Standards for COVID-19 Vaccination Centres

Version 2.1

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Health Policies and Standards Department

Health Regulation Sector (2021)

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.
- Managing health advertisement and marketing of healthcare products.
- 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 Centres aims to fulfil the following overarching DHA Strategic Objectives and Program within the Dubai Health Strategy (2016–2021):

- **Objective 1:** Position Dubai as a global medical destination by introducing a value-based, comprehensive, integrated and high-quality service delivery system.
- **Objective 2:** Direct resources to ensure happy, healthy and safe environment for Dubai population.
- **Strategic Program 10:** Excellence & Quality, which promotes excellence in healthcare service delivery in Dubai while enhancing patient happiness, experience, satisfaction and trust.

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

TABLE OF CONTENTS

EXECUTIVE SUMMARY

This is the second 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 2.1:

- mRNA COVID-19 (BNT162b2) Vaccine (Pfizer-BioNTech):
    - Updates for Eligibility and Exclusion criteria, p. 19-21
    - Addition of Third Dose Recommendations, p. 21-23
    - Updates for Special Considerations, p. 24-25
    - Updates for Switching of Vaccines: , p. 25
    - Updates for Co-administration With Other Vaccines, p. 25
    - Updates for Vaccination in pregnant/lactating women and women contemplating pregnancy, p. 25-26-27
    - Updates for Postponing vaccination, p. 28

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
MOHAP	:	Ministry of Health and Prevention
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).

Some of the available vaccines can be given to everyone starting from the age of 12 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.

5. STANDARD ONE: HEALTH FACILITY REQUIREMENTS AND ELIGIBILITY FOR COVID-19 VACCINATION PROGRAMS

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

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

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

5.3.1. Hospitals.

5.3.2. Day Surgery Centres.

5.3.3. Outpatient health facilities.

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

5.3.5. Licensed school clinic.

5.3.6. Mobile healthcare units.

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

5.4.1. 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**).

5.4.2. 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.

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

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

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

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

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

5.5.5. 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).

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

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

5.6.1. 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.

5.6.2. 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.

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

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

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

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

6.8.1. Health care professionals licensed by DHA.

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

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

7.1. Approved vaccines by DHA are:

7.1.1. mRNA COVID-19 (BNT162b2) COVID-19 Vaccine (Pfizer-BioNTech).

7.1.2. ChAdOx1 nCoV- 19 (Recombinant) COVID-19 Vaccine (AstraZeneca).

7.1.3. Inactivated SARS-CoV-2 (BBIBP-CorV) COVID-19 Vaccine (Sinopharm).

7.1.4. Gam-COVID-Vac Vaccine (Sputnik).

7.2. Managing vaccine stockpile:

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

7.2.2. 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.

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

7.2.4. 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.

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

7.2.6. 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.

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

7.2.8. Patients requiring second doses should be prioritized.

7.2.9. 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.

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

7.3. Operational Considerations:

7.3.1. 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.

7.3.2. 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.

7.3.3. 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.

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

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

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

7.3.7. 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).

7.4. Vaccine Storage:

7.4.1. 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.

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

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

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

7.4.5. 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.

7.5. Vaccine Transport:

7.5.1. 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.

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

7.5.3. 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.

7.6. Transport of frozen solid mRNA (BNT162b2) COVID-19 Vaccine vials:

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

7.6.2. Frozen mRNA (BNT162b2) COVID-19 Vaccine is maintained at a temperature of −80ºC to −60ºC (−112ºF to −76ºF).

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

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

7.7. Transport of thawed, multi-dose mRNA (BNT162b2) COVID-19 Vaccine vials:

7.7.1. Health facilities should Use a continuous temperature-monitoring device to ensure consistent temperature monitoring during transport.

7.7.2. Undiluted vials can be maintained at refrigeration temperatures at 2ºC to 8ºC (35ºF to 46ºF) for 120 hours.

7.7.3. Undiluted vials can be maintained at room temperature for up to 25ºC (77ºF) for 30 minutes.

7.7.4. Diluted vials can be maintained at room temperature for up to 25ºC (77ºF) for 6 hours and must be discarded after 6 hours.

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

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

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

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

8. **STANDARD FOUR:** PATIENT ELIGIBILITY AND EXCLUSIONS

8.1. **mRNA COVID-19 (BNT162b2) Vaccine (Pfizer-BioNTech):**

8.1.1. Inclusion Criteria:

a. Adults and adolescent ≥ 12 years.

b. People with chronic illnesses: asthma, COPD, chronic lung diseases, heart failure, chronic renal diseases, chronic liver diseases, diabetes mellitus, thyroid diseases, hypertension and ischemic heart disease.

c. Immunocompromised individuals are recommended to receive COVID-19 vaccination and are eligible for a third dose if they have no absolute contraindications to vaccination.

d. Persons with autoimmune conditions who have no contraindications to vaccination may receive an mRNA COVID-19 vaccine.

e. Uncontrolled diabetes is not a contraindication to the vaccine. In fact, because these patients are at risk of severe COVID-19, they should be encouraged to be vaccinated.

f. Individuals with HIV regardless of CD4 count or viral load, these include people on anti-retroviral therapy.

g. Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness, Recovery means that the person has completed 10 days from the first positive COVID-19 test with no symptoms for the last 3 days without anti-pyretic.

h. If a person contracts COVID-19 after the first vaccine dose, the second dose should be deferred until recovery of the acute infection, even if the dose is delayed. Therefore, prior COVID-19 infection is not a contraindication to the vaccine.

i. Pregnant women beyond the first trimester of pregnancy, following an explanation of the benefits and possible risks of vaccination in pregnancy.

j. Other individuals eligible to or willing to take the vaccine if there is no absolute contraindication.

k. Allergy to food, drugs, pets, insect bites etc. is not a contraindication to mRNA vaccine.

l. No contraindications for patients with psychiatric disorders and those on psychiatric medications.

m. Other people eligible to or willing to take the vaccine if there is no absolute contraindication.

8.1.2. Exclusion Criteria:

a. Individuals with active COVID-19 infection.

b. Adolescents in COVID-19 vaccine or medication trials.

c. Severe or immediate allergic reaction of any severity to a previous mRNA vaccine dose for e.g. anaphylaxis.

d. Previous immediate allergic reaction of any severity to a component of the vaccine [polyethylene glycol (PEG) or polysorbate].

8.1.3. Third Dose Recommendations:

a. An additional dose of an mRNA vaccine can be offered to patients after an initial 2-dose primary series in immunocompromised people:

I. Pfizer-BioNTech COVID-19 vaccine (≥12 years).

II. Moderna COVID-19 vaccine (≥18 years).

b. An attempt should be made to match the additional dose type to the mRNA primary series; however if that is not feasible, a heterogeneous additional dose is permitted (e.g. individuals who have received Pfizer-BioNTech should receive Pfizer-BioNTech, if not feasible can receive Moderna and vice versa).

c. The additional dose of mRNA COVID-19 vaccine should be administered at least 28 days after the completion of the primary mRNA COVID-19 vaccine series.

d. Moderately and severely immunocompromised people are eligibility for a third dose:

I. Active treatment for solid tumor and hematologic malignancies.

II. Receipt of solid-organ transplant and taking immunosuppressive therapy.

III. Receipt of CAR-T-Cell or hematopoietic stem cell transplant (within 2 years of transplant or taking immunosuppression therapy).

