5.4. Health facilities should adhere to the DHA guidelines on eligibility for mRNA COVID-19 (BNT162b2) Vaccine updates and circulars related to it thereafter.

5.5. COVID-19 vaccination services can be provided in the below settings following approval from DHA:

5.5.1. Hospitals.

5.5.2. Day Surgery Centres.

5.5.3. Outpatient health facilities.

5.5.4. Home Healthcare Providers – Standalone/service licensed under other health facilities.

5.5.5. School clinic.

5.5.6. Mobile healthcare units.

5.5.7. Drive-through vaccination centres.

5.6. All new Vaccination Centres should submit new applications to the Health Licensing Department in the Health Regulation Sector (HRS) for the approval and licensing.

5.6.1. Apply for amendment of Facility license – "Add service of COVID-19 Vaccination" (via Sheryan).

a. Refer to requirement checklist for covid-19 vaccination centers in (**Appendix 1**).

b. Refer to the checklist for Vaccination clinics held at satellite, temporary, or off-site locations in (**Appendix 2**).

5.6.2. Existing Health Facilities undergoing changes and refurbishment, such as re-modelling, changing the type of service (i.e. the use of space, converting Administration

Department into Vaccination Centre) should submit applications for the modification of previous license approvals.

5.7. Health facility should maintain availability of Person In-charge for each working shift in the vaccination site.

5.7.1. A paediatric specialist should be available on each working shift in the vaccination site for health facilities approved to provide COVID-19 vaccine for children.

5.8. Preventive precautionary measures should be applied in the health facility, the facility should comprise of:

5.8.1. Reception area; which includes patient registration and patient queuing system.

5.8.2. Waiting areas; should accommodate a wide range of occupants including those less mobile or in wheelchairs.

5.8.3. Patient screening/vital signs room(s); will be used for measurement and recording of patient vital signs prior to consultation.

5.8.4. Vaccination room (s)/cubicle(s)/bay(s); where patients will receive the vaccine by a licensed trained healthcare professional ensuring privacy.

5.8.5. Designated room(s)/cubicle(s) at the site for management of Adverse Drug Reactions (ADRs) and management of patients with urgent medical problems (e.g., fainting, high blood pressure, etc.) and for referral to other entities (if applicable).

5.8.6. Observation area; where patients will be monitored closely after being vaccinated for any adverse reaction or immediate allergic reaction.

5.9. Health facilities and healthcare providers may apply for mobile vaccination unit for COVID-19 Vaccination services.

5.9.1. A Mobile Healthcare Unit is a specially designed mobile, transportable or re-locatable structure, which serves to provide dynamic healthcare options and services in response to community's immediate or longer-term healthcare demands.

5.9.2. Proper consideration needs to be given with respect to turning radius, manoeuvrability of the unit, parking, delivery and service access to the mobile healthcare unit.

5.9.3. For further details, refer to the checklist for Mobile Vaccination Units in (**Appendix 3**).

5.10. Health facilities and healthcare providers may apply for Drive-through vaccination centres.

5.10.1. The drive through unit must preferably be located in, or close to, a larger permanent facility with which the unit shares support services.

5.10.2. Facility should adhere to the relevant local environmental laws and regulations that may apply.

5.10.3. Standard precautions should be implemented to prevent cross infection between potentially infectious patients.

5.10.4. The facility should set in place all clinical considerations for planning a vaccination drive thru clinic, including but not limited to: vaccine storage, handling, administration, and documentation.

5.10.5. Facility shall assure and maintain the vaccines from any Vaccine Temperature excursion.

5.10.6. For further details, refer to the checklist for Drive-through vaccination centre in (**Appendix 4**).

6. **STANDARD TWO:** PROFESSIONAL REQUIREMENTS

6.1. All healthcare professionals in the health facility should hold an active DHA professional license and work within their scope of practice.

6.2. The Medical Director of the health facility should privilege the health professional based on his/her education, training, experience and competencies.

6.3. Healthcare professional(s) should have experience with Intramuscular (IM) injection and up-to-date skills training.

6.4. Healthcare professional(s) administering vaccines should review vaccine manufacturer instructions for administration before the vaccination.

6.5. Healthcare professionals should ensure reporting and record keeping compliance for all vaccinations administered.

6.6. Healthcare professionals should understands the procedures, indications, contraindications, and all other pertinent administration information including side effects, reactions, and life-saving measures.

6.7. Vaccination Centres should ensure the training and education of the staff involved in the vaccination service.

6.8. All healthcare professionals who provide vaccine administration are required to:

6.8.1. DHA vaccination education module completion, though the following link: https://learn.mbru.ac.ae/courses/covid-19-pfizer-vaccine-training

6.9. The below categories of professionals can administer COVID-19 vaccine:

6.9.1. Health care professionals licensed by DHA.

6.9.2. Paramedics and advanced emergency medical technician (EMTs), Licensed or certified as a Paramedic, Advanced EMT, or EMT by DCAS.

7. STANDARD THREE: MANAGING VACCINE STOCKPILE, STORAGE, TRANSPORTATION, AND COLD CHAIN REQUIREMENTS

7.1. Managing vaccine stockpile:

7.1.1. All types of COVID-19 vaccination will be provided by DHA/governmental entity in coordination with DHA.

7.1.2. Health facilities should have a policy and a clear official pathway in place to manage the stockpile of the available vaccine in a way that no dose is wasted.

7.1.3. Health facilities should have a contingency plan for extra doses at the end of each shift to avoid wastage of open vials.

7.1.4. COVID-19 vaccines require two doses to be administered 3-12 weeks apart (depending on vaccine product type). Health facilities must carefully manage vaccine inventory to ensure completion of the vaccine series.

7.1.5. Predictable amount of vaccine should be provided to the vaccination centre. This allows efficient management of patient scheduling and second dose administration plans.

7.1.6. Once first doses of the vaccine are administered, the health facilities should be able to estimate the number of patients that will require a second dose each week.

7.1.7. Health facilities should make sure that every first dose-vaccinated client has an appointment for second dose and the appointment is communicated to client.

7.1.8. Patients requiring second doses should be prioritized.

7.1.9. On a daily basis, providers should review missed appointments or other reasons for scheduled second doses not being used, and remaining doses should be repurposed for use as first doses.

7.1.10. Vaccines should be delivered to the patients free of charge and health facilities should refrain from billing the patients for any cost.

7.2. Operational Considerations:

7.2.1. Health facilities should ensure vaccine with matching number of syringes and needles as per each vaccine type should be shipped directly to the facility/vaccination site, where appropriate and adequate storage is available.

7.2.2. Upon arrival at the facility/clinic, vaccines should remain protected from light (per manufacturer's package insert/guide) until ready for use at the vaccination clinic.

a. Expiration dates of vaccines and any medical equipment (syringes, needles, alcohol wipes) used should be checked for validity.

7.2.3. A contingency plan is in place in case vaccines need to be replaced. The plan addresses scenarios for vaccine compromised before arrival at the clinic and for vaccine compromised during clinic hours.

7.2.4. Health facility should maintain clearly written, detailed, and up-to-date receiving, storage, handling, and transporting SOPs.

7.2.5. An emergency medical kit should be available at the site of the clinic/vaccination centre. (Kit may include; epinephrine, Hydrocortisone, Chlorpheniramine Inj. and equipment for maintaining an airway).

7.3. Vaccine Storage:

7.3.1. Proper storage, handling, and transportation of COVID-19 vaccines are critical activities in their integrated supply chain.

7.3.2. Failure to store and handle vaccines properly can potentially reduce potency, leading to inadequate immune response in patients and poor protection against COVID-19.

7.3.3. Proper storage, handling, and transportation of the COVID-19 vaccines begins with an effective cold chain process, which is temperature-controlled, using related equipment and procedures.

