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Guidelines

COVID-19 Vaccination Moderna Vaccine Guidelines

Objective

To provide guidelines for the Moderna vaccine storage, handling, administration, and safe disposal along with recommendations for vaccine recipients.

Rationale

Vaccines are important part of strategies to curtail the devastating Covid-19 pandemic. Moderna vaccine needs special handling and cold chain maintenance to preserve the vaccine's effectiveness. Safe transportation, storage, administration, and disposal of vaccine waste must be ensured at all vaccination facilities.

Instructions

Vaccine Storage

- Store vaccine in a freezer or refrigerator.
- First use vaccine vials stored in the refrigerator before removing vials from frozen storage.
- Check and record storage unit temperature regularly each workday.


Freezer

Frozen vials prior to use should be stored at temperatures of -50°C to -15 °C and protected from light, in the original packaging.

Do not store on dry ice or below -50°C.

Refrigerator

Thawed, unpunctured vials may be stored in the refrigerator between 2° to 8°C (36 to 46 F) for up to 30

| Moderna COVID-19 Vaccine | | | |
|--|---------------|---------------|---------------|
| Store vaccine between 2°C and 8°C (36°F and 46°F) for up to 30 days. | | | |
| Lot number(s): | 123456A | | |
| Today's date: | 4 / 01 / 2021 | USE BY* Date: | 5 / 01 / 2021 |
| *After this date/time, do NOT use. Contact the manufacturer for guidance. If directed to discard the vaccine, follow the manufacturer's and your jurisdiction's guidance on proper disposal. | | | |
| Vaccine may be transported for 12 cumulative hours. | | | |
| Transport date | 4/5/21 | | |
| Time in transport: | 2 hrs | | |
| Time remaining: | 10 hrs | | |
| Name: | Amy Nurse RN | | |
|  | | | |



days. Do NOT freeze thawed vaccine during storage, vials should be protected from light, in the original packaging.

Punctured vial can be stored at 2 to 25°C (36 to 77 F) for upto 6 hours.

- Do NOT refreeze thawed vaccine.
- Thawed, punctured vials should be stored between +20 C to +25o C and used within 6 hours from the time of first puncture. During storage, vials should be protected from light.
- Monitor how long the vaccine has been in the refrigerator using beyond-use date labels.
- Remove the vaccine container boxes from frozen storage, rather than taking out vaccine vials from the freezer/frozen storage.
- Complete/fill the information on the storage label.
- Attach the storage label it to the box holding the vaccine vials.

Preparation: Thaw each vial before use:

- Thaw in refrigerated conditions between 2°C to 8°C for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw at room temperature between 15°C to 25°C for 1 hour.

Who should receive the Vaccine

Moderna Vaccine will be administered to all eligible individuals who are 18 years of age and above including pregnant and lactating women.

Students aged 16 years and above, whose universities mandate evidence of mRNA vaccine administration, are also eligible.

Who should NOT receive Vaccine

- If you have had a severe allergic reaction (anaphylaxis) or an immediate allergic reaction, even if it was not severe:
 - to any ingredient in an mRNA COVID-19 vaccine (such as polyethylene glycol).
 - or after getting the first dose of the vaccine, should not get a second dose of either of the mRNA COVID-19 vaccines.
- The vaccine is not recommended for persons younger than 18 years of age pending the results of further studies.
- In general, persons with an immediate non-anaphylactic allergic reaction to the first dose should not receive additional doses, unless recommended after review by a health professional with specialist expertise.



- Those who have experienced a mild episode of COVID-19 in the recent past can receive the vaccine once the isolation period is completed. Those with severe COVID-19 can receive the vaccine once they become clinically stable.

Adverse Effects

Pain, redness, swelling at injection site. Fever, myalgia, headache

There have been reports of myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines, including the Moderna vaccine. Available information indicates that cases have been mild, occurring more commonly after the second dose of vaccine and more often in male adolescents and young adults. Symptoms have been reported to start within several days after vaccination

Vaccine Administration

- Route of Administration: **Intra-muscular**
- Site of Administration: **Lateral Deltoid Muscle (Upper Arm), Non-dominant side**
- Regimen: **Two doses one month (28 days) apart**
- Dose: **0.5ml/vial** (5×10^{10} viral particles)
- Authorized Interval: 28 days
- Presentation: **Single dose vial**
- **No additional booster dose required**