IV. Moderate or severe primary immunodeficiency (e.g. DiGeorge, Wiskott-Aldrich syndrome).

V. Advanced or untreated HIV infection.

VI. Asplenia.

VII. Active treatment with: High dose corticosteroids (i.e. ≥20 mg prednisone, or equivalent, per day), Alkylating agents, antimetabolites ,Transplant-related immunosuppressive drugs, Cancer chemotherapeutic agents classified as severely immunosuppressive ,TNF blockers and Other biologic agents that are immunosuppressive or immunomodulatory (this includes Rituximab and other related agents).

e. Solid Organ Transplant Recipients:

I. All solid organ transplant recipients, their eligible household and close contacts are recommended to get vaccinated against SARS-CoV-2.

II. If possible, vaccination should be done prior to transplantation, ideally with completion of vaccine series a minimum of 2 weeks prior to transplant.

III. Based on current evidence, a third dose of mRNA vaccine for solid organ transplant recipients that have previously completed a 2-dose mRNA vaccine series is recommended, based on individual patients' unique situation.

f. Serious Adverse Events, though rare, can still occur after a 3–dose series

8.1.4. Precautions:

a. An immediate allergic reaction to any other vaccine or injectable medication is considered a precaution and not a contraindication.

b. People with acute febrile illness (AFI) at the time of vaccination.

c. Patients treated with rituximab clearly have diminished humoral responses to vaccinations.

I. Patients treated with rituximab and naturally infected with SARS-Cov-2 appear to be one of the highest risk group for COVID-19 morbidity and mortality. It is recommended that patients are vaccinated prior to initiation of therapy (e.g. both doses completed ≥ 4 weeks prior to initiation of B-cell directed therapy), when feasible. If it is not feasible to delay rituximab based therapy, it is still reasonable to consider vaccination during times of high community transmission given that vaccination can generate T-cell memory responses even in the absence of humoral immunity. (Therefore, these patients are considered for 3 doses of mRNA COVID-19 vaccine).

d. Patients on high dose steroids should be cautioned on the inadequate response to the vaccine.

I. There is debate on what constitutes 'high dose' but generally patients on prednisone 20mg or more per day for >2 weeks, or equivalent, may have diminished responses to vaccinations. These groups are among the high-risk group and therefore are considered for 3 doses of mRNA COVID19 vaccine.

e. People with bleeding disorders or on anti-coagulation with documented uncontrolled INR.

8.1.5. Special Considerations:

a. Individuals with a reaction to the first dose of vaccine should not be given an antihistamine or other anti-allergic medications prior to the second dose as this may delay the early warning signs of anaphylaxis.

b. Serology testing to determine level of immunity in vaccine decision-making is not recommended. Hence, testing of neutralising antibody levels should be reserved for the setting of clinical trials.

c. The second dose of the vaccine should be administered as close to the second dose schedule as possible. If for any reason there is a delay, the second dose can be given up to 42 days (6 weeks) after the first dose.

d. If for any reason the person presents beyond 42 days for the second dose, this dose should be given as a second dose; the vaccination schedule should not be repeated.

e. In a patient with lymphedema of the arm of any cause e.g. after axillary node dissection for breast cancer, the vaccine should be given in the opposite arm. If both arms are affected, then it should be given in the thigh or buttock.

f. Screening for breast cancer should be done before women receive their first dose of vaccine, or 4-6 weeks after the second dose, if possible. This would avoid confusion of any axillary lymph node enlargement due to the vaccine.

8.1.6. Switching of vaccines:

a. If a person develops severe allergic reaction to the first dose of mRNA vaccine, he/she should not receive the second dose of the same mRNA vaccine. These individuals will be candidates for switching to another type of vaccine.

b. For persons who have had two doses of an inactivated vaccine e.g. Sinopharm, it is permissible to administer Pfizer as a two-dose regimen. The first dose of Pfizer should be given beyond 3 months of the second dose of Sinopharm, with the usual interval of 3 weeks between the Pfizer doses. Antibody level estimation is not required as a determinant of vaccination.

8.1.7. Co-administration with other vaccines:

a. COVID-19 vaccines were previously recommended to be administered alone, with a minimum interval of 14 days before or after administration of any other vaccines. This was out of abundance of caution and not due to any known safety or immunogenicity concerns.

b. COVID-19 vaccines and other vaccines may now be administered without regard to timing. This includes administration of COVID-19 vaccines and other vaccines on the same day, as well as co-administration within 14 days.

c. It is unknown whether reactogenicity is increased with co-administration, including with other vaccines known to be more reactogenic, such as adjuvant vaccines (protein subunit) or live vaccines.

8.1.8. Vaccination in pregnant/lactating women and women contemplating pregnancy:

a. Pregnant women are at increased risk of severe illness from COVID-19 when compared to non-pregnant women. They are also at increased risk for poor birth outcomes including pre-term birth. Therefore, they should be encouraged to receive mRNA COVID-19 vaccine.

b. American College of Obstetrics & Gynecology (ACOG) recommendation for mRNA COVID-19 vaccine for pregnant women.

c. ACOG recommends that in the interest of patient autonomy, pregnant women should be free to make their own decision regarding COVID-19 vaccination.

d. While pregnant women are encouraged to discuss vaccination consideration with their clinical care team when feasible, documentation of such a discussion should not be required prior to receiving a COVID-19 vaccine.

8.1.9. Additional considerations for pregnant women:

a. Pregnant women who experience fever following vaccination should be counselled to take paracetamol.

b. Women should complete their 2-dose series with the same vaccine product if receiving a mRNA vaccine unless there is severe allergic reaction to first dose, in that case; the vaccine can be switched.

c. Anti-D immunoglobulin (i.e. Rhogam) should not be withheld from woman who is planning or has recently received a COVID-19 vaccine, as it will not interfere with the immune response to the vaccine.

d. For any concerns, women should consult with their obstetricians.

8.1.10. Lactating women:

a. American College of Obstetrics & Gynaecology (ACOG) recommends COVID-19 vaccines be offered to lactating women same as non-lactating women when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP.

b. Theoretical concerns regarding the safety of vaccinating lactating women do not outweigh the potential benefits of receiving the vaccine.

c. There is no need to avoid initiation or to discontinue breastfeeding in patients who receive a COVID-19 vaccine.

8.1.11. Women Contemplating Pregnancy:

a. ACOG recommends vaccination of women who are actively trying to become pregnant/contemplating pregnancy and meet the criteria for vaccination based on ACIP prioritization recommendations.

b. Given the mechanism of action and the safety profile of the vaccine in non-pregnant women, COVID-19 mRNA vaccines are not thought to cause an increased risk of infertility. It is not necessary to delay pregnancy after completing both doses of the COVID-19 vaccine.

c. If a woman becomes pregnant after the first dose of the COVID-19 vaccine series, the second dose should be administered as indicated.

d. Pregnancy testing should not be a requirement prior to receiving any COVID-19 vaccine.

8.1.12. Postponing vaccination:

a. Consider postponing vaccination for people with acute moderate to severe illness such as the following conditions, until the clinical condition returns to baseline or is controlled with treatment:

i. Acute kidney injury.

ii. Acute urinary tract infection, except maybe mild cystitis.

iii. Acute rejection of renal transplant.

iv. Recent renal transplant recipients.

v. Acute and significant electrolyte imbalances.

vi. Hypertensive crisis/accelerated hypertension – resting systolic ⩾160 mmHg and/or resting diastolic ⩾100 mmHg – provided that they are asymptomatic.

vii. The patients on hemodialysis with tendency to easy bleeding/bruising would need to check with their nephrologist regarding the timing of the vaccine with regards to the hemodialysis session.

