Operational Guidelines
Introduction of
Newer COVID-19 Vaccine

16 – 01 - 2021
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Department of Community Medicine,
KVG Medical College, Sullia,
Dakshina Kannada,
Ph: 9900131066; PIN: 574 327
Outline

- Goal & Objective
- Whom, Where and When
- Vaccine characteristics
- Vaccine administration, Safety & Waste management
- Planning
- Areas of concern
- Way forward
COVID-19 Vaccination

- **Goal:** To protect people, minimize societal and economic impact by reducing COVID-19 mortality.

- **Objective:** To protect the integrity of the Healthcare system in the first phase

- **Strategy:** In Multiple Phases, largely to **preregistered** beneficiaries with **photo ID**
Prioritized Population Groups For COVID-19 Vaccination

PHASE I - Approximately 30 Crore population

- Health Care Workers (Approx. 1 Cr)
- Front line Workers (Approx. 2 Cr)
- Prioritized Age Group*
  (Population ≥50 yrs. of age) and <50yrs with associated comorbid conditions (Approx. 26 +1 Cr)

*Age considered as on 1 January 2021

- Population ≥50 yrs group may be further sub-categorized into: - 50 – 60 years and > 60 years
- Latest electoral roll for Lok Sabha and Legislative Assembly election will be used to identify population aged 50 years or more

Goal is to protect people, minimize societal and economic impact by reducing COVID-19 mortality
1297 Pre-Registered beneficiaries are expected to receive SMS from the CoWIN for vaccination on ‘D’ days.
**Inclusion and exclusion for vaccination**

- **Inclusion**: Include pre registered HCWs of 9 subcategories with no co-morbidity in this phase.

- **Exclusion**: Among the registered, exclude those who had severe allergic reaction (anaphylaxis) after any drug, food, any vaccine or any ingredients of this vaccine / after a previous dose of COVID-19 vaccine,

- has fever, bleeding disorder or on a blood thinner, on a medicine that affects immune system / immunocompromised, pregnant or planning to conceive, breastfeeding,

- COVID-19 patients within 14 days of last negative report,

- Received COVID-19 vaccine of another brand
Where to get Vaccinated?

- In KVG Medical College Hospital.
- 3 booths are arranged, each with 5 team members.
- Between 9 AM and 4 PM with formal breaks.
- 3 booths will operate for 4 days.
- One booth will operate on 5th day.
- 1297 beneficiaries line-listed, expected to receive SMS a day before ‘D’day.
**Who are the service providers**

**Institutional Supervisor:** Dr Narayana Holla  
Dr Apoorva Dore  

<table>
<thead>
<tr>
<th>Team Members</th>
<th>Details of Vaccination of Team Members</th>
<th>Name</th>
<th>Designation</th>
<th>Mobile Number</th>
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<tbody>
<tr>
<td>Vaccinator Officer</td>
<td></td>
<td>Shobitha M</td>
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<td>9449770432</td>
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<tr>
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<td>Mr Jaya</td>
<td>Security Staff</td>
<td>7353750744</td>
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<td>Security Staff</td>
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<td>8971693773</td>
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<td>Sumithra</td>
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Why to know Vaccine Characteristics

- Vaccination: A few general considerations
- WHO iteration “… reference is incomplete unless one reads product specific notes” hence incorporate for effective training well before launch.
- Smaller the molecular size of an antigen, duration of specific protection is short requiring multiple primary doses and intermittent boosters [Basic Microbiology].
- “Flu” vaccines are “strain specific” and they frequently change genetic/antigenic configuration, necessitating strain specific annual re-vaccination.
- Generally quality of vaccination service is taken for granted but sustained supportive supervision [SSS] can ensure the quality and country specific vaccination to combat country specific Vaccine Preventable Diseases [VPDs].
- Live attenuated vaccines like OPV/BCG/Measles… have non targeted activity/functions like promoting innate immunity in addition to adaptive immunity providing both targeted and extra-targeted benefits.
- Product specific effects/side effects and specific management are described in the leaflet for ready reference, hence wise to keep it handy at service delivery point.
- Compensation following “Vaccination Injury” is generally linked with manufacturer and hence adhering to product specific contraindications/practicing cautions in special conditions by the service provider will facilitate the beneficiary / dependant in claiming the compensation…………..
COVID-19 vaccine characteristics

