

- Electronic copy is controlled under document control procedure. Hard copy is uncontrolled & under responsibility of beholder. النسخة الإلكترونية هي النسخة المضبوطة وفق إجراء ضبط الوثائق. النسخ الورقية غير مضبوطة وتقع على مسؤولية حاملها.
- It is allowed ONLY to access and keep this document with who issued, who is responsible and to whom it is applicable. يسمح بالوصول وباحتفاظ بهذه الوثيقة مع مصدرها أو مع المسؤول عن تطبيقها أو مع المطبق عليهم.
- Information security code: ☒ Open ☐ Shared - Confidential ☐ Shared-Sensitive ☐ Shared-Secret تصنيف أمن المعلومات: ☒ بيانات مفتوحة ☐ مشارك - خاص ☐ مشارك - حساس ☐ مشارك - سري

# GUIDELINES ON ELIGIBILITY FOR mRNA COVID-19 (BNT162b2) VACCINE

Version 7.4

Issue date: 24/07/2023

Effective date: 24/07/2023

Health Policies and Standards Department

Health Regulation Sector (2023)

## INTRODUCTION

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

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

The Guidelines for Eligibility of mRNA COVID-19 (BNT162b2) aims to fulfil the following overarching DHA Strategic Priorities (2022-2026):

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

## ACKNOWLEDGMENT

The Health Policy and Standards Department (HPSD) developed this Guideline in collaboration with Subject Matter Experts and would like to acknowledge and thank these health 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

<b>INTRODUCTION</b>	<b>2</b>
<b>ACKNOWLEDGMENT</b>	<b>3</b>
<b>EXECUTIVE SUMMARY</b>	<b>5</b>
<b>DEFINITIONS/ABBREVIATIONS</b>	<b>6</b>
<b>1. BACKGROUND</b>	<b>8</b>
<b>2. SCOPE</b>	<b>10</b>
<b>3. PURPOSE</b>	<b>10</b>
<b>4. APPLICABILITY</b>	<b>10</b>
<b>5. RECOMMENDATION ONE: m-RNA COVID-19 VACCINE (MONOVALENT OR BIVALENT) INCLUSION AND EXCLUSION CRITERIA</b>	<b>11</b>
<b>6. RECOMMENDATION TWO: ADDITIONAL DOSES RECOMMENDATIONS</b>	<b>13</b>
<b>7. RECOMMENDATION THREE: BIVALENT m-RNA VACCINE RECOMMENDATIONS</b>	<b>16</b>
<b>8. RECOMMENDATION FOUR: PRECAUTIONS</b>	<b>17</b>
<b>9. RECOMMENDATION FIVE: SWITCHING OF VACCINES</b>	<b>19</b>
<b>10. RECOMMENDATION SIX: CO-ADMINISTRATION WITH OTHER VACCINES</b>	<b>19</b>
<b>11. RECOMMENDATION SEVEN: VACCINATION IN PREGNANT/LACTATING WOMEN AND WOMEN CONTEMPLATING PREGNANCY</b>	<b>20</b>
<b>12. RECOMMENDATION EIGHT: CLINICAL CONSIDERATIONS</b>	<b>22</b>
<b>REFERENCES</b>	<b>40</b>
<b>APPENDICES</b>	<b>47</b>
<b>APPENDIX 1 - Common parenteral medications containing potential PEG and/or polysorbate</b>	<b>47</b>
<b>APPENDIX 2- list of drugs that may be taken by immunocompromised patients</b>	<b>49</b>
<b>APPENDIX 3- Instruction for use of PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT</b>	<b>52</b>
<b>APPENDIX 4- List of illnesses and conditions</b>	<b>53</b>

## EXECUTIVE SUMMARY

This document addresses updated recommendations for m-RNA COVID-19 vaccination in individuals over the age of 12 years. It is based on current knowledge of the situation in the UAE and across the globe; it is aligned with current international guidelines, expert opinion and circulars issued by DHA related to the subject. The document aims to ensure public and patient health protection and to support healthcare professionals in providing advice to patients on mRNA COVID-19 vaccine. This guideline is subject to regular revision by Dubai Health Authority and Dubai Academic Health Corporation supported by updated international recommendations. Updates in Version 7.4 include revised recommendations on the use of BIVALENT m-RNA COVID-19 vaccine (Pfizer-BNT) in the following scenarios:

- Primary vaccine series.
- Booster vaccine doses.
- Booster vaccine doses for immunocompromised patients.
- Pregnant and lactating women.
- Persons who received non-m-RNA COVID-19 vaccine in the past.
- Appendix (3)- Instruction for Use of Pfizer-Biontech COVID-19 Vaccine, Bivalent.

## DEFINITIONS/ABBREVIATIONS

**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.

**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).

<b>AA</b>	:	Aplastic Anaemia
<b>ACIP</b>	:	Advisory Committee on Immunization Practices
<b>ACOG</b>	:	American College of Obstetrics & Gynaecology
<b>ATG/CSA</b>	:	Anti-thymocyte globulin/cyclosporin
<b>ADRs</b>	:	Adverse Drug Reactions
<b>AFI</b>	:	Acute febrile illness
<b>ASH</b>	:	American Society of Haematology
<b>ASTCT</b>	:	American Society of Transplantation and Cellular Therapy
<b>cGVHD</b>	:	Chronic Graft Versus Host Disease
<b>CLL</b>	:	Chronic Lymphocytic Leukaemia

<b>CML</b>	:	Chronic Myeloid Leukaemia
<b>COVID</b>	:	Corona Virus Disease
<b>COPD</b>	:	Chronic obstructive pulmonary disease
<b>DHA</b>	:	Dubai Health Authority
<b>DM</b>	:	Diabetes Mellitus
<b>HPSD</b>	:	Health Policies and Standards Department
<b>HRS</b>	:	Health Regulation Sector
<b>MM</b>	:	Multiple Myeloma
<b>MPN</b>	:	Myeloproliferative Neoplasm
<b>PEG</b>	:	Polyethylene Glycol
<b>RMDs</b>	:	Rheumatological and musculoskeletal disease
<b>WHO</b>	:	World Health Organization

## 1. BACKGROUND

Coronavirus Disease (COVID-19) is a disease caused by new strain of coronavirus (SARS-CoV-2) 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 asymptomatic to mild and 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 UAE was one of the first countries to implement a national COVID-19 vaccine campaign and several vaccine platforms were used since the beginning of the pandemic. Health authorities have been rigorously reviewing data related to each vaccine platform and updated recommendations were implemented accordingly.

These guidelines will focus on recommendations for the use of m-RNA COVID-19 vaccine from Pfizer-BioNTech for healthcare providers in the Emirate of Dubai. It will also give updates on recommendations for COVID-19 BIVALENT vaccine (Pfizer-BioNTech) based on CDC and FDA updated recommendations.

### COVID-19 BIVALENT vaccine (Pfizer-BioNTech):

In view of the ongoing mutations in SARS-CoV-2 virus, there was a need to modify the components of COVID-19 vaccines to offer a broader cover and expanded spectrum of protection to the community. Eligibility for the bivalent vaccine depends on age, immune



status, previous COVID-19 vaccine history, including the use of booster doses of monovalent or bivalent vaccines.

