



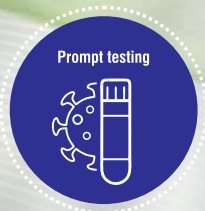
सत्यमेव जयते

Ministry of Health & Family Welfare  
Government of India

# COVID-19 VACCINES

OPERATIONAL GUIDELINES

(Updated as on 28 December 2020)



24x7 helpline no. 1075 (Tollfree)  
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# ABBREVIATIONS



<b>AEFI</b>	Adverse Event Following Immunization
<b>AIIMS</b>	All India Institute of Medical Sciences
<b>ANM</b>	Auxiliary Nurse Midwife
<b>ASHA</b>	Accredited Social Health Activist
<b>AS-MD</b>	Additional Secretary and Mission Director
<b>AWW</b>	Anganwadi Worker
<b>AYUSH</b>	Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy
<b>BBIL</b>	Bharat Biotech International Ltd
<b>BDO</b>	Block Development Officer
<b>BMGF</b>	Bill and Melinda Gates Foundation
<b>CDSCO</b>	Central Drugs Standard Control Organization
<b>CMO</b>	Chief Medical Officer
<b>CoV</b>	Coronaviruses
<b>COVID-19</b>	Coronavirus Disease-19
<b>CSOs</b>	Civil Society Organizations
<b>CTF</b>	City Task Forces
<b>DBT</b>	Department of Biotechnology
<b>DHR</b>	Department of Health Research
<b>DIKSHA</b>	Digital Infrastructure for Knowledge Sharing
<b>DIO</b>	District Immunization Officer
<b>DNA</b>	Deoxyribo Nucliec Acid
<b>DST</b>	Department of Science and Technology
<b>DTFI</b>	District task forces for Immunization
<b>DUDA</b>	District Urban Development Authority
<b>ENT</b>	Ear Nose Throat
<b>eVIN</b>	electronic Vaccine Intelligence Network
<b>FLW</b>	Front-Line Worker
<b>GAVI</b>	Global Alliance for Vaccine and Immunization
<b>GOI</b>	Government of India
<b>HCW</b>	Health Care Worker
<b>IAP</b>	Indian Academy of Paediatricians
<b>IAPSM</b>	Indian Association of Preventive and Social Medicine
<b>ICMR</b>	Indian Council of Medical Research
<b>IDSP</b>	Integrated Disease Surveillance Project
<b>IEC</b>	Information Education and Communication
<b>iGOT</b>	Integrated Government Online Training
<b>IMA</b>	Indian Medical Association
<b>IPHA</b>	Indian Public Health Association
<b>IT</b>	Information Technology
<b>ITSU</b>	Immunization Technical Support Unit

<b>JSI</b>	John Snow Inc
<b>JS</b>	Joint Secretary
<b>LHV</b>	Lady Health Visitor
<b>MAS</b>	Mahila Aarogya Samiti
<b>MD-NHM</b>	Mission Director National Health Mission
<b>MERS</b>	Middle East Respiratory Syndrome
<b>MO</b>	Medical Officers
<b>MOHFW</b>	Ministry of Health and Family Welfare
<b>MR</b>	Measles-Rubella
<b>NARI</b>	National AIDS Research Institute
<b>NCC</b>	National Cadet Corps
<b>NCCVMRC</b>	National Cold Chain & Vaccine Management Resource Centre
<b>NCDC</b>	National Centre for Disease Control
<b>nCoV</b>	novel Coronavirus
<b>NEGVAC</b>	National Expert Group on Vaccine Administration for COVID-19
<b>NHM</b>	National Health Mission
<b>NIHFW</b>	National Institute of Health and Family Welfare
<b>NIMHANS</b>	National Institute of Mental Health and Neuro Sciences
<b>NIV</b>	National Institute of Virology
<b>NPSP</b>	National Public Health Surveillance Project
<b>NTAGI</b>	National Technical Advisory Group on Immunization
<b>NYKS</b>	Nehru Yuva Kendra Sangathan
<b>PHC</b>	Primary Health Center
<b>PRIs</b>	Panchayati Raj Institutions
<b>PS</b>	Principal Secretary
<b>RCH</b>	Reproductive and Child Health
<b>RMNCH+A</b>	Reproductive, Maternal, Newborn, Child and Adolescent Health
<b>RNA</b>	Ribo Nucliec Acid
<b>RWA</b>	Resident Welfare Association
<b>SARS</b>	Severe Acute Respiratory Syndrome
<b>SARS-CoV-2</b>	Severe Acute Respiratory Syndrome Coronavirus 2
<b>SDM</b>	Sub District Magistrate
<b>SEPIO</b>	State Expanded Programme on Immunization Officer
<b>SIO</b>	State Immunization Officer
<b>SNID</b>	Sub National Immunization Days
<b>SOPs</b>	Standard Operational Procedures
<b>SPMU</b>	State Programme Management Unit
<b>SSC</b>	State Steering Committee
<b>STFI</b>	State Task Force for Immunization
<b>ToTs</b>	Training of Trainers
<b>UNDP</b>	United Nations Development Project
<b>UNICEF</b>	United Nations Children's Fund
<b>UTF</b>	Urban Task Forces
<b>WCD</b>	Women and Child Development
<b>WHO</b>	World Health Organization

**DISCLAIMER:** COVID-19 PANDEMIC IS EVOLVING IN A DYNAMIC MANNER, THEREFORE, THIS OPERATIONAL GUIDELINE IS A LIVE AND DYNAMIC DOCUMENT AND WILL BE UPDATED AS PER THE EVOLVING SITUATION





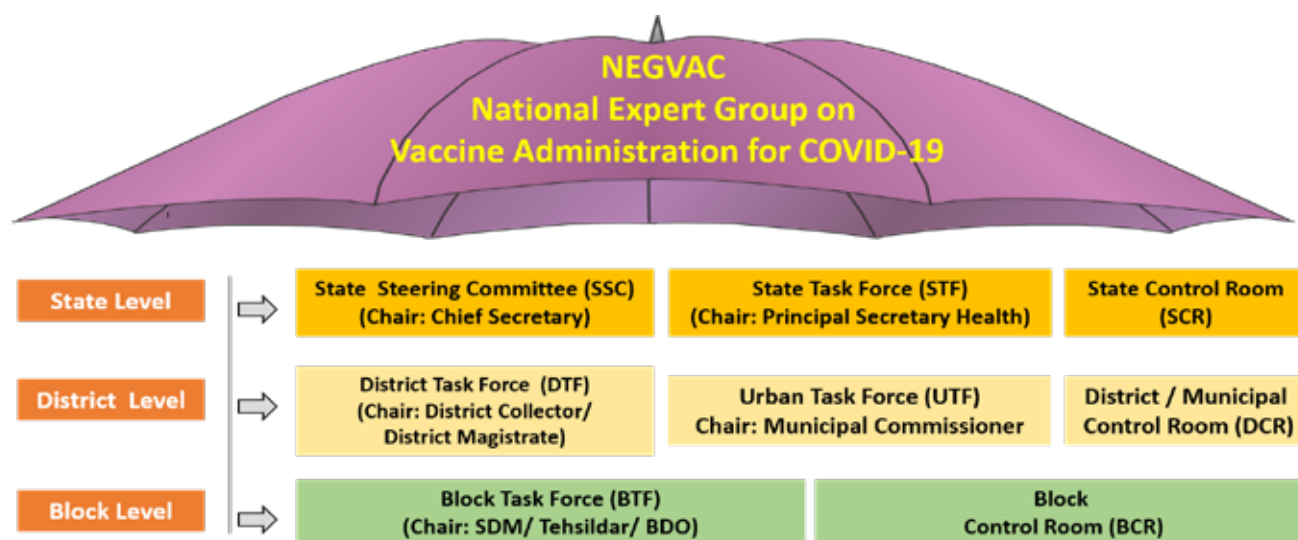


# 1. EXECUTIVE SUMMARY

Coronavirus disease (COVID-19), is an infectious disease caused by a newly discovered coronavirus (SARS-CoV-2), which has spread rapidly throughout the world. In March 2020, the World Health Organization (WHO) declared the COVID-19 outbreak a pandemic. The pandemic has severely ravaged health systems, and economic and social progress globally.

In India, 96,06,810 confirmed COVID-19 cases and over 1,39,700 deaths have been reported as of 4 December 2020.<sup>1</sup> COVID-19 most commonly manifests as fever, dry cough, shortness of breath and tiredness. Most people (~80%) experience mild disease and recover without hospitalization, while around 20% may become more seriously ill.

While countries, including India, have taken strong measures to contain the spread of COVID-19 through better diagnostics and treatment, vaccines will provide a lasting solution by enhancing immunity and containing the disease spread. In response to the pandemic, the vaccine development process has been fast-tracked. Globally, over 274 candidate vaccines are in different stages of development as of 4 December 2020.<sup>2</sup> The majority of vaccines in clinical evaluation as of 4 December 2020 will require a two-dose schedule to be administered two, three or four weeks apart, and is need to be administered through the intramuscular route.<sup>3</sup>



Anticipating that the COVID-19 vaccine may soon be available, the Government of India (GoI) is preparing for its it to be introduced in the country so that it can be expeditiously rolled out when available.