- Name: COVISHIELD™ monovalent vaccine.
- ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant): replication deficient,
- Clear liquid vaccine in colorless vial.
- Per vial 5mL = 10 doses; 0.5mL per dose.
- Course: 2 doses of 0.5mL each: 4 to 6 weeks apart.
- Route: Intra Muscular [IM] only.
- Administered with 0.5mL AD Syringe
- No VVM, protect from light
- No open vial policy, use within 4-6 hrs of starting
COVID-19 vaccine characteristics

WHAT ARE THE INGREDIENTS IN THE COVISHIELD™ VACCINE?
The COVISHIELD™ Vaccine includes the following ingredients:
L-Histidine, L-Histidine hydrochloride monohydrate, Magnesium chloride hexahydrate,
Polysorbate 80, Ethanol, Sucrose, Sodium chloride, Disodium edetate dihydrate (EDTA), Water for
injection. Has no preservative.

What a beneficiary has to tell vaccinator

- If you have ever had a severe allergic reaction (anaphylaxis) after any drug, food, any vaccine or
  any ingredients of COVISHIELD™ vaccine
- If you have fever
- If you have a bleeding disorder or are on a blood thinner
- If you are immunocompromised or are on a medicine that affects your immune system
- If you are pregnant or plan to become pregnant
- If you are breastfeeding
- If you have received another COVID-19 vaccine

WHO SHOULD NOT GET THE COVISHIELD™ VACCINE?
You should not get the COVISHIELD™ Vaccine if you:
- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

WHAT IF I DECIDE NOT TO GET THE COVISHIELD™ VACCINE?
It is your choice to receive or not receive the COVISHIELD™ Vaccine. You may prefer to consult your
healthcare provider.
### Protective immune response after 4 weeks of 2\textsuperscript{nd} dose

**Report to Nodal Officer**  
Dr Suresh Baliga  
Ph: 9606500525  
08257-235561

<table>
<thead>
<tr>
<th>WHAT ARE THE RISKS OF THE COVISHIELD™ VACCINE?</th>
<th>Side effects that have been reported with the COVISHIELD™ Vaccine include:</th>
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<tbody>
<tr>
<td><strong>Very Common (may affect more than 1 in 10 people)</strong></td>
<td>tenderness, pain, warmth, redness, itching, swelling or bruising where the injection is given</td>
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<tr>
<td>generally feeling unwell</td>
<td>feeling tired (fatigue)</td>
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<tr>
<td>feeling tired (fatigue)</td>
<td>chills or feeling feverish</td>
</tr>
<tr>
<td>headache</td>
<td>feeling sick (nausea)</td>
</tr>
<tr>
<td>feeling sick (nausea)</td>
<td>joint pain or muscle ache</td>
</tr>
<tr>
<td>joint pain or muscle ache</td>
<td><strong>Common (may affect up to 1 in 10 people)</strong></td>
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<tr>
<td>a lump at the injection site</td>
<td>fever</td>
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<tr>
<td>fever</td>
<td>being sick (vomiting)</td>
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<td>flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills</td>
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<td><strong>Uncommon (may affect up to 1 in 100 people)</strong></td>
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<tr>
<td>feeling dizzy</td>
<td>decreased appetite</td>
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<td>decreased appetite</td>
<td>abdominal pain</td>
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<td>abdominal pain</td>
<td>enlarged lymph nodes</td>
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<tr>
<td>enlarged lymph nodes</td>
<td>excessive sweating, itchy skin or rash</td>
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Precautions and Contraindications for COVID-19 Vaccination

1. **Authorized Age Group:** Under the EUA, COVID-19 vaccination is indicated only for 18 years and above.