The bivalent COVID-19 vaccines include a component that corresponds to the original virus strain to provide broad protection against COVID-19 plus a component that corresponds to the omicron variant for expanded protection. The FDA has issued an emergency use authorization for the Moderna COVID-19 Vaccine, Bivalent and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Pfizer-BioNTech Bivalent COVID-19 vaccine is available in the UAE and below recommendations are to guide physicians on its eligibility and exclusion criteria. The bivalent COVID-19 vaccines have two mRNA components: one of which corresponds to the original strain of the virus that is broadly protective against COVID-19 and the other corresponds to the omicron variant BA.4 and BA.5 lineages to provide better protection against COVID-19 caused by the omicron variant.

Bivalent Pfizer-BNT can be given as booster dose (1 dose only for the time being after completing previous required vaccine series), or as a single dose of primary vaccine series in those who did not receive COVID-19 vaccine in the past and meet eligibility criteria.

- The current recognized COVID-19 vaccines in the country are:
  - mRNA COVID-19 Vaccine (Pfizer-BioNTech).
  - mRNA COVID-19 BIVALENT COVID-19 Vaccine (Pfizer-BioNTech).
  - Inactivated SARS-CoV-2 COVID-19 Vaccine (Sinopharm).
  - Recombinant SARS-CoV-2 COVID-19 Vaccine.

- The current available WHO COVID-19 vaccines given Emergency Use Authorization:
  - Pfizer-BNT (Comirnaty) (mRNA).
  - Moderna (mRNA).
  - Oxford AstraZeneca (non-replicating viral vector).
  - COVISHIELD, Serum Institute of India (non-replicating viral vector).
  - Johnson and Johnson (viral vector).
  - Sinopharm (inactivated whole virus).
  - Sinovac (inactivated whole virus).
  - COVAXIN, Bharat Biotech BBV152 (whole virion inactivated SARS-CoV-2).
  - Novavax (recombinant spike protein nanoparticle).
  - The Sputnik vaccine (non-replicating viral vector).

## 2. SCOPE

- 2.1. Providing advice to people eligible for COVID-19 vaccines.

## 3. PURPOSE

- 3.1. To ensure public and patient health protection.
- 3.2. To support healthcare professionals in providing advice to people eligible for COVID-19 vaccines.

## 4. APPLICABILITY

- 4.1. Health facilities and healthcare professionals licensed under DHA's jurisdiction.

## 5. **RECOMMENDATION ONE:** m-RNA COVID-19 VACCINE (MONOVALENT OR BIVALENT)

### INCLUSION AND EXCLUSION CRITERIA

#### 5.1. Inclusion Criteria:

- 5.1.1. Eligible patients might receive the first dose as monovalent m-RNA vaccine or BIVALENT m-RNA vaccine (Pfizer-BNT) and subsequent vaccine doses, including booster doses, if needed, can be decided as per the below criteria.
- 5.1.2. Persons  $\geq 12$  years. Whilst the bivalent vaccine is approved by the FDA for ages 5 and above, in the UAE approval is for ages 12 years and above.
- 5.1.3. People with chronic illnesses: asthma, COPD, heart failure, chronic renal diseases, chronic liver diseases, DM, hypertension, ischemic heart disease.
- 5.1.4. People with HIV regardless of CD4 count or viral load; these include people on anti-retroviral therapy.
- 5.1.5. 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.
- 5.1.6. If a person contracts COVID-19 after the first vaccine dose, the second dose should be deferred until recovery of the acute infection (as defined above), even if the dose is delayed. Therefore, prior COVID-19 infection is not a contraindication to the vaccine.

- 5.1.7. Immunocompromised are highly encouraged to receive COVID-19 vaccination and are eligible for additional booster doses as clinically indicated.
- 5.1.8. Persons with autoimmune conditions who have no contraindications to vaccination may receive an mRNA COVID-19 vaccine.
- 5.1.9. Other persons eligible to or willing to take the vaccine if there is no absolute contraindication. Please see note below regarding vaccination in pregnancy and lactation.
- 5.1.10. Uncontrolled diabetes is not a contraindication to the vaccine. In fact, because these patients are at risk of severe COVID-19 and they should be encouraged to be vaccinated.
- 5.1.11. Pregnant women beyond the first trimester of pregnancy, following an explanation of the benefits and possible risks of vaccination in pregnancy.
- 5.2. Exclusion Criteria:
- 5.2.1. People who have participated in COVID-19 vaccine clinical trials.
- 5.2.2. People with active COVID-19 infection.
- 5.2.3. People with Acute Febrile Illness (AFI) at the time of vaccination.
- 5.2.4. Severe or immediate allergic reaction of any severity to a previous mRNA vaccine dose e.g. anaphylaxis.
- 5.2.5. Previous immediate allergic reaction of any severity to a component of the vaccine [polyethylene glycol (PEG) or polysorbate] refer to **(Appendix 1)**.

5.2.6. People with acute or chronic medical conditions justifying temporary or permanent vaccine exemption as per clinical data and managing physician decision.

5.2.7. People who developed any cardiac event, particularly pericarditis / myocarditis, that was probably linked to COVID-19 vaccine.

5.2.8. People who developed serious or severe reaction related to any COVID-19 vaccine and were eligible for vaccine exemption (managing physician decision is needed).

5.2.9. People who developed severe reaction after any COVID-19 vaccine.

## 6. RECOMMENDATION TWO: ADDITIONAL DOSES RECOMMENDATIONS

6.1. Eligibility for subsequent doses of m-RNA COVID-19 monovalent or bivalent vaccine:

As mentioned above, majority of persons who received a single dose of m-RNA BIVALENT COVID-19 vaccine will not need additional doses for the time being. Below recommendations will be applicable for persons who received the first dose/s as monovalent vaccine.

6.2. Immunocompromised Individuals:

6.2.1. Additional third dose to be given at least (28) days after the second dose of the primary mRNA series.

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

- a. Pfizer-BioNTech COVID-19 vaccine ( $\geq 12$  years).
- b. Moderna COVID-19 vaccine ( $\geq 18$  years).

6.2.3. 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).

6.3. Moderately and severely immunocompromised persons eligibility for a third dose:

6.3.1. Active treatment for solid tumor and hematologic malignancies.

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

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

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

6.3.5. Advanced or untreated HIV infection.

6.3.6. Active treatment with:

a. High dose corticosteroids (i.e.  $\geq 20$  mg prednisone, or equivalent, per day)

b. Alkylating agents, antimetabolites.

c. Transplant-related immunosuppressive drugs.

d. Cancer chemotherapeutic agents classified as severely immunosuppressive

e. TNF blockers

f. Other biologic agents that are immunosuppressive or immunomodulatory (this includes Rituximab and other related agents). A list of drugs that may be taken by immunocompromised patients is available in **(Appendix 2)**.

