مجلس الصحة
لدول مجلس التعاون
Gulf Health Council

الدليل الخليجي لاستخدامات لقاحات كوفيد-19

GCC Guideline for COVID-19 Vaccines Uses

(version 1.1) June 2021

A. general information about available vaccines in GCC country

	Category						
Name of the vaccine	Pfizer-BioNTech	Astra-Zeneca	Sinovac	Sinopharm	Sputnik-V	Moderna	Janssen/J&J vaccine
Type of the vaccine	• Messenger RNA (mRNA) Vaccine BNT162b2	• Recombinant adenoviral vector-based vaccine	• Adjuvanted, inactivated vaccine	• Inactivated vaccine	• Recombinant human adenoviral vector-based vaccine	• Messenger RNA (mRNA) Vaccine (mRNA1273)	• A replication-incompetent recombinant adenovirus type 26 (Ad26) vector
Indication Immunocompromised Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response.	Age • 12 years and above. Immunocompromised • Yes Recent data showed reduced efficiency in renal transplant receipts	Age • 18 years and above. Immunocompromised • Yes Efficacy, safety and immunogenicity have not been assessed.	Age • 18 years and above. Immunocompromised • Yes Efficacy, safety and immunogenicity have not been assessed.	Age • 18 years and above. Immunocompromised • Yes Efficacy, safety and immunogenicity have not been assessed.	Age • 18 years and above. Immunocompromised • Yes. Short term Immunosuppressive medications: Vaccinate 28 days after medication ends Chronic immunosuppressive therapy: Post transplantation – 3 months after transplant Post chemotherapy-28 days after chemotherapy	Age • 18 years and above. Immunocompromised • Yes	Age • 18 years and above. Immunocompromised • Yes, Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response.

	Category						
Name of the vaccine	Pfizer-BioNTech	Astra-Zeneca	Sinovac	Sinopharm	Sputnik-V	Moderna	Janssen/J&J vaccine
					Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response.		
<u>Pregnancy</u> Pregnant women are at an increased risk for severe illness from COVID-19 when compared to non- pregnant women and might be at increased risk of preterm and other poor outcomes related to pregnancy.	<u>Pregnancy</u> Yes <u>Lactation</u> Yes	<u>Pregnancy</u> No. limited data <u>Lactation</u> Yes	<u>Pregnancy</u> Yes. <u>Lactation</u> Yes	<u>Pregnancy</u> Yes <u>Lactation</u> Yes	<u>Pregnancy</u> No. No data <u>Lactation</u> No	<u>Pregnancy</u> Yes <u>Lactation</u> Yes	<u>Pregnancy</u> • No <u>Lactation</u> No. Data unavailable on effects on the breastfed infant or on milk production / excretion.
	<u>Children</u> Yes. 12-18 years age	<u>Children</u> • No	<u>Children</u> • No	<u>Children</u> • No	<u>Children</u> • Contraindicated	<u>Children</u> • No	<u>Children</u> • No

	Category						
Name of the vaccine	Pfizer-BioNTech	Astra-Zeneca	Sinovac	Sinopharm	Sputnik-V	Moderna	Janssen/J&J vaccine
Contraindication	• Anaphylaxis to any component of the vaccine • Hypersensitivity • Acute severe febrile illness- should be postponed in individuals suffering from acute severe febrile illness. **In events of anaphylaxis:** A second dose should not be given to those who have experienced anaphylaxis to the first dose.	• Anaphylaxis to any component of the vaccine • Hypersensitivity • Acute severe febrile illness - should be postponed in individuals suffering from acute severe febrile illness.	• Anaphylaxis to any component of the vaccine • Hypersensitivity • Acute severe febrile illness- should be postponed in individuals suffering from acute severe febrile illness.	• Anaphylaxis to any component of the vaccine • Hypersensitivity • Acute severe febrile illness- should be postponed in individuals suffering from acute severe febrile illness.	• Hypersensitivity to any component of the vaccine, or a vaccine that has similar components • H/o severe allergic reactions • Acute infectious and non-infectious diseases, flares of chronic diseases; vaccine can be administered 2-4 weeks after recovery or remission • In non-severe acute respiratory viral illness or acute gastrointestinal infections, vaccination is administered after the body temperature normalizes • Pregnancy and breastfeeding	• Anaphylaxis to any component of the vaccine • Hypersensitivity • Acute severe febrile illness- should be postponed in individuals suffering from acute severe febrile illness.	• Anaphylaxis to any component of the vaccine • Hypersensitivity • Acute severe febrile illness: the vaccine should be postponed in individuals suffering from acute severe febrile illness.