7.3.4. Storage units are required to maintain the product temperature between the limits defined on the product label and manufacture's product Packaging and Storage Requirements.

7.3.5. Pharmaceutical-grade refrigerators and freezers are preferred because they are designed specifically for storing biopharmaceuticals, including vaccines.

7.3.6. Food and drinks and/or biological specimens should not be stored in the same unit as the vaccine.

7.3.7. SOPs should be in place to ensure power supply or alternative options when power outage occurs.

7.3.8. Temperature excursions or inappropriate storage conditions require immediate action.

a. A temperature excursion is any temperature reading outside of the recommended range for vaccine storage as defined in the manufacturer's package insert.

7.3.9. When the vaccine's storage condition is changed, it is critical to utilize appropriate labelling to indicate the beyond-use date, per the manufacturer.

7.3.10. Beyond-Use Dating Considerations for Pre-drawn Syringes of Purple vial cap:

a. For the purple vial cap, the vaccine maintains all its measured quality attributes when diluted vaccine is stored in polycarbonate and polypropylene syringes with stainless steel needles for 6 hours at 2°C to 25°C (35°F to 77°F) after the source vial is diluted.

b. Microbiological growth has a greater potential to occur after 6 hours.

c. 0.9% sodium chloride injection, preservative-free, diluent should not be drawn up in advance as it is preservative-free.

d. Keep out of direct sunlight and ultraviolet light.

7.3.11. Beyond-Use Dating Considerations for Pre-drawn Syringes of Orange vial cap:

a. For the orange vial cap ,the vaccine maintains all of its measured quality attributes when the diluted vaccine is stored in polycarbonate or polypropylene syringes for a cumulative time up to 24 hours post-dilution with no more than 12 hours at room temperature (up to 30°C or 86F).

b. Microbial growth has a greater potential to occur after 12 hours.

c. 0.9% sodium chloride injection, preservative-free, diluent should not be drawn up in advance as it is preservative-free.

d. Keep out of direct sunlight and ultraviolet light.

7.4. Vaccine Transport:

7.4.1. Vaccine transport off-site or to vaccination facilities involves the process of transporting vaccines over short distances and periods in accordance with practice setting SOPs.

7.4.2. Transport of the vaccines should be done using a portable refrigerator and/ or freezer unit with a temperature-monitoring device.

7.4.3. Health facilities should use a continuous temperature-monitoring device to ensure consistent temperature monitoring during transport.

7.4.4. The total time for transport should be minimized to reduce potential risk for a temperature excursion due to a storage unit or thermal packaging system failure.

7.5. Transport of frozen solid mRNA (BNT162b2) COVID-19 Vaccine vials prior to use:

7.5.1. Frozen mRNA (BNT162b2) COVID-19 Vaccine can be transported at ultra-low-temperature of -90ºC to -60ºC (-130ºF to -76ºF).

7.5.2. Frozen Pfizer-BioNTech COVID-19 Vaccine purple vial cap can be transported and stored at conventional pharmaceutical freezers for a period of up to two weeks at the freezer temperature of -25°C to -15°C (-13°F to 5°F). The frozen vaccine may be returned one time to the recommended storage condition of -90ºC to -60ºC (-130ºF to -76ºF). Total cumulative time the purple vial cap and label formulation are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks.

7.5.3. Health facilities should use the only allowable containers and cold freezers as per product manufacturer labelling.

7.5.4. Appropriate measures should be taken to ensure the vaccine is cushioned and protected from agitation during transport.

7.6. Transport of multi-dose mRNA (BNT162b2) COVID-19 Vaccine vials outside of frozen state or those that do not require freezing:

7.6.1. Undiluted vials can be maintained at refrigeration temperatures at 2ºC to 8ºC (35ºF to 46ºF) for 1 month for purple vial cap and 10 weeks for orange vial cap.

7.6.2. Undiluted vials can be maintained at room temperature for up to 25ºC (77ºF) for 2 hours for purple vial cap and 12 hours for orange vial cap (prior to first puncture).

7.6.3. Diluted vials can be maintained at room temperature for up to 25ºC (77ºF) for 6 hours and must be discarded after 6 hours for the purple vial cap and for up to 12 hours for orange vial cap.

7.6.4. A portable refrigerator unit can be utilized to transport thawed vaccine product.

7.6.5. Appropriate measures should be taken to ensure the vaccine is cushioned and protected from agitation.

7.6.6. Expanded polystyrene foam containers can be used for maintaining cold chain/temperature consistency across transport to administration site.

7.6.7. When the product is thawed, do not refreeze.

8. **STANDARD FOUR:** DOCUMENTATION

8.1. Health facilities should maintain proper and complete documentation of patient details on HASANA platform in addition to their EMR systems.

8.2. The below details should be documented in the patient file:

8.2.1. Complete patient demographics:

a. Emirates ID number or Passport Number.

b. First name, last name, gender, date of birth and nationality.

c. Home address: District, Area.

8.2.2. Occupational details:

a. Main Occupation: Labourer/Non-Labourer.

b. Name the company/authority.

c. Emirate.

8.2.3. Vaccine details (date and time, site and route, brand, batch number, dose, etc.).

8.2.4. Pre-vaccination assessment and counselling.

8.2.5. Vaccination consent form (**Appendix 5**).

8.2.6. Post-vaccine assessment and any ADRs.

8.2.7. Issuance of "COVID-19 Vaccination Card" post vaccination

8.2.8. Documentation of the "COVID-19 Vaccination Exemption Certificate" when necessary (**Appendix 6**).

a. Exemption certificate is issued only by DHA government hospitals and primary healthcare centres.

b. Physicians at private health facilities should issue a medical report to the patient stating the condition that entitles the exemption and in accordance with the approved regulations.

c. Patients should be directed to the concerned DHA government health facilities to apply for the exemption certificate along with the related medical report.

d. For further information refer to DHA circular no. DHA/OUT/2022/0000242 regarding Process for issuing COVID-19 Vaccine Exemption Certificate (linked)

8.3. Patient information confidentiality should be maintained as per UAE laws and regulations.

8.4. Health facilities should have access to HASANA platform once approved to provide the service.

8.5. Training to use the vaccination module will be delivered by the HASANA Helpdesk team.

8.6. Health facilities are responsible to enter all the required details in HASANA on timely manner.

8.7. Patient vaccine consent form (**Appendix 5**) should be signed and uploaded to the health facility's electronic health records.

8.8. Health facilities should ensure that each client receives vaccination certificate per each dose.

8.9. Record patient refusals in the individual medical record.

9. **STANDARD FIVE:** PRE-SCREENING AND PROTOCOL FOR ADMINISTERING VACCINE

9.1. Health facilities should provide adequate information to patients or their legal guardians regarding the risk weighing benefit of the vaccine and document that information in compliance with service-specific guidelines.

9.2. Health facilities should ensure that pre-screening is done for each patient prior to vaccine administration.

9.3. Pre-screening:

9.3.1. Prior to vaccination, the healthcare professional/vaccine injector should:

a. Confirm the recipient's identity from the EID or passport.

b. Check ALHOSN application for previous vaccine doses.

c. Assess the vaccine recipient's current state of health.

d. Check the patient Age.

e. Stability of current medical condition before vaccination.

f. Active covid-19 infection, close contact or in the event of quarantine period.

g. Former receiving of any COVID-19 vaccine before (one or two doses).

h. Provide information regarding the benefits and risks of receiving or not receiving the vaccine using content and language appropriate to the vaccine recipient or guardian.

i. Provide Education for patient about pain management for vaccine injection on the day of immunization.

j. Assess contraindications and precautions to receiving the vaccine, including any history of potential immediate or anaphylactic hypersensitivity to a previous dose of the vaccine or to any of the vaccine components.

k. Evaluate reactions to previous vaccinations.

l. Discuss frequently occurring minor adverse events and potential rare severe adverse events.

m. Provide ways of communicating adverse events to facility for purpose of providing help and documentation of Adverse Event Following Immunization (AEFI) reports.

   i. DHA Call centre.

   ii. Visit any GP/ER.

n. Take full history on chronic diseases, medication used (if applicable).

o. Provide an opportunity for the vaccine recipient or guardian to ask questions.

p. Provide full explanation and obtain patient consent, (**Appendix 5**).