#### 6.3.7. Solid Organ Transplant Recipients:

- a. All solid organ transplant recipients, their eligible household and close contacts are recommended to get vaccinated against SARS-CoV-2.
- b. If possible, vaccination should be done prior to transplantation, ideally with completion of vaccine series a minimum of 2 weeks prior to transplant.
- c. 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.
- d. Serious adverse events, though rare, can still occur after a 3-dose series.

#### 6.3.8. Heterologous stem cell transplant (HSCT) and chimeric antigen receptor T-cell (CART) therapy:

- a. Patients who have undergone HSCT or CART therapy and who have been previously vaccinated with COVID-19 vaccine(s) are to be considered non-vaccinated and should receive a 3-dose primary series.
- b. The first dose is generally given 3 months after therapy, followed by a second dose 2-3 months after the first dose and the third dose 2 months after the second dose.
- c. Earlier dosing intervals are not recommended.

#### 6.3.9. Patients receiving B-cell depletion therapy should ideally be vaccinated prior to initiation of therapy

## 7. RECOMMENDATION THREE: BIVALENT m-RNA VACCINE RECOMMENDATIONS

7.1. The Pfizer BioNTech bivalent vaccine has been approved in the UAE for persons 12 years of age and older; it should not be used in individuals 6 months through 11 years of age.

7.2. The vaccine comes in single dose and multiple dose vials with grey caps and labels with grey borders. It must not be diluted prior to use. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Do not refreeze thawed vials; the thawed vials can be stored at 2°C to 8°C (35°F to 46°F) for up to 10 weeks. Each dose is 0.3 mL and multiple dose vials contain 6 doses. Persons 12 years of age and over can get Bivalent COVID-19 vaccine as:

7.2.1. As a single primary dose for unvaccinated

7.2.2. As a single booster dose after at least 2 months of completion of any of the following:

- a. Have had primary vaccinations with any type of approved COVID-19 vaccine.
- b. Have had a booster dose of any approved monovalent COVID-19 vaccine.
- c. Individuals 65 years of age and older who have received a single dose of a bivalent vaccine may receive one additional dose at least four months following their initial bivalent dose.
- d. Immunocompromised individuals who have received a single dose of a bivalent vaccine may receive one additional dose at least two months following their initial bivalent dose.



I. For further information please refer to (**Appendix 3**).

- e. Patients with chronic conditions are advised to receive a booster dose of the Bivalent vaccine. for a list of these conditions please refer to (**Appendix 4**).

## 8. RECOMMENDATION FOUR: PRECAUTIONS

- 8.1. An immediate allergic reaction to any other vaccine or injectable medication is considered a precaution and not a contraindication.
- 8.2. People with acute febrile illness (AFI) at the time of vaccination.
- 8.3. Patients treated with rituximab clearly have diminished humoral responses to vaccinations. 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  $\geq 4$  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.
- 8.4. Patients on high dose steroids should be cautioned on the inadequate response to the vaccine. 'High dose' generally indicates a dose of prednisone 20mg or more per day for >2 weeks, or equivalent; such patients may have diminished responses to vaccinations. These groups are among the high-risk group and therefore are considered for 3 doses of mRNA COVID-19 vaccine.

- 8.5. People with bleeding disorders or on anti-coagulation with documented uncontrolled INR.
- 8.6. According to DHA External Circular number #0631, reporting of suspected adverse reactions should be followed by all the healthcare providers and professionals in the Emirate of Dubai. [\[link\]](#).
- 8.7. Special Considerations:
- 8.7.1. Individuals with a reaction to the first dose of vaccine should not be given an anti-histamine or other anti-allergic medications prior to the second dose as this may delay the early warning signs of anaphylaxis.
- 8.7.2. Serology testing to determine level of immunity in vaccine decision-making is not recommended as individuals with low antibody levels may have rapid production of antibodies by the memory cells on exposure to the virus. Additionally, the cellular component of immunity is not tested. Hence, testing of neutralising antibody levels should be reserved for the setting of clinical trials.
- 8.7.3. 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.
- 8.7.4. 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.
- 8.7.5. However, the primary series can be repeated if the person presents beyond 6 months of the first dose.

8.7.6. In a patient with lymphoedema 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.

8.7.7. 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.

## 9. RECOMMENDATION FIVE: SWITCHING OF VACCINES

9.1. 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.

9.2. 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.

## 10. RECOMMENDATION SIX: CO-ADMINISTRATION WITH OTHER VACCINES

10.1. 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.

10.2. 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.

## **11. RECOMMENDATION SEVEN: VACCINATION IN PREGNANT/LACTATING WOMEN AND WOMEN CONTEMPLATING PREGNANCY**

### **11.1. Pregnant women:**

11.1.1. 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, including the Bivalent.

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

- a. ACOG recommends that COVID-19 vaccine should not be withheld from pregnant women who meet the criteria for vaccination based on Advisory Committee on Immunization Practices (ACIP) recommended priority group.
- b. ACOG recommends that in the interest of patient autonomy, pregnant women should be free to make their own decision regarding COVID-19 vaccination.
- c. 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.

### 11.1.3. Additional considerations for pregnant women:

- a. Similar to their non-pregnant peers, vaccination of pregnant women with a COVID-19 mRNA vaccine may occur in any setting authorized to administer these vaccines. This includes any clinical setting and non-clinical community-based vaccination sites such as schools, community centers, and other mass vaccination locations.
- b. Pregnant women who experience fever following vaccination should be counselled to take paracetamol.
- c. Women should complete their 2-dose series with the same vaccine product if receiving an mRNA vaccine unless there is severe allergic reaction to first dose, in that case; the vaccine can be switched.
- d. 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.
- e. For any concerns, women should consult with their obstetricians.

### 11.2. Lactating women:

- 11.2.1. 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.
- 11.2.2. Theoretical concerns regarding the safety of vaccinating lactating women do not outweigh the potential benefits of receiving the vaccine.

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

### 11.3. Women Contemplating Pregnancy:

11.3.1. 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.

11.3.2. 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.

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

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

## 12. RECOMMENDATION EIGHT: CLINICAL CONSIDERATIONS

### 12.1. Clinical considerations for people with a history of Multisystem Inflammatory Syndrome in Adult (MIS-A):

12.1.1. The mechanisms of MIS-A are not well understood but include a dysregulated immune response to SARS-Cov-2. Adult with MIS-A have high antibody titers to SARS-Cov-2, however, it is unknown if this correlates with protection against

reinfection and for how long protective antibody levels persist. It is unclear if people with a history of MIS-A are at risk for recurrence of the same dysregulated immune response following reinfection with SARS-Cov-2 or in response to a COVID-19 vaccination.

12.1.2. People with a history of MIS-A may choose to be vaccinated.

12.1.3. Current evidence suggests that the risk of SARS-Cov-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. Thus, people with a history of MIS-A should consider delaying vaccination until they have recovered from illness and for 90 days after the date of the diagnosis of MIS-A, recognizing that the risk of reinfection and, therefore, the benefit from vaccination, might increase with time following initial infection.