One of the milestones in this direction has been the constitution of a National Expert Group on Vaccine Administration for COVID-19 (NEGVAC). The NEGVAC will guide all aspects of the COVID-19 vaccine introduction in India.

1 <https://www.mohfw.gov.in/> accessed 4 December 2020

2 [https://vac-lshtm.shinyapps.io/ncov\\_vaccine\\_landscape/](https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/) accessed on 4 December 2020

3 <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>, accessed 4 December 2020

High-level coordination at the national, state and district levels must be established for effective cooperation and collaboration among the key departments. 19 ministries at national level, 23 departments at state/district and numerous developmental partners are involved in planning the COVID-19 vaccine introduction; their roles have been described in these operational guidelines.

The Successful introduction of the COVID-19 vaccine will largely depend upon the quality of training conducted for enumerators for beneficiary listing, health functionaries for vaccination activities, social mobilizers for all mobilization activities and communication training for all workers involved in the process of vaccination. As demonstrated during recent experiences with pneumococcal conjugate vaccine (PCV) introduction and polio supplementary immunization activities (SIAs) conducted during the COVID-19 pandemic, national and state training of trainers (ToT) may be successfully conducted on virtual platforms and cascaded to district and sub-district levels using a mix of virtual and face-to-face training. The COVID-19 vaccine will be introduced once all training is completed in the district/block/planning unit.

COVID-19 vaccine will be offered first to healthcare workers, frontline workers and population above 50 years of age, followed by population below 50 years of age with associated comorbidities based on the evolving pandemic situation, and finally to the remaining population based on the disease epidemiology and vaccine availability. The priority group of above 50 years may be further subdivided into those above 60 years of age and those between 50 to 60 years of age for the phasing of roll out based on pandemic situation and vaccine availability. The latest electoral roll for the Lok Sabha and Legislative Assembly election will be used to identify the population aged 50 years or more.

The COVID-19 Vaccine Intelligence Network (Co-WIN) system, a digital platform will be used to track the enlisted beneficiaries for vaccination and COVID-19 vaccines on a real-time basis. At the vaccination site, only pre-registered beneficiaries will be vaccinated per the prioritization, and there will be no provision for on-the-spot registrations.

Based on the numbers of registered beneficiaries and the priority accorded, vaccination sessions will be planned with the following considerations:

- One session for 100 beneficiaries;
- While most of the healthcare and frontline workers would be vaccinated at fixed session sites that may be government health facilities above PHCs or private health facilities identified by district administration, vaccination of other high-risk populations may require outreach session sites, and mobile sites/teams; and
- State/UT can identify specific days for vaccination;
- The entire vaccination process will be broadly similar to the election process.
- The vaccination team will consist of five members as follows:
  - ♦ **Vaccinator Officer**—Doctors (MBBS/BDS), staff nurse, pharmacist, auxiliary nurse midwife (ANM), lady health visitor (LHV); anyone authorized to administer an injection may be considered as a potential vaccinator;
  - ♦ **Vaccination Officer 1:** At least one person (Police, home guard, civil defense, national cadet corps (NCC), national service scheme (NSS), endr yuva kendra sangathan (NYKS) who will check the registration status of a beneficiary at the entry point and ensure the regulated entry to the vaccination session;
  - ♦ **Vaccination Officer 2:** Is the verifier who will authenticate/verify the identification documents; and
  - ♦ **Vaccination Officer 3 & 4** are the two-support staff who will be responsible for crowd management and ensure 30 minutes of waiting time by beneficiary post-vaccination. Support staff will provide information, education and communication (IEC) messages and support to vaccinator as well as the vaccination team.

**Essential health services including existing routine immunization sessions should not be impacted or interrupted.**

Vaccine safety need to be ensured during storage, transportation and delivery of vaccine with sufficient police arrangements so that there are no leakages in the delivery system.

**Safety precautions**, including infection prevention and control practices, safe injection practices and waste disposal, will be followed during vaccination sessions. As large population groups will be vaccinated over a short period with a new vaccine, monitoring the safety of these vaccines will be critical. The existing adverse events following immunization (AEFI) surveillance system will be utilized to monitor adverse events and understand the safety profile of the vaccines. To ensure confidence in the vaccine and the immunization programme during COVID-19 vaccine introduction, states/UTs must rapidly detect and promptly respond to all AEFIs. The reporting of AEFI through surveillance and action for events following vaccination (SAFEVAC) has been integrated with Co-WIN software and every AEFI to be reported at the district level and facilitate the referral mechanisms in case any AEFI needs to be put in place.

Requirements for **management of the cold chain** for COVID-19 vaccination will vary depending on the type of COVID-19 vaccine, as different vaccines have different storage temperature ranges. Cold chain assessments and gap analysis have been completed, and there are plans in place for supplying additional cold chain equipment where required. States/UTs must ensure adequate cold chain storage capacity for the COVID-19 vaccine campaign. Cold chain handlers, and vaccinators at all levels will be trained on procedures for vaccine and logistics management as well as infection prevention and control precautions.

Every effort is being made to ensure that everyone in the country has access to timely, accurate and transparent information about the COVID-19 vaccine(s). This requires a meticulous, structured, informative and clear communication strategy to create adequate awareness, ensure accurate knowledge, generate and manage adequate demand, facilitate eagerness and address vaccine hesitancy and confidence, and mitigate for unintended situations (e.g. AEFI clusters, delay in vaccine roll-out for certain population categories) to ensure the smooth introduction and roll-out of COVID-19 vaccine(s). Key communication and demand generation strategies include advocacy at national, state, district and sub-district levels; capacity building, media engagement, social mobilization and partnership, community engagement and empowerment is included at family and community levels. Key areas to be addressed in the communication plan includes information on COVID-19 vaccine, vaccine eagerness, vaccine hesitancy and COVID-19 appropriate behavior.

A vaccination programme of this scale will require close monitoring and supportive supervision at all levels to identify bottlenecks and challenges faced at the ground level. Each step-in the vaccine introduction will be monitored. This includes:

- **Tracking the progress of introduction activities** – beneficiary registration training, vaccine logistics availability, and task forces. This will be supported by partners through tracking mechanisms;
- **Readiness assessment before vaccine introduction** – field visits and desk review of data at national and state levels;
- **Concurrent monitoring of vaccination activities** – daily evening meetings, standardized monitoring tools, mobile-based apps, real-time data from the planning unit to the national level; and
- **Knowledge management** – the best practices and innovations at all levels would be shared to improve the implementation in the next phase of scale-up.







## 2. INTRODUCTION: COVID-19, PREVENTION, VACCINES

### 2.1 ABOUT COVID-19

**C**oronavirus disease (COVID-19) is an infectious disease that has spread rapidly throughout the world. In March 2020, the World Health Organization (WHO) declared the COVID-19 outbreak a pandemic. The pandemic has severely impacted health systems, economic and social progress throughout the world. From a few thousand confirmed COVID-19 cases in January, cases continue to grow globally, as of 4 December 2020, there have been 6,46,03,428 confirmed cases of COVID-19, including 15,00,614 deaths, reported to WHO<sup>4</sup>

COVID-19 is caused by a newly discovered coronavirus now named as the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Coronaviruses (CoV) are zoonotic, and are transmitted between animals and humans. Coronaviruses cause diseases such as the Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS) and more mild illnesses including the common cold.<sup>5</sup>

The most common signs of infection with COVID-19 include fever, dry cough, shortness of breath or difficulty in breathing, and tiredness or fatigue.<sup>6</sup> Most people (~80%) experience mild disease and recover without requiring hospitalization. However, globally, around 20% of people who contract COVID-19 become more seriously ill and have trouble in breathing.<sup>7</sup> In more severe cases, the infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even lead to death.

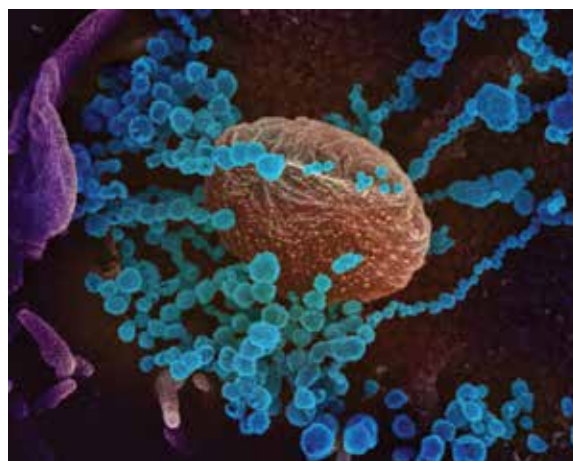


Figure 2.1: Novel Coronavirus SARS-CoV-2.  
Credit: NIAID-RML, NIH Image Gallery.

