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

Version 7.0

Issue date: 26 October 2021

Effective date: 26 October 2021

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.
- 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 on Eligibility For mRNA COVID-19 (BNT162b2) Vaccine 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 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

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EXECUTIVE SUMMARY

This document 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. DHA will update these Guidelines as new information becomes available.

Updates in Version 7.0:

- Booster Dose Recommendations. Page (14-18).

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).

AA	:	Aplastic Anemia
ACIP	:	Advisory Committee on Immunization Practices
ACOG	:	American College of Obstetrics & Gynaecology
ATG/CSA	:	Anti-thymocyte globulin/cyclosporin
ADRs	:	Adverse Drug Reactions
AFI	:	Acute febrile illness
ASH	:	American Society of Hematology
ASTCT	:	American Society of Transplantation and Cellular Therapy

cGVHD	:	Chronic Graft Versus Host Disease
CLL	:	Chronic Lymphocytic Leukemia
CML	:	Chronic Myelocytic Leukemia
COVID	:	Corona Virus Disease
COPD	:	Chronic obstructive pulmonary disease
DHA	:	Dubai Health Authority
DM	:	Diabetes Mellitus
HPSD	:	Health Policies and Standards Department
HRS	:	Health Regulation Sector
MM	:	Multiple Myeloma
MPN	:	Myeloproliferative Neoplasm
PEG	:	Polyethylene Glycol
RMDs	:	Rheumatological and musculoskeletal disease
WHO	:	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 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).
- The current available WHO approved COVID-19 vaccines:
  - Pfizer-BNT (Comirnaty) (mRNA).
  - Moderna (mRNA).
  - Oxford AstraZeneca (non-replicating viral vector).
  - Serum institute of India (Covishield) (non-replicating viral vector).
  - Johnson and Johnson (viral vector).

- Sinopharm (inactivated whole virus).
- Sinovac (inactivated whole virus).

The Sputnik vaccine (non-replicating viral vector) is currently still being evaluated by the WHO and is widely used in many countries. Different countries are using other vaccines, some of which are pending approval from WHO, ECDC and the FDA, and are not listed here.

2. SCOPE

2.1. Providing advice to patients on mRNA COVID-19 vaccine.

3. PURPOSE

3.1. To ensure public and patient health protection.

3.2. To support healthcare professionals in providing advice to patients on mRNA COVID-19 vaccine.

4. APPLICABILITY

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

5. **RECOMMENDATION ONE:** PATIENT ELIGIBILITY AND EXCLUSIONS

5.1. Inclusion Criteria:

5.1.1. Adults and adolescents ≥ 12 years.

5.1.2. People with chronic illnesses: asthma, COPD, heart failure, chronic renal diseases, chronic liver diseases, DM, hypertension, ischemic heart disease.

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

5.1.4. 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.

5.1.5. 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.

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

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

5.1.8. Other people eligible to or willing to take the vaccine if there is no absolute contraindication. Please see note below regarding vaccination in pregnancy and lactation.

5.1.9. 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.

5.1.10. 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 with active COVID-19 Infection.

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

5.2.3. Previous immediate allergic reaction of any severity to a component of the vaccine [polyethylene glycol (PEG) or polysorbate] refer to **Appendix 1.**

6. **RECOMMENDATION TWO**: ADDITIONAL DOSE RECOMMENDATIONS

6.1. Immunocompromised Individuals:

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

6.1.2. 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 (≥12 years).

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

6.1.3. 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).

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

6.2.1. Active treatment for solid tumor and hematologic malignancies.

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

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

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

6.2.5. Advanced or untreated HIV infection.

6.2.6. Active treatment with:

a. High dose corticosteroids (i.e. ≥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**.

6.2.7. 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.

7. **RECOMMENDATION THREE:** BOOSTER DOSE RECOMMENDATIONS

7.1. A booster dose of Pfizer should be given at least six months after the second dose of the primary series of an mRNA vaccine – either Pfizer or Moderna).

7.2. The booster dose program will be implemented in phases. Currently, the under-mentioned groups are eligible:

7.2.1. Individuals ⩾60 years of age.

7.2.2. Individuals ⩾50 years of age with chronic illnesses making them prone to contracting Covid-19 and with an increased risk of hospital admission and mortality. Refer to **Appendix 3** for a list of illnesses and conditions.

7.2.3. Individuals ⩾18 years of age in long-term care facilities or being cared for at home.

7.3. Heterologous COVID-19 Vaccine Boosters:

7.3.1. Since the start of the COVID-19 pandemic, countries have dedicated huge resources in the development of vaccines to end the disease. Different vaccines have been developed, each with different levels of immunity as per current data but all have proven to provide protection against severe disease, hospitalization and deaths, to varying degrees. With the new virus variants putting the gained immunity at risk and the reported waning of immunity over time, WHO, FDA and CDC have recommended boosters to be administered to further enhance the immunity.