	Category						
Name of the vaccine	Pfizer-BioNTech	Astra-Zeneca	Sinovac	Sinopharm	Sputnik-V	Moderna	Janssen/J&J vaccine
					• Individuals under 18 years of age as no data on the drug's safety and efficacy		
Efficacy Symptomatic COVID-19	95%	76% - 85% (aged 65 years and over)	51 % - 84 %	78.2 % (No data on aged 65 years and over)	91.6%	80%-90%	66%-72%
Critical disease/ Hospitalization	95%	100%	100 % against severe illness and 85 % -100 % against hospitalization	100%	100% against severe illness	94%	86%
Death	100%	No data	80 % against death	No data	No data	>99%	100%
Number of doses / intervals	• 2 doses / 3 weeks apart	• 2 doses / 8-12 weeks apart	• 2 doses, 2–4 weeks apart	• 2 doses / 3-4 weeks apart	• 2 doses, 3 weeks apart	• 2 doses / 1 month apart	• Single dose

	Category						
Name of the vaccine	Pfizer-BioNTech	Astra-Zeneca	Sinovac	Sinopharm	Sputnik-V	Moderna	Janssen/J&J vaccine
Storage/Handling	• Store in a freezer at -80°C to -60°C shelf life 6 months. Store in the thermal container at -90°C to -60°C. • Store in the original package to protect from light. • Once removed from the freezer, the undiluted vaccine can be stored for up to 1 month at 2°C to 8°C, and up to 2 hours at temperatures up to 25°C, prior to use. • During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. • Thawed vials can be handled in room light conditions.	• Temperature 2-8 °C	• Temperature 2-8 °C	• Temperature 2-8 °C	**Storage Conditions:** Store in a dark location at a temperature no higher than minus 18 °C. Re-freezing is prohibited! Keep out of the reach of children. **Transportation Conditions:** Transportation of the drug shall be at a temperature not exceeding minus 18°C. **Shelf life:** Component I - 6 months. Component II - 6 months. Do not use the drug with the expired shelf life.	• Store frozen between -25° to -15°C. Store in the original box to protect from light. After the first dose has been withdrawn, the vial should be held between 2° to 25°C. Discard vial after 6 hours. Do not refreeze. • Do not mix with a diluent. • Discard vial when there is not enough vaccine to obtain a complete dose. Do not combine residual vaccine from multiple vials to obtain dose.	• Store at 2°C to 8°C (36°F to 46°F) and protect from light. Do not store frozen. • Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours • After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours

	Category						
Name of the vaccine	Pfizer-BioNTech	Astra-Zeneca	Sinovac	Sinopharm	Sputnik-V	Moderna	Janssen/J&J vaccine
	• After dilution, store vaccine at 2°C to 25°C and use as soon as practically possible and within 6 hours. • Once diluted, the vials should be marked with the dilution time and discarded within 6 hours of dilution. • Once thawed, the vaccine cannot be re- frozen. • Multidose vial which must be diluted before use. • One vial (0.45ml) contains 5 doses of 30 micrograms of BNT162b2 RNA.						
Sides effect	• Injection site swelling, pain and redness. • Fatigue • headache • muscle pain, arthralgia • chills • nausea/vomiting	• Injection site swelling, pain and redness. • Fatigue • headache • muscle pain, arthralgia • chills • nausea/vomiting	• Injection site swelling, pain and redness. • Fatigue • headache • muscle pain, arthralgia • chills • nausea/vomiting	• Injection site swelling, pain and redness. • Fatigue • headache • muscle pain, arthralgia • chills • nausea/vomiting	• **Injection site:** hyperthermia, tenderness, edema and pruritus, asthenia, pain, malaise, pyrexia, increased site skin temperature, decreased appetite. Incidence rate –	• Injection site swelling, pain and redness. • Fatigue • headache • muscle pain, arthralgia • chills • nausea/vomiting	• Injection site swelling, pain and redness. • Fatigue • headache • muscle pain, arthralgia • chills • nausea/vomiting