Steps of Administration

1. Wear mask and observe COVID-19 SOPs
2. **Greet** the client
3. Complete **verification** process in the NIMS
4. Ensure **consent** by stating “that you are receiving this COVID-19 vaccine because you have registered yourself into the system”
5. Expose site (**deltoid** of non-dominant arm) for administration
6. **Explain the procedure and inform** that some pain on giving injection, discomfort at the site of injection or fever after the injection may happen
7. Swab the injection site with an alcohol swab for **30 seconds**, then let the area dry for another 30 seconds so that the alcohol doesn't enter the puncture and sting
8. Take vaccine vial out of the vaccine carrier
9. Open the vial by removing plastic cover/cap
10. Take out **22G-25G 0.5ml** syringe and remove needle cap
11. Discard the cap in safety box
12. Insert the syringe needle through the top rubber pad of vaccine vial
13. Draw **0.5ml** of the vaccine from the vial
14. Inject intra muscularly at the site of injection at an angle of 90° (right angle)



15. Dispose the syringe in the safety box
16. Complete entry in the **NIMS**
17. Send the client to observation area for **30 minutes**
18. After 30 minutes if no acute adverse event is experienced by the client, send the client home. Also, advise the client to **report to health facility /1166 helpline** if any adverse event is experienced.

Vaccine Waste Management

- Used vials and syringes must be **collected safely** by the vaccinator
- **Syringes must be disposed through environment friendly incinerators** where available.
- In case of non-availability of incinerators, follow the under mentioned link for proper disposal of the vaccine waste.
https://apps.who.int/iris/bitstream/handle/10665/43476/9241594284_eng.pdf?sequence=1&isAllowed=y
- The **vaccinator under supervision of the health facility in-charge** of the concerned health facility will ensure proper disposal of COVID-19 vaccination waste
- **Daily waste generation and disposal record** must be maintained by the vaccinator

During vaccination, Do NOT

- Touch the rubber pad of vaccine vial (causes contamination and can result in an AEFI)
- Recap needle of syringes (to prevent needle stick injuries)

Please refer to “Annexure A” checklist for covid-19 vaccine administration

Note: The above recommendations are being regularly reviewed by the Ministry of National Health Services, Regulations & Coordination and will be updated based on the international & national recommendations and best practices.

The Ministry acknowledges the contribution of Mr Shamim Raza, Ms. Amina Ehsan Qazi, EPI Team and HSA/HPSIU/NIH team to compile these guidelines.



References

1. <https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/storage-summary.pdf>
2. <https://www.fda.gov/media/144637/download>
3. <https://www.who.int/publications/i/item/interim-recommendations-for-use-of-the-moderna-mrna-1273-vaccine-against-covid-19>
4. <https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html>
5. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html>
6. https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_Moderna_vaccine_admin.pdf

For more information, please contact:

HSA/ HPSIU/ NIH, PM National Health Complex, Islamabad

<http://covid.gov.pk/>

<http://nhsrcofficial.gov.pk/>

<https://www.facebook.com/NHSRCOfficial>

<http://www.hsa.edu.pk/>

<https://twitter.com/nhsrcofficial>

<https://www.nih.org.pk/>

<https://www.youtube.com/NHSRC-PK>



Annex-A

| CHECKLIST FOR COVID-19 VACCINE ADMINISTRATION | |
|---|--------------------------|
| Client Name: | Age: |
| ID Card: | Gender: |
| Address: | |
| Staff name/Signatures | |
| 1. Greet the Client | <input type="checkbox"/> |
| 2. Make sure that you and client are wearing face mask | <input type="checkbox"/> |
| 3. Complete the 2-step verification of client | <input type="checkbox"/> |
| 4. Ensure consent by stating that "you are receiving this COVID-19 vaccine because you registered yourself in the system" | <input type="checkbox"/> |
| 5. Prepare dose | <input type="checkbox"/> |
| 6. Explain the procedure and inform that some pain on giving injection, and discomfort or fever after the injection can occur | <input type="checkbox"/> |
| 7. Sterilize injection site with alcohol swab | <input type="checkbox"/> |
| 8. Administer injection | <input type="checkbox"/> |
| 9. Properly dispose the injection waste | <input type="checkbox"/> |
| 10. Send the client to observation section for 30 minutes | <input type="checkbox"/> |
| 11. After 30 minutes, and with no acute AEFI, client is ready to be sent home. | <input type="checkbox"/> |
| 12. Respond to Qs if any, as the last step. | <input type="checkbox"/> |