2. **Co-administration of vaccines:** If required, COVID-19 vaccine and other vaccines should be separated by an interval of at least 14 days

3. **Interchangeability of COVID-19 Vaccines** is not permitted: Second dose should also be of the same COVID-19 vaccine which was administered as the first dose.

**Contraindication**

1. Persons with history of:
   - Anaphylactic or allergic reaction to a previous dose of COVID-19 vaccine
   - Immediate or delayed-onset anaphylaxis or allergic reaction to vaccines or injectable therapies, pharmaceutical products, food-items etc.

2. Pregnancy & Lactation:
   - Pregnant & Lactating women have not been part of any COVID-19 vaccine clinical trial so far. Therefore, women who are pregnant or not sure of their pregnancy; and lactating women should not receive COVID-19 vaccine at this time

**Provisional / temporary contraindications:** In these conditions, COVID vaccination is to be deferred for 4-8 weeks after recovery

1. Persons having active symptoms of SARS-CoV-2 infection.
2. SARS- COV-2 patients who have been given anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma
3. Acutely unwell and hospitalized (with or without intensive care) patients due to any illness
Special precautions: 
Vaccine should be administered with caution in persons with history of any bleeding or coagulation disorder (e.g., clotting factor deficiency, coagulopathy or platelet disorder).

Following conditions are not contraindicated for COVID vaccines
- Persons with a past history of SARS-CoV-2 infection (sero-positivity) and or RT-PCR positive illness
- History of chronic diseases and morbidities (cardiac, neurological, pulmonary, metabolic, renal, malignancies)
- Immuno-deficiency, HIV, patients on immune-suppression due to any condition (the response to the COVID 19 vaccines may be less in these individuals)

Other Important Issues to consider
- Vaccine specific contraindications may apply as the new information becomes available

Guideline provided more clarity
Cold Chain

- To be stored in the ILR, upper basket between 2 & 8\(^{0}\)C, do not freeze,
- Transported to site in Vaccine Carrier with 4 conditioned ice packs on vaccination day
- Icepacks not to be taken out of Vaccine Carrier during session
- Take out only one vial at a time, label date and time
- Do not shake as it has Polysorbate 80 to prevent froth
- Keep the vial taken out from the VC in a wide mouth container to prevent exposure to light while using
Keep the vaccine in the upper basket in ILR. One carton containing 50 vials (500 doses) occupies 1055mL space.

At the session site, keep the running vial labeled with date and time in a container containing manufacturer’s notes as a ready reckoner.
Vaccine usage / wastage

- **Wastage Multiplying Factor [WMF]:** 1.11; doses required = No. to be vaccinated by the planning unit (N) \( \times 1.11 \div 10 \) expressed as whole vials, e.g. \( 1297 \times 1.11 = 1440 \div 10 = 144 \) Vials. [~3 liters cold space]

- Take out only one vial at a time, keep in a container, stick a label to the vial mentioning date and time, use within 4 - 6 hrs.

- Only one beneficiary enters vaccination room-2, do not make ready multiple syringes

- At the end of the session nil or only one partially used vial will be left, return to ILR point, **not for re use.** Returned un opened vials are for use on successive day.

- Enter the brand, batch number of Vaccine Vial against the first beneficiary for that vial for tracking beneficiary & doses per vial
How to set up a vaccination site

- Designate a separate entry and exit if possible
- Open windows for ventilation
- Designate three separate rooms or areas
  - Waiting room/area
  - Vaccination Room
  - Observation Room
- Ensure adequate physical distance between chairs/seats in waiting rooms
- Avoid criss-cross movement of beneficiaries at session site
  - Make arrow marks/foot step marks to show directions
Waiting Area: Room 1

- Facility for hand washing/sanitization at entrance
- Seating arrangement to ensure physical distancing of 2 gaja / 6 feet
- Only one person to enter vaccination room at a time
- Communication materials on COVID appropriate behaviour (hand hygiene, use of mask and physical distancing) to be displayed
Vaccination Room: Room 2