7.3.2. However, for the moment, the definition of being fully vaccinated remains the same i.e. two weeks after a recommended primary vaccine series.

7.3.3. With the new emerging data on vaccines and vaccination recommendations across the globe, individuals are choosing to get heterologous boosters.

7.3.4. Currently, there are no published data from large scale randomized controlled trials on the efficacy, immunogenicity or safety of mixing COVID-19 vaccines in different populations.

7.3.5. Individuals receiving extra doses of vaccines should be informed about potential vaccine related adverse events.

7.3.6. The categories of individuals eligible for heterologous booster doses are similar to those above (under 'Booster dose recommendations').

7.3.7. Mixing vaccines include, though not limited to, the following factors:

a. Immune status of vaccine recipient as per recommendation from treating physician.

b. Risk of acquiring COVID-19 Infection.

c. Risk of potential progression to severe disease.

d. Work permit/restrictions, including applicants for medical fitness in Dubai.

e. Travel to countries mandating mRNA vaccine for entry.

f. Severe/serious vaccine adverse event after initial vaccine series (1st or 2nd dose of any vaccine) with recommendation from managing physician to switch vaccine.

7.3.8. Individuals who received only 1 dose of a WHO-approved non-mRNA vaccine:

a. It is recommended to start a new series of mRNA vaccine, at least 21 days after first dose.

b. Pfizer-BNT, 2 doses, 21 days apart.

c. Individuals who received 1 dose of SPUNIK V: give 1 dose of Pfizer-BNT at least 6 months later.

7.3.9. Individuals who received two doses of WHO-approved non-mRNA vaccine, excluding inactivated vaccines:

a. It is recommended to give one booster dose of Pfizer-BNT vaccine at least 6 months after the second dose of the primary vaccine.

b. Individuals who received two doses of SPUTNIK vaccine: give 1 dose of Pfizer-BNT at least 6 months after second dose.

c. Individuals who received 2 doses of AZ vaccine: give 1 dose of Pfizer-BNT at least 6 months after second dose.

d. Individuals who received 1 dose of AZ vaccine and 1 dose of Pfizer-BNT: give 1 dose of Pfizer-BNT at least 6 months after the second dose.

e. Individuals who received 1 dose of J&J vaccine: give 1 dose of Pfizer-BNT at least 2 months later as per J&J data submitted to FDA.

7.3.10. Individuals who received 2 doses of WHO-approved inactivated vaccines (Sinopharm or Sinovac):

a. It is recommended to give 2 doses of Pfizer-BNT, the first dose being at least 3 months after second dose of Sinopharm or Sinovac.

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 ≥ 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. 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 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. 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.

8.7.6. 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.

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

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.

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 hemophilia 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 hemostatic treatment. If there is any uncertainty, advice should be sought from the patient's hematologist/hemophilia 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 hemophilia.

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 hematological 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/romiplastim) can receive vaccination if platelet is ≥ 30, 000 per microliter of blood.

12.2.4. Hemoglobinopathies and Rare Inherited Anemias:

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 anemias who have severe iron overload. Patient with G6PD deficiency can receive Covid-19 vaccine.

b. Patients aged ≥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 anemia patients who have had their spleen removed.

12.2.5. Acute Leukemias (AML, APL and ALL):

a. Patients with acute leukemias should not delay their treatment for vaccination.

b. As a general statement, the American Society of Hematology (ASH) supports giving people with acute leukemia 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 Hematology (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 ≤ 0.5mg/kg prednisolone (or equivalent).

v. For patients with moderate/severe cGVHD or on more intensive immunosuppressive therapy (high dose steroids >0.5mg/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 x 109/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 x 109/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 Anemia (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 Hematology COVID-19 and AA guidance is that the risk versus benefit would favor 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 (eg: 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 ≥ 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, gynecological 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.

vii. 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 ≥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 hemodialysis 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 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.

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.

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APPENDICIES

1. **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	
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

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

- High dose corticosteroids (i.e. ≥20 mg prednisone, or equivalent, per day)
    - Prednisone ≥20 mg
    - Methylprednisolone≥15 mg; 500mg inj, 40mg/ml inj, 2ml
    - Dexamethasone ≥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 50mj inj IV
    - 5-Fluorouracil50mg/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
    - Sirolumus 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

- Ustekimumab 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
  - Leflunomide20mg, 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

3. **APPENDIX 3-** 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 >25kg/m2 or if 12-17 years of age, BMI ⩾85th 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