9.4. Vaccine administration:

9.4.1. Vaccines should be administered to the right person using the correct indication, correct vaccine, correct dose, correct route of administration, correct injection site (if applicable) and correct time to optimize vaccine effectiveness and to reduce the risk of local reactions or other adverse events.

9.4.2. Healthcare professionals administering vaccinations should follow appropriate precautions to minimize risk for disease exposure and spread.

9.4.3. Hands should be cleansed with an alcohol-based waterless antiseptic hand-rub or washed with soap and water before preparing vaccines for administration and between each patient contact.

9.4.4. Vaccines should be drawn up in a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed.

9.4.5. Multi-dose vials to be used for more than one patient should not be kept or accessed in the immediate patient treatment area.

a. This is to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment that could lead to infections in subsequent patients.

9.4.6. To prevent contamination of the vial, the patient area should be clean and free of potentially contaminated equipment.

9.4.7. Injectable Route-SARS-CoV-2 vaccines are administered via IM injection.

9.4.8. The manufacturer for each vaccine recommends routes of administration. Deviation from the recommended route of administration might reduce vaccine efficacy or increase the risk for local adverse reactions.

9.4.9. The health facility should have in place a protocol for incident reporting related to vaccine administration and ensure risks are controlled effectively.

10. STANDARD SIX: PREPARATION REQUIREMENT FOR VACCINES

10.1. Environmental Considerations for Vaccine Preparation:

10.1.1. Health facilities should follow vaccine manufacturer requirements supplied information on the steps for vaccine preparation.

10.1.2. The following considerations should be made when selecting an environment for preparation of vaccines:

a. The dedicated area or room should be a clean, uncluttered, and a functionally separate workspace.

b. The dedicated area or room should be away from windows, doors, air vents, etc. to minimize airflow disruptions.

c. Items that are not necessary for vaccine preparation should be removed from the vaccine preparation area (i.e., food, drinks, and other materials).

d. Alcohol-based hand sanitizer should be available. For alcohol-based hand sanitizers, the Centers for Disease Control & Prevention (CDC) recommends a concentration of 60% to 95% ethanol or isopropanol (i.e., isopropyl6) alcohol.

e. Whenever possible, the area dedicated for vaccine preparation should not be located in or close to where environmental control challenges could negatively affect the air quality (e.g., restrooms, warehouses, or food preparation areas).

10.1.3. Equipment to include in the dedicated area or room may comprise of sharps container, alcohol swabs, sink and/or hand sanitizer, and materials for personnel hygiene and garbing.

10.1.4. Adhere to aseptic technique to ensure the quality and safety of the preparation of these vaccine products.

a. Clean and disinfect the surface where the vaccine preparation will take place using a solution of at least 70% isopropyl alcohol.

10.1.5. Personnel should avoid preparing different vaccine type in the same vaccine preparation area.

10.2. Personnel Hygiene and Garbing:

10.2.1. All staff members who are exposed to the vaccines, or who administer the vaccines should be trained on all relevant practices and procedures.

10.2.2. Healthcare professionals who supervise the preparation of the vaccines should ensure that personnel are adequately skilled, educated, and trained to correctly perform preparation of the COVID-19 vaccines.

10.2.3. Before beginning preparation of COVID-19 vaccines, personnel should consider the following aspects of hygiene and garbing:

a. Personnel should remove hand, wrist, and other exposed jewellery that could interfere with the effectiveness of garbing or otherwise increase the risk of contamination of the vaccines.

b. Fingernails should be clean and neatly trimmed to minimize particle shedding and avoid glove punctures.

c. Personnel should perform hand hygiene by washing hands with soap and water for at least 30 seconds or by using hand sanitizer rubbed between hands and fingers and allowed to dry.

d. Personnel should don powder-free gloves before preparing vaccines for administration. Powder-free gloves should be inspected regularly for holes, punctures, or tears and must be replaced immediately if such defects are detected.

e. Personnel should don and replace garb (e.g., masks, freshly laundered lab coat, powder-free gloves, and clean scrubs) immediately if it becomes visibly soiled or if its integrity is compromised.

10.3. Basic Aseptic Considerations for Vaccine Preparation:

10.3.1. Aseptic technique should be utilized to prepare vaccines for administration in order to prevent the vaccines from being contaminated with microorganisms from the environment or from the persons preparing them.

10.3.2. Aseptic technique considerations for vaccine preparation should include the following:

a. Follow internal facility standard operating procedures (SOPs) and regulatory requirements related to competency, training, or certification of vaccine preparation and administration, as appropriate.

b. Inspect vials for cracks or leaks prior to proceeding further.

c. Disinfect entry points on the diluent and vaccine vials (e.g., vial stoppers) by wiping the vials with single-use alcohol swabs. Allow the alcohol to dry before piercing stoppers with sterile needles.

d. During preparation of the vaccine, personnel should avoid touching critical parts of the components being used for preparation of the vaccines (e.g., needles, disinfected vial stoppers) in order to minimize microbial contamination.

e. Place all used syringes, needles, and vials into sharps container and dispose the containers according to DHA regulatory requirements.

10.4. Withdrawing Doses:

10.4.1. The following considerations should be done to ensure complete doses are withdrawn and safe practices:

a. Ensure needle and syringe are tightly Luer Locked together.

b. Consider using the smallest syringe appropriate for the dose to improve dose accuracy.

c. Consider using a syringe with appropriate measuring lines on the barrel of the syringe to further improve dose accuracy.

d. The same needle should be used for withdrawal and administration. This eliminates the need to change needles and therefore reduces the risk of touch contamination to the vaccine and potential loss of volume.

e. Exercise care to avoid contaminating or bending the needle if being used for both withdrawal and administration.

f. Refrain from using transfer devices, mini spikes, or one needle to prepare multiple syringes due to potential loss of medicine in dead space.

g. Refrain from using dispensing pins or needleless devices due to risk of vaccine loss or incompatibility with materials.

h. Utilize safe practices when recapping the needle after withdrawing and before administration.

i. In the case of excess air bubbles in the syringe, small bubbles can be ignored. Personnel should avoid tapping the syringe due to theoretical risk of inactivating the vaccine or degraded quality.

10.5. mRNA COVID-19 (BNT162b2) Vaccine Considerations:

10.5.1. Health facilities should follow manufacturer-supplied information on the steps for dilution is available on the Vaccine.

10.5.2. The manufacturer recommends preferentially using a low dead-volume syringe or needle to maximize the number of doses per vial.

a. Utilizing low dead-volume syringes and needles whenever possible, to maximize doses withdrawn from vials (at least 6 doses for the purple vial cap, and 10 doses for the orange vial cap).

10.5.3. A low dead-volume syringe is designed to limit dead space that exists between the syringe hub and needle. A low dead-volume needle is designed with less space between the needle and the plunger.

10.5.4. For the purple vial cap, regardless of diluent vial size, only a single needle entry can be used to withdraw a single 1.8 mL volume of 0.9% sodium chloride injection, preservative-free, diluent to prepare one vial of the Pfizer-BioNTech COVID-19 vaccine. Any excess diluent must be discarded.

