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Guidelines

COVID-19 Vaccination

Updated Sputnik V Vaccine Guidelines

Objective

To provide guidelines for the Sputnik 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. Sputnik V Covid-19 vaccine needs special handling to maintain its effectiveness. Safe transportation, storage, administration and disposal of vaccine waste must be ensured at all vaccination facilities.

Basic Information:

Component I – **1st Dose:** Each dose of 0.5 ml contains Serotype 26 (Recombinant) Adenovirus particles containing SARS-COV-2 protein S gene $(1.0 \pm 0.5) \times 10^{11}$

Component II – **2nd Dose:** Each dose of 0.5 ml contains Serotype 5(Recombinant) Adenovirus particles containing SARS-COV-2 protein S gene $(1.0 \pm 0.5) \times 10^{11}$

Instructions for Use:

Current preparation: Frozen preparation; 0.5 ml single dose ampoule, to be used immediately after thawing, if multi-dose vial, it is to be thawed and used immediately and not to be used beyond 2 hours (once out of Freezer).

Vaccine Dose:

- Vaccination course consists of two separate doses of 0.5 ml each
- The second dose with separate components (I and II) should be administered after interval of 21 days
- It is recommended that individuals who receive first dose of Sputnik V, complete the vaccination course with the Sputnik vaccine (component II)

Shelf life:

- **Frozen preparation:** The approved shelf life for both components (I & II) is 6 months kept at -18°C (in dark place).
- **Liquid preparation:** This preparation is currently under research.
- **Solid preparation:** The lyophilized powder form of vaccine can be kept at $2-8^{\circ}\text{C}$.
- The expiry date of vaccine is indicated on the label and packaging



- All opened multi-dose vials (1vial = 3.0ml) of Sputnik V should be discarded at the end of administering 05 doses and within two hours of its removal from -18°C storage; whichever is earlier.

Vaccine Storage:

- Frozen Preparation; Store in a Freezer (-18°C).
- For vaccine administration once the product is removed from the freezer (-18°C) it is kept at room temperature until completely thawed and to be used within 02 hours, once thawed, then gently shake the vial. Do not shake sharply.
- The solid lyophilized powder for vaccine can be kept at 2-8 °C.
- **Refreezing is not allowed.**

Who should receive the Vaccine?

- Individuals who are 18 years of age and over
- Vaccination is recommended for persons with comorbidities that have been identified as increasing the risk of severe COVID-19, including obesity, cardiovascular disease, respiratory disease and diabetes.
- Pregnant women may receive the vaccine after consultation with their doctor. Women who are breastfeeding may take the vaccine
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Who should NOT receive Sputnik Vaccine?

- Individuals having **fever at the time of coming for vaccination** (Can be rescheduled after the illness is settled)
- Patients with **active COVID-19**
 - Those with mild COVID-19 can receive the vaccine once the isolation period complete.
 - Those with severe COVID-19 can receive the vaccine once they become stable
- Individuals who had severe post vaccination complication with **component I** should not receive **component II**

Vaccine Administration

- Route of Administration: **Intra-muscular**
- Site of Administration: **Deltoid Muscle (Upper Arm), Non-dominant side**
- Dose: **2 doses (21 days apart)**
- Presentation: 0.5ml **Single dose ampoule/ 05dose vial (3ml)**

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. Take vaccine vial/ampoule out of the vaccine carrier
8. Open the vial by removing plastic cover/cap or opening the ampoule.
9. Take out 0.5ml syringe and remove needle cap
10. Discard the cap in safety box
11. Insert the syringe needle through the top rubber pad of vaccine vial or into the opened ampoule
12. Draw **0.5ml** of diluted vaccine from the vial/ampoule
13. Inject intra muscularly at the site of injection at an angle of 90° (right angle) following “**No-touch technique**”
14. Dispose the syringe in the safety box
15. Complete entry in the **NIMS**
16. Send the client for observation area for **30 minutes**
17. After 30 minutes if no acute adverse events experienced by the client, explain the next steps on follow up visit for second dose and to **report to health facility /1166 helpline** if any adverse event is experienced.
18. Get ready for next vaccination

Special Warnings and Special Precautions:

Vaccine should be taken after consultation with your physician to weigh possible benefits over risks.

Hypersensitivity

- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of anaphylactic event following the administration of the vaccine.

Concurrent Illness

- As with other vaccines, administration of Sputnik V should be postponed in individuals suffering from an acute severe febrile illness. However, the presence of a minor infection, such as cold, and/or low-grade fever should not delay vaccination.

Thrombocytopenia and Coagulation Disorders

- Sputnik V should be given with caution to individuals with thrombocytopenia, any coagulation disorder or to persons on anticoagulation therapy, because bleeding or bruising may occur following an intramuscular administration in these individuals.

Immuno-compromised Individuals

- It is not known whether individuals with impaired immune responsiveness, including individuals receiving immunosuppressant therapy, will elicit the same response as immune-competent individuals to the vaccine regimen. Immuno-compromised individuals may have relatively weaker immune response to the vaccine regimen.
- Individuals on short-term immune-suppressive medication should wait for 28 day after the medication ends
- Those chronically immune-suppressed may receive the vaccine, though efficacy may be uncertain (Ref: leaflet insert)
 - Those post-transplantation may receive the vaccine 3 months after transplantation
 - Those post chemotherapies may receive the vaccine 28 days after chemotherapy

Duration and Level of Protection

- The duration of protection has not yet been established.



- As with any vaccine, Sputnik V may not protect all vaccine recipients

Pregnancy

- There is a limited experience with the use of Sputnik V in pregnant women so it should be avoided. Consult a physician to assess if benefits outweigh the risks.

Breastfeeding

- It is unknown whether Sputnik V is excreted in human milk. It should be avoided

Sputnik Vaccine Waste Management

- Used vials/ampoules and syringes must be **collected safely** by the vaccinator
- **Syringes must be disposed through environment friendly incinerators** where available
- The **vials/ampoules and syringes must be disposed together in burial/burning pits**
- Pit must be closed with 50cm (half ft.) **soil layer** before the pit is completely filled
- 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 /top of the ampoule (causes contamination and result in AEFI)
- Recap needle of syringes (can cause 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 Ms. Amina Ehsan Qazi, EPI team and HSA/ HPSIU/ NIH team to compile these guidelines.

References

- [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00234-8/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00234-8/fulltext)
- <https://www.pharmaceutical-technology.com/news/russia-sputnik-senior-citizens/#:~:text=The%20Sputnik%20V%20vaccine%20is,and%20effective%20for%20older%20people.>

For more information, please contact:

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

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

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

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

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

<https://twitter.com/nhsrcoofficial>

<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 appear	<input type="checkbox"/>
7. Administer injection	<input type="checkbox"/>
8. Properly dispose the injection waste	<input type="checkbox"/>
9. Send the client to observation section for 30 minutes	<input type="checkbox"/>
10. After 30 minutes, and with no acute AEFI, handover the letter of next appointment to the client	<input type="checkbox"/>
11. Explain the next steps	<input type="checkbox"/>



12. Respond to Qs if any, as the last step.