**In India, 1,01,46,845 confirmed COVID-19 cases and over 1,47,092 deaths** have been reported as of 25<sup>th</sup> December 2020. While strong measures were adopted and some progress was made in containing the spread through better public health interventions, diagnostics and treatments, scientists across the world have accelerated the process to develop a safe and effective vaccine that will break the chain of transmission.

4 <https://covid19.who.int/> accessed 4 December 2020.

5 <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/q-a-coronaviruses>, and <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.htm> accessed 08 October 2020

6 <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/q-a-coronaviruses>, and <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.htm> accessed 08 October 2020

7 <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>, accessed 08 October 2020

## 2.2 PREVENTION OF COVID-19

The best way to prevent infection from COVID-19 is to avoid exposure to the virus. The virus spreads mainly from person-to-person through close contact (within about 2 Gaz). When an infected person coughs, sneezes or talks, respiratory droplets are produced. Other people can catch COVID-19<sup>8</sup> if they breathe in these droplets. In addition, people may come to be infected if they touch surfaces, such as doorknobs or tables on which infected droplets have landed, and then touch their mouth, nose or eyes. COVID-19 also spreads by asymptomatic people.<sup>8</sup>

The basic preventive measures include simple public health measures that are to be followed to reduce the risk of infection with COVID-19. These measures must always be observed by all individuals. These include:

### 2.2.1 PHYSICAL DISTANCING

- Ensure a physical distance of at least **2 gaz or 6 feet** to reduce the spread; and
- Stay away from crowded environments, where physical distancing cannot be ensured.

### 2.2.2 USE OF MASK – WEARING A MASK PROPERLY

- Ensure hand hygiene (thorough washing of hands by soap & water or use an alcohol-based sanitizer), is performed before putting on the mask;
- Place the mask carefully, ensuring it covers the mouth and nose, and tie it securely to minimize any gaps between the face and the mask;
- Avoid touching the mask while wearing it. If a used mask is inadvertently touched, use an alcohol-based hand rub or soap and water to clean hands;
- Replace masks as soon as they become damp with a new clean, dry mask;
- Remove the mask using the appropriate technique: do not touch the front of the mask but untie it from behind or from the straps;
- After removal of the used mask, clean hands either using alcohol-based hand rub or use soap and water (if hands are visibly soiled); and
- Do not re-use single-use masks. Discard after each use and dispose them of in a closed bin immediately upon removal.

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<sup>8</sup> <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html> and <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/q-a-coronaviruses>, accessed 08 October 2020

## 2.2.3 HAND HYGIENE

The WHO guidelines on hand hygiene in healthcare (2009) suggest that<sup>9</sup> hand hygiene is the single most important measure for the prevention of infection. Practice frequent hand washing (for at least 40-60 seconds) even when hands are not visibly dirty and use alcohol-based hand sanitizers (for at least 20 seconds).

- Use appropriate product and technique;
- Rub hands for 20–30 seconds, using an alcohol-based hand rub product is preferable, if hands are not visibly soiled; and
- Wash hands for 40–60 seconds with soap and running water and dry with a single-use towel, when hands are visibly dirty or contaminated with proteinaceous material.



## 2.2.4 RESPIRATORY HYGIENE

Respiratory hygiene are measures taken by a person to contain respiratory secretions and prevent the transmission of the infection to other persons. Good respiratory hygiene/cough etiquette can reduce the spread of microorganisms into the environment that cause respiratory infections.

**The following measures are recommended:**

- Cover the nose and mouth when sneezing and/or coughing with a tissue or your sleeve/inside of your elbow, if no tissue is available;
- Perform hand hygiene afterwards with alcohol-based hand rub products or water and soap if hands are visibly soiled;
- Stay away from others when ill (particularly for health workers to avoid coming to work when ill);
  - ◆ Avoid introductory shaking hands;
  - ◆ Avoid close contact with people who exhibit symptoms; and
  - ◆ Wear a mask if showcasing respiratory symptoms.



<sup>9</sup> WHO guidelines on hand hygiene in health care. WHO; 2009 (<https://www.who.int/gpsc/5may/tools/9789241597906/en/>)



## 2.2.5 PROMPT SELF ISOLATION

All those who get symptoms of COVID-19 should seek medical advice and get promptly isolated at home. This will help to prevent spread of infection and thereby, save your family members, neighbors and friends from disease.



## 2.2.6 PROMPT TESTING

A person having symptoms such as fever, dry cough, shortness of breath or difficulty in breathing, and tiredness or fatigue should seek medical advice to get tested for COVID-19 infection. These tests are available at government hospitals as well as private laboratories. Early detection of COVID-19 infection helps in management and prevention of complications.

## 2.3 VACCINES FOR COVID-19

The overarching goal is for COVID-19 vaccines to contribute significantly to the equitable protection and promotion of human well-being among people globally. Global equitable access to a vaccine, particularly protecting health care workers and those most-at-risk is the only way to mitigate the public health and economic impact of the pandemic and is the current priority. The vaccine is to be used in conjunction with other control measures. In the longer term, the vaccine is intended to be used for active immunization of people at-risk to prevent COVID-19. While countries, including India, have taken strong measures to contain the spread of COVID-19 through better diagnostics and treatment, vaccines will provide a solution by enhancing immunity and containing the disease spread.



Scientists throughout the world have accelerated the process to develop safe and effective COVID-19 vaccines. Vaccines aim to expose the body to an antigen and provoke an immune response that can block or kill the virus if a person becomes subsequently infected, without causing the disease. As part of the global efforts for rapid development of a safe and effective COVID-19 vaccine, various scientific techniques like the use of different viruses or viral parts<sup>10</sup> are being developed. The COVID-19 vaccines under development use one of the following techniques:



### **VIRUS VACCINES**

These vaccines use the virus itself in a weakened or inactivated form. Vaccines against measles and polio (oral) are made in this manner. There are two types of virus vaccines under development against coronavirus, weakened virus and inactivated virus vaccines.<sup>10</sup>

### **VIRAL-VECTOR VACCINES**

In the development of these vaccines, a virus (such as adenovirus or measles), is genetically engineered to produce coronavirus proteins in the body, but the virus is weakened and cannot cause disease. The two types of viral-vector vaccines under development are replicating viral vector (can replicate within cells) and non-replicating viral vector (cannot replicate within cells).<sup>10</sup>

### **NUCLEIC-ACID VACCINES**

In these vaccines, nucleic acid (DNA or RNA) is inserted into human cells. These human cells then produce copies of the virus protein which produces an immune response. The two types of nucleic-acid vaccines under development are DNA vaccine and RNA vaccine.<sup>10</sup>

### **PROTEIN-BASED VACCINES**

These vaccines use virus protein fragments or protein shells which are injected directly into the body. The two types of protein-based vaccines being developed against the coronavirus are the protein subunit vaccines and virus-like particle vaccines.<sup>10</sup>

<sup>10</sup> <https://www.bing.com/search?q=5.+The+race+for+coronavirus+vaccines%3A+a+graphical+guide+%26+cvid=28742fcc7339430588804723de9c6831&pglt=547&FORM=ANSPA1&PC=U531>

## 2.3.1 DEVELOPMENT OF COVID-19 VACCINE

The Development of a vaccine is a time-consuming process that includes the following phases:

**Table.2.1. Phases of vaccine development**

Phases of vaccine development/trial	Purpose
Pre-clinical	Vaccine development in laboratory
Phase 1 Clinical trial (8-10 participants)	For testing vaccine safety
Phase 2 Clinical trial (50-100 participants)	For testing vaccine immunogenicity i.e. production of antibodies against virus
Phase 3 Clinical trial (30,000-50,000 participants)	For testing actual protection offered by the vaccine

The vaccine development process has been fast-tracked and multiple platforms are under development. Among those with the greatest potential for speed are DNA and RNA-based platforms, followed by those for developing recombinant-subunit vaccines. RNA and DNA vaccines can be made quickly because they require no culture or fermentation, instead use synthetic processes.<sup>11</sup>

Per the tracker developed by the Vaccine Centre at the London School of Hygiene and Tropical Medicine, a total of 274 candidate vaccines are in different stages of development as of 4 December 2020, preclinical (215), phase I (25), phase I/II (17), phase II (5), phase II/III (1), phase III (10) and licensed (1).<sup>12</sup>

**Table 2.2: Progress on COVID-19 Vaccine Development (Source: Vaccine Centre of London School of hygiene and Tropical Medicine, accessed 4 December 2020).**

Types of COVID-19 vaccines		Pre-clinical	Phase I	Phase I/II	Phase II	Phase II/III	Phase III	Licensed
Virus Vaccine	Live-attenuated	3	1					
	Inactivated virus	11	1	2	1		4	
Viral vector vaccine	Replicating viral vector	18	1	2	1			
	Non-replicating viral vector	26	6				4	
Nucleic acid vaccines	DNA vaccine	16	2	5				
	RNA vaccine	29	2	2	1		1	1
Protein based vaccine	Protein subunit	64	9	5	2		1	
	Virus like particle	17		1		1		
Unknown	–	31	3					
<b>Total</b>		<b>215</b>	<b>25</b>	<b>17</b>	<b>5</b>	<b>1</b>	<b>10</b>	<b>1</b>

With multiple COVID-19 vaccines under development, key characteristics regarding dosage, storage requirements, efficacy, route of administration, etc., currently remain unknown. However, a recent landscape document by WHO<sup>13</sup> details 51 vaccines in clinical evaluation. The landscape document, as of 2 December 2020, indicates that most vaccines will require a two-dose schedule to be administered two, three or four weeks apart, and will be administered through-the intramuscular IM route.