10.5.5. For the orange vial cap, regardless of diluent vial size, only a single needle entry can be used to withdraw a single 1.3 mL volume of 0.9% sodium chloride injection, preservative-free, diluent to prepare one vial of the Pfizer-BioNTech COVID-19 vaccine. Any excess diluent must be discarded.

10.5.6. 0.9% sodium chloride injection, preservative-free, diluent should not be drawn up in advance as it is preservative-free.

10.5.7. The manufacturer provides that for dose preparation, a 21-gauge or narrower needle helps prevent leaking from the stopper when doses are withdrawn.

10.5.8. Health facility may carefully consider the number of pre-drawn syringes to prepare to minimize vaccine waste.

10.5.9. Purple Vial Cap and Label Border (must dilute) for 12 years and older (final diluted conc: 30 mcg/ 0.3 mL).

10.5.10. Orange Vial Cap and Label Border (must dilute) for 5 through 11 years (final diluted conc: 10 mcg/ 0.2 mL).

10.5.11. The Pfizer-BioNTech COVID-19 Vaccine that is supplied in vials with purple vial cap should not be used for individuals 5 through 11 years of age because of the potential for vaccine administration errors, including dosing errors.

10.6. mRNA COVID-19 (BNT162b2) Purple vial cap Vaccine Dilution:

10.6.1. Prepare for Dilution:

a. A Pfizer-BioNTech COVID-19 vaccine vial must reach room temperature before dilution and be diluted within 2 hours of removal from frozen or refrigerated storage.

b. Inspect liquid to ensure it is a white to off-white suspension which may contain white to off-white opaque amorphous particles.

c. Invert vaccine vial gently 10 times. Do not shake.

10.6.2. Dilute the vaccine:

a. Visually inspect vial for cracks and leaks.

b. Wipe diluent vial stopper using sterile 70% isopropyl alcohol swab and allow to dry.

c. If applicable, ensure needle and syringe are tightly luer locked together.

d. Withdraw 1.8 mL 0.9% sodium chloride injection, preservative free, diluent into syringe. Discard vial after diluent withdrawal.

e. To prevent excess foaming or bubbling, slowly inject 1.8 mL of 0.9% sodium chloride injection, preservative free, diluent onto the wall of the vaccine vial.

f. Before removing the needle from the vaccine vial, move needle tip to the air headspace of the vial and draw out 2.1 mL of air to optimize vial pressure.

g. The vial pressure must at least be equalized by withdrawing 1.8 mL of air into the empty diluent syringe per the labeling.

h. Gently invert the diluted vial 10 times to mix. Do not shake.

i. Record dilution date and time on vaccine vial and store diluted vaccine for up to 6 hours at 2°C to 25°C (35°F to 77°F).

10.6.3. Draw up each dose of the vaccine:

a. Wipe vaccine vial stopper using sterile 70% isopropyl alcohol swab and allow to dry.

b. If applicable, ensure needle and syringe are tightly luer locked together.

c. Inject 0.2 mL of air into the vial of reconstituted vaccine to optimize vial pressure.

d. Slowly withdraw 0.3 mL of vaccine into the administration syringe.

e. While small air bubbles can be ignored, large air bubbles can lead to underdosing and should be addressed. Minimize tapping of the syringe due to theoretical risk of inactivating the vaccine or degrading quality.

f. Utilize safe practices when recapping the needle after withdrawing and before administrating.

g. Rotate the insertion point of the needle across various locations of the vial septum for each withdrawal to reduce leakage of vaccine.

10.7. mRNA COVID-19 (BNT162b2) Orange vial cap Vaccine Dilution:

10.7.1. Prepare for Dilution:

a. A Pfizer-BioNTech COVID-19 vaccine orange cap vial must reach room temperature before dilution and be diluted within 12 hours of removal from frozen or refrigerated storage.

b. Inspect liquid to ensure it is a white to off-white suspension which may contain white to off-white opaque amorphous particles.

c. Invert vaccine vial gently 10 times. Do not shake.

10.7.2. Dilute the vaccine:

a. Visually inspect vial for cracks and leaks.

b. Wipe diluent vial stopper using sterile 70% isopropyl alcohol swab and allow to dry.

c. If applicable, ensure needle and syringe are tightly luer locked together.

d. Withdraw 1.3 mL 0.9% sodium chloride injection, preservative free, diluent into syringe. Discard vial after diluent withdrawal.

e. To prevent excess foaming or bubbling, slowly inject 1.3 mL of 0.9% sodium chloride injection, preservative free, diluent onto the wall of the vaccine vial.

f. Gently invert the diluted vial 10 times to mix. Do not shake.

g. Record dilution date and time on vaccine vial and store diluted vaccine for up to 12 hours at 2°C to 25°C (35°F to 77°F).

10.7.3. Draw up each dose of the vaccine:

a. Wipe vaccine vial stopper using sterile 70% isopropyl alcohol swab and allow to dry.

b. If applicable, ensure needle and syringe are tightly luerlocked together.

c. Inject 0.2 mL of air into the vial of reconstituted vaccine to optimize vial pressure.

d. Slowly withdraw 0.2 mL of vaccine into the administration syringe.

e. While small air bubbles can be ignored, large air bubbles can lead to underdosing and should be addressed. Minimize tapping of the syringe due to theoretical risk of inactivating the vaccine or degrading quality.

f. Utilize safe practices when recapping the needle after withdrawing and before administrating.

g. Rotate the insertion point of the needle across various locations of the vial septum for each withdrawal to reduce leakage of vaccine.

10.8. Labelling Considerations:

10.8.1. When the COVID-19 Vaccines are not being prepared for immediate administration, appropriate labelling considerations for each vaccine type should be undertaken.

10.8.2. If the vaccines are sent outside the facility in which they were prepared for administration, a designated person must ensure that contact information of the preparation facility is conveyed and available at the site where they will be administered.

10.8.3. Labels should be adhered to the container(s) (e.g., light protected zip-lock bag in which pre-drawn syringes are stored and transported).

10.8.4. Pre-drawn syringes prepared for administration must be labelled with legible identifying information to prevent errors during storage, dispensing, transport, and use.

10.8.5. Personnel should consider adding the following labelling components to the containers in which the pre-drawn vaccine syringes are stored as well as the pre-drawn vaccine syringe:

a. Facility name and license no.

b. Quantity of syringes.

c. Name and amount of vaccine.

d. Primary or Booster dose (if applicable).

e. Age range (if applicable).

f. The exact beyond-use date and time.

g. Batch number.

h. Initials of preparer.

11. STANDARD SEVEN: OBSERVATION POST VACCINE

11.1. Patient monitoring following Immunization for COVID-19 vaccines may include a collaborative approach between patient care providers, physicians, pharmacists, the patient and the family or caregivers.

11.2. Monitoring and assessing the potential side effect of the vaccine includes direct observation of the patient's physiological response to the vaccine administered and any problems or adverse effects associated with the vaccine.

11.3. Adult vaccine recipients should be kept under observation as listed below:

11.3.1. No observation time for individuals aged below 60 years with:

a. No significant past medical history

b. No comorbidity

c. No adverse event after the first or second dose

11.3.2. A 5 minutes observation time for individuals aged 60 years and above with:

a. Significant past medical history

b. Comorbidities

c. History of an adverse drug reaction after receiving the first and/or second dose

11.3.3. Observation for 30 minutes for individuals with history of allergies

11.3.4. Observation for 20 minutes for children 5-11 years

11.3.5. Observation for 30 minutes for children aged 5-11 years with a history of allergy

11.4. All healthcare professionals should monitor for adverse reactions (e.g. anaphylaxis), in the designated post vaccine observation area and initiate immediate treatment as follow:

11.4.1. If mild injection site reaction or allergic reaction consult on-call physician.

11.4.2. If signs of severe allergic reaction/anaphylaxis (dyspnoea, stridor, severe urticaria, tachycardia, hypotension, or Altered Mental Status) activate emergency response system and initiate treatment if available:

a. Inj. Epinephrine (EpiPen) Auto-Injector 0.3 mg.

b. Hydrocortisone or Diphenhydramine Injection.

c. Perform Airway Management as required.

d. Initiate cardiac monitoring (or AED).

e. Albuterol 2.5 mg nebulized if wheezing/dyspnoea.

f. Initiate or request transport per local EMS protocols.

g. Report any adverse reactions.

h. Additional ALS management may be provided as available.