	Category						
Name of the vaccine	Pfizer-BioNTech	Astra-Zeneca	Sinovac	Sinopharm	Sputnik-V	Moderna	Janssen/J&J vaccine
	• fever • Lymphadenopathy • Malaise • Myocarditis/Pericarditis • Thrombosis	• fever • Thrombosis • Vaccine Induced Immune Thrombotic Thrombocytopenia • Capillary leak syndrome	• fever	• fever	very common and common. • **Respiratory, chest, and mediastinal:** oropharyngeal pain, nasal congestion, sore throat, rhinorrhea. Incidence rate – common. • **Nervous system:** common – headache; rare – dizziness, syncope. • **Gastrointestinal:** nausea, vomit, dyspepsia – common. • **Laboratory changes:** divergent deviations of immunological status indicators Most AEs have abated completely, without any consequences.	• fever • COVID arm Severe allergic reaction. • Myocarditis /Pericarditis • Thrombosis	• fever • Severe allergic reactions have been reported • Thrombosis
Required Monitoring	• Close observation for at least 15 minutes is recommended following	• Close observation for at least 15 minutes is recommended following	• Close observation for at least 15 minutes is recommended following	• Close observation for at least 15 minutes is recommended following	• Close observation for at least 15 minutes is recommended following	Close observation for at least 15 minutes is recommended	• Close observation for at least 15 minutes is recommended following

	Category						
Name of the vaccine	Pfizer-BioNTech	Astra-Zeneca	Sinovac	Sinopharm	Sputnik-V	Moderna	Janssen/J&J vaccine
	vaccination and 30 minutes for history of allergy	vaccination and 30 minutes for history of allergy	vaccination and 30 minutes for history of allergy	vaccination and 30 minutes for history of allergy	vaccination and 30 minutes for history of allergy	following vaccination and 30 minutes for history of allergy	vaccination and 30 minutes for history of allergy
Vaccination Post COVID-19 infection	• After 90 days.	• After 90 days.	• After 90 days	• After 90 days	• After 90 days.	• After 90 days	• After 90 days
Recommendation after getting infected following first dose	• Can receive the 2nd dose after recovery (10 days after the result date or start of symptoms).	• At least 14 days after COVID-19 infection, can elect to go up to 6 months post infection	At least 14 days after COVID-19 infection	• At least 14 days after COVID-19 infection	At least 14 days after COVID-19 infection.	• After 90 days	• No Data

B. Priority groups of vaccination:

People at risk of severe outcome:

- Older than 55 years
- Adults aged 18 to 54 years at high risk due to underlying health condition-
    - Diabetes mellitus
    - Cardiovascular diseases including hypertension
    - Respiratory diseases including bronchitis, emphysema or severe asthma
    - Renal diseases and dialysis

- Liver diseases
- Hematological malignancies
- Immunosuppressed or on immunosuppressive medications including HIV, long term steroids use, chemotherapy, radiotherapy, rheumatoid arthritis, systemic lupus erythematous, psoriasis and solid organ and hemopoietic stem cell transplant
- Neurological disease - Stroke or muscle wasting condition
- Sickle cell disease, thalassemia, and post splenectomy
- BMI of 35 and above
- Tobacco dependents

People at high risk of infection and essential workers:

- Healthcare workers
- Other frontline workers (Police, military, ports, …etc)
  (i) Teachers and educational facilities staff
  (ii) Residents of long-term facilities, nursing homes and assisted living facilities
  (iii) Correction facilities population
- Participation in high risk activities (e.g., sports, attendance at large social or mass gatherings, hairdressers/barbers, supermarkets and convenience stores personal.
- Other personnel in public sectors who might have close and direct contact with the public

C. Coadministration with other vaccination:

COVID-19 vaccines and other vaccines can be administered without regard to timing. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day, as well as coadministration within 14 days. It is unknown whether reactogenicity of COVID-19 vaccine is increased with coadministration, including with other vaccines

known to be more reactogenic, such as adjuvanted vaccines or live vaccines. When deciding whether to co-administer another vaccine(s) with COVID-19 vaccine, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and the reactogenicity profile of the vaccines.

If multiple vaccines are administered at a single visit, administer each injection in a different injection site. For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection.

Best practices for multiple injections include:

- Label each syringe with the name and the dosage (amount) of the vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
- Separate injection sites by 1 inch or more, if possible.
- Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible.

D. Interchangeability of the existing covid-19 vaccines:

In general, efforts should be made to determine which vaccine the individual received for their first dose and to complete the two-dose course with the same vaccine. However, evidence on the interchangeability of the different COVID-19 vaccines is emerging from several trials conducted in the UK, Germany and Spain with reports on the safety and immune responses produced from mixed COVID-19 vaccine schedules.