11 Developing Covid-19 Vaccines at Pandemic Speed Nicole Lurie, M.D., M.S.P.H., Melanie Saville, M.D., Richard Hatchett, M.D., and Jane Halton, A.O., P.S.M.

12 [https://vac-lshtm.shinyapps.io/ncov\\_vaccine\\_landscape/](https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/) accessed on 4 December 2020

13 <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>

## VACCINE SPECIFICATIONS

In June 2020, the United Nations Children’s Fund (UNICEF) gathered information on vaccine specifications from 26 vaccine developers and manufacturers (10 manufacturing in China, 6 in India, 3 in the United States of America, 2 each in Belgium, Russia and Japan, 1 each in France, South Korea, Switzerland and the United Kingdom).

From the results, which were made public on 31 August 2020, characteristics of the COVID-19 vaccines under development from these 26 developers are:

### Common characteristics of vaccines under advanced stages:

- Mostly liquid products (few are freeze-dried);
- Majority are intramuscular injections;
- Majority are 2-dose courses;
- Most vaccines would be provided in a multi-dose vial; and
- Most have a targeted temperature range of 2°C to 8°C, however, there is a possibility of temperature requirements of -60°C and a shorter life.

Of the four vaccines with preliminary efficacy data available as of 4 December 2020, all are intramuscular (IM) injections with 2-dose courses.

- The University of Oxford/AstraZeneca vaccine can be stored, transported and handled at +2° to 8°C.<sup>14</sup>
- BioNTech/Fosun Pharma/Pfizer vaccine has a recommended temperature condition of -80°C and can be stored for five days at +2° to 8°C.<sup>15</sup>
- The Moderna/NIAID vaccine remains stable at -20°C for up to six months and remains stable at +2° to 8°C for 30 days<sup>16</sup> and the Gamaleya institute, Sputnik-V vaccine can be stored at +2° to 8°C.<sup>16</sup>

## 2.4 COVID-19 VACCINE DEVELOPMENT IN INDIA

There are 9 COVID-19 vaccine candidates in different phases of development in India, of these 3 are in pre-clinical phase whereas 6 are under clinical trials.

**Table.2.3. Indian landscape of COVID-19 vaccines under development**

S. No	Product	Indian Manufacturer	Collaborator	Current stage
1	Covishield (Chimpanzee Adenovirus)	Serum Institute of India, Pune	Astra Zeneca	Phase II/III
2	Covaxin (Inactivated Virus)	Bharat Biotech International Ltd, Hyderabad	Indian Council of Medical Research, India	Phase III (advanced)
3	ZyCoV-D (DNA vaccine)	Cadila Healthcare Ltd, Ahmedabad (Zydus Cadila)	Dept of Biotechnology, India	Phase II (advanced)
4	Sputnik V (Human Adenovirus vaccine)	Trialed and manufactured in India by Dr. Reddy Lab.	Gamaleya National Center, Russia	Phase-II over, Phase-III to start
5	NVX-CoV2373 (Protein Subunit)	Serum Institute of India, Pune	Novavax	Ph III under consideration in India
6	Recombinant Protein Antigen based vaccine	Biological E Ltd, Hyderabad	MIT, USA	Phase I plus II human clinical trials started
7	HGCO 19 (mRNA based vaccine)	Genova, Pune	HDT, USA	Pre clinical animal studies over.
8	Inactivated rabies vector platform	Bharat Biotech International Ltd, Hyderabad	Thomas Jefferson University, USA	Pre-clinical (Advanced)
9	Vesiculo Vax Platform	Aurobindo Pharma Ltd, Hyderabad	Aurovaccine, USA	Pre-clinical (Advanced)

14 UNICEF: Expression of Interest for supply of COVID-19 vaccines. <https://www.unicef.org/supply/sites/unicef.org/supply/files/2020-08/COVID-19-vaccine-expression-of-interest-for-procurement-general-public-briefing-August-2020.pdf>, accessed 08 October 2020.

15 [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/941452/Information\\_for\\_healthcare\\_professionals.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/941452/Information_for_healthcare_professionals.pdf)

16 About Vaccine | Official website vaccine against COVID-19 Sputnik V. ([sputnikvaccine.com](http://sputnikvaccine.com))

# ಮಂಗಳೂರು ಮಹಾನಗರ ಪಾಲಿಕೆ ಮಂಗಳಾ ಸಭಾಂಗಣ



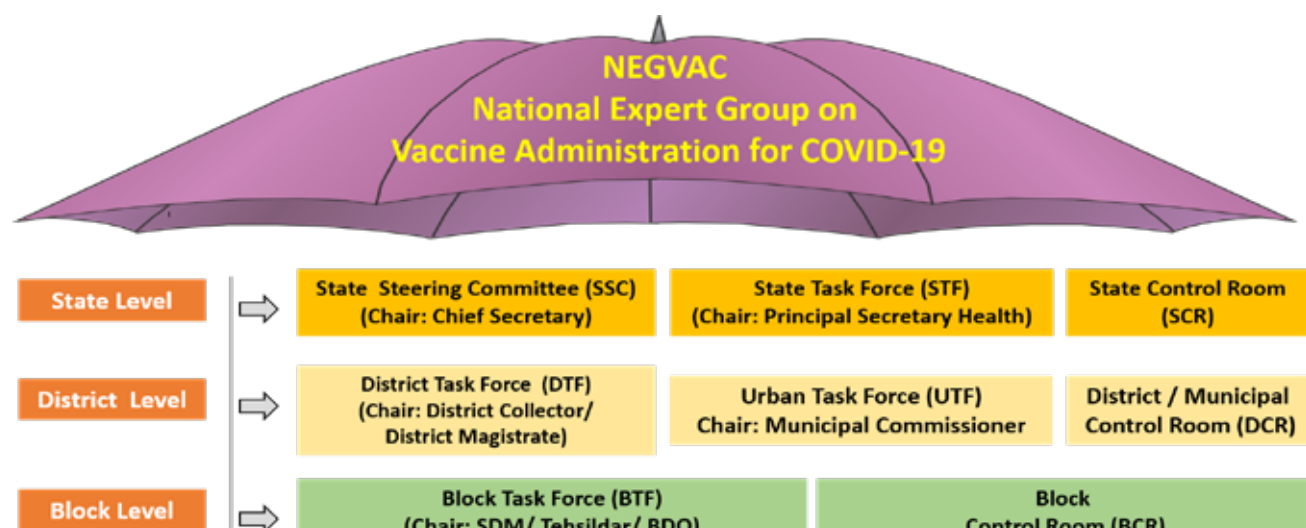




## 3. MULTILEVEL GOVERNANCE MECHANISMS

The highest level of political and administrative ownership, commitment and support needs to be sustained for the successful implementation of the COVID-19 vaccine.

The structure of the governance mechanism for COVID-19 response is as follows:



### 3.1 NATIONAL LEVEL

To fast-track policy decisions and timely implementation, the following mechanisms are established:

#### 3.1.1 NATIONAL EXPERT GROUP ON VACCINE ADMINISTRATION FOR COVID-19 (NEGVAC)

NEGVAC has been constituted under chairpersonship of Member (Health) NITI Aayog and Co-chairpersonship of the Secretary (Ministry of Health and Family Welfare) with the representation from Secretaries from Ministry of External Affairs, Department of Biotechnology, Department of Health Research, Department of Pharmaceuticals, Ministry of Electronics and Information Technology and Director General Health Services, Director of AIIMS Delhi, Director NARI representatives from the National Technical Advisory Group on immunization (NTAGI), Ministry of Finance and 5 State Governments representing all the regions in India.

NEGVAC aims to guide on all aspects of the COVID-19 vaccine introduction in India including regulatory guidance on vaccine trials, vaccine selection, equitable distribution of vaccine, procurements, financing, delivery mechanisms, prioritization of population groups, vaccine safety surveillance, regional cooperation and assisting neighboring countries, communication & media response etc.

### 3.2 STATE LEVEL

At the state level, there will be a Steering Committee, a Task Force and control room as given below. The composition and activities of the various committees is indicative, and states may add members and enhance their activities based on local contexts and requirements.