12.1.4. Individuals may be vaccinated after 90 days of diagnosis of MIS-A after consultation with their treating physician where the following should be considered:

12.1.5. Considerations for vaccination may include:

- a. Clinical recovery from MIS-A, including return to normal cardiac function.
- b. Personal risk of severe acute COVID-19 (e.g., underlying conditions).
- c. Level of COVID-19 community transmission and personal risk of reinfection.
- d. Lack of safety data of COVID-19 vaccination following illnesses.
- e. Timing of any immunomodulatory therapies.

## **12.2. Hematological Disorders & Malignancies:**

12.2.1. Bleeding Disorders and Thrombosis:

- a. Heritable bleeding disorders do not increase the risk of acquiring COVID-19. Hence, patients with such conditions may be vaccinated according to the published schedule. The vaccine itself does not present any additional safety concerns for these patients but the intra-muscular route of administration may increase the risk of bleeding at the injection site. Patients with severe haemophilia on prophylaxis with factor concentrate should have their normal prophylactic dose prior to the injection.
- b. Patients with mild bleeding disorders can generally have an intra-muscular injection without any haemostatic treatment. If there is any uncertainty, advice should be sought from the patient's haematologist/haemophilia centre.
- c. Those on Emicizumab can have the vaccination without any additional treatment if they are at steady state because it is similar to mild haemophilia.
- d. Patients receiving regular platelet transfusions should have their vaccine after a platelet transfusion.
- e. Other patients not falling into these categories should be managed on an individual basis.

#### 12.2.2. Anticoagulation or anti-platelet therapy:

- a. Patients with bleeding disorders may have a slightly increased risk of bleeding due to the intra-muscular route of administration.
- b. Patients on standard intensity anticoagulation with warfarin (target INR 2.0–3.0) can receive intramuscular injections as long as the most recent INR is 3.0. There



is no need for an extra INR check prior to vaccination. However, pressure should be applied at vaccine site for 5 minutes.

- c. Patients on maintenance therapy with direct oral anticoagulants, therapeutic low-molecular weight heparin or fondaparinux can delay the dose on the day of vaccination until after the intramuscular injection but do not need to miss any doses.
- d. Patients on single agent anti-platelet therapy (e.g. aspirin or clopidogrel) can continue these medications without any adjustment.
- e. Patients with higher intensity anti-thrombotic treatment, for example warfarin with a target INR > 3.0 or dual antithrombotic medications, should be managed on an individual basis. For patients with higher ranges, recommendation is to ensure that the INR is <3. The risk of hematoma formation should be reduced by application of pressure at the injection site for at least 5 minutes afterwards (without rubbing the injection site).

#### 12.2.3. Auto-immune haematological conditions on immunosuppression (Autoimmune haemolytic anaemia and immune thrombocytopenic purpura - ITP):

- a. Adults who are receiving immunosuppressive agents including but not restricted to rituximab, cyclophosphamide, mycophenolate or steroids (equivalent of prednisolone 20mg/day for >2 weeks) are deemed as clinically extremely vulnerable and should be encouraged to receive the vaccine and are eligible to also receive a third dose (see above).

- b. Patients with ITP on thrombopoetin stimulating agent (eltrombopag/romiplostim) can receive vaccination if platelet is  $\geq 30,000$  per microliter of blood.

#### 12.2.4. Hemoglobinopathies and Rare Inherited Anaemias:

- a. Patients with hemoglobinopathy are deemed “clinically extremely vulnerable” and should be offered the vaccine. This includes all adults with sickle cell disease and some patients with thalassemia and inherited rare anaemias who have severe iron overload. Patient with G6PD deficiency can receive Covid-19 vaccine.
- b. Patients aged  $\geq 12$  and older with underlying health conditions should be offered vaccination. This group includes people who receive the flu vaccine every year because they have problems with their spleen or have had their spleen removed. This group include sickle cell disease, thalassemia and rare inherited anaemia patients who have had their spleen removed.

#### 12.2.5. Acute Leukaemia (AML, APL and ALL):

- a. Patients with acute leukaemia should not delay their treatment for vaccination.
- b. As a general statement, the American Society of Haematology (ASH) supports giving people with acute leukaemia undergoing treatment SARS-Cov-2 vaccine (no-live) although they may not mount an effective immune response; trial results are awaited.

- c. The timing of vaccination is important; it should be avoided during the neutropenia period. It is important for patients to complete induction then consolidation to make sure that the second dose can be given at the appropriate time.

#### 12.2.6. Blood and Marrow Transplantation & Cellular Therapy:

- a. Allogeneic:
  - i. In general, it is considered safe and appropriate for transplanted patients to receive vaccines, as long as they are not live, attenuated virus vaccines.
  - ii. COVID-19 vaccination should take priority over the regular vaccination schedules.
  - iii. The American Society of Transplantation and Cellular Therapy (ASTCT) and American Society of Haematology (ASH) strongly support early access to vaccines for these vulnerable patients, along with their caregivers, family and household contacts when and if vaccine supply permits.
  - iv. Consider vaccination of patients with mild chronic graft versus host disease (cGVHD) and/or receiving  $\leq 0.5\text{mg/kg}$  prednisolone (or equivalent).
  - v. For patients with moderate/severe cGVHD or on more intensive immunosuppressive therapy (high dose steroids  $>0.5\text{mg/kg}$ ) consider COVID-19 vaccination (please see above regarding third dose).
- b. CART cell therapy:
  - i. Early vaccination is recommended as per ASTCT/ASH regardless of their B cell count

#### 12.2.7.Lymphoma:

- a. Patients with lymphoma may be immunosuppressed to a varying extent depending on the lymphoma diagnosis and treatment history. This has implications for overall vaccination strategy and treatment decisions, safety and efficacy of COVID-19 vaccines in immunocompromised patients. There are no data regarding the safety or efficacy of currently available COVID-19 vaccines in immunosuppressed patients.
- b. However, there is no evidence that replication-deficient vaccines are unsafe in this setting. Regarding clinical efficacy, it is reasonable to assume that patients with B-cell depletion/dysfunction are likely to have an impaired humoral response to vaccination, while those with T-cell depletion/dysfunction are likely to have an impaired cellular response and possibly also an impaired humoral response due to loss of T helper function.
- c. Overall COVID-19 vaccination strategy:
  - i. Based on current safety/benefit considerations and in the absence of data or guidance to the contrary, it is recommended that all patients with lymphoma should receive a non-replicating COVID-19 vaccine (unless explicitly contraindicated), accepting that this might not achieve full protection if there are pre-existing defects in humoral and/or cellular immunity. For these patients, vaccination of close contacts may at least be as important. It should be

emphasized that neither of these measures removes the need for social distancing and other precautionary measures.

ii. Implications for lymphoma treatment:

- The predicted effects of specific lymphoma treatments on cellular and humoral responses to COVID-19 vaccination should be considered and discussed with patients in a balanced way alongside other treatment considerations, e.g., the desire to maximize progression-free survival and minimize overall treatment-related toxicity. This is particularly relevant for drugs such as bendamustine and rituximab/obintuzumab, which deplete T and B cells, respectively, but may also improve long-term disease control.

iii. Timing of COVID-19 vaccine:

- If the patient's condition is not urgent, COVID-19 vaccination should be completed at least 2 weeks before any immunosuppressive treatment is given.
- For patients that have received lymphocyte depleting therapy, ie rituximab, blinatumomab, and anti-thymocyte globulin, alemtuzumab, etc. COVID-19 vaccination (3 doses) should be given as early as possible irrespective of their B cell count, given that COVID-19 vaccination generate T-cell memory that may offer some protection.