11.4.3. Vaccination providers should have appropriate medications and equipment such as epinephrine, antihistamines, stethoscopes, blood pressure cuffs, and timing devices to check pulse at all COVID-19 vaccination centres.

11.4.4. Documentation:

a. Prompt documentation should be done to avoid the possibility of accidentally repeating the administration of the drug.

b. Use provided forms to document vaccine manufacturer, injection site, batch number and expiration date.

c. Reporting of suspected adverse reactions should be followed by the healthcare providers and professionals, and reported to the DHA (See policy on reporting COVID-19 Adverse Event Following Immunization (AEFI) protocol).

12. **STANDARD EIGHT:** INFECTION CONTROL MEASURES

12.1. Health facilities should ensure patient protection and infection control measures are implemented at all times to bring the risk of COVID-19 infection to the least minimum.

12.2. Adequate infection control supplies are provided, including biohazard containers and supplies for hand hygiene. If administering injectable vaccines, adhesive bandages, individually packaged sterile alcohol wipes, and a sufficient number of sterile needles and syringes and a sharps container are provided.

12.3. Health Facilities should follow several precautions, including but not limited to:

12.3.1. Universal masking policy for all healthcare workers and patients.

12.3.2. Activate daily monitoring for all facility staff before starting their work and it should be documented. (Measuring temperature, reporting symptoms and history of contact with COVID-19 patient).

12.3.3. Any symptomatic or suspected patient should be isolated as soon as possible.

12.3.4. Promote adherence to respiratory hygiene, cough etiquette and hand hygiene among everyone in the facility.

12.3.5. Maintain physical distance between patients at the waiting area.

12.3.6. Utilize electronic communications as much as possible.

12.3.7. For specific, detailed storage and handling protocols for individual vaccine products, always refer to the manufacturers' product information or contact the manufacturer directly.

12.4. Hand hygiene:

12.4.1. Health care personnel should practice proper hand hygiene using an alcohol-based waterless antiseptic hand rub or washed with soap and water before vaccine preparation, between patients, when changing gloves, and at any time the hand become soiled. Hand washing with soap and water is recommended if there is visible contamination with blood or body fluids.

12.5. Personal Protective Equipment:

12.5.1. Facemasks are recommended for all healthcare workers.

12.5.2. Face shield is recommended only in area of substantial community transmission, otherwise it is optional.

12.5.3. Gloves are not required unless the person administering the vaccine is likely to encounter potentially infectious body fluids or has open lesions on his hands. If worn, perform hand hygiene and change gloves between patients. Gloves is optional for subcutaneous or intramuscular vaccines, but they are recommended for intranasal or oral vaccines.

12.6. Health facilities should ensure their clinic has the supplies needed to administer vaccines including sterile single use needles and syringes, alcohol swab, cotton balls, hand hygiene supplies, personal protective equipment, sharp and medical waste containers.

13. **STANDARD NINE:** WASTE MANAGEMENT AND DISPOSAL

13.1. Facilities should follow the internal facility SOPs and regulatory requirements about appropriate disposal requirements for medical waste.

13.2. The disposal of COVID-19 vaccine vials should be secured in a way to mitigate potential tampering.

13.3. Empty vaccine vials are usually not considered hazardous or medical waste and do not require disposal in a biomedical waste container.

13.4. Needles must be discarded in biohazard containers that are closable, puncture-resistant, leak-proof on sides and bottom, labelled, and color-coded (e.g., sharps container). Then dispose of the biohazard containers according to facility and regulatory requirements.

13.5. The following Items to be discarded immediately after use or when the vaccine exceeds beyond-use-date and time:

13.5.1. Empty vials.

13.5.2. Vials with unused vaccine.

13.5.3. Vials with unused diluent.

13.5.4. Pre-drawn syringes and needles.

13.5.5. Used syringes and needles (e.g., post patient injection, used in dilution process, etc.).

14. STANDARD TEN: REPORTING DATA AND ADVERSE EVENTS

14.1. All health facilities administering COVID-19 vaccines or managing any AEFI should develop and implement internal policy and procedure for reporting process for any side effect, unpredicted adverse effect or serious adverse event related to COVID-19 vaccines based on DHA rules and regulation, Ministry of Health and Prevention (MOHAP) ministerial decrees and UAE federal laws.

14.2. The health facility should ensure the awareness of all healthcare staff on the ADRs monitoring and reporting program.

14.3. The health facility should implement an ongoing and concurrent surveillance system to identify potential AEFI.

14.4. Healthcare professionals should counsel the patient for any ADRs.

14.5. The DHA licensed treating physician must take full responsibility for any AEFI.

14.6. Physicians/nurses/paramedics are responsible to report to the pharmacist/deputy in charge the identified AEFI.

14.7. The responsible healthcare professionals should ensure confidentiality of the ADR records.

14.8. All reported AEFI should be evaluated and any required medical action should be taken by the health facility.

14.9. The health facility Medical Director will evaluate all data related to AEFI.

14.10. The health facility should follow the steps for reporting AEFI as per the DHA Policy for Adverse Drug Reaction Reporting for COVID-19 Vaccine.

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APPENDICES

APPENDIX 1. REQUIREMENT CHECKLIST FOR COVID-19 ON-SITE VACCINATION CENTERS

Facility Name:				
S.No	**Criteria**	**Yes**	**No**	**Documents Required**
Accreditation/License				
1	Holds a valid DHA License			Provide a copy of DHA facility license.
2	Previous HRS approval obtained for another location			Provide copy of approval
Qualified personnel				
3	Physician* must have a valid DHA license, completed infection control training, and COVID-19 vaccination training.			Provide a copy of DHA License & training log
4	Registered nurse and any healthcare professional involved in the vaccination must have completed infection control training, and COVID-19 vaccination training.			Provide training log
5	PPE and Infection Control Policy is in place.			Provide copy of policy
6	Adverse Drug Reactions reporting Policy is in place.			Provide copy of policy
Health facility design standards				
7	If new facility or adding a new service apply via facility Sheryan account.			
8	Accessibility: Wheelchair access is required in all patient areas including Consult, Treatment, Procedure and Waiting rooms.			
9	Main Reception used for appointment registration and Enquiries.			
10	Waiting areas with amenities for visitors.			
11	Examination room used for patient screening prior to vaccination.			
12	Preparation and storage room for general consumables, sterile stock and equipment.			
13	Vaccination/treatment room(s).			
14	Observation area should include crash cart and emergency medication.			
15	Fully equipped room with bed for resuscitation, advanced life support management, with crash cart (if applicable).			
16	Data entry policy is in place.			Provide copy of policy
Note: DHA inspection will be conducted to ensure the accuracy of the provided details.				

*Pediatrician in case the facility is providing vaccine for children.