8.2. **ChAdOx1 nCoV- 19 Corona Virus Vaccine Recombinant (AstraZeneca):**

8.2.1. Inclusion Criteria:

a. Adults' ⩾ 18 years.

b. Individuals with medically stable chronic diseases.

c. Individuals with increased-risk for exposure to SARS-CoV-2 and COVID-19.

d. People with the following risk factors: Obesity , Cardiovascular disease , Chronic Respiratory disease , Diabetes Mellitus , On immunosuppression , Chronic neurologic disease , Asplenia/dysfunction of spleen ,Severe mental illness and Adult caregivers.

8.2.2. Exclusion Criteria:

a. Individuals with active COVID-19 infection.

b. Persons younger than 18 years of age.

c. People who have an anaphylactic reaction following the first dose of this vaccine should not receive a second dose of the same vaccine.

d. Vaccination should be postponed in individuals suffering from an acute moderate to severe febrile illness (temperature >38ºC) or acute infection from any aetiology, infectious or non-infectious.

e. Persistently elevated blood pressure levels during pre-assessment - resting systolic >160 mmHg and/or resting diastolic >100 mmHg.

f. Systolic blood pressure >140 mmHg with symptoms of hypertension.

g. Pregnancy and breastfeeding.

h. Hypersensitivity to the active substance or to any of the following excipients:

i. L-Histidine.

ii. L-Histidine hydrochloride monohydrate.

iii. Magnesium chloride hexahydrate.

iv. Polysorbate 80 (E 433).

v. Ethanol.

vi. Sucrose.

vii. Sodium chloride.

viii. Disodium edetate (dihydrate).

ix. Water for injection.

8.2.3. Special Considerations:

a. Rare thrombotic events have been associated with the first dose of AstraZeneca vaccine in younger individuals, particularly females.

b. Individuals who have had the first dose without serious/severe adverse event, particularly thrombosis, can be given the second dose.

c. Screening for breast cancer should be done before women receive their first dose of vaccine, or 4-6 weeks after the second dose, if possible. This would avoid confusion of any axillary lymph node enlargement due to the vaccine.

d. The efficacy, safety and immunogenicity of the vaccine have not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapies.

e. The efficacy of COVID-19 Vaccine AstraZeneca may be lower in immunosuppressed individuals.

f. Available data are currently insufficient to assess vaccine efficacy or vaccine-associated risks in severely immunocompromised persons, including those receiving immunosuppressant therapies.

g. Individuals who received first dose AstraZeneca and developed adverse drug reactions can receive second dose Pfizer-BioNTech vaccine.

8.2.4. Vaccination in pregnant/lactating women:

a. There is limited experience with use of COVID-19 Vaccine AstraZeneca in pregnant women. Taking into consideration that pregnant women are prone to thrombosis, which is a rare adverse event of the AstraZeneca vaccine; it is advisable that pregnant women should not be given the vaccine.

b. WHO does not recommend pregnancy testing prior to vaccination.

c. WHO does not recommend delaying pregnancy because of vaccination.

d. It is unknown whether COVID-19 Vaccine AstraZeneca is excreted in human milk.

e. There is insufficient data on the use of the vaccine in breastfeeding.

f. The WHO does not recommend discontinuation of breastfeeding after vaccination.

8.2.5. Co-administration with other vaccines:

a. There should be a minimum interval of (14) days between administration of this vaccine and any other vaccine against other conditions.

8.2.6. Precautions:

a. Vaccine should be given with caution to individuals with thrombocytopenia, or to persons on anticoagulation therapy or any coagulation disorder (such as haemophilia), since bleeding/bruising may occur following an intramuscular administration in these individuals.

b. Immunocompromised individuals, it is not known whether individuals with impaired immune responsiveness, including individuals receiving immunosuppressant therapy, will elicit the same response as immunocompetent individuals to the vaccine regimen. Immunocompromised individuals may have relatively weaker immune response to the vaccine regimen, duration and level of protection.

c. No data are currently available on the safety and efficacy of AZD1222 in persons with autoimmune conditions.

d. Data on administration of the vaccine are currently insufficient to allow assessment of vaccine efficacy or safety for persons living with HIV.

e. Persons with PCR-confirmed SARS-CoV-2 infection in the preceding 6 months may delay vaccination until near the end of this period.

f. Should be postponed in individuals suffering from an acute severe febrile illness.

8.3. **Inactivated SARS-CoV-2 (BBIBP-CorV) COVID-19 Vaccine (Sinopharm):**

8.3.1. Inclusion Criteria:

a. Adults' ≥16 years.

b. Healthy or have medically stable chronic diseases.

c. Individuals with increased-risk for exposure to SARS-CoV-2 and COVID-19.

8.3.2. Exclusion Criteria:

a. SARS-CoV-2 Infection confirmed cases, suspected cases or asymptomatic infection.

b. Fever (axillary temperature > 37.0 ℃), dry cough, fatigue, nasal obstruction, runny nose, pharyngeal pain, myalgia, diarrhea, shortness of breath and dyspnoea occurred within 14 days before vaccination.

c. Axillary body temperature > 37.0 ℃ before vaccination.

8.3.3. Precautions:

a. Previous severe allergic reactions to vaccination (such as acute allergic reactions, urticaria, dyspnoea, angioneurotic edema or abdominal pain) or allergy to known ingredients of inactivated SARS CoV 2 vaccine have occurred.

b. Have a history of convulsion, epilepsy, encephalopathy, mental illness or family history.

c. Congenital malformations or developmental disorders, genetic defects, severe malnutrition, etc.

d. Severe liver and kidney diseases, uncontrollable hypertension (systolic blood pressure ≥ 140 mmHg, diastolic blood pressure ≥ 90 mmHg), diabetic complications, malignant tumors, various acute diseases or acute attack period of chronic diseases.

e. Congenital or acquired immune deficiency, HIV infection, lymphoma, leukemia or other autoimmune diseases.

f. Severe respiratory diseases, severe cardiovascular diseases, liver and kidney diseases, and malignant tumors.

g. History of coagulation dysfunction (e.g. Coagulation factor deficiency, coagulation disease).

h. Receiving anti TB therapy.

i. Patients receiving immunotherapy or inhibitor therapy within 3 months.

j. Patients receiving blood products within 3 months before this vaccination.

k. Pregnancy.

8.4. **Gam-COVID-Vac Vaccine (Sputnik):**

8.4.1. Inclusion Criteria:

a. Adults' ≥ 18 years.

b. Healthcare providers.

c. Negative HIV, hepatitis B, hepatitis C, and syphilis test results.

d. No evidence of vaccine-induced reactions or complications after receiving immunobiological products in medical history.

e. No acute infectious and/or respiratory diseases within at least (14) days before the enrolment.