## 3.2.1 STATE STEERING COMMITTEE

**Chairperson:** Chief Secretary

**Convener:** Principal Secretary, Health

**Members:** Government Departments: Health, Women & Child Development (WCD), Rural Development & Panchayati Raj, Municipal Corporations, Urban Development, Revenue department, Home department, Social Welfare, Sports & Youth Affairs, National Cadet Corps (NCC), Nehru Yuva Kendra Sangathan (NYKS), National Service Scheme (NSS), Education, Minority Affairs, Information & Broadcasting, Labor and Employment, Transport, Mining, Tribal Affairs, other relevant departments and representatives of central ministries/departments/agencies needed for COVID-19 vaccination purpose (Railways, Central Paramilitary forces, Defence establishments etc.)

**Development partners** - World Health Organization (WHO), United Nations Children's Fund (UNICEF), United Nations Development Programme (UNDP), Bill & Melinda Gates Foundation (BMGF), John Snow Inc (JSI), Clinton Health Access Initiative (CHAI), Infrastructure Professionals Enterprise Private Limited (IPE Global), Rotary International, Lions Club International and representatives from NGOs & civil society organization (CSOs) which can contribute to COVID-19 vaccination activities.

**Frequency:** At least once in a month. Additional meetings may be held if required.

## ACTIVITIES TO BE CONDUCTED

### 1. PREPARATORY PHASE

- Ensure active engagement of other line departments for various activities related to the COVID-19 vaccine introduction as and when the vaccine is made available.
- Oversight on creating a database of Health Care Workers (HCWs) for COVID-19 vaccination in the Co-WIN software which will prioritize beneficiaries for vaccination in the 1st phase.
- Review of the state's preparatory activities in terms of cold chain preparedness, operational planning, communication planning, strategies for anticipated state-specific challenges in terms of geographical terrain, network connectivity, hard to reach areas etc.
- Mobilize human/other resources and coordinate planning and other activities with other departments. HR with expertise in medical/health may be utilized for vaccination while other HR personnel may be used for operational support, IEC, resource mobilization, community mobilization etc.
- Financial planning for COVID-19 vaccine introduction amongst the priority groups.
- Explore the utilization of Corporate Social Responsibility (CSR) for financing various activities related to COVID-19 vaccination.
- Devising a plan for the utilization of Common Service Centres and other public infrastructure as per need.
- Review and ensure that regular meetings of the State Task Force (STF) and District Task Force (DTF) are held.
- Ensure that the State AEFI Committee and District AEFI Committees are expanded, members are oriented on AEFI surveillance and regular meetings are held.

### 2. IMPLEMENTATION PHASE (UPON THE AVAILABILITY OF A VACCINE)

- An oversight on microplanning and other operational aspects of COVID-19 vaccine introduction.
- Ensure active involvement of all concerned departments and stakeholders as per their pre-defined roles in the process of the COVID-19 vaccine introduction.
- Ensure early tracking of social media and other platforms for possible misinformation and rumors around the COVID-19 vaccine that could impact the community acceptance of the COVID-19 vaccine.

- Ensure safe storage, transportation and delivery of vaccine doses with sufficient police arrangements so that there are no leakages in the delivery system.
- Devise innovative strategies to improve community engagement 'Jan Bhagidaari' for improved coverage of the COVID-19 vaccine.
- Regular review of coverage of the COVID-19 vaccine and guidance to STF for corrective actions.
- Institute reward/recognition mechanisms for best performing district/block/urban area/ ward etc.
- Ensure that all AEFIs are investigated on a timely basis and causality assessment is expedited.

### 3.2.2 STATE TASK FORCE FOR IMMUNIZATION

**Chairperson:** Additional Chief Secretary/Commissioner/Principal Secretary, Health

**Member Secretary:** State Immunization Officer (SIO)

**Members:** Mission Director, National Health Mission (MD, NHM) and other State-level implementing officers from the health department, key government departments like Urban development, Information and Public Relations, Women & Child Development including Integrated Child Development Services (ICDS), Panchayati Raj Institutions (PRI), Urban local bodies, Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH), representatives of Central Government Ministries & Institutions which have healthcare workers (HCWs) and frontline workers (FLWs) that need to be vaccinated and also those who can contribute to vaccination process like ESIC hospitals, Railways Hospitals, Defence Forces representatives, CPSU hospitals, Central Armed Forces personnel etc., partner agencies like WHO, UNICEF, UNDP, BMGF, JSI, CHAI, IPE Global etc., NGOs & civil society organization (CSOs), which can contribute to COVID-19 vaccination activities, Indian Medical Association (IMA) etc.

**Frequency of meeting:** At least once every fortnight. Additional meetings may be held as per need.

## ACTIVITIES TO BE CONDUCTED

### 1. PREPARATORY PHASE

- Regularly monitor the progress of the database of beneficiaries on the COVID-19 Vaccine Intelligence Network (Co-WIN).
- Provide guidance, including funding and operational guidelines, and fix timelines for districts to plan and implement the introduction of the COVID-19 vaccine as and when the vaccine is made available.
- Involve other relevant departments including ICDS, PRI, Urban local bodies and key immunization partners such as UNDP, UNICEF, WHO, Rotary International, lead partners and other organizations at the state level. CSOs, including professional bodies such as IMA should also be involved.
- Review cold chain preparedness across the state for the possible introduction of the COVID-19 vaccine and guide strengthening measures for the same given the increased cold chain space requirement.
- Identify vaccinators across government and private sectors to minimize the disruption of Routine Immunization services while introducing the COVID-19 vaccine. Anyone authorized to administer an give injection may be considered a potential vaccinator.
- Planning and mapping of vaccination sessions where HCWs/FLWs/other Priority Groups like those above 50 years of age will be vaccinated during the initial phase of the COVID-19 vaccine roll-out.
- Mapping of human resources across departments that could be deployed for vaccination sessions for verification of beneficiaries, crowd management and overall coordination at the session site.
- Communicate with District Magistrates (DM) to conduct meetings of the District Task Forces for Immunization (DTFI).
- Ensure that the District AEFI Committees are expanded, members are oriented on AEFI surveillance and regular meetings are held.

## 2. IMPLEMENTATION PHASE (UPON THE AVAILABILITY OF THE VACCINE):

- Track districts for adherence to timelines for the overall implementation of the COVID-19 vaccine introduction as per the guidelines approved by NEGVAC and communicated from the national level.
- Deploy senior state-level health officials to each district identified for monitoring and ensuring accountability of the framework. They should visit these districts and oversee the activities for the roll-out of the COVID-19 vaccine, including participation in DTFI meetings and assessment of district preparedness.
- Develop a media plan to address rumor-mongering as well as vaccine eagerness. Ensure an adequate number of IEC materials (as per prototypes) are printed and disseminated to districts in time.
- Involve youth organizations like NCC/NYKS/NSS for social mobilization of the identified group of beneficiaries to be prioritized from time to time. Similarly, ensure the involvement of self-help groups.
- Regularly evaluate with districts and urban local bodies to review and resolve issues related to microplanning, vaccines and logistics, human resources availability, training, waste management, AEFI and IEC, and behaviour change communication (BCC).
- Review and to issue a need-based approval of additional fund requirement.
- Ensure that all AEFIs are investigated timely and causality assessment is expedited.

### 3.2.3 STATE CONTROL ROOM

A state control room will be set up by the SEPIO, with the participation of key officials responsible for Cold Chain and IEC/social mobilization and partners including WHO, UNICEF, UNDP etc. It will have 24\*7 telephone helpline.

They will be involved in day to day planning especially mobilization of human and other resources like transport; inter-sectoral coordination, implementation and monitoring of activities during the COVID-19 vaccination preparedness and roll out. They need to oversee that while planning for the sessions and session site allocation, the respective district includes the HCWs and FLWs belonging to Central Government Institutions.

A clear chain of command, communication system and accountability framework should be established to ensure that there is no delayed decision making. Control room should function round the clock with senior officers linked to it to take decisions and provide guidance to field level operations. The control room will provide regular feedback to the State Steering Committee and STFI on the progress.

## 3.3 DISTRICT LEVEL

### 3.3.1 DISTRICT TASK FORCE (DTF)

The composition and activities of the District Task Forces is indicative, and districts may add members and enhance their activities based on local contexts and requirements.