Interchangeability is reasonable for:

- Individuals who started the schedule and who attend for vaccination at a site where the same vaccine is not available and likely to be at immediate high risk or considered unlikely to attend again or where the first product received is unknown

- Individuals received AstraZeneca and are at potential risk for Vaccine Induced Immune Thrombotic Thrombocytopenia (VITT). Although the **rate of VITT** after the second dose of AstraZeneca/ vaccine appears to be lower than with the first dose, in some countries it has increased over time, with current estimates of approximately 1 per 600,000 people vaccinated. Current evidence suggests first dose of the AstraZeneca vaccine followed by a second dose of mRNA vaccine (Pfizer-Biontech was used in studies) has a **good safety profile** at shorter (4-week) and longer (8- to 12-week) intervals. There is a possibility of increased **short-term side effects** when using mixed covid-19 vaccine schedules, including headache, fatigue and feeling generally ill. This was particularly noted with a short interval of 4 weeks between the first and second dose. These side effects are temporary and resolve without complications.
- As a booster to boost the response to the previous doses or waning immune response. There is evidence that providing an mRNA vaccine after AstraZeneca vaccine will **boost the immune response**. Further doses of vaccine are not required unless additional information becomes available. No similar data available for other vaccines.
- Booster doses: No current data on the need for booster doses for any of the addressed vaccines. Several studies are ongoing. Further evidence is required before any recommendations are given in regard to the timing, target population, frequency and the best vaccines matches.

The task force members advice countries adopting option of interchangeability for close monitoring of the evolving evidence on mixed COVID-19 vaccine schedules

E. Special consideration for giving covid-19 vaccine with other therapeutics:

- individuals who are immunosuppressed
  - Individuals with immunosuppression may not make a full immune response to vaccination. As there is no evidence on response in immunosuppressed individuals; there is limited evidence upon which to base advice on the optimal timing of vaccination. Health care providers may advise their patients based on their knowledge and understanding of their immune status and likely immune response to vaccination but should also consider the risk from COVID-19 and the patient's likelihood of exposure.
  - Patients who are about to receive planned immunosuppressive therapy should be considered for vaccination prior to commencing therapy (ideally at least two weeks before), when their immune system is better able to make a response. Where possible, it would also be preferable for the 2-dose schedule to be completed prior to commencing immunosuppression. This would entail offering the second dose at the recommended minimum for that vaccine (three or four weeks from the first dose) to provide maximum

benefit that may not be received if the second dose was given during the period of immunosuppression. Any decision to defer immunosuppressive therapy or to delay possible benefit from vaccination until after therapy should not be taken without due consideration of the risks from COVID- 19 and from their underlying condition.

- People who have autoimmune conditions

  - People with autoimmune conditions may receive an COVID-19 vaccine. However, they should be aware that no data are currently available on the safety and efficiency of COVID-19 vaccines. Individuals from this group are eligible for enrollment in clinical trials.

- People who have previously had Guillain-Barre syndrome

  Persons who have previously had GBS may receive an COVID-19 vaccine. To date, no cases of Guillain-Barre syndrome (GBS) have been reported following vaccination among participants in the COVID-19 vaccine clinical trials.

- People who have previously had Bell's palsy

  Cases of Bell's palsy were reported in participants in the COVID-19 vaccine clinical trials. However, the rate expected in the general population and were not caused by vaccination. Therefore, persons who have previously had Bell's Palsy may receive an COVID-19 vaccine.

- People with advance liver disease

  Persons who have liver disease may receive any COVID-19 vaccine

F. Spacing of COVID-19 Vaccines and Antibody-Containing Products:

As the COVID-19 vaccines are non-live vaccines, COVID-19 treatments such as dexamethasone, convalescent plasma or monoclonal antibody treatment are not anticipated to contraindicate vaccine administration. Although theoretically, high levels of antibodies in the convalescent plasma could interfere with the immune response to the vaccine,

passively acquired antibodies from the plasma treatment are not thought to persist for long, so by the time a person who has received this is well enough to receive a COVID-19 vaccination, these antibodies are likely to have gone. In addition, as COVID-19 vaccines do not contain a live virus, response to vaccination will not be affected by prior or recent anti-viral medication. However, since no data on safety or efficacy of COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma, precaution is advised for now. Vaccination should be deferred for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses.

G. Testing for antibody response post vaccination:

- Not Recommended routinely unless advised by Infectious Disease Specialist.

H. Efficacy of Existing COVID-19 vaccines and the new variants:

- There is limited evidence from laboratory studies and real-world data that some immune responses driven by current vaccines could be less effective against some of the new SARS-CoV-2 variants. Nevertheless, individuals are encouraged to receive the current available vaccines at their countries.
- Tracking emerging variants through genomic surveillance and routine analysis of genetic sequence is highly recommend to detect variants with ability to evade vaccine-induced immunity or impact the effectiveness of vaccines.

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