8.4.2. Exclusion Criteria:

a. persons younger than 18 years

b. Hypersensitivity to any of the vaccine components, or a vaccine containing similar components.

c. Severe allergic reactions in the past.

d. Acute infectious and non-infectious illnesses (e.g. pneumonia, fever >37ºC, infectious diarrhoea, etc.)

e. Temperature >37ºC.

f. Flares of chronic diseases (e.g. asthma, COPD, ulcerative colitis, etc.).

   i. Vaccine can be administered 2-4 weeks after recovery or remission. In non-severe Acute Respiratory Viral Infection (ARVI) or acute gastrointestinal infections - vaccination is administered after resolution of fever.

g. Pregnancy, as there is limited available data for use of the vaccine in pregnancy.

   i. Women who are planning a pregnancy within three months of the scheduled first dose.

   ii. Women with high-risk pregnancies and those with previous pregnancy complications should be considered for vaccination, based on recommendation by the treating physician.

h. Women who are currently breastfeeding.

i. Immunosuppressive drugs:

   i. Administered within at least 1 month before and after vaccination).

j. Administration of steroids (except hormonal contraceptives) and/or immunoglobulins or other blood products therapy within (30) days before the enrolment.

k. Tuberculosis, chronic systemic infections in medical history.

l. Contraindications for component II:

i. Severe post-vaccination complications (anaphylactic shock, severe generalized allergic reactions, convulsive disorder, temperature above 40°C etc.) after administering the vaccine Component I.

m. People diagnosed with HIV/AIDS due to lack of data on safety and efficacy in clinical trial population.

8.4.3. Special Considerations:

a. Patients receiving immunosuppressive therapy and patients with immunodeficiency may not develop sufficient immune response. Therefore, any drugs that suppress the immune system's function are contraindicated within at least 1 month before and after vaccination due to the risk of immunogenicity reduction.

b. Should be given with caution to individuals with thrombocytopenia, any coagulation disorder, or persons on anticoagulation therapy because bleeding/bruising may occur following an intramuscular administration in these individuals.

c. The drug is contraindicated during pregnancy and breastfeeding, since its efficacy and safety for those persons have not been studied.

d. In a patient with lymphedema of the arm of any cause e.g. after axillary node dissection for breast cancer, the vaccine should be given in the opposite arm. If both arms are affected, then it should be given in the thigh or buttock.

9. **STANDARD FIVE:** MEDICAL INDICATIONS FOR EXEMPTION FROM COVID-19 VACCINATION

9.1. The following list of medical indications is to be considered for individuals who are unable to take one of the Covid-19 vaccines available in Dubai:

9.1.1. Severe allergic reaction to first dose of a vaccine e.g. anaphylaxis.

9.1.2. Immediate severe allergic reaction to first dose of a COVID-19 vaccine, defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress such as wheezing, or anaphylaxis that occur within four hours following exposure.

a. Most reactions occur 15-30 minutes following vaccination and should be distinguished from other symptoms, such as vasovagal attack or vaccine side effects. The majority of people with anaphylaxis also present with skin findings.

9.1.3. Persons with mild immediate allergic reaction can be given the second dose under medical supervision.

9.1.4. Person's choice not to have a second dose following a documented allergic reaction to the first dose.

9.1.5. Known proven and documented allergy to any of the vaccine components, polysorbate or polyethylene glycol. The (**Appendix 7**) provides a list of medications that contain these products.

9.1.6. Patients on long-term steroids- prednisone 20mg/day for more than a month, or equivalent.

9.1.7. Serious Adverse Event Following Immunization (AEFI) after a first dose of Covid-19 vaccine that:

a. Required in-patient hospitalization.

b. Resulted in permanent or significant disability.

9.1.8. Persons who have had a confirmed permanent neurological complication after the first dose, for which there was not a similar history prior to vaccination.

9.1.9. Patients on immunosuppression, exempted on request, due to unknown vaccine safety profile and effectiveness and the potential for reduced immune response.

9.1.10. Persons who temporarily cannot take the vaccine:

a. Patients with active cancer and/or on therapy and supported by a report from the treating physician.

b. Pregnant women not willing to take the vaccine, if the exemption is given for a specific reason e.g. work or travel. (Pregnant women with a high-risk pregnancy should be encouraged to be vaccinated).

c. Patients with active COVID-19. In patients with mild and asymptomatic disease, the vaccine can be given after the de-isolation period of (10) days provided that they were asymptomatic for the last (3) days. In patients who have had moderate to severe disease, it is preferable to wait for a period of (90) days before vaccination.

9.1.11. Patients with chronic disease deemed as contraindication for vaccine by their treating physician and supported by a medical report.

9.1.12. Patients with HIV/AIDS and CD4 <200 cells/ul (immunological failure).

9.1.13. Patients with uncontrolled HIV viremia (virological failure, a temporary contraindication).

9.1.14. Patients with uncontrolled HCV or HBV viremia (pending initiation of antiviral therapy and achieving control).

9.2. The exemption from covid-19 vaccination Certificate are only issued by DHA Government hospitals and primary health centers (**Appendix 6**).

9.3. Weekly Audit will be conducted by taskforce team in DHA to review the exemption conditions.

10. STANDARD SIX: DOCUMENTATION

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

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

10.2.1. 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.

10.2.2. Occupational details:

a. Main Occupation: Labourer/Non-Labourer.

b. Name the company/authority.

c. Emirate.

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

10.2.4. Pre-vaccination assessment and counselling.

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

10.2.6. Post-vaccine assessment and any ADRs.

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

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

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

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

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

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

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

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

10.9. Record patient refusals in the individual medical record.

11. STANDARD SEVEN: PRE-SCREENING AND PROTOCOL FOR ADMINISTERING VACCINE

11.1. 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.

11.2. Health facilities should ensure that pre-screening is done for each patient prior to vaccine administration (**Appendix 4**).

11.3. Pre-screening:

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

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

b. Stability of current medical condition before vaccination.

c. 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.

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

e. 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.

f. Evaluate reactions to previous vaccinations.

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

h. Provide ways of communicating adverse events to facility for purpose of providing help and documentation of AEFI reports.

   i. DHA Call centre.

   ii. Visit any GP/ER.

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

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

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

11.4. Vaccine administration:

11.4.1. 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.

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

11.4.3. 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.

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

11.4.5. 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.

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

11.4.7. Injectable Route-SARS-CoV-2 vaccines are administered via Intramuscular (IM) injection.

11.4.8. 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.

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

12. STANDARD EIGHT: PREPARATION REQUIREMENT FOR VACCINES

12.1. Environmental Considerations for Vaccine Preparation:

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

12.1.2. 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).

12.1.3. 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.

12.1.4. 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.

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

12.2. Personnel Hygiene and Garbing:

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

12.2.2. 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.

12.2.3. 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.

12.3. Basic Aseptic Considerations for Vaccine Preparation:

12.3.1. 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.

12.3.2. 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.

12.4. Withdrawing Doses:

12.4.1. 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.

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

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

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

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

12.4.6. 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.

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

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

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

a. Vaccine vials can produce more than six (6) doses per a single vial.

12.5.3. A low dead-volume syringe is designed to limit dead space that exists between the syringe hub and needle.

12.5.4. A low dead-volume needle is designed with less space between the needle and the plunger.

12.5.5. To ensure practice settings who may not have adequate quantities of low dead-volume syringes to more consistently achieve the maximum doses withdrawn, a combination of low dead-volume syringes and non-low dead-volume syringes could also maximize

doses withdrawn (e.g., 3 low dead-volume syringes and 3 non-low dead-volume syringes).

12.5.6. Inserting the needle in various locations of the vial septum can reduce leaking of vaccine and maximize doses withdrawn.

12.5.7. The facility should carefully consider the number of pre-drawn syringes to prepare to minimize vaccine waste.

12.5.8. If pre-drawn syringes are used, the facility should consider the manufacturer released information supporting stability data of vaccine pre-drawn into syringes.