#### 12.2.8. Chronic Lymphocytic Leukemia (CLL):

- a. Patients with CLL of all stages (including patients on watch and wait) have a degree of immunosuppression and are at high risk for COVID-19 infection. Patients with CLL are advised against receiving live vaccines but attenuated and mRNA-based vaccines can be safely given.
- b. If patients are asymptomatic from a CLL standpoint, we would recommend holding B-cell depleting therapy until 1 month after completion of vaccination (both doses for mRNA vaccination).
- c. For small molecule inhibitor therapy (Ibrutinib, Idelalisib and venetoclax) in symptomatic patients, we would recommend COVID-19 vaccination irrespective of B cell count.
- d. When chronic therapy for symptomatic patients is required, vaccination should be considered as it may still generate T-cell memory responses in the absence of B-cell recovery.

#### 12.2.9. Multiple Myeloma (MM):

- a. Patient with multiple myeloma (MM) are extremely vulnerable because of age (median age at diagnosis is 70 years), disease and treatment-related immunocompromise.
- b. The use of high dose steroids as the backbone of therapy with the addition of agents known to cause/exacerbate panhypogammaglobulinemia (e.g., daratumumab) increase the vulnerability further.

- c. Live vaccines are not generally recommended in MM patients but attenuated and mRNA-based vaccines can be safely given.
- d. Patients with MM are considered immunocompromised and are strongly recommended to receive COVID-19 vaccine (3 doses).

#### 12.2.10. Myelodysplasia:

- a. Patients with myelodysplastic syndrome (MDS) is amongst the highest risk groups for COVID-19 and as the Pfizer/BioNTech vaccine is not a 'live' vaccine, it should be safe for blood cancer patients, including MDS patients. The consensus is that generally, for patients with blood cancer, the benefits of the vaccine far outweigh any potential side effects of the vaccine and the risks associated with having COVID-19 infection. Therefore, vaccination is recommended, except in people with a history of severe allergic reactions.
- b. This should include all MDS subtypes regardless of age:
  - i. All IPSS & IPSS-R risk groups
  - ii. MDS patients on observation or on active therapy with hypomethylating agent now or those who have received treatment in the past.
  - iii. MDS patients in clinical trial.
- c. Patients who have a low platelet count may bleed or bruise at the injection site. To reduce this risk, it is recommended that the platelet count should be  $30 \times 10^9/l$  or above and that prolonged pressure at the injection site should be applied for 5 minutes. Those receiving regular platelet transfusions should have their vaccine

after a platelet transfusion. If the platelet count is less than  $30 \times 10^9/l$  and the patient is not receiving regular platelet transfusions, they should receive platelet transfusion prior to vaccination.

- d. Patients receiving PRBC transfusion can safely receive the Covid-19 vaccine.

#### 12.2.11. Myeloproliferative Neoplasm (MPN) Essential Thrombocythemia, Polycythemia

Vera OR Myelofibrosis:

- a. Having an MPN and any MPN treatment (ruxolitinib, pegasys, etc) is not a contraindication to receiving the vaccine. If the patient is taking an anticoagulant, e.g., warfarin, rivaroxaban, apixaban etc. should follow the same recommendation as mentioned in the “anticoagulation section.

#### 12.2.12. Chronic Myelocytic Leukemia (CML)

- a. Patients receiving TKIs such as imatinib, dasatinib, nivolumab, ponatinib, bosutinib (with or without remission) should be vaccinated.

#### 12.2.13. Aplastic Anaemia (AA):

- a. There are case reports of AA developing post-vaccination with other vaccines, and of recovered AA patients relapsing following vaccine administration. The evidence is limited and based also on an appreciation that a viral insult is likely to be an important trigger in the pathogenesis of AA.
- b. In the setting of the COVID-19 pandemic, current American Society of Haematology COVID-19 and AA guidance is that the risk versus benefit would favour vaccine administration, particularly in those with additional risks for severe



COVID-19 disease (age, obesity, other comorbidities associated with increased risk).

- c. No data on efficacy in immunosuppressed patients has been made available to date for any of the SARS-CoV-2 vaccines in development. Those patients within 6 months of anti-thymocyte globulin/cyclosporin (ATG/CSA) initiation are unlikely to mount an appropriate immune response to a vaccine. Those patients with AA remaining on CSA for more than 6-12 months post-ATG treatment may respond to a vaccine. Post-transplantation patients with AA should follow standard post-transplantation guidelines for vaccine administration.
- d. These patients are considered among the high-risk group and should receive COVID-19 vaccine (3 doses).

#### 12.2.14. Therapy Specific Recommendations:

- a. Steroids: Patients treated with corticosteroids may have diminished responses to vaccination. Corticosteroids are detrimental to patients with mild Covid-19 yet appear beneficial to patients with severe Covid-19. It is recommended that patients treated with corticosteroids are vaccinated prior to therapy if possible. These patients are also eligible for a third vaccine dose.
- b. IVIG: Covid-19 vaccines may be administered to patients receiving plasma therapy not specific to Covid-19 (e.g.: IVIG), as these are unlikely to substantially impair development of protective antibody responses.

- c. Rituximab: Patients treated with rituximab clearly have diminished humoral responses to vaccination. Patients treated with rituximab and naturally infected with SARS-CoV2 appeared to be one of the highest risk groups for Covid-19 morbidity and mortality. It is recommended that patients are vaccinated prior to initiation of therapy (e.g: both doses completed  $\geq 2$  weeks prior to initiation of B-cell directed therapy.). If it is not feasible to delay rituximab based therapy, they should receive vaccination during times of high community transmission given that vaccination can generate T-cell memory responses even in the absence of humoral immunity.

12.2.15. Patients with solid tumors (breast cancer, lung cancer, GI cancer, genitourinary cancer, gynaecological cancer etc.) receiving chemotherapy, checkpoint inhibitors (pembrolizumab, nivolumab, ipilimumab) etc :

- a. Patients with solid tumor cancers should be offered the vaccine if the component of the vaccine are not contraindicated. The rationale for Covid-19 vaccine in patients with solid tumor malignancies is to reduce the risk of Covid-19 morbidity and mortality. Covid-19 vaccination will also enable ongoing receipt of disease-specific therapy and avoid delays in cancer care.
- b. Patients with active cancer have a high risk of morbidity and mortality from Covid-19.

- c. Data from other vaccine preventable illnesses such as influenza, pneumococcal disease and herpes zoster suggest a protective effect of vaccination in cancer patients.
- d. Antibody responses to vaccines are generally lower in patients received cytotoxic chemotherapy compared with healthy individuals or cancer patients who are not actively receiving treatment.
- e. Patients with solid tumor malignancies should receive the COVID-19 vaccine.