APPENDIX 2. EVALUATION CHECKLIST FOR VACCINATION CLINICS HELD AT TEMPORARY OR OFF-SITE LOCATIONS

Facility/Location:				
S.No:	**Criteria**	**Yes**	**No**	**Comments**
Vaccine Transport and Arrival at Temporary/Off-site Clinic				
1	Vaccines are transported using a portable vaccine refrigerator within the temperature range recommended by the manufacturers.			If NO DO NOT move forward with the clinic.
2	Vaccines are immediately unpacked and placed in proper storage equipment.			If NO DO NOT move forward with the clinic.
3	Vaccines remain protected from light (per manufacturer's package insert) until ready for use at the vaccination clinic.			
4	Expiration dates of vaccines and any medical equipment (syringes, needles, alcohol wipes) being used were checked, and they had not expired.			If NO DO NOT move forward with the clinic.
Clinic preparation and supplies				
5	Contingency plan is in place in case vaccines need to be replaced.			Provide a copy of contingency plan.
6	An emergency medical kit (including epinephrine and equipment for maintaining an airway) is at the site for the duration of the clinic.			If NO DO NOT move forward with the clinic.
7	All vaccination providers at the site are certified in cardiopulmonary resuscitation (CPR), are familiar with the signs and symptoms of anaphylaxis, know their role in an emergency.			If NO DO NOT move forward with the clinic.
8	There is a designated area at the site for management of patients with ADRs and urgent medical problems (e.g., fainting).			
9	Adequate infection control supplies are provided, including biohazard containers and supplies for hand hygiene.			
10	Staff members administering vaccines have reviewed vaccine manufacturer instructions for administration before the vaccination clinic and DHA protocols for each vaccine.			
11	A designated clean area (aseptic) for vaccine preparation has been identified and set up prior to the clinic.			
12	A qualified individual has been designated to oversee infection control at the clinic.			
13	Sufficient supply of PPE for staff is available, including face masks, gloves.			

14	Sufficient hand sanitizer is available so that staff and patients can repeatedly practice hand hygiene.			
15	Signs, barriers, and floor markers to instruct patients to social distance from other patients and clinic staff have been set up before the clinic			
16	Sufficient supply of thermometers and vital sign monitoring devices to check patient temperatures prior to entering the vaccination clinic and COVID symptom checklists.			
Vaccine Preparation and Administration				
17	Expiration dates of vaccines (and diluents, if applicable) are being checked again during preparation, and only vaccines that have not expired are being administered.			If NO DO NOT move forward with the clinic.
18	Vaccines are being prepared in a clean, designated medication area, away from any potentially contaminated items. (Each type of vaccine to be prepared in a separate vaccination preparation area).			
19	Vaccines are prepared at the time of administration.			
20	If using single-dose or multi-dose vials, syringes are labelled with the name of the vaccine.			
21	All patients are screened for contraindications and precautions for the specific vaccine(s) in use before receiving that vaccine(s).			If NO DO NOT move forward with the clinic.
22	Staff is using proper hygiene techniques to clean hands before vaccine administration, between patients, and anytime hands become soiled.			
23	If more than one vaccine type is being administered, separate preparation stations are set up for each vaccine type to prevent medication errors.			
24	Vaccines are being administered using aseptic technique.			
25	Staff is administering vaccines using the correct route per manufacturer instructions.			If NO DO NOT move forward with the clinic.
26	Staff is administering the correct dosage (volume) of vaccine. (Using a proprietorially designated syringes and needles per each type of vaccine).			If NO DO NOT move forward with the clinic.
Vaccine Documentation				
27	Patients are receiving documentation for their personal records and to share with their medical providers			
28	All patient medical information was placed in a secured storage location for privacy protection.			If NO DO NOT move forward with the clinic
Note: DHA inspection will be conducted to ensure the accuracy of the provided details.				

APPENDIX 3. EVALUATION CHECKLIST FOR MOBILE VACCINATION UNIT

Mobile clinic/Location:				
S. No	**Criteria***	**Yes**	**No**	**Comments**
Approvals/policies				
1	Approval obtained from DHA to set up mobile healthcare unit.			If NO DO NOT move forward with the clinic.
2	Operational policy is in place that is adapted by the related departments or the main facility/clinic that the mobile healthcare unit is affiliated to.			If NO DO NOT move forward with the clinic.
3	The location of the unit should preferably be in close proximity to its related department or its patient base.			
Mobile Healthcare Unit Location				
4	The unit has is located on a solid and levelled surface to prevent instability of the structure when in use.			If NO DO NOT move forward with the clinic.
5	Access to the unit is located where it does not interfere with emergency exits of an adjacent building unless the exits are specifically permitted to serve both buildings.			
6	The location of the Mobile Healthcare Unit complies with relevant local environmental laws and regulations.			If NO DO NOT move forward with the clinic.
7	Wheelchair and stretcher access is provided.			
Functional Areas				
8	Entrance/reception area of the mobile healthcare unit is well-lit and clear sign-posted.			
9	The facility should provide waiting space for patient privacy as close to the unit docking area as possible.			
10	The facility should provide or be in close proximity of patient/staff toilets as close to the unit docking area as possible.			
11	The clinical areas should have easy access to the relevant departments and other critical resources required to provide the services.			
12	The internal planning of the unit should provide patient and staff direct access to services located in the mobile healthcare unit.			
13	Adequate hand wash basins should be provided according to infection control guidelines.			

Mobile Healthcare Unit preparation				
14	Schedule date, time and location for mobile healthcare unit.			
15	Pre-registration for patients with appointment times when possible, include pre-screening questions for both COVID symptoms and exposure, and contraindications for vaccine.			
16	Ensure enough staff are available to promote patient flow with proper distancing.			If NO DO NOT move forward with the clinic.
17	Ensure proper PPE for all staff working at event. At minimum, wear surgical masks.			If NO DO NOT move forward with the clinic.
18	Set up physical space with hand hygiene station, screening for COVID symptoms or exposure.			
19	Designate a staff monitored waiting area (outdoor or indoor)			
Vaccine Transport between Provider Clinic and Mobile Healthcare Unit				
20	Transport vaccine in the passenger compartment of the vehicle (not the trunk) and limit vaccine quantities to amount needed in the unit.			
21	Store vaccine in a qualified container that has kept the vaccine within the recommended range by manufacturers.			
22	Protect vaccines from light until ready to use.			
23	Check expiration dates for vaccines, diluents, needles, syringes, and alcohol wipes			
24	Develop a contingency plan in case vaccine needs to be replaced – stored too warm or too cold.			
Preparing vaccine				
25	Anaphylaxis protocol and emergency medical kit readily available.			
26	Adequate infection control measures are present.			
27	Vaccines and diluents are prepared in a clean, designated area at the time of administration.			
*Follow Checklist for vaccination clinics held at temporary or off-site locations for more details on vaccine preparation, administration, and storage.				
Note: DHA inspection will be conducted to ensure the accuracy of the provided details.				

APPENDIX 4. EVALUATION CHECKLIST FOR DRIVE-THROUGH VACCINATION CENTRES

Facility Name:				
No:	**Criteria**	**Yes**	**No**	**Documents Required**
License				
1	Valid DHA License: • Online application through Sheryan, for COVID vaccination centres **"Add-on Drive through service".**			• Official proposal letter. • Target group. • Location. • Copy of authorization / approval from other authorities, if available. ○ Approval for operation dates and times: DM, RTA, Dubai Police and Civil defense. • Setup and Infrastructure details *(Layout details).* • Information on maintenance of medical record. • Valid facility and professionals licenses.
Qualified personnel				
2	• Physician* must have a valid DHA license, completed infection control training, and COVID-19 vaccination training. • Registered nurse and any healthcare professional involved in the vaccination must have completed infection control training, and COVID-19 vaccination training. • PPE and Infection Control Policy is in place. • Adverse Drug Reactions reporting Policy is in place.			• Valid License for healthcare professionals. • Infection control training. • Training of COVID-19 vaccination. • Staffing details: admin, security, coordinators, HCP details who will provide the service, training etc. • Provide training log. • Provide copy of policy.