- Only one beneficiary to enter vaccination room at a time to ensure privacy
- Logistics to be made available
  - 2 vaccine carriers with 4 conditioned ice packs each
  - Adequate COVID-19 vaccine vials in one of the vaccine carriers
  - Adequate numbers of AD syringes
  - Hand sanitizer and masks
  - Vaccine vial opener
  - Hub cutter
  - Partition Screen
  - AEFI/Anaphylaxis kit
  - Red and yellow bags, blue puncture proof container, bag for municipal waste
Observation Room: Room 3

- Will require more space as beneficiaries will wait for 30 minutes after vaccination
- Seating arrangement to ensure physical distancing of 6 feet
- Communication materials on COVID appropriate behaviour to be displayed
- Drinking water and toilet facility should be available
Guidance for Vaccination Teams

- Reach allocated session site before time **8 AM**
- Inform supervisor/Medical Officer if you are sick
- Wear a mask at all times
- Composition of team
  - 4 Vaccination Officers with defined roles
  - 1 Vaccinator Officer

Make list of team members for each booth; seek support from other line departments; letters from district administration for deputation on day of training and vaccination session
Screening points

- Check physical parameters as per COVID guideline,
- Any history of severe life-threatening allergy to
  1. any drugs / previous dose of the vaccine or / any of its components
  2. Co-morbid conditions: Diabetes / Hypertension
  3. Pregnancy / planning to conceive / Lactating mother
- Within 14 days of negative test of a COVID-19 patient
- Disease or treatment compromising immunity
- Severe bleeding disorder
- H/O previous COVID-19 vaccination – Match the brand
Role of Vaccination Officer - 1

- May belong to police/home guard/NCC/others
- Will be stationed at the entry gate
- Will identify the beneficiary based on available list and message received by beneficiary
- Ask beneficiary to wash or sanitize hands before entry
- Advise beneficiaries to follow COVID appropriate behaviour
  - Wear mask/face cover
  - Maintain physical distance from each other
- Be aware of cultural sensitivities like purdah/hijab
  - Take need based support from female teammates
Role of Vaccination Officer - 2

- Will be available inside the vaccination room
- Cross check the name of the beneficiary in the Co-WIN application
- Will verify the identity of the beneficiary through
  - Aadhaar Card
  - Other Govt photo ID
  - Service ID/ Proof of employment of healthcare worker
Role of Vaccinator Officer

- Ensure privacy of beneficiary
  - Allow only one beneficiary at a time in the vaccination room
  - Use a partition screen
  - Ensure a female attendant if a male vaccinator is vaccinating a female beneficiary
- Ensure safe injection practices
- Reporting vaccination in Co-WIN app
- Manage injection waste as per guideline
- Provide key messages to beneficiary
  - Detail of the COVID vaccine given
  - Contact the nearest ANM/ASHA/ Medical officers for any support post vaccination
  - You will receive the date and venue for second dose through SMS
  - Follow COVID appropriate behavior even after vaccination
- Ask beneficiaries to wait for 30 minutes in observation room
- Manage and report AEFI(s), if any. Transfer to designated AEFI Management Centre if required
Giving a safe injection

- Wash hands with soap and water before and after the session
- Cover any small cuts on your skin
- Avoid giving injections at the injection site where there is local skin lesion, cut or dermatitis
- Always use AD syringes for COVID-19 vaccination
- Use a new sterile packed AD syringe for each injection for each beneficiary
- Discard AD syringes that have damaged packaging, or have passed the manufacturer expiry date
- Do not pre-fill syringes
- Sanitize your hands before vaccinating each beneficiary
Waste Management at session

- Cut the hub of the syringe after giving the injection
- Store broken vials in the blue puncture proof container
- Segregate and store the plastic portion of the cut syringes in the red bag
- Cotton swabs soiled with blood will go in the yellow bag
- All other non-infectious wastes will be collected as municipal waste in a separate bag
- Immunization waste to be collected by designated person for safe disposal at the end of the day
Role of Vaccination Officer - 3

- Will be available in observation room at all times
- Ensure that the beneficiaries maintains physical distancing of 2 gaj from each other
- Ensure that each beneficiary is under observation for 30 minutes
- Inform vaccinator in case any beneficiary has adverse event
- Support vaccinator to manage the AEFI and inform the Medical Officer

Maintain session site Tally sheet of vaccinated
Before leaving the observation room, look for bruises. “Namaste” to beneficiary for availing service.

