

JOB AID FOR COVID-19 VACCINE ADMINISTRATION

Moderna COVID-19 (mRNA-1273) vaccine

GENERAL INFORMATION

- Vaccine: mRNA-vaccine, multidose vial containing 5 ml dispersion, for 10 vaccine doses of 0.5 ml each
- Age indication: 18 years of age and older
- Schedule: 2 doses, 28 days apart*, a minimum interval of 14 days between administration of mRNA-1273 and any other vaccine
- Route and site of administration: Intramuscular, in the deltoid muscle of the upper arm

* Countries that have not yet achieved high vaccination coverage rates in the high-priority groups and that are experiencing a high incidence of COVID-19 cases combined with vaccine supply constraints may extend the inter-dose interval up to 12 weeks to achieve high first-dose coverage in high priority groups.

STORAGE CONDITION AND SHELF LIFE OF VACCINE

STORAGE CONDITION	SHELF LIFE	
Unopened vaccine vials:		
-25 °C to -15 °C	7 months	 Avoid exposure to direct sunlight and ultraviolet light.
Other conditions, if within 7-month shelf life:		• Do NOT store on dry ice or below -40 °C.
+2 °C to +8 °C	Up to 30 days	
Punctured vaccine vials:		 Punctured vaccine vials should be discarded at the end of the immunication coscion or after 6 hours from first nuncturing
+2 °C to +25 °C	Up to 6 hours	immunization session, or after 6 hours from first puncturing, whichever comes first.

HOTE: Ensure all vaccines are kept in their original secondary packaging to protect from light and are clearly labelled.

MATERIAL NEEDED FOR VACCINATION AND SUPPLIES

- Syringe for vaccine administration (0.5 ml or 1 ml syringe with 0.1 ml graduations) with 23-gauge needle for administration
- Sterile single-use antiseptic swabs
- Safety box for sharps disposal
- Medical treatment kits to manage allergic reactions in the event of an acute anaphylactic reaction
- Personal protective equipment (PPE) for vaccinators (gown; gloves; medical mask, face shield, goggles) as per the national infection prevention and control guidelines
- Hand hygiene (alcohol-based hand rub or running water and soap) and surface cleaning agents

THAWING FROZEN VACCINE

Frozen vaccine vials may be thawed in the refrigerator or at room temperature.

- HOTE: Record on the secondary packaging the date of thawing. Do NOT refreeze thawed vaccine.
 - Thawing in refrigerator (+2 °C to +8 °C) may take 2 hours and 30 minutes •
 - Thawing at room temperature (+15 °C to +25 °C) may take 1 hour •

5. CONTRAINDICATION AND PRECAUTIONS FOR VACCINATION

Contraindications

• History of anaphylaxis to any component of the vaccine. If anaphylaxis occurs after the first dose, a second dose should not be administered.

Precautions

- A history of anaphylaxis to any other vaccine or injectable therapy or to the first dose of this vaccine (Subject to individual risk-benefit assessment, this vaccine could be provided under close medical supervision).
- Acute febrile illness (body temperature over 38.5 °C).
- Individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia), because bleeding or bruising may occur following an intramuscular administration.

6. PREPARATION AND ADMINISTRATION OF VACCINE

NOTE:

- The thawed vaccine is ready to use. Do NOT dilute the vaccine.
- One thawed vaccine vial contains 10 vaccine doses (each of 0.5 ml).
- Swirl the vaccine vial gently after thawing and before each withdrawal. Do NOT shake the vaccine vial.

PREPARATION FOR VACCINE ADMINISTRATION ENVIRONMENT

1		• Be sure to wear correct personal protective equipment (PPE) before administering vaccines. Ensure that the implemented policies for the use of face coverings for vaccine recipients are in place.
		Assess recipient status:
2		 Screen for contraindications and precautions (see above).
		 Review vaccination history: Which dose will be administered (first/second)? Has any other vaccine been administered within the previous 14 days? If yes, discuss delaying of vaccination (a minimum interval of 14 days following other vaccines should be observed).
		 Place the patient in a sitting position, looking to the other side.
WITHDRAW OF VACCINE		
 NOTE: NEVER use expired vaccine. NEVER use thawed vaccine beyond the indicated storage-dependent shelf life (see above): Unopened vaccine vials stored at +2 °C to +8 °C: max. 30 days Punctured vaccine vials stored at +2 °C to +25 °C: 6 hours 		
		 Perform hand hygiene before vaccine preparation. Follow aseptic technique throughout vaccine

3		 Perform hand hygiene before vaccine preparation. Follow aseptic technique throughout vaccine preparation.
4		• If vaccine vial was thawed in refrigerator, remove thawed vaccine vial from the refrigerator and allow thawed vaccine to come to room temperature (up to +25 °C) for about 15 minutes before administration.
5		 With the vaccine at room temperature (up to +25 °C), hold the vaccine vial upright and gently swirl it. Gently swirl the vaccine vial before each withdrawal. Do NOT shake the vaccine vial.
		 The vaccine is white to off-white in colour and may contain white or translucent product-related particulates.
		NOTE: If the vaccine vial is shaken, discard the vaccine vial. Do not use use if liquid is discoloured or contains particulate matter.
6		• Wipe off the stopper of the vaccine vial using a NEW sterile single-use antiseptic swab.
		• Using a NEW sterile 23-gauge needle, withdraw 0.5 ml of vaccine from the vial.
	0,5 ml	• Write the date and time the vaccine was first punctured (withdraw from first dose) on the vaccine vial.
	A	 10 doses (of 0.5 ml each) can be withdrawn from each vial. An additional overfill is included in each vial to ensure that 10 doses of 0.5 ml can be delivered.
		NOTE: The same needle can be used to withdraw and administer the vaccine, unless contaminated or damaged.