12.5.9. mRNA COVID-19 (BNT162b2) COVID-19 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 (35.6°F to 77°F) after the source vial is diluted.

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

12.5.11. The hold time of 6 hours, from the time the source vial is diluted.

12.5.12. Keep out of direct sunlight.

12.5.13. Weeks Apart: 3

12.6. ChAdOx1 nCoV-19 (AZD1222) Vaccine Considerations:

12.6.1. Health facilities should follow the manufacturer-supplied information available for administration of the vaccine.

12.6.2. Chemical and physical in-use stability have been demonstrated from the time of vial opening (first needle puncture) to administration for no more than 48 hours in a refrigerator (2°C – 8°C).

12.6.3. Unopened multidose vial should be stored in a refrigerator (2°C – 8°C). Do not freeze.

12.6.4. The vaccine should be inspected visually for particulate matter and discolouration prior to administration.

12.6.5. COVID-19 Vaccine AstraZeneca is a colourless to slightly brown, clear to slightly opaque suspension. Discard the vial if the suspension is discoloured or visible particles are observed. Do not shake. Do not dilute the suspension.

12.6.6. Keep the vials in outer carton in order to protect from light.

12.6.7. Weeks Apart: 8-12.

12.7. Inactivated SARS-CoV-2 (BBIBP-CorV) vaccine Considerations:

12.7.1. Health facilities should follow the manufacturer-supplied information available for administration of the vaccine.

12.7.2. Storage and transportation in refrigerated 2–8 °C condition.

12.7.3. Do not freeze the vaccine in any circumstance.

12.7.4. Protect the vaccine from direct exposure to sunlight.

12.7.5. Route of Administration: Intra-muscular.

12.7.6. Weeks Apart: 3-4.

12.8. Gam-COVID-Vac Vaccine Considerations:

12.8.1. Health facilities should follow the manufacturer-supplied information available for administration of the vaccine.

12.8.2. For intramuscular injection only.

12.8.3. Administered in two stages:

a. First 0.5 mL of Component I.

b. Then, three weeks afterwards, 0.5 mL of component II is injected.

12.8.4. Weeks Apart: 3

12.8.5. The vaccine has to be stored at -18°C during transport and storage until use.

12.8.6. The vaccine must be kept in its original packaging, protected from light.

12.8.7. All opened multi-dose vials (1vial = 3.0ml) of Sputnik V should be discarded at the end of administering 05 doses and within two hours of its removal from -18°C storage; whichever is earlier.

12.8.8. For vaccine administration once the product is removed from the freezer (-18°C) it is kept at room temperature until completely thawed and to be used within 02 hours, once thawed, then gently shake the vial. Do not shake sharply.

12.8.9. Vaccine recipients should be observed for 30 minutes post-vaccine administration.

12.9. Labelling Considerations:

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

12.9.2. 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.

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

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

12.9.5. 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. The exact beyond-use date and time (e.g., 6 hours for pre-drawn syringes for mRNA (BNT162b2) COVID-19 Vaccines from when the vaccine is diluted or the first dose is withdrawn from vial, respectively.

e. Batch number.

f. Initials of preparer.

13. STANDARD NINE: OBSERVATION POST VACCINE

13.1. 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.

13.2. 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.

13.3. Vaccine recipients should be kept under observation for at least 15 minutes after vaccination; 30 minutes is a safer interval when there is a specific concern about possible vaccine allergy or a history of anaphylaxis.

13.4. All healthcare professionals should monitor for adverse reactions (e.g. anaphylaxis), in the designated post vaccine observation area for a minimum 15 minutes and initiate immediate treatment as follow:

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

13.4.2. 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.

13.4.3. 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.

13.4.4. 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).

14. STANDARD TEN: INFECTION CONTROL MEASURES

14.1. 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.

14.2. 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.

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

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

14.3.2. 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).

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

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

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

14.3.6. Utilize electronic communications as much as possible.

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

14.4. Hand hygiene:

14.4.1. 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.

14.5. Personal Protective Equipment:

14.5.1. Facemasks are recommended for all healthcare workers.

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

14.5.3. 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.

14.6. 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.

15. STANDARD ELEVEN: WASTE MANAGEMENT AND DISPOSAL

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

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

15.3. 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.

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

15.4.1. Empty vials.

15.4.2. Vials with unused vaccine.

15.4.3. Vials with unused diluent.

15.4.4. Pre-drawn syringes and needles.

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

15.5. COVID-19 Vaccine AstraZeneca contains genetically modified organisms (GMOs). Any unused vaccine or waste material should be disposed off in compliance with the local guidance for genetically modified organisms or biohazardous waste. Spills should be disinfected using agents with activity against adenovirus.

16. STANDARD TWELVE: REPORTING DATA AND ADVERSE EVENTS

16.1. 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.

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

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

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

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

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

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

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

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

16.10. 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.			
16	Data entry policy is in place.			Provide copy of policy
Note: DHA will review the above and might request further information from your facility. Physical inspection will be conducted to ensure the accuracy of the provided details.				
For DHA Official Use Only				
Evaluation Report	**……(*Facility Name*) has ……(*met/not met/partially met*) all the required criteria set by Dubai Health Authority, for performing COVID-19 Testing at their facility.**			
Additional Comments if Any:				

APPENDIX 2. 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 will review the above and might request further information from your facility. Physical inspection will be conducted to ensure the accuracy of the provided details.				
For DHA Official Use Only				
Evaluation Report	**……(*Facility Name*) has ……(*met/not met/partially met*) all the required criteria set by Dubai Health Authority, for performing COVID-19 vaccination in their facility.**			
Additional Comments if Any:				

APPENDIX 3. 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	Vaccine administers are CPR-certified and trained in epinephrine.			
27	Adequate infection control measures are present.			
28	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 will review the above and might request further information from your facility. Physical inspection will be conducted to ensure the accuracy of the provided details.				

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Evaluation Report	**……(*Facility Name*) has ……(*met/not met/partially met*) all the required criteria set by Dubai Health Authority, for performing COVID-19 Vaccination at their facility.**
Additional Comments if Any:	

APPENDIX 4. PATIENT SCREENING

Sinopharm: pre-assessment form for IVR

(Any yes will stop vaccination)

- Are you less than 16 years old?
- Did you receive any COVID-19 vaccine before (one or two doses) other than Sinopharm?
- Do you have History of severe or critical COVID-19 infection (needed hospitalization), or currently have COVID-19 infection and did not finish 10 days isolation?
- If female:
    - Do you breast-feed a baby less than 6 months old?
    - Are you pregnant?
- Do you have history of severe reaction associated with any vaccine (e.g. anaphylaxis)?
- Do you have history of taking vaccine within last 14 days?
- Do you have history of active cancer or in remission for less than 6 months?

Pfizer vaccine: pre-assessment form for IVR

(Any yes will stop vaccination)

- Are you less than 12 years old?
- Do you have COVID-19 now and did not finish 10 days isolation?
- Did you receive any COVID-19 vaccine before (one or two doses)?
- Do you have severe allergy/anaphylaxis or known hypersensitivity to any of the Pfizer vaccine components or had history of severe or immediate allergic reaction to a previous Pfizer vaccine?
- If female, are you pregnant?
- Did you receive any vaccine within the last 14 days?