#### 12.2.16. Additional considerations related to mRNA vaccination in patients with solid tumors:

- a. There is no contraindication to receipt of Covid-19 vaccine across the broad range of therapies that patients with solid tumors may receive, inclusive of:
  - i. Cytotoxic chemotherapy.
  - ii. Radiation therapy.
  - iii. Hormonal therapy.
  - iv. Targeted therapy.
  - v. Immunotherapy.
  - vi. Corticosteroids.
- i. Surgical management.
- b. If feasible for patient planned for but not yet on immunosuppressive cancer directive therapy, time first dose of vaccine to be given  $\geq 2$  weeks prior to initiation of therapy.

- c. For patients already on cytotoxic chemotherapy, time first dose of vaccine in between chemotherapy cycles and away from nadir period.
- d. For patients completing cytotoxic therapy, time first dose of vaccine to be given after therapy complete and nadir period resolved, i.e. avoid vaccination during neutropenia period.

### **12.3. Renal conditions:**

#### **12.3.1. Eligibility for mRNA vaccination**

- a. Chronic kidney disease, including patients with chronic glomerular disease, end-stage renal disease on haemodialysis or peritoneal dialysis.
- b. Chronic, mild and stable electrolyte and acid-base imbalances.
- c. Stable renal transplant patients.
- d. Congenital anomalies of the kidneys and urinary tract.
- e. Asymptomatic nephrolithiasis.
- f. Immunosuppressed patients (on immunosuppressive treatment for renal transplant, glomerular diseases, interstitial nephritis, or immunocompromised conditions such as chronic kidney disease).

#### **12.3.2. Caution**

- 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 haemodialysis with tendency to easy bleeding/bruising would need to check with their nephrologist regarding the timing of the vaccine with regards to the haemodialysis session.

#### **12.4. Endocrine disorders:**

- 12.4.1. There are no absolute contraindications for any endocrine conditions.
- 12.4.2. Poor glycaemic control itself puts the patient at high risk and patients should be vaccinated regardless of his/her blood glucose levels they should be directed to seek advice from their physician to improve their diabetes control.
- 12.4.3. There is no contraindication or cut-off for blood glucose level to vaccinate but the patient should be advised to seek urgent appointment with his/her physician to improve glycaemia as vaccination might further elevate blood glucose levels.
- 12.4.4. People with the following endocrine conditions can be vaccinated:
  - a. Obesity BMI>35.
  - b. Type 1 diabetes above 16 years.

- c. Type 2 diabetes.
- d. Hypoadrenalism/patients on long term steroids.
- e. Pituitary disease on hormone replacement.
- f. Diabetes insipidus with pituitary disease.
- g. Hyperthyroidism on anti-thyroid drugs.
- h. Other types of Diabetes-MODY.
- i. Cushing's disease.
- j. Pituitary adenoma/previous pituitary surgery on hormone replacement.

#### **12.5. Allergic conditions:**

- 12.5.1. Known allergy to one of the inactive ingredients of the mRNA vaccine – polyethylene glycol (PEG) or polysorbate– is a contraindication to getting the vaccine. Refer to **(Appendix 1)**.
- 12.5.2. Allergy to food, drugs, pets, insect bites etc. is not a contraindication to mRNA vaccine.
- 12.5.3. Patients with previous immediate allergic reaction to any other vaccine or those with severe allergies should be observed for at least 30 minutes following vaccine administration, rather than the usual 15 minutes.
- 12.5.4. Persons with a severe allergic reaction or an immediate allergic reaction of any severity to the first dose should not receive the second dose.

#### **12.6. Rheumatological and musculoskeletal disease (RMDs) conditions**

12.6.1. mRNA vaccines can be given safely in patients with RMDs and in patients treated with drugs that influence the immune system, with the following precautions:

- a. Avoid vaccination during active disease phase.
- b. Vaccinate before planned immunosuppression, if possible.
- c. The vaccine can be given to patients with autoimmune diseases provided they do not have any contraindications to vaccines.

## **12.7. Psychiatry disorders:**

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

## **12.8. Epilepsy:**

12.8.1. Persons with epilepsy can be given the vaccine. There is no evidence for its contraindication, either related to the disease or medications.

## REFERENCES

1. American College of Obstetrics & Gynaecology (2021). Recommendation for mRNA COVID-19 vaccine for pregnant women.
2. American College of Rheumatology (2021). COVID-19 Vaccine Clinical Guidance Summary for Patients with Rheumatic and Musculoskeletal Diseases.
3. American Society of Transplantation (2020). Covid-19 Vaccine FAQ sheet.
4. American Society of Transplantation (2021). Statement about Vaccine Efficacy in Organ Transplant Recipients. Available online at: [ast ishlt guidance vaccine 08132021FINAL DRAFT2.pdf \(myast.org\)](#)
5. American Medical Association (2021). Antibody Response After a Third Dose of the mRNA-1273 SARS-CoV-2 Vaccine in Kidney Transplant Recipients With Minimal Serologic Response to 2 Doses. Available online at:



[Antibody Response After a Third Dose of the mRNA-1273 SARS-CoV-2 Vaccine in Kidney Transplant Recipients With Minimal Serologic Response to 2 Doses | Nephrology | JAMA | JAMA Network](#)

6. British Society of Haematology (2020). COVID-19 Vaccine in patients with haematological disorders British Society for Haematology. Available online at: [haematology-covid-19-v10-vaccination-statement-231220.pdf \(b-s-h.org.uk\)](#)
7. British Medical Journal (2021). Covid-19, Schedule breast screening before vaccine or 4 to 6 weeks after to avoid false positives, says guidance. Available online at: [Covid-19: Schedule breast screening before vaccine or 4 to 6 weeks after to avoid false positives, says guidance | The BMJ](#)
8. British Medical Journal (2021). Risk prediction of covid-19 related death and hospital admission in adults after covid-19 vaccination, national prospective cohort study. Available online at: [Risk prediction of covid-19 related death and hospital admission in adults after covid-19 vaccination: national prospective cohort study | The BMJ](#)
9. British Lymphology Society (2021). Consensus document on COVID-19 vaccination for patients with lymphoedema. Available online at: [BLS vaccination.pdf \(lk-lymphoedema.com\)](#)
10. Centers for Disease Control and Prevention (2023). Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States. Available online at: [https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html](#)

11. Centers for Disease Control and Prevention (2023). COVID-19 ACIP Vaccine Recommendations. Advisor Committee on Immunization Practices (ACIP). Available online at: <https://www.cdc.gov/vaccines/acip/index.html>
12. Centers for Disease Control and Prevention (2021). Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19, Information for Healthcare Providers. Available online at: [Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Providers \(cdc.gov\)](#)
13. Centers for Disease Control and Prevention (2021). Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots. Available online at: [Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots | CDC Online Newsroom | CDC](#)
14. Centers for Disease Control and Prevention (2021). COVID-19 Vaccines for Moderately to Severely Immunocompromised People. Available online at: [COVID-19 Vaccines for Moderately to Severely Immunocompromised People | CDC](#)
15. Centers for Disease Control and Prevention (2021). Pfizer-BioNTech COVID-19 Vaccine Overview and Safety. Available online at: [Pfizer-BioNTech COVID-19 Vaccine Overview and Safety | CDC](#)
16. Centers for Disease Control and Prevention (2021). COVID-19 Vaccine Inventory Management Best Practices. Available online at: <https://www.cdc.gov/vaccines/covid-19/vaccine-inventory-management.html>

17. Centers for Disease Control and Prevention (2021). Pfizer-BioNTech COVID-19 Vaccine

Storage and Handling Summary. Available online at:

<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf>

18. Centers for Disease Control and Prevention (2021). Interim Clinical Considerations for

Use of COVID-19 Vaccines. Available online at:

<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

19. Centers for Disease Control and Prevention (2021). Vaccine Information Statements

(VISs). Available online at:

<https://www.cdc.gov/vaccines/hcp/vis/index.html>

20. Centers for Disease Control and Prevention (2021). Fact Sheet For Healthcare Providers

Administering Vaccine (Vaccination Providers).