1. Felicitate as a proud beneficiary of COVID-19 vaccine
2. To report any untoward events like dizziness / fever / itching etc, following vaccination, up to 30 days to the nodal officer.
3. Course will be complete after receiving 2nd dose.
4. Hence, return for the 2nd dose on due date.
5. On completion of the course, e-certificate can be procured.

Dr Suresh Baliga; Ph: 9606500525; 08257-235561.
Role of Vaccination Officer - 4

- Ensure COVID Vaccine IEC are displayed at the site
- Ensure beneficiaries are mobilized in staggered way to avoid overcrowding at the session site
- Ensure one influencer to be present at the venue to support the activity
- Inform the beneficiaries that they will be informed the day and time of subsequent dose/vaccination
- Provide the contact details of ANM/ASHA/Medical officer to beneficiary for any support post vaccination, if required
<table>
<thead>
<tr>
<th>Sl. No</th>
<th>Name of Health Facility / Institution / research centre / Laboratory / Health administration office etc. (State Govt/ Central Govt/ Pvt)</th>
<th>Number of beneficiaries uploaded on Co-WIN portal</th>
<th>No. of sessions / vaccinators required</th>
<th>Name and address of vaccination booths (To be uploaded on Co-WIN Portal) (If multiple sessions are required at single facility, multiple sessions should be created on Co-WIN)</th>
<th>Type of Vaccination Booth / Session Site (Government, Private, others)</th>
<th>PIN Code of the Vaccination Booth (Session Site)</th>
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<td>KVG Medical College Hospital; Sullia</td>
<td>1297</td>
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<td>KVG MCH - Booth 1</td>
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## Annexure - 1: COVID-19 Vaccination Planning Template

<table>
<thead>
<tr>
<th>Team No.</th>
<th>Session Site Location (with Address and PIN CODE)</th>
<th>Name of Health facilities linked to this session site</th>
<th>PIN CODE</th>
<th>Number of Beneficiaries</th>
<th>Booth Team Members</th>
<th>Details of Vaccination of Team Members</th>
<th>AEFI Management center</th>
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<tr>
<td>1</td>
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<td>KVG Medical College Hospital 574327</td>
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<td>Vaccination officer-4 Shalin</td>
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<td>Vaccinator Officer Shobha</td>
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<td>Vaccination officer-2 Mr Yakshitha</td>
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<td>Vaccination officer-4 Sumithra</td>
<td>Staff Nurse 9632192141</td>
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**Name of District:** Dakshina Kannada  
**Taluka:** Sullia  
**Cold Chain Point / PHC / UPHC:** KVG Medical College  
**Name of Medical [Nodal] Officer:** Dr Narayana Holla; Professor, Department of Community Medicine, 9900131066  
**Date of Vaccination:** 00-01-21 to 00-01-21  
**Name and Designation of Supervisor:** Dr Narayana Holla  
**Mobile Number of Supervisor:** 9900131066
## Annexure - 2: COVID-19 Vaccine Logistics and Transport planning Form

Name of District: Dakshina Kannada;  
Taluka: Sullia;  
Planning Unit: KVG Medical College