AstraZeneca vaccine: pre-assessment form for IVR

(Any yes will stop vaccination)

- Are you less than 18 years old?
- Do you have COVID-19 now and did not finish 10 days isolation?
- Did you receive any COVID-19 vaccine before (one or two doses)?
- Do you have severe allergy/anaphylaxis or known hypersensitivity to any of the AstraZeneca vaccine components or had history of severe or immediate allergic reaction to a previous AstraZeneca vaccine?
- If female, are you pregnant?
- Did you receive any vaccine within the last 14 days?

APPENDIX 5. PATIENT CONSENT FORM FOR COVID-19 VACCINE

A. Sinopharm COVID-19 vaccination patient consent form

SINOPHARM COVID-19 vaccination Consent form	
تعهد واقرار موافقة على اخذ لقاح كوفيد-19	
Consent form to take registered COVID-19 vaccine. Inactivated (Vero cell), Beijing – "Sinopharm" in the UAE (Copy of this consent form will be kept in your medical record file)	
الموافقة على اخذ لقاح كوفيد-19 من نوع الغير نشط (سينوفارم) المسجل في دولة الامارات العربية المتحدة (سيتم وضع نسخة من هذا النموذج في السجل الطبي الخاص بك)	
Statement of the vaccine interested individual I have fully read the COVID-19 information leaflet. As a result, I am aware of the risk and benefits of the COVID-19.	**تصريح الموافق على أخذ اللقاح** لقد قرأت بالكامل نشرة المعلومات حول لقاح كوفيد-19 وبناء على ذلك فأنا على دراية بمخاطر وفوائد لقاح كوفيد-19
By signing this consent, I hereby acknowledge that:	من خلال التوقيع على هذه الموافقة, أقر بما يلي:
1. All my questions have been answered to my satisfaction. 2. I understand that taking this vaccine means to get two doses from the same type of SARS-Cov2 inactivated vaccine. 3. I understand that the use of this vaccine might cause some side effects, ranging from some common reactions like pain, tenderness, redness, induration and pruritus at the vaccination site to systemic reactions such as fever, headache, fatigue, nausea, vomiting, diarrhea, cough, allergy, muscle pain, arthralgia, and lethargy, which may occur in some patients. Generally, the mild symptoms subside without treatment. If experienced moderate to severe symptoms, then symptomatic treatment under the guidance of doctors is required.	1. تمت الإجابة عن كافة أسئلتي بشكل يرضيني. 2. أتفهم بأن اختياري لهذا اللقاح سيكون من خلال أخذي لجرعتين من نفس نوع لقاح فيروس سارس-كوفيد2-الغير النشط. 3. أدرك ان استخدام هذا اللقاح قد يسبب آثارا جانبية تتراوح بين آثار جانبية شائعة مثل الألم عند اللمس، والاحمرار والتصلب والحكة في مكان التطعيم، الى حدوث ردود فعل جهازية مثل الحمى، والصداع، والارهاق، والغثيان، والقيء، والاسهال، والسعال، والحساسية، والام العضلات، والام المفاصل والخمول، والتي قد تحدث عند بعض المرضى. عادة ما تزول الاعراض هذه الخفيفة دون الحاجة الى علاج. إذا وجد أعراض معتدلة إلى شديدة، فيجب علاج الأعراض تحت إشراف الأطباء.

4. I understand that is vaccine has been registered based on fulfilling the required standards for the UAE. 5. I understand that signing this form does not waive any of my medical and legal rights. 6. I understand that I still have to take all precautionary measures to prevent coronavirus infection (COVID-19). 7. This consent is applicable to the administration of the first and second doses from the same type of COVID-19 inactivated vaccine.	4. افهم بان هذا اللقاح قد تم تسجيله وفق اللوائح والاشتراطات الخاصة بدولة الامارات العربية المتحدة. 5. أفهم بان توقيعي على هذا النموذج لا يعني تنازلي عن حقوقي الطبية او القانونية. 6. أفهم انه لا يزال يتعين على اتخاذ جميع الإجراءات الاحترازية لمكافحة فيروس كورونا المستجد (كوفيد-19). 7. تنطبق هذه الموافقة على اخذ الجرعتين الأولى والثانية من نفس نوع لقاح كوفيد-19 .
I hereby do acknowledge that <u>I am not having any of the below mentioned:</u> 1. Previous hospitalization/ICU admission due to COVID-19 infection. 2. Had previous severe allergic reactions to vaccination. 3. Uncontrolled epilepsy or other progressive neurological disorders. 4. Diagnosed with acute cancer. 5. Has history of coagulopathy or thrombocytopenia. 6. Receiving immunotherapy or inhibitor therapy or treatment has could suppress my immune defences within the last 3 months. 7. Received any vaccine within last 14 days or less than one month. 8. Severe uncontrolled cardio vascular disease.	**اتعهد بأنني <u>ليس لدى</u> كل ما هو مذكور أدناه:** 1. دخولي المستشفى/العناية المركزة بسبب إصابة سابقة بكوفيد-19 2. حساسية شديدة من لقاحات تم اخذها سابقا. 3. مصاب بمرض صرع غير مسيطر عليه أو غيره من الاضطرابات العصبية التقدمية. 4. مشخص بمرض السرطان الحاد. 5. لديه تاريخ من اعتلال التخثر او قلة الصفيحات. 6. اتناول الادوية المثبطة للمناعة او من يتعاطون عقاقير ذات أثر مثبط على فعالية الجهاز المناعي خلال الثلاثة أشهر الماضية. 7. اخذت أي لقاح خلال فترة 14 يوم السابقة او شهر من الان. 8. أعاني من مرض حاد في القلب وغير مسيطر عليه طبيا.
This vaccine will be administered by the health care professional as a registered vaccine in the UAE which already fulfilled all required standards	سيتم إعطاء هذا اللقاح المستوفى شروط تسجيل اللقاح حسب قوانين ولوائح دولة الامارات العربية المتحدة من قبل اخصائي الرعاية الصحية.
For ladies the followings are important: • No current pregnancy.	**ملاحظات مهمة للسيدات:** • تمنع المرأة الحامل من اخذ لقاح الكوفيد-19.

• Lactating mother if her baby is less than 6 months • After taking COVID-19 vaccine, you should avoid. Being pregnant during the upcoming three months.	• المرضعات إذا كان عمر الطفل الرضيع اقل من 6 شهور. • بعد أخذ لقاح الكوفيد-19 يجب تجنب حدوث حمل خلال الثلاثة شهور القادمة.
By signing below, I agree to take the COVID-19 Vaccine.	بالتوقيع ادناه, أوافق على أخذ لقاح كوفيد-19.
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
I have discussed the information contained in this document with the individual interested in taking the vaccine and in my opinion that person understands the risks and benefits.	لقد ناقشت المعلومات الواردة في هذه الوثيقة مع الفرد المهتم بأخذ اللقاح وفي رأيي أن هذا الشخص يتفهم المخاطر والفوائد
The patient approves that his demographics information will be shared with the 3rd party provider 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.	يوافق المريض على مشاركة المعلومات الديموغرافية الخاصة به مع مزود الطرف الثالث لإدارة التطعيم وفي حالة الأحداث 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):**	

B. Pfizer COVID-19 vaccination patient consent form

PFIZER COVID-19 Vaccination Consent form **تعهد وإقرار موافقة على لقاح 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 12 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 12 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 Food and Drug Administration (FDA) has authorized the vaccine	**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 (FDA) وافقت على اللقاح للاستخدام الطارئ للتحصين النشط للوقاية من كوفيد-19 لدى الافراد الذين تبلغ أعمارهم 12 عاما فما فوق.

for emergency use for active immunization to prevent COVID-19 in individuals aged 12 and older.	
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 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 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 • Redness at injection site • Nausea	**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 • غثيان

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.	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 او اخصائي الرعاية الصحية على الفور إذا كان لديك رد فعل تحسسي يمكن ان تكون مهددة للحياة.
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.	**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. • أي امراض مزمنة.