Infection Control				
3	• Safety protocols & infection control measures: • Personal protective equipment (PPE), and enhanced sanitation efforts.			• Infection Control Policy.
Design Requirements				
4	• Open area. • Proper ventilation system. • One-way passage for vehicles with entrance separate from exit. • Divided into stations for parking, registration, and vaccine administration. • Vehicles queue in lanes and pass through a set of designated vaccination stations.			Provide the design plan with all necessary information.
Facility Operations				
5	Timing - As per the allowed time of operation and manpower capacity			Operational details and standards including sample collection, storing and transportation.
6	Service provided preferably by appointment.			• Call Center / Hotline details. • Brochures/information for vaccination procedures, pre-screening, ADR precaution and contraindications. • Standard precautions should be implemented to prevent cross infection between potentially infectious patients.
7	Availability of Medical Record			Provide details of the HIS.
Clinical Considerations				
8	Vaccine storage, handling, administration, and documentation			• Maintain the product temperature between the limits defined on the product label and manufacture's product packaging and storage requirements. • Using portable vaccine refrigerator. • Proper conditioning of coolants are followed. • A digital data logger with a buffered probe are available.

				• Availability of valid Certificate of Calibration Testing directly with the vaccines. • Assure and maintain the vaccines from any Vaccine Temperature excursion.
Administration Protocol				
09	Prescreening			• A process for screening for contraindications and precautions is in place.
Reporting				
10	HASANA Facility Account			• Provide date of registration and user details (name , designation) • Reporting and communication channels with patients. • Reporting Data And Adverse Events
11	Result Reporting Policy Keep patients informed by SMS, email, phone call			• Provide copy of the policy
Note: DHA inspection will be conducted to ensure the accuracy of the provided details.				

*Pediatrician in case the facility is providing vaccine for children.

APPENDIX 5. PATIENT CONSENT FORM FOR COVID-19 VACCINE

A. Pfizer COVID-19 vaccination patient consent form

PFIZER COVID-19 Vaccination Consent form **تعهد وإقرار موافقة على لقاح فايزر كوفيد-19**	
Name **MRN:** **DOB:** **Sex:** **Emirates ID:** **Nationality:**	
Please indicate your understanding and agreement to the statements below:	**الرجاء القراءة والموافقة على البنود المذكورة ادناه:**
Consent to take COVID-19 vaccine Emergency Use Authorization in the UAE. Food and Drug Administration (FDA) of the authorized product, Pfizer-BioNTech COVID-19 Vaccine BNT162b2, for active immunization to prevent COVID-19 in individuals aged 5 years and older. **(Copy of this form will be kept in the participant's medical record file)**	**الموافقة على الحصول على تصريح الاستخدام الطارئ للقاح كوفيد-19 في دولة الامارات العربية المتحدة. المنتج-Pfizer BioNTech COVID-19 Vaccine BNT162b2 معتمد من إدارة الغذاء والدواء (FDA) للتطعيم وللوقاية من كوفيد-19 أدى الافراد الذين تبلغ أعمارهم 5 عاما فما فوق. (سيتم الاحتفاظ بنسخة من هذا النموذج في سجل الملف الطبي للشخص المشارك)**
By signing this consent I hereby acknowledge that:	من خلال التوقيع على هذه الموافقة, اقر بالموافقة التامة على ما ورد في هذا التعهد والاقرار, كما اقر بانني اعي وادرك الآتي:
Statement of Participant I have fully read the COVID-19 vaccine information available in this consent. As a result, I am aware of the risks and benefits of the COVID-19 vaccine. I am aware that the vaccine is COVID-19 mRNA Vaccine BNT162b2 that is used for active immunization to prevent COVID-19 disease caused by SARS-CoV-2 virus. The vaccine triggers the body's natural production of antibodies and stimulates immune cells to protect against COVID-19 disease. I am aware that this vaccine is authorized to Emergency use in the UAE and in some countries around the world. The	**إقرار المشارك** لقد قرأت بالكامل معلومات لقاح كوفيد-19 المتوفرة في هذه الموافقة. فانا على ذلك، فأنا دراية تامة بمخاطر وفوائد لقاح كوفيد-19 وأدرك ان اللقاح هو المنتج Pfizer-BioNTech COVID-19 Vaccine BNT162b2 للوقاية من مرض كوفيد-19 الناجم عن فيروس SARS-CoV-2. ويحفز اللقاح انتاج الجسم الطبيعي للأجسام المضادة ويحفز الخلايا المناعية للحماية من مرض كوفيد-19. وأدرك ان هذا اللقاح مصرح به للاستخدام في حالات الطوارئ في الامارات العربية المتحدة وفي بعض البلدان حول العالم. وان إدارة الغذاء والدواء في الولايات المتحدة الامريكية

Food and Drug Administration (FDA) has authorized the vaccine for emergency use for active immunization to prevent COVID-19 in individuals aged 5 and older.	(FDA) وافقت على اللقاح للاستخدام الطارئ للتحصين النشط للوقاية من كوفيد-19 لدى الافراد الذين تبلغ أعمارهم 5 أعوام فما فوق.
I understand that my participation Or give it to whoever is under my guardian is voluntary by taking two doses from this vaccine, given 21 days apart to complete the vaccination series. Protection against COVID-19 diseases may not be effective until at least 7 days after the second dose, and it's given after dilution as an injection of 0.3 mL for adult and 0.2 mL for children, into a muscle of upper arm.	كما انني اقر بأن مشاركتي في اخذ اللقاح أو اعطاءه لمن هو تحت وصايتي طوعية من خلال اخذ جرعتين من هذا اللقاح، مع إعطاء مهلة زمنية لمدة 21 يوما على حدة لإكمال سلسلة التطعيم. كما انني أدرك بأنه قد لا تكون الحماية من مرض كوفيد-19 فعالة الا بعد 7 أيام على الأقل من الجرعة التالية. ويتم بعد تخفيفها كحقن 0.3 مل للبالغين و 0.2 مل للأطفال ,في عضلة اعلى الذراع.
Possible side effects I understand that Like all vaccines, COVID-19 mRNA Vaccine BNT 162b2 can cause side effects, although not everybody gets them. Most side effects are mild or moderate and go away within a few days of appearing. If side effects such as pain and/or fever are troublesome, they are being treated by medicines for pain and fever such as paracetamol. If still troublesome, can seek medical advice from your doctor, or call 800342 and they will advise you on best next step. **Side effects may occur with the following frequencies:** Very common: may affect more than 1 in 10 people • Pain at injection site • Tiredness • Headache • Muscle pain • Chills • Joint pain • Fever Common: may affect up to 1 in 10 people • Injection site swelling	**الاثار الجانبية المحتملة** انا على دراية مثل جميع اللقاحات، يمكن ان يتسبب لقاح كوفيد-19 mRNA Vaccine BNT 162b2 في حدوث اثار جانبية، على الرغم من عدم حدوثها لدى الجميع. معظم الاثار الجانبية خفيفة او معتدلة وتختفي في غضون أيام قليله من ظهورها. إذا كانت الاثار الجانبية مثل الألم و/او حمى مزعجة، فيمكن علاجها بأدوية للألم والحمى مثل الباراسيتامول. إذا كنت لا تزال مزعجه، يمكن طلب المشورة الطبية من طبيبك، او الاتصال على 800342 وسوف ينصحك بأفضل خطوة تالية. **قد تظهر الاثار الجانبية مع المعدلات التالية:** شائعة جدا: قد تظهر لدى أكثر من 1 من كل 10 اشخاص • ألم في نوقع الحقن • صداع الراس • ألم عضلي • قشعريرة • ألم المفاصل • حمى شائعه قد تظهر لدى حتى 1 من كل 10 اشخاص • انتفاخ موقع الحقن • احمرار في موقع الحقن