21. Centers for Disease Control and Prevention (2020). COVID-19 Vaccination Program

Interim Playbook for Jurisdiction Operations. Available online at:

[https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim\\_Playbook.pdf](https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf)

22. Centers for Disease Control and Prevention (2020). Checklist of Best Practices for

Vaccination Clinics Held at Satellite, Temporary or off site locations. Available online at:

<https://www.izsumitpartners.org/content/uploads/2019/02/off-site-vaccination-clinic-checklist.pdf>

23. Department of Health and Social Care UK (2021). Joint Committee on Vaccination and Immunization, advice on priority groups for COVID-19 vaccination. Available online at: [Joint Committee on Vaccination and Immunisation: advice on priority groups for COVID-19 vaccination, 30 December 2020 - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/news/joint-committee-on-vaccination-and-immunisation-advice-on-priority-groups-for-covid-19-vaccination)
24. Diabetes UK community (2021). Coronavirus vaccines and diabetes. Available online at: [Coronavirus vaccines and diabetes | Latest updates | Diabetes UK](https://www.diabetes.org.uk/conditions/coronavirus-vaccines-and-diabetes)
25. European Thyroid Association (2021). Vaccination and Thyroid Disease. Available online at: [ETA-PHB-Vaccination.pdf \(eurothyroid.com\)](https://eurothyroid.com/ETA-PHB-Vaccination.pdf)
26. European Society of Endocrinology (2021). COVID-19 and endocrine disease. Available online at: [COVID-19 and endocrine disease | ESE \(ese-hormones.org\)](https://ese-hormones.org/covid-19-and-endocrine-disease)
27. FDA (2023). EMERGENCY USE AUTHORIZATION (EUA) for PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5). Available online at: <https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/pfizer-biontech-covid-19-vaccines#:~:text=On%20April%2018%2C%202023%2C%20the,4%2FBA.>
28. FDA (2021). Comirnaty and Pfizer-BioNTech COVID-19 Vaccine. Available online at: [Comirnaty and Pfizer-BioNTech COVID-19 Vaccine | FDA](https://www.fda.gov/emergency-preparedness-response-recovery/medical-products/ucm496041.htm)
29. FDA (2021). Coronavirus (COVID-19) Update: FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals. Available online at:

[Coronavirus \(COVID-19\) Update: FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals | FDA](#)

30. FDA (2020). Vaccines and Related Biological Products Advisory. Briefing Document Pfizer-BioNTech COVID-19 Vaccine. Available online at:

<https://www.fda.gov/media/144245/download>

31. Government of Canada (2021). Recommendations on the Duration of the Post-vaccination Observation Period for Influenza Vaccination during the COVID-19 Pandemic. Available online at:

<https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-duration-observation-period-post-influenza-vaccination-during-covid-19-pandemic.html>

32. Journal of The American Society Of Nephrology (2021). Antibody and T Cell Response to SARS-CoV-2 Messenger RNA BNT162b2 Vaccine in Kidney. Available online at:

<https://jasn.asnjournals.org/content/32/9/2147>

33. NHS. (2021). Using COVID-19 vaccines in patients taking immunosuppressive medicines. Available online at:

[Using COVID-19 vaccines in patients taking immunosuppressive medicines – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#)

34. National Kidney Foundation (2020). Statement on Kidney Patient Prioritization for COVID-19 Vaccines and Therapeutics. Available online at:

[Statement on Kidney Patient Prioritization for COVID-19 Vaccines and Therapeutics | National Kidney Foundation](#)

35. National Center for Biotechnology Information (2021). Safety and Immunogenicity of a Third Dose of SARS-CoV-2 Vaccine in Solid Organ Transplant Recipients. Available online at: [Safety and Immunogenicity of a Third Dose of SARS-CoV-2 Vaccine in Solid Organ Transplant Recipients: A Case Series \(nih.gov\)](#)
36. Pfizer Inc. (2021). Coronavirus Disease (COVID-19) Resources. Available online at: [Coronavirus disease \(COVID-19\) Facts, News & Information | Pfizer](#)
37. Public Health England (2021). COVID-19 vaccination programme Information for healthcare practitioners. Available online at: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1009174/COVID19\\_vaccination\\_programme\\_guidance\\_for\\_healthcare\\_workers\\_6\\_August\\_2021\\_v3.10.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1009174/COVID19_vaccination_programme_guidance_for_healthcare_workers_6_August_2021_v3.10.pdf)
38. The New England Journal of Medicine (2021). Randomized Trial of a Third Dose of mRNA-1273 Vaccine in Transplant Recipients. Available at: [https://www.nejm.org/doi/full/10.1056/NEJMc2111462?query=recirc\\_curatedRelated\\_article](https://www.nejm.org/doi/full/10.1056/NEJMc2111462?query=recirc_curatedRelated_article)
39. The Green Book, chapter 14a (2022), COVID-19 - SARS-CoV-2. Available at: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1057798/Greenbook-chapter-14a-28Feb22.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1057798/Greenbook-chapter-14a-28Feb22.pdf)
40. WHO (2021). Scientific Brief: Multisystem Inflammatory System in Children and Adolescence with COVID-19.