• 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.	• 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.
For ladies the following is important: **Pregnancy and breast-feeding** I understand that there is currently limited data available on the use of this vaccine in pregnant women. Based on that, I declare that I am not pregnant or breastfeeding, or planning to have a baby. As a precaution, I would avoid becoming pregnant until at least 2 months after the vaccine.	**ملاحظات مهمة للسيدات** **الحمل والرضاعة** انا على دراية ان هناك حاليًا بيانات محدودة متاحة حول استخدام هذا اللقاح لدى النساء الحوامل. وعليه فأنا أصرح بأنني لست حاملاً أو مرضعاً أو أنوي الإنجاب. كإجراء احترازي، سأتجنب الحمل حتى شهرين على الأقل بعد التطعيم.
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 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.	يوافق المريض على مشاركة المعلومات الديموغرافية الخاصة به مع مزود الطرف الثالث لإدارة التطعيم وفي حالة الأحداث 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):**	

C. AstraZeneca COVID-19 vaccination patient consent form

ASTRAZENECA COVID-19 Vaccination Consent form	
تعهد وإقرار موافقة على لقاح كوفيد-19	
Please indicate your understanding and agreement to the statements below:	**الرجاء القراءة والموافقة على البنود المذكورة ادناه:**
Consent to take Oxford-AstraZeneca's Covid-19 vaccine Covishield (ChAdOx1 nCoV-19 RECOMBINANT), which is authorised for emergency use in the United Kingdom and EU, and by a few other countries. This vaccine has been developed by the University of Oxford and AstraZeneca, and manufactured in India by the Serum Institute of India by the Serum Institute of India (SII). **COVISHIELD COVID-19 vaccine is indicated for active immunization of individual's ≥ 18 years old for the prevention of Covid-19 disease.** **(A copy of this form will be kept in the participant's medical record file)**	**الموافقة على اخذ القاح كوفيد-19 (كوفيشيلد)** **Oxford -AstraZeneca's Covid-19 vaccine COVISHIELD (ChAdOx1 nCoV- 19 RECOMBINANT) الذي تم ترخيصه للاستخدام الطارئ في المملكة المتحدة حيث ، والاتحاد الأوربي بالإضافة الى بعض الدول الأخرى طورته جامعة أكسفورد وشركة أسترازينيكا الدوائية وتم.) لقاح SIIتصنيعه في الهند بواسطة معهد سيروم في الهند (كوفيشيلد يستخدم للتحصين النشط للأفراد الذين تبلغ أعمارهم 18 فما فوق لغرض الوقاية من مرضً كوفيد-19** **(سيتم الاحتفاظ بنسخة من هذا النموذج في سجل الملف الطبي للشخص المشارك)**
By signing this consent, I hereby acknowledge that:	أقر خلال التوقيع على هذا التعهد بالتالي:
Statement of Participant I have fully read the COVISHIELD 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 Oxford-AstraZeneca's Covid-19 vaccine Covishield (ChAdOx1 nCoV-19 RECOMBINANT) which is used for active immunization to prevent COVID-19 disease. I am aware that this vaccine is authorized for emergency use in the UAE and in some other countries around the world for active immunization to prevent COVID-19 in individuals aged 18 years and older.	**اقرار المشارك** لقد قرأت كافة المعلومات الخاصة بلقاح كوفيد-19 كوفيشيلد المتوفرة في هذا التعهد، وبناء عليه فوائد ومنافع لقاحً أدرك تماما كوفيشيلد بالإضافة الى المخاطر المحتملة من أخذ اللقاح، كما وأدرك أن اللقاح Oxford-AstraZeneca's Covid-19 vaccine Covishield (ChAdOx1 nCoV-19 RECOMBINANT) يستخدم للتحصين النشط للوقاية من مرض الناجم COVID-19 عن فيروس. ويحفز قيام الجسم الطبيعي SARS-CoV-2 انتاج للأجسام المضادة ويحفز الخلايا المناعية للحماية من مرض COVID-19. وأدرك أن هذا اللقاح مصرح به للاستخدام في حالات الطوارئ في دولة الإمارات العربية المتحدة وفي بعض الدول الأخرى حول العالم للاستخدام الطارئ للتحصين

النشط للوقاية من كوفيد-19 لدى الافراد الذين تبلغ أعمارهم 18 عاما فما فوق.	
كما أنني أقر بأنني على دراية بالتالي: • مشاركتي طوعية بأخذ جرعتين كل منهما 0.5 مل من هذا اللقاح، بفاصل 4 الى 12 أسبوعا لإكمال سلسلة التطعيم. • يوصى بأن يكمل الافراد الذين يتلقون الجرعة الأولى من كوفيشيلد دورة التطعيم. • لم يتم تحديد مدة الحماية حتى الان وكأي لقاح، فان التطعيم بيكوفيشيلد قد لا يحمي جميع متلقي اللقاح من الإصابة بفيروس كوفيد-19. • يعطى التطعيم بالحقن العضلي (IM) فقط، ويفضل ان يكون ذلك في عضلة اعلى الذراع. • موافقتي على مشاركة المعلومات الديموغرافية مع مزود الطرف الثالث لإدارة التطعيم وفي حالة الاحداث السلبية, أوافق على التصريح لمقدم الرعاية الصحية التابع للطرف الثالث للوصول الى المعلومات السريرية لي حتى يتم التمكن من التعامل مع الموقف.	I understand the following points: My participation is voluntary by taking two doses of 0.5 ml each from this vaccine, given 4 to 12 weeks apart to complete the vaccination series. It is recommended that individuals who receive a first dose of COVISHIELD complete the vaccination course with COVISHIELD. The duration of protection has not yet been established, and as with any other vaccine, vaccination with COVISHIELD may not protect all vaccine recipients. • It is given as an intramuscular (IM) injection only, preferably into a muscle of the upper arm. • I approves that my demographics information will be shared with the 3rd party provider to administer the vaccination and in case of adverse events the I authorizes the 3rd party health care provider to access my clinical information to be able to handle the situation
الآثار الجانبية المحتملة أنا على دراية تامة بأن لقاح كوفيشيلد كأي لقاح، قد يؤدي إلى حدوث بعض الأعراض الجانبية، على الرغم من عدم حدوثها لدى كافة متلقين اللقاح. معظم الآثار الجانبية خفيفة أو معتدلة وتختفي في غضون أيام قليلة من ظهورها. وإذا تم التعرض لآثار جانبية مثل ألم أو ارتفاع درجات الحرارة فمن الممكن علاجها بأدوية للألم والحمى مثل الباراسيتامول وغيرها.. وإذا كنت الأعراض شديدة فينصح بطلب الاستشارة الطبية من طبيبك، او الاتصال على **800342** حيث سيتم تقديم النصيحة لما يتوجب فعله. **قد تظهر الآثار الجانبية مع المعدلات التالية:** **شائعة جدا:** قد تظهر لدي أكثر من 1 من كل 10 اشخاص • في موقع الحقن الم او انتفاخ او احمرار او سخونة او حكه او كدمات.	**Possible side effects** I understand that like all vaccines, Oxford-AstraZeneca's Covid-19 vaccine Covishield 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 can be treated by medicines for pain and fever such as paracetamol. If still troublesome, please seek medical advice from your doctor, or call **800342** and they will advise you on the next best step. Side effects may occur with the following frequencies: **Very common:** may affect more than 1 in 10 people • Pain at injection site, warmth, erythema, pruritus, swelling, bruising