• Redness at injection site • Nausea Uncommon: may affect up to 1 in 100 people • Enlarged lymph nodes • Feeling unwell However, some people might develop other side effects; this includes any possible side effects not listed in this consent, or more serious medical condition or have signs of severe allergic reaction such as itchy skin rash, shortness of breath and swelling of the face or tongue. Contact your doctor or healthcare professional immediately or go to the nearest hospital emergency room right away, if you have an allergic reaction. It can be life threatening. **Reporting of side effects** I understand if I get any non-self-limiting troublesome side effects to report by calling **800342** I understand by reporting side effects, I help provide more information on the safety of this vaccine.	• غثيان غير شائعه: قد تظهر لدى حتى 1 من كل 100 شخص • تضخم الغدد الليمفاوية • الشعور بتوعك ومع ذلك، قد يصاب بعض الأشخاص بأثار جانبية أخرى، وهذا يشمل أي اثار جانبية محتملة غير مدرجة في هذه الموافقة. او حالة طبيه أكثر خطورة او لديهم علامات رد فعل تحسسي شديد مثل طفح جلدي وحكة وضيق في التنفس وتورم في الوجه او اللسان. اتصل بطبيبك أو أخصائي الرعاية الصحية على الفور أو اذهب إلى أقرب غرفة طوارئ في المستشفى على الفور، إذا كان لديك رد فعل تحسسي. يمكن أن تكون مهددة للحياة. **التبليغ عن الاعراض الجانبية** انا على دراية انه في حالة ظهور أي اثار جانبية غير نائية التحديد يمكنني الإبلاغ عنها عن طريق الاتصال بالرقم **800342** انا على دراية انه من خلال الابداع عن الاثار الجانبية, اساعد في تقديم مزيد من المعلومات حول سلامة هذا اللقاح.
Warnings and precautions I understand that I should declare my condition to the nurse, or doctors at vaccination facility before given the vaccine if I have: • Had any problems following previous administration of other vaccines suck as allergic reaction or breathing problems. • A severe illness with high fever. However, a mild fever or upper airway infection, like a cold, are not reasons to delay vaccination. • A weakened immune system, such as due to HIV infection, or are on a medicine that affects your immune system e.g. cancer chemotherapy. • A bleeding problem, bruise easily or use a medicine to inhibit blood clotting. • Any chronic disease or illness.	**المحاذير والاحتياطات** انا على دراية انه ينبغي أعلن حالتي للممرضة او الأطباء في مرفق التطعيم قبل اخذ اللقاح إذا كان لدى: • أي مشاكل بعد اخذ أي لقاح سابق مثل الحساسية او مشاكل التنفس. • مرض شديد مع ارتفاع في درجة الحرارة. ومع ذلك، فأن الحمى الخفيفة او عدوى مجرى الهواء الملوي. مثل الزكام، ليست أسبابا لتأخير التطعيم، • ضعف الجهاز المناعي، مثل الإصابة بفيروس نقص المناعة البشرية او تناول دواء يؤثر على جهاز المناعة لديك، على سبيل المثال العلاج الكيميائي للسرطان. • مشاكل النزيف، وسهولة الإصابة بالكدمات او استخدام دواء لمنع تختر الدم.

• I understand that, as with any vaccine, this vaccine may not fully protect all those who receive it. No data are currently available in individuals with a weakened immune system or who are taking chronic treatment that suppresses or prevents immune responses. • I understand to declare to the nurse, doctor or pharmacist if I am using, have recently used or might use any other medicines or have recently received any other vaccine, or have had any serious reaction to any other vaccine in the past. • I understand to declare to the nurse, doctor or pharmacist any other significant health or drug history not covered above.	• أي امراض مزمنة. • انا على دراية ان هذا اللقاح كما هو الحال مع أي لقاح، قد لا يوفر الحماية الكلمة لمن يتلقونه، لا توجد بيانات متاحة حاليا للأفراد الذين يعانون من ضعف في جهاز المناعة او الذين يتناولون علاجا مزمنا او يمنع الاستجابات المناعية. • انا على دراية ان ابلغ الطبيب أو الممرضة أو الصيدلي إذا كنت أستخدم أو استخدمت مؤخرًا أو قد أستخدم أي أدوية أخرى أو تلقيت مؤخرًا أي لقاح آخر أو كان لدي أي رد فعل خطير تجاه أي لقاح آخر في الماضي. • انا على دراية بوجوب ابلاغ الطبيب أو الصيدلي عن أي تاريخ صحي او دوائي مهم اخر لم يتم ذكره أعلاه.
I understand that is vaccine will be administered by a healthcare professional in accordance with emergency use authorization made in accordance with the United Arab Emirates laws and regulations	انا على داريه ان هذا اللقاح سيتم ادارته بواسطه اخصائي رعاية صحية وفقا لترخيص الاستخدام في حالات الطوارئ وفقا لقوانين دولة الامارات العربية المتحدة.
I declare that I have a copy of this consent.	اقر بان لدي نسخة من هذه الموافقة.
I understand that signing this form does not waive any of my medical and legal rights.	افهم ان التوقيع على هذا النموذج لا يتناول عن أي من حقوقي الطبية و القانونية.
Vaccination, related health services, and treatment of side effects will be covered by government and insurance coverage	سيتم تغطية التطعيم والخدمات الصحية ذات الصلة وعلاج الاثار الجانبية من قبل الحكومة والتأمين.
Name (الاسم): **Date & Time (التاريخ والوقت):**	**Patient signature (التوقيع):**
If the patient is unable to sign or if patient is a minor, a legal representative or guardian should sign below:	إذا كان المريض غير قادر على التوقيع يجب أن يوقع عنه ممثله القانوني أو وصيه (المذكور أدناه) إذا كان قاصرا:
Relation of person signing on behalf of patient:	صلة الشخص الموقع بالمريض:
The patient approves that his demographics information will be shared with the 3rd party provider	يوافق المريض على مشاركة المعلومات الديموغرافية الخاصة به مع مزود الطرف الثالث لإدارة التطعيم وفي حالة الأحداث

to administer the vaccination and in case of adverse events, the patient authorizes the 3rd party health care provider to access the patient clinical information to be able to handle the situation.	السلبية ، يصرح المريض لمقدم الرعاية الصحية التابع لجهة خارجية للوصول إلى المعلومات السريرية للمريض حتى يتمكن من التعامل مع الموقف.
Admission Officer/Clerk Name (الموظف المسؤول عن التسجيل/الادخال): **Staff No. (الرقم الوظيفي):**	

APPENDIX 6. COVID-19 VACCINATION EXEMPTION CERTIFICATE*

DUBAI HEALTH AUTHORITY

GOVERNMENT OF DUBAI

Healthcare Facility / Healthcare Center: AL BARSHA CLINIC

License Number: 3620756

Reference Number (for review and auditing): 12017299

Date (dd/mm/yy): 09/05/2021

Medical Exemption Certificate from Taking COVID-19 Vaccine

Healthcare Facility / Healthcare Center AL BARSHA CLINIC

hereby confirms that Mr./s TEST DHAAPP FOUR

Nationality UNITED ARAB EMIRATES

Emirate ID Number 784-1990-4516744-6

is not eligible for taking COVID-19 vaccine due to medical reasons.

Special Note:
This certificate is valid for:

One Month [X] Three Months [ ] Six Months [ ] Permanent [ ]

Physician Name: TEST 2

License Number: 00029384

This certificate is issued by Dubai Health Authority
Dubai - United Arab Emirates

هذه الشهادة صادرة عن هيئة الصحة بدبي
دبي - الامارات العربية المتحدة

In case of any queries, please call 800342 (DHA)

في حال وجود أي استفسار، يرجى الاتصال على 800342 (DHA)

*The exemption from covid-19 vaccination Certificate are only issued by DHA Government hospitals and primary health centers