7		 Ensure the prepared syringe is not cold to the touch. Ensure the liquid in the syringe is white to off-white in colour. Ensure the vaccine volume in the syringe is 0.5 ml.
8		 Keep punctured vaccine vial at +2 °C to +25 °C and administer within 6 hours. Do not return vaccine vial once punctured to refrigerator or freezer storage. Discard any unused vaccine of punctured vaccine vials at the end of the immunization session, or within 6 hours after first puncturing, whichever comes first.
ADI	MINISTRAT	ION OF VACCINE
9	2.	 Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration. Administer the vaccine immediately by intramuscular injection in the deltoid muscle of the upper arm.
10	+	• Discard the used syringe into the safety box or safe syringe container (without recapping the needle).
11		 Observe recipients after vaccination for an immediate adverse reaction: 30 minutes: persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause 15 minutes: all other persons.
12	œ,	• Record vaccination including date, name and batch number of vaccine. Provide a document to the vaccinated person recording the vaccination.
13	Z	• Report any suspected adverse reactions according to the national procedures

7.

MANAGEMENT OF ANAPHYLAXIS AND ANXIETY-RELATED REACTIONS

Events of anaphylaxis and anxiety-related reactions may occur. The vaccine should be administered only in settings where anaphylaxis can be treated. Make sure that a health-care worker competent in identifying and treating these reactions, and any necessary equipment and medications, are available. Take precautions to avoid injury from fainting.

8.

MYOCARDITIS AND PERICARDITIS

Very rare cases of myocarditis and pericarditis have been observed following vaccination with the mRNA COVID-19 vaccines. These cases occurred more often in younger men and after the second dose of the vaccine, typically within few days after vaccination. Current evidence suggests a likely causal association between myocarditis and the mRNA vaccines. The risk of myocarditis and pericarditis is very low and the benefits of mRNA COVID-19 vaccines in reducing hospitalizations and deaths due to COVID-19 infections outweigh the risks.

Clinicians should Instruct vaccinated individuals to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as new onset and persisting chest pain, shortness of breath, or palpitations following vaccination. Healthcare providers should report all myocarditis and other adverse events observed following administration of mRNA or other vaccines.

COMMUNICATION DURING VACCINATION VISIT

1 Explain the benefits of the vaccine "The COVID-19 vaccine is a safe way to protect yourself from the COVID-19 (coronavirus) disease." Enquire about and screen for contraindications and precautions 2 1.... "We want to make sure it will be safe for you to receive the vaccine." [Ask about the contraindications and precautions listed above.] 3 **Explain the process** "The vaccine is given through an injection into the upper arm. You may feel a slight pinch when the needle goes in. Afterwards, we want you to stay here for [15 or 30 minutes, depending on patient history] to be sure you don't have any allergic reactions." 4 Explain the common side effects "We want you to be aware of some common side effects of the vaccine. [Explain common and rare side effects.] You might have some redness and soreness at the injection site, or you might have a mild fever and body aches. These usually improve within a few days after vaccination, but if for some reason they last longer contact health-care professionals." 5 **Resolve concerns and answer questions** Listen actively to show interest and concern and ask about any questions or concerns about receiving the COVID-19 vaccine. Respond with empathy and understanding. • Offer positive encouragement. Be respectful and avoid arguing.

COMMON PATIENT CONCERNS	EXAMPLE RESPONSES FROM HEALTH WORKERS	
"I am worried about the possible side effects."	"I understand that you want to make the best choice for yourself. What potential side effects are you concerned about?" [Address as appropriate]	
"I am not sure what to do. I have heard and read so many things about the vaccine that I don't know what to believe."	"I understand that so much contradictory information can be confusing. I am happy to answer your questions and also refer you to trustworthy sources of information online."	
6 Inform about the necessary follow-up		

"Remember that you will still need to have a second injection of the COVID-19 vaccine in about 3–4 weeks. Please make an appointment for that time so we can give you the second injection."

10. SOURCES

- 1. WHO Interim recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19.Geneva: World Health Organization; 2021<u>https://www.who.int/publications/i/item/interim-recommendations-for-use-of-the-moderna-mrna-1273-vaccine-against-covid-19</u>, accessed 23 July 2021.
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- WHO recommendation for an emergency use listing of COVID-19 mRNA vaccine (nucleoside modified) submitted by Moderna Biotech (Spain); 2020 <u>https://extranet.who.int/pqweb/sites/default/files/documents/COVID-19_Moderna_PEG-TAG_report.pdf</u> To, accessed 23 July 2021
- Aide-memoire: infection prevention and control (IPC) principles and procedures for COVID-19vaccination activities, 15 January 2021. Geneva: World Health Organization; 2021 <u>https://apps.who.int/iris/handle/10665/338715</u>, accessed 11 February 2021.

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