**Chairperson:** District Magistrate

**Member Secretary:** District Immunization Officer (DIO)

**Responsibility:** Chief Medical Officer (CMO)

**Members:** CMO, key departments including WCD, PRI, Urban Development, Cantonment boards, Sports & Youth Affairs, National Cadet Corps (NCC), Nehru Yuva Kendra Sangathan (NYKS), National Service Scheme (NSS), Education, Social Welfare, Minority Affairs, Information & Broadcasting, Railways, Home dept., Revenue dept., Labor dept., Mining, Tribal Affairs, Energy/Power department, representatives of Central Government Ministries & Institutions which have healthcare workers (HCWs) and frontline workers

(FLWs) that need to be vaccinated and who can also contribute to vaccination process (e.g. ESIC hospitals, Railways Hospitals, hospitals of Defence Forces, representatives of Defence Forces, Central Armed Forces personnel, CPSU hospitals, etc., Institutions and any other relevant departments and District-level partner agencies like WHO, UNICEF, UNDP, BMGF, JSI, CHAI, Rotary International, Lions Clubs International etc. representatives from NGOs & civil society organizations (CSOs) which can contribute to COVID-19 vaccination activities in the district's context, professional bodies like IMA.

**Frequency:** Weekly

## ACTIVITIES TO BE CONDUCTED

### 1. PREPARATORY PHASE

- Monitor progress of database of beneficiaries on COVID-19 Vaccine Intelligence Network (Co-WIN).
- Ensure training of all concerned HR on COVID-19 Vaccine Intelligence Network (Co-WIN).
- Monitor progress on key activities such as microplanning, communication planning, cold chain and vaccine logistics planning. Accountability to be fixed for each activity at all levels.
- Planning and mapping of vaccination sessions where HCWs and FLWs (including those of central ministries) and other Priority Groups like those above 50 years of age will be vaccinated during the initial phase of COVID-19 vaccine roll-out.
- Involve other relevant departments including ICDS, PRI, ULBs, Central Ministries & Institutions and key immunization partners such as UNDP, UNICEF, WHO, Rotary International, lead partners and other organizations at district levels. CSOs, including professional bodies such as IMA should be involved. Involve local and religious leaders.
- Identify vaccinators across government and private sectors to minimize disruption of Routine Immunization services while introducing COVID-19 vaccine. Anyone authorized to give injection may be considered as potential vaccinator.
- Mapping human resources across departments that could be deployed for vaccination sessions for verification of beneficiaries, crowd management and overall coordination at session site.

### 2. IMPLEMENTATION PHASE (UPON AVAILABILITY OF VACCINE)

- Monitor the roll-out of COVID-19 vaccine in the district for progress made and resolving bottlenecks.
- Requisition of required human resource and infrastructure including vehicles if needed from other departments for implementation and monitoring.
- Ensure all Central Ministries/Institutions related healthcare workers (HCWs) and frontline workers (FLWs) as per NEGVAC decisions are covered for vaccination sites and also with vaccination. For Defence personnel, district shall ensure that sufficient vaccine is allotted to them to undertake the vaccination of the Defence Forces which will be organized by the Defence hospitals. The allotment of vaccine to Defence personnel posted at states/districts will be indicated by MoHFW separately.
- Ensure minimal disruption of other routine health services during rollout of COVID-19 vaccine.
- Ensure identification and accountability of senior officers in the blocks and the urban areas. They should visit these blocks and provide oversight to activities for rollout of COVID-19 vaccine, including participation in training, monitoring etc.
- Ensure safe storage, transportation and delivery of vaccine doses with sufficient police arrangements so that there are no leakages in the delivery system.
- Robust communication planning at all levels to address rumor mongering as well as vaccine eagerness. Ensure adequate number of printed IEC materials (as per prototypes) are printed and disseminated to blocks/planning units in time. Ensure that these materials are discussed and used in the sensitization workshops.
- Track blocks and urban areas for adherence to timelines for various activities required for introduction of COVID-19 vaccine.



- Ensure timely disbursement of funds to ASHAs, Alternate vaccinators and alternate vaccine delivery (AVDs) persons engaged in COVID-19 vaccine drive.
- Share key qualitative and quantitative feedback at state level for review.
- Monitor meetings of District AEFI Committee for expedited investigation of AEFI cases.

### 3.3.2 URBAN TASK FORCE (UTF)

In urban areas where the health services are under the ambit of Municipal Corporations, Urban Task Force should be constituted on the lines of District Task Force. The Urban Task Force will be **chaired by Municipal Commissioner** and the member secretary will be Municipal Health Officer/Chief Medical Officer of the Municipal Corporation.

The urban task force will have similar composition and activities as District Task Force.

### 3.3.3 DISTRICT CONTROL ROOM/URBAN CONTROL ROOM

A District Control Room should be set up at the district level by the DIO with participation of District Program Manager, Nodal Officer, National Urban Health Mission (NUHM), District Cold Chain Officer, representatives of key departments and partner representatives. Ensure participation of mahila arogya samitis (MAS), CSOs, residence welfare associations (RWAs), religious leaders, CSOs, non-governmental organizations (NGOs), and private practitioners or any other key stakeholders at local level.

In Municipal Areas, an Urban Control Room should be chaired by Medical Officer of the Municipal Corporation with the participation of Municipal Health Officer and relevant officials, departments and stakeholders as detailed above for District Control Room.

District Control Room/Urban Control Room will monitor preparedness of blocks/PHCs/urban areas on a day-to-day basis, monitor implementation of the vaccine roll out during the activity and give feedback to the State Control Room. It will also collate, compile, analyse and report administrative coverage. It will also have 24\*7 telephone helpline.

A clear chain of command, communication system and accountability framework should be established to ensure that there is no delayed decision making. Control room should function round the clock with senior officers linked to it to take decisions and provide guidance to field level operations. The control room will provide regular feedback to the DTFI on the progress.

## 3.4 BLOCK LEVEL

### 3.4.1 BLOCK TASK FORCE (BTF)

The composition and activities of the Block Task Forces is indicative, and blocks may add members and enhance their activities based on local contexts and requirements.

**Chairperson:** Sub-Divisional magistrate/Tehsildar/(Block Development Officer) BDO

**Convener:** Block Medical Officer In-charge

**Members:** Government Departments: Block Development Officer, Child Development Project Officer (CDPO), Block Education Officer, Elected Representative of Block Panchayat, Representative of youth organizations like National Cadet Corps (NCC), Nehru Yuva Kendra Sangathan (NYKS), National Service Scheme (NSS), Representative of any other relevant departments like Public Works Department, Animal Husbandry, NGOs working in Health sector, Power department officials.

**Development partners:** WHO, UNICEF, Other Partners, Community Based Organizations, Local Non-Government Organizations, Rotary International, Lions Club International and representatives from NGOs & CSOs subject to their presence at block level, local influencers and religious leaders.

**Frequency:** Weekly

## ACTIVITIES TO BE CONDUCTED

### 1. PREPARATORY PHASE

- Monitor progress of database of beneficiaries to be shared with district for upload on Co-WIN software.
- Ensure training of all concerned HR on Co-WIN software.
- Monitor progress on key activities such as microplanning, communication planning, cold chain and vaccine logistics planning. Accountability to be fixed for each activity.
- Planning and mapping of vaccination sessions where HCWs/ FLWs/other Priority Groups like those above 50 years of age will be vaccinated during the initial phase of COVID-19 vaccine roll-out.
- Involve all relevant departments including ICDS, PRI and key immunization partners such as UNICEF, WHO, Rotary International, Civil Society Organizations, Non-Government Organizations at block level.
- Identify vaccinators across government and private sectors to minimize disruption of Routine Immunization services while introducing COVID-19 vaccine. Anyone authorized to give injection may be considered as potential vaccinator.
- Mapping human resources across departments that could be deployed for vaccination sessions for verification of beneficiaries, crowd management and overall coordination at session site
- While planning for the sessions and session site allocation, it will be the prime responsibility of respective district to include the HCWs and FLWs belonging to Central Government Institutions.

### 2. IMPLEMENTATION PHASE (UPON AVAILABILITY OF VACCINE)

- Monitor the roll-out of COVID-19 vaccine in the block for progress made and resolving bottle-necks.
- Requisition of required human resource and infrastructure including vehicles if needed from district and/or other department for implementation and monitoring.
- Ensure minimal disruption of other routine health services during rollout of COVID-19 vaccine.
- Ensure supervision of vaccination sessions being conducted for COVID-19 vaccine.
- Implementation of communication plan while addressing the local context and needs to address rumor mongering as well as vaccine eagerness. Maximize use of local influencers (including religious leaders) for countering misinformation.
- Ensure adequate number of IEC material pertaining to COVID-19 vaccination is displayed at prominent places and at session site.
- Ensure adherence to timelines for various activities required for introduction of COVID-19 vaccine.
- Ensure timely disbursement of incentives to ASHAs, Alternate Vaccinators and Alternate Vaccine Delivery (AVD) Human resources involved in COVID-19 vaccination drive.
- Share key qualitative and quantitative feedback at district level for review.

### 3.4.2 BLOCK CONTROL ROOM

A control room should be set up at the block level by the Medical Officer In charge, with participation of Block Program Officers, representatives from ICDS, education and other government departments, Block Cold Chain Officer including partner representatives. It will monitor preparedness in blocks/PHCs/ urban areas on a day-to-day basis, monitor implementation of the vaccine roll out during the activity and give feedback to the District Control Room. It will also collate, compile, analyse and report administrative coverages.