• Tiredness • Headache • Muscle pain • Chills • Joint pain • Fever • Nausea **Common:** may affect up to 1 in 100 people: • Vomiting or influenza like illness **Uncommon:** may affect more than 1 in 1000 people • Enlarged lymph nodes • Excessive sweating, itchy skin, rash. • Dizziness, abdominal pain, decreased appetite. However, some people might develop other side effects, this includes any possible side effects not listed in this consent, or more serious medical conditions 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 uncommon or rare side effects to report by calling **800342** I understand that by reporting side effects, I help provide more information on the safety of this vaccine.	• التعب • صداع الراس • الم عضلي • قشعريرة • الم المفاصل • حمى • غثيان **شائعة:** قد تظهر لدى 1 من كل 100 شخص. • قيء او اعراض شبيه بالأنفلونزا. **غير شائعة:** قد تظهر لدى حتى 1 من كل 1000 شخص • تضخم الغدد الليمفاوية • الشعور بتوعك • فرط تعرق او حكة او طفح جلدي • دوار او الام في البطن او قلة الشهية ومع ذلك، يحتمل اصابة بعض الأشخاص بآثار جانبية أخرى محتملة غير مدرجة في هذا التعهد أو التعرض لحالات طبية أكثر خطورة أو لديهم علامات رد فعل تحسسي شديد مثل طفح جلدي وحكة وضيق في التنفس وتورم في الوجه أو اللسان. عليه ينصح بالاتصال بطبيبك الشخصي أو أخصائي الرعاية الصحية على الفور أو الذهاب إلى أقرب مركز طوارئ مباشرة وخاصة في حال الاصابة بردة فعل تحسسية ذات خطورة عالية. **التبليغ عن الأعراض الجانبية** أنا على دراية أنه في حالة ظهور أي آثار جانبية غير شائعة وغير ذاتية التحديد يمكنني الإبلاغ عنها عن طريق الاتصال بالرقم **800342** أنا على دراية أنه من خلال الإبلاغ عن الآثار 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 the vaccination facility before I am given the vaccine if I have:	**المحاذير والاحتياطات** أنا على دراية أنه ينبغي أن أعلن عن حالتي للممرضة أو الأطباء في مرفق التطعيم قبل أخذ اللقاح إذا كان لدي:

• Had any hypersensitivity to the active substance or to any of the components of the present in COVISHIELD vaccine • Had any problems following previous administration of other vaccines such 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; due to HIV infection, or are on a medicine that affects your immune system such as cancer chemotherapy. • A bleeding problem, bruise easily or use a medicine to inhibit blood clotting • Any chronic disease or illness. 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 that I am 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 that I am to declare to the nurse, doctor, or pharmacist any other significant health or drug history not covered above	• أي حساسية تجاه المادة الفعالة أو أي من المواد الموجودة في لقاح كوفشيلد. • أي مشاكل بعد أخذ أي لقاح سابق مثل الحساسية أو مشاكل التنفس. • مرض شديد مع ارتفاع في درجة الحرارة، ومع ذلك فإن مثل الزكام، الحمى الخفيفة أو عدوى مجرى الهواء العلوي اً ليست أسباب لتأخير التطعيم. • مثل الإصابة بفيروس نقص، ضعف الجهاز المناعي أو تناول دواء يؤثر على جهاز المناعة، المناعة البشرية. على سبيل المثال العلاج الكيميائي للسرطان، • لديك مشاكل النزيف، وسهولة الإصابة بالكدمات أو استخدام دواء لمنع تخثر الدم.. • أي أمراض مزمنة • ، أنا على دراية أن هذا اللقاح، كما هو الحال مع أي لقاح قد لا، يوفر الحماية الكاملة وانه لا توجد بيانات متاحة لمن يتلقونه وانه لا توجد بيانات متاحه حاليا للأفراد الذين يعانون من ضعف في جهاز المناعة او يمنع الاستجابات المناعية. انا على دراية ان أبلغ الطبيب إذا كنت أستخدم أو قد استخدمت أي أ أدوية أخرى أو تلقيت مؤخرً مؤخر آخر أو كان لدي أي رد فعل خطير تجاه أي لقاح آخر في الماضي. • انا على دراية بوجوب ابلاغ الطبيب عن أي تاريخ صحي او دوائي لم يتم ذكره أعلاه.
For ladies the following is important: **Pregnancy and breast-feeding** I understand that there is currently limited data available on the use of this vaccine in pregnant women. Based on that, I declare that I am not pregnant or breast-feeding, or planning to have a baby, and as a precaution, I would avoid becoming pregnant until at least 2 months after the vaccine.	**ملاحظات مهمة للسيدات:** **الحمل والرضاعة** أنا على دراية بأن هناك حاليًا بيانات محدودة متاحة حول استخدام هذا اللقاح لدى النساء الحوامل. وبناءً على ذلك، أصرح بأنني لست حاملاً أو مرضعة، أو أنوي الإنجاب، وكإجراء احترازي، سأتجنب الحمل إلا بعد شهرين على الأقل من التطعيم.

I understand that this 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 government and personal health 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
Admission Officer/Clerk Name (الموظف المسؤول عن التسجيل/الادخال): **Staff No. (الرقم الوظيفي):**	

APPENDIX 6. COVID-19 VACCINATION EXCEPTION 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)

APPENDIX 7: LIST OF MEDICATIONS THAT CONTAIN POLYSORBATE OR POLYETHYLENE GLYCOL

Common parenteral medications containing potential PEG and/or polysorbate

Formulary Medications (PARENTERAL ROUTES only)	Polysorbate 80 (PS80)	Polysorbate 20 (PS20)	Polyethylene Glycol (PEG)
Ado-trastuzumabemtansine		X	
ALEMTUZUmab	X		
Alteplase	X		
Atezolizumab		X	
Avelumab		X	
Bamlaniuimab	X		
BEVACIZUmab		X	
Blinatumomab	X		
Brentuximab	X		
Cemiplimab	X		
Cyclophosphamide			X
Daratumumab		X	
Depomedrol			X
Depoprovera			X
Dinutuximab		X	
Docetaxel	X		
Durvalumab	X		
Elotuzumab	X		
Etoposide (inj. solution)	X		
Fam-trastuzumab	X		
Fosaprepitant	X		
Fulvestrant	X		
Gemcitabine			X
Herceptin			X
Infliximab	X		
Ipilimumab	X		
Isatuximab-irfc	X		
Lorazepam			X
Mogamulizumab	X		
Neulasta			X
Nivolumab	X		
Ofatumumab	X		
PEGaspargase			X
Pembrolizumab	X		
Pertuzumab		X	
Phytonadione	X		
Polatuzumab		X	
Ramucirumab	X		
Rituximab	X		
SacituzumabGovitecan	X		
Temozolomide	X		
Trastuzumab		X	
Ustekinumab	X		
Vancomycin			X