Cold Chain Point Type: Rural

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Date of vaccination</th>
<th>Name of Health Facility / Institution/ research centre / Laboratory / Health administration office etc. (State Govt/ Central Govt/ Pvt)</th>
<th>Number of sessions planned</th>
<th>Total Number of Beneficiaries</th>
<th>Number of Vaccine vials required (e x 1.11)</th>
<th>Number of 0.5ml syringes required (e x 1.11)</th>
<th>Number of AEFI kits required (i=d)</th>
<th>Number of Vial Openers (l=d)</th>
<th>Number of Hub Cutter (j=d)</th>
<th>Waste bags</th>
<th>Tally sheets, Reporting Formats and Handouts (one set per each team)</th>
<th>Other logistics</th>
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</thead>
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Soap for hand washing
Key Points on Operational Guidelines for COVID-19 vaccine by MoHFW 12 Jan 2021* - continued:
1. Only one person to enter vaccination room at a time.
2. Observation time for 30min post vaccination in the waiting room.
3. Maintain temp range of +2 to +8 Deg C only; not below or above it.
4. IM in upper arm
5. 0.5ml dosage
6. No VVM on vials
7. To write date and time of opening on vial.
8. Open vials not to be used after 4 hours of opening / at end of the session.
9. Vaccines not interchangeable
10. DIOs will handover vaccines to respective CC points
11. AD syringes will be supplied as per vaccine doses
12. **Vaccine to be avoided in pregnant women and co-morbid individuals presently to be given only in healthy individuals**
13. Not to be stored in normal refrigerator
14. Temperature monitoring twice / day
15. **Freezing destroys vaccine**
16. In freezing temperature areas use warm packets
17. **WMF** added in your vaccine demand figure
Key Points on Operational Guidelines for COVID-19 vaccine by MoHFW 12 Jan 2021*

18. Vaccine shelf life **6months**
19. Individual vaccinated after **14 days of testing negative**
20. In AEFI / Anaphylaxis event avoid 2nd dose
21. 2nd dose of vaccine from same manufacturer.
22. If delayed in 2nd dose, to vaccinate as early as possible.
23. No specific duration for AEFI to occur
24. Encourage AEFI reporting
26. Start Dry run in your areas
27. Continuous power supply mandatory.
28. Prevent pilferage and theft, any such activities to be reported
29. **Never expose vials to direct sunlight**
30. **Keep vaccine on table and not on ice pack.**
31. Never Pre-fill syringes
32. Use all vaccine contents in a vial before opening a new vial.
33. Partially used vaccine vials not be used on subsequent days. Open vial policy not applicable.
34. Vials properly discarded as per BMWs norms.
Ensure practicing COVID Appropriate Behavior [CAB] throughout
Ensure practicing COVID Appropriate Behavior [CAB] throughout

After registration you will receive SMS messages on the registered mobile number.

1. First SMS will be generated for confirmation of registration.
2. Second SMS will be generated mentioning the date, time and place of vaccination.
3. Third SMS will be generated for completion of vaccination and due date for next vaccine.
4. Fourth SMS will be after completion of 2nd dose along with link for digital certificate.

For calls 24x7 Toll Free number 1075
Email at ncov2019@gov.in, ncov2019@gmail.com

mohfw.gov.in  @MohFWIndia  @MoHFW_INdia  @mohfwindia  @mohtwindia
On the vaccination site, Vaccination Officer-1 (police/NCC/NYK, etc.) to check registration & verify Photo ID of the beneficiary.
Ensure practicing COVID Appropriate Behavior throughout.
Following vaccination, all beneficiaries should wait in the observation area for 30 minutes.
Vaccination officer 4 and 5 to ensure 30 minutes wait, monitoring and guiding the non-registered beneficiaries.
Come for second dose of vaccine on the due date as per SMS received.
Ensure practicing COVID Appropriate Behavior throughout
Post Campaign activity

1. Utilizing adequately documented data for deriving the performance indicators for timely feedback / feed forward & Operational Research

2. Tracking of vaccinees for delayed AEFI’s for 30 days from the date of vaccination

3. Proper & detailed recording of monitoring observations for improving quality in the subsequent campaigns.
Areas of concern

- Ensuring achievement of program objectives
- Challenge:- Addressing AEFI, Media to promote positive activity

Way forward

- Post - campaign evaluation
- Expansion & sustenance of Programme.
○ Additional points from viewers