## 4. INTERSECTORAL CONVERGENCE

The highest level of political and administrative ownership, commitment and support is vital for successful planning and implementation of COVID-19 vaccination. Coordination mechanisms at national, state, district and block levels established for effective cooperation and collaboration among the key ministries/departments at all levels.

### Key Ministries and Institutions coordinating at national level

Under the guidance of NEGVAC, various ministries are converging at national level to support various aspects of COVID-19 vaccination. The individual ministries have been communicated about the support required in COVID-19 vaccine roll out:

S.No	Name of Ministries/Departments
1	Ministry of Women and Child Development
2	Ministry of Rural Development
3	Ministry of Housing and Urban Affairs
4	Ministry of Human Resource Development
5	Ministry of Panchayati Raj
6	Ministry of Defence
7	Ministry of Home Affairs
8	Ministry of Sports and Youth
9	Ministry of Information and Broadcasting
10	Ministry of AYUSH
11	Ministry of Railways
12	Ministry of Power
13	Ministry of Food and Consumer Affairs
14	Ministry of Social Justice and Empowerment
15	Ministry of Tribal Affairs
16	Ministry of Minority Affairs
17	Department of Animal Husbandry
18	Ministry of Labour & Employment
19	Ministry of Information Technology

### Inter-departmental coordination at state, district and block levels

It is important that all stakeholders should collectively work in coordination and synergy towards successful planning and implementation of COVID-19 vaccination. State steering committee, task forces at state, district and urban / blocks task forces will provide oversight for intersectoral coordination at corresponding respective levels.



The roles and responsibilities of each department is illustrated in the table below, however, state may customize and expand the list of responsibilities of the departments involved as per local requirement. Convergence of medical college representatives, professional bodies such as Indian Medical Association (IMA), Indian Academy of Paediatricians (IAP), representatives at district level, developmental partners including WHO, UNICEF, UNDP, BMGF, voluntary organizations such as NCC, NSS and NYKS, non-government organizations such as Lions Club International, Rotary International, Red Cross, CSOs etc will be required. Department of Information and Publicity and state media agencies will need to be optimally utilized during the campaign. Designated officers including those from Information and Broadcasting (I&B) department would need to be involved in organizing and overseeing all communication and public relations' (PR) activities to ensure effective communication with stakeholders, media and the public at state and district level.

## 4.1 ROLES OF DIFFERENT MINISTRIES/DEPARTMENTS IN COVID-19 VACCINE IMPLEMENTATION

Roles expected from different government departments to support COVID-19 vaccination have been defined, however, the list is indicative and task forces may engage with more departments or assign additional roles depending on local needs.

S.No	Department	Vaccine rollout - Planning & Implementation	Social Mobilization and awareness generation
1	Women and Child Development / Integrated Child Development Services (ICDS)	<ul style="list-style-type: none"> <li>Share data on ICDS staff for inclusion in COVID-19 vaccine beneficiary list</li> <li>Provide team members and monitors for vaccination</li> <li>Support supervision and monitoring of vaccination</li> </ul>	<ul style="list-style-type: none"> <li>Capacity building of AWW / other staff on interpersonal communication for COVID 19 Vaccine</li> <li>Generate community awareness on COVID-19 vaccination mainly through inter personal communication (IPC)</li> </ul>
2	Panchayati Raj	<ul style="list-style-type: none"> <li>Ensure registration of health care workers working in health facilities under Zila Parishad/ Panchayat</li> <li>Identification and planning for vaccination site</li> <li>Support in organizing vaccination sessions including vaccine site preparation and logistics</li> </ul>	<ul style="list-style-type: none"> <li>Create awareness through community meetings, Special Gram Sabhas and messages to PRIs</li> </ul>
3	Rural Development	<ul style="list-style-type: none"> <li>Support SHG engagement in vaccine roll out at vaccination site including working as team members, (wherever needed)</li> <li>SHG support in logistics management, including vaccine site preparation, cleaning etc.</li> <li>BDOs and village functionaries to help in vaccine delivery and monitoring</li> <li>SHG engagement &amp; support in effective communication at grass roots level to address issues of "vaccine hesitancy" &amp; "vaccine eagerness"</li> </ul>	<ul style="list-style-type: none"> <li>Through National Rural Livelihood Mission (NRLM) engage all SHGs for social mobilization, awareness generation, house visits etc.</li> <li>SHGs to conduct local plays, nukkad nataks, be part of community radio engagements, conduct group meetings</li> </ul>

S.No	Department	Vaccine rollout - Planning & Implementation	Social Mobilization and awareness generation
4	Education	<ul style="list-style-type: none"> <li>Support in management of vaccination session site including working as team members, (wherever needed)</li> </ul>	<ul style="list-style-type: none"> <li>Community awareness through school teachers, shiksha mitra,</li> <li>Educate parents on why school children are not being vaccinated in early stages etc.</li> </ul>
5	AYUSH	<ul style="list-style-type: none"> <li>Identification of HCW with AYUSH</li> <li>Provide vaccinators authorized to give injections and other team members</li> </ul>	<ul style="list-style-type: none"> <li>Use their platforms for dissemination of IEC</li> </ul>
6	Urban Development	<ul style="list-style-type: none"> <li>Ensuring registration of health care workers and other front-line workers working in Municipal Corporation, Municipality, etc. Enlisting of corporation staff as and when it is decided to vaccinate them</li> <li>Support identification of session site with enough space for vaccination and session logistic planning in urban areas including, ULB, corporations and big municipal corporation areas</li> </ul>	<ul style="list-style-type: none"> <li>Involve providing lead role in communication and social mobilization activities for COVID-19 vaccine roll out in urban areas including, ULB, corporations and big municipal corporation areas</li> <li>Active involvement of urban Self-Help groups under National Urban Livelihood Mission.</li> <li>Mahila Arogya Samitis under NUHM to increase awareness on importance of COVID-19 vaccination in urban areas Spreading the awareness on COVID-19 appropriate behavior</li> <li>Spreading the awareness on COVID-19 appropriate behavior</li> </ul>
7	Sports and Youth	<ul style="list-style-type: none"> <li>NYKS/ NSS to support session management and crowd control at session site</li> </ul>	<ul style="list-style-type: none"> <li>NYKS, NSS and national youth clubs to participate and support COVID-19 vaccine communication through its social mobilization activities</li> </ul>
8	State Police Department	<ul style="list-style-type: none"> <li>Support identification and vaccination of beneficiaries from police department</li> <li>Support vaccine delivery in hard to reach and left wing extremist (LWE) areas</li> <li>Provide security to vaccine during storage, shipment and at session site</li> <li>Support to vaccination team members – police personnel/ home guards etc. for site management and crowd management</li> </ul>	<ul style="list-style-type: none"> <li>Support and facilitation of COVID-19 communication in areas of the Police to help in spreading awareness on COVID-19 appropriate behavior</li> </ul>

S.No	Department	Vaccine rollout - Planning & Implementation	Social Mobilization and awareness generation
9	Revenue	<ul style="list-style-type: none"> <li>Support identification and/or making available land/space for organizing session sites where required</li> </ul>	<ul style="list-style-type: none"> <li>Generating awareness on COVID-19 vaccination and mobilization of the concerned population groups</li> </ul>
10	Public Works Department	<ul style="list-style-type: none"> <li>Support identification of session sites</li> <li>Support in ensuring logistics and drinking water at session sites</li> </ul>	<ul style="list-style-type: none"> <li>Dissemination of awareness messages</li> </ul>
11	Public Health Engineering	<ul style="list-style-type: none"> <li>Support identification of session sites</li> <li>Support in ensuring logistics and drinking water at session sites</li> </ul>	<ul style="list-style-type: none"> <li>Dissemination of awareness messages</li> </ul>
12	Information & Broadcasting		<ul style="list-style-type: none"> <li>Community awareness through Satellite TV Channels and frequency modulation (F.M.) Radio Channels, community Radios</li> <li>Identifying champions/ ambassadors and opinion makers and dissemination of the right messaging through opinion articles.</li> </ul> <p><b>Through Bureau of Outreach and Communication (BOC)</b></p> <ul style="list-style-type: none"> <li>To conduct special folk programmes nation wide</li> <li>Conduct exhibitions at district level</li> <li>Hoardings and wall writings</li> </ul> <p><b>Through Press Information Bureau (PIB) and state I&amp;B departments</b></p> <ul style="list-style-type: none"> <li>Media Relations</li> <li>Issue of press releases</li> </ul>
13	Defence	<ul style="list-style-type: none"> <li>Support in registration of Armed forces beneficiaries</li> <li>Supply for vaccine delivery in hard to reach and security sensitive areas</li> <li>Liasoning with district administration for session planning and training of vaccinators in their system to ensure vaccination of their staff either at vaccination session sites planned by district administration or within the facilities/units of Defence force/ establishments.</li> </ul>	<ul style="list-style-type: none"> <li>Utilization of ex-servicemen in social mobilization activities</li> <li>Ensure participation of NCC in social mobilization and awareness generation.</li> </ul>