## APPENDICIES

### APPENDIX 1 - 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	
ALEMTUZUAb	X		
Alteplase	X		
Atezolizumab		X	
Avelumab		X	
Bamlanivimab	X		
BEVACIZUAb		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



## **APPENDIX 2- list of drugs that may be taken by immunocompromised patients**

- High dose corticosteroids (i.e.  $\geq 20$  mg prednisone, or equivalent, per day)
  - Prednisone  $\geq 20$  mg
  - Methylprednisolone  $\geq 15$  mg; 500mg inj, 40mg/ml inj, 2ml
  - Dexamethasone  $\geq 40$  mg
- Alkylating agents, antimetabolites
  - Bendamustine hydrochloride 90mg/ml injection
  - Cyclophosphamide 50mg tablet
  - Cyclophosphamide 500mg injection
  - Melphalan 2mg, 5mg tablet
  - Dacarbazine 200mg injection
  - Cisplatin 50mg injection
  - Carboplatin 150mg injection
  - Oxaliplatin injection
- Antimetabolites
  - Capecitabine 150mg, 500mg tab
  - Cytarabine 500mg IV/SC, 1g IV, 100mg Inj
  - Fludarabine 50mg inj IV
  - 5-Fluorouracil 50mg/ml inj, 5ml
  - Gemcitabine 200mg, 1G inj
  - Hydroxyurea 500mg cap
  - 6-Mercaptopurine 50mg tab
  - Thioguanine 40mg tab
  - Ifosfamide 1 G inj IV
  - Cladribine 1mg/ml inj, 10ml vial
- Transplant-related immunosuppressive drugs
  - Azathioprine 25, 50mg tab
  - Lenalidomide 10mg, 15mg, 25mg cap
  - Methotrexate 2.5mg tab, 5mg/2ml inj, 50mg/2ml inj, 500 mg inj, 25/ml PF inj.
  - Tacrolimus 0.5mg cap, 1mg cap

- Sirolimus 1mg tab
- Cyclosporine 25, 50, 100mg cap, 100mg/ml soln. 50ml
- Cancer chemotherapeutic agents classified as severely immunosuppressive (included in other categories; alkylating agents, metabolites)
- TNF blockers
  - Adalimumab 40mg inj
  - Certolizumab 200mg inj.
  - Etanercept 25mg inj, 50mg/ml inj.
  - Golimumab 100mg inj.
  - Infliximab 5mg/ml, 20ml inj.
- Other biologic agents that are immunosuppressive or immunomodulatory (this includes Rituximab and other related agents)
  - Rituximab 10mg/ml inj, 10ml, 50ml
  - Abatacept 250mg/15ml inj.
  - Ixekizumab 80mg inj.
  - Omalizumab 150mg inj.
  - Vedolizumab 300mg inj.
  - Natalizumab 300mg inj.
  - Belimumab
  - Ofatumumab 20mg inj.
  - Secukinumab 150mg inj.
  - Pertuzumab 30mg/ml inj.
  - Eculizumab 10mg/ml inj
  - Ustekinumab 90mg inj.
  - Ado Trastuzumab 100mg, 160mg inj.
  - Nivolumab 40mg, 100mg inj.
  - Tocilizumab 200mg/10ml inj.
  - Panitumumab 20mg/ml inj.
- Other immunosuppressant
  - Tofacitinib 5mg tab

- Mycophenolate mofetil 250mg 500mg tab, 200mg/ml inj.
- Everolimus 0.5, 0.75, 10mg tab
- Baricitinib 4mg tab
- Fingolimod 0.5mg cap
- Dimethyl fumarate 120mg, 240mg cap
- Leflunomide 20mg, 100mg tab
- Other meds used in Oncology
  - Bevacizumab 100mg Inj
  - Bevacizumab 400mg Inj
  - Daunorubicin HCl 20mg Inj.
  - Docetaxel 40mg/ml Inj. IV-0.5ml
  - Docetaxel 40mg/ml Inj. IV-2ml infusion
  - Doxorubicin HCl 50mg Inj.
  - Epirubicin HCl 50mg Inj.
  - Etoposide 100mg IV Inj.
  - Filgrastim 300mcg/ml Inj. 1ml vial (30 million units Inj.)
  - Folinic acid (Calcium leucovorine) 15 mg Tab
  - Folinic acid (Calcium leucovorine) 50 mg Inj. 5ml
  - Idarubicin HCl 10mg Inj. IV
  - Irinotecan HCl 20mg/ml concentrate for IV infusion 5ml
  - Letrozole 2.5mg Tab
  - Levamisole HCl 50mg Tab
  - Megestrol acetate 40mg Tab
  - Mitomycin C 10mg Inj.
  - Mustine HCl 10mg inj
  - Oncotice 120mg Inj.
  - Paclitaxel 300mg Inj.(vial)
  - Sodium clodronate 400mg Cap.
  - Tamoxifen citrate 10mg Tab
  - Thioguanine 40mg Tab
  - Triptorelin 3.75mg Inj.

- Vinblastine sulphate 10mg Inj.
- Vincristine sulphate 1mg Inj.
- Vinorelbine 10mg/ml Inj.-5ml

### **APPENDIX 3- Instruction for use of PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT**

Instruction for use of PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5)							
<p><b>FOR 12 YEARS OF AGE AND OLDER</b>  <b>Should not be used in individuals 6 months through 11 years of age.</b>  <b>MUST NOT BE DILUTED PRIOR TO USE.</b>  <b>Single dose and multiple dose vials with gray caps and labels with gray borders.</b>  During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.  Do not refreeze thawed vials.  Thawed vials stored at 2°C to 8°C (35°F to 46°F) for up to 10 weeks  Each dose is 0.3 mL  Multiple dose vials contain 6 doses</p>							
Customer at age 12 years and older wants to take COVID-19 vaccine							
	Original status	Primary vaccination		Recommendation and duration			
1	unvaccinated customer age 12 to 64 Yrs.	No vaccination		Can take	One dose of Pfizer-Biontic, Bivalent (available in UAE and at DHA)	No need to take second dose or Booster dose	
2	unvaccinated customer age 65 and older	No vaccination		Can take	Pfizer-Biontic, Bivalent (available in UAE and at DHA)	After 4 months (120day)	Can take Booster Dose 2 of Pfizer-Biontic, Bivalent
3	customer at age 12 to 64 Yrs. took any type of authorized or approved Monovalent COVID-19 vaccine	Sinopharm, Pfizer, AstraZeneca, Covisheild, Sputnik, Sinovac, Moderna	Any number of doses (1 or more)		After 2 months (60 days)	Can take	One dose Pfizer-Biontic, Bivalent (available in UAE and at DHA)
4	customer at age 65 Yrs and older took any type of authorized or approved Monovalent COVID-19 vaccine	Sinopharm, Pfizer, AstraZeneca, Covisheild, Sputnik, Sinovac, Moderna	Any number of doses (1 or more)	Can take	Dose 1 of Pfizer-Biontic, Bivalent (available in UAE and at DHA)	After 4 months (120 days)	Booster Dose 2 of Pfizer-Biontic, Bivalent

#### APPENDIX 4- List of illnesses and conditions

- List of chronic illnesses and conditions for which a booster dose is recommended (the list may be adjusted as further evidence becomes available):
  - Diabetes mellitus

- Cardiovascular disease, including congenital heart diseases
- Hypertension
- Stroke
- Heart failure
- Coronary heart disease
- Atrial fibrillation
- Thromboembolism
- Peripheral vascular disease
- Obesity – adults with BMI  $>25\text{kg/m}^2$  or if 12-17 years of age, BMI  $\geq 85$ th percentile
- Chronic lung diseases e.g. COPD, moderate to severe asthma, interstitial lung disease, cystic fibrosis, pulmonary hypertension
- Sickle cell disease
- Down's syndrome
- Transplanted patients
- HIV/AIDS
- Liver cirrhosis
- Neurological conditions
- Parkinson's disease
- Chronic kidney disease
- Autoimmune disorders