S.No	Department	Vaccine rollout - Planning & Implementation	Social Mobilization and awareness generation
14	Food and Civil Supplies	<ul style="list-style-type: none"> <li>Support in providing cold storage spaces and transport system, if needed</li> <li>Facilitate biometric authentication or finger print readers at session sites</li> </ul>	<ul style="list-style-type: none"> <li>Generating awareness on COVID-19 vaccination</li> </ul>
15	Social Welfare	<ul style="list-style-type: none"> <li>Support setting up session sites in welfare home premises, if needed</li> </ul>	<ul style="list-style-type: none"> <li>Generating awareness among identified priority group for COVID-19 vaccination</li> </ul>
16	Minority Affairs	<ul style="list-style-type: none"> <li>Support setting up session sites in premises of affiliated institutions, if needed</li> </ul>	<ul style="list-style-type: none"> <li>Generating awareness among identified priority group for COVID-19 vaccination</li> </ul>
17	Tribal Affairs	<ul style="list-style-type: none"> <li>Allow setting up session sites in schools premises</li> </ul>	<ul style="list-style-type: none"> <li>Generating awareness on COVID-19 vaccination in tribal communities and their mobilization</li> </ul>
18	Animal Husbandry	<ul style="list-style-type: none"> <li>Support in provision of dedicated cold storage equipment/facilities for vaccine storage, if required</li> </ul>	
19	Railways	<ul style="list-style-type: none"> <li>Support identification and vaccination of HCW with the railways</li> <li>Coordinate with DM / DC for vaccination of railway HCW</li> <li>Support in conducting vaccination sessions in railway hospitals, dispensaries and other premises.</li> </ul>	<ul style="list-style-type: none"> <li>Support communication through screening of AV spots on trains and platforms and use COVID-19 vaccine branding on the tickets</li> </ul>
20	Labour & Employment	<ul style="list-style-type: none"> <li>Support identification and vaccination of HCW with the ESI</li> <li>Coordinate with DM / DC for vaccination of ESI HCW</li> <li>Support in conducting vaccination sessions in ESI hospitals</li> </ul>	<ul style="list-style-type: none"> <li>Support COVID-19 vaccination through institutions under Ministry of Labour and Employment (MOLE), such as ESIC to conduct awareness programmes through their networks.</li> </ul>
21	Information and Technology	<ul style="list-style-type: none"> <li>Village level engagement of Common Service Centers for beneficiary registration, monitoring, printing of beneficiary certification and other services where connectivity and web-based methods are required</li> </ul>	<ul style="list-style-type: none"> <li>Encouraging mobile service providers to send text and voice messages, caller tunes on COVID vaccination</li> <li>Message and IEC on telephone bills etc.</li> </ul>
22	State AIDS Control Society	<ul style="list-style-type: none"> <li>(Integrated Counselling Testing Centre)ICTC Counsellors/</li> <li>Counsellors in TI projects to provide counselling on hesitancy, eagerness etc.</li> </ul>	<ul style="list-style-type: none"> <li>ICTC Counsellors to provide counselling on hesitancy, eagerness etc.</li> <li>TI projects to undertake campaigns on anti-stigma, eagerness, hesitancy</li> <li>State AIDS Control Societies to support trainings and awareness campaigns</li> </ul>
23	Department of Power	<ul style="list-style-type: none"> <li>Ensure uninterrupted power supply at vaccine storage point and session site</li> </ul>	



## 4.2 ROLE OF DEVELOPMENT PARTNERS

The technical and monitoring support of partner agencies such as WHO, UNICEF, UNDP, JSI, ITSU, BMGF Rotary International and other stakeholders continues to be of significance in strengthening of health systems and programmes in India. States must actively engage these partner agencies in their core areas of strength.

### 4.2.1 WHO

WHO India through its NPSP network will provide technical support to national, state and districts in planning, training and monitoring of COVID-19 vaccine introduction activities. Support will be provided for following key activities:

- Coordinate with developmental partners, professional organizations and facilitate partners mapping in identified districts/ urban areas;
- Support state and facilitate trainings at state, district and select high risk blocks / urban areas to build capacity of medical officers, health workers and mobilisers on operationalization of COVID-19 vaccine including adverse events following immunization. Develop and disseminate training materials;
- Coordinate to develop microplanning for COVID-19 vaccination at state, district and block levels;
- Track implementation of COVID-19 vaccine rollout activities, undertake preparedness assessment at state and districts and provide feedback to task forces to take action; and
- Prepare plan for concurrent monitoring, need based deployment of external monitors and rapid response team members, share concurrent monitoring data at task forces to guide corrective actions.

### 4.2.2 UNICEF

UNICEF will provide technical support to National and State Governments in planning, implementation and monitoring of COVID-19 vaccine rollout. While providing holistic and blended support on all aspects of vaccine introduction, the following activities will be prioritized:

- Support in development of operational guidelines, training content and capacity building of various cadre, in collaboration with WHO, specifically in the domain of cold chain and communication;
- Support in cold chain assessment, planning for need based augmentation, procurement supply and installation of cold chain equipment, pre-campaign assessment and supportive supervision using standardized checklists, creating a feedback loop with an aim to remove bottlenecks and challenges;
- Support in development of communication and social mobilization strategy including community engagement, collaborate with states in developing state specific plans and support in implementation, monitoring and upgradation of communication strategy as per programmatic needs; and
- Support in media engagement at National and State level to provide relevant, timely and clear information to media to avoid rumors and misconceptions. Develop and engage in implementation of a social media strategy at national and state level as part of a 360 degree communication strategy.

### 4.2.3 UNDP

UNDP is leading the development of the Co-WIN system which is a cloud-based IT platform that will allow beneficiary registration, session microplanning, real time reporting of vaccination and issuing of vaccination certificate to all beneficiaries who will be successfully vaccinated. The Co-WIN system will be linked to existing IT platforms being used in the UIP programme like eVIN and SAFEVAC to allow complete end to end vaccination management system:

- Development of Co-WIN and its integration with eVIN and SAFEVAC;
- Support in registration of beneficiaries at the level of the identified central ministries as well as states;
- Assist in capacity building of managers, supervisor, and vaccinators to use the Co-WIN system;
- Support states, districts and blocks for microplanning, including cold chain and vaccine logistics planning;
- Review of COVID-19 vaccine micro plans in priority blocks/urban areas;
- Reporting of vaccination coverages through Co-WIN; and
- Attend regular debriefing meetings at planning unit and district level.

#### 4.2.4 JSI

- Support states, districts and blocks for microplanning, capacity building and monitoring in select districts with staff deployed; and
- Implement rapid immunization skills enhancement (RISE) platform for capacity building on COVID-19 vaccination.

#### 4.2.5 BMGF

- Support operationalization of COVID-19 vaccination activities through staff in Bihar and Uttar Pradesh and supported projects in districts / blocks wherever deployed; and
- Facilitate engagement with large-subscriber base platforms including private health sector to augment community outreach and awareness generation.

#### 4.2.6 ROLE OF PROFESSIONAL BODIES, CSOS, NGOS, RED CROSS, ROTARY, LIONS INTERNATIONAL CLUBS ETC.

Additional partners may have their presence at state, district and block levels. Task forces at state and districts may proactively engage with these partners and assign roles to these agencies depending on their capacity and resources. The aim must be to involve all stakeholders in vaccine administration and transform the vaccination exercise into a “Jan Andolan”.

The areas of support are:

- Support IEC activities with focus on addressing Vaccine Hesitancy and vaccine eagerness;
- Advocacy with leading medical professionals at National/State/Districts level for positive messaging the COVID-19 vaccination;
- Support media scanning across digital platforms to flag misinformation and rumors and countering the same effectively particularly those relating to “vaccine hesitancy” and “vaccine eagerness”;
- Participate in State, District and Block level Task Forces for overall support in planning and implementation of COVID-19 vaccination drive;
- Facilitate identification of potential vaccinators working in health facilities being managed by CSOs / NGOs; and
- In consultation with Block and District Administration, support vaccination team at session site management and smooth flow of beneficiaries.





## 5. HUMAN RESOURCES: TRAINING & CAPACITY BUILDING

Successful introduction of COVID-19 vaccine will largely depend upon the quality of training conducted for human resources. The COVID-19 vaccine introduction, unlike other new vaccine introductions includes a mammoth activity of training the staff not usually engaged in routine immunization programme.

While majority trainings were conducted through facilitated classroom platform before the advent of the pandemic, newer training modalities or channels will have to be leveraged in view of “the new normal” to mitigate the risk of transmission. These platforms have been successfully utilized for various recent trainings for PCV introduction and Polio SNID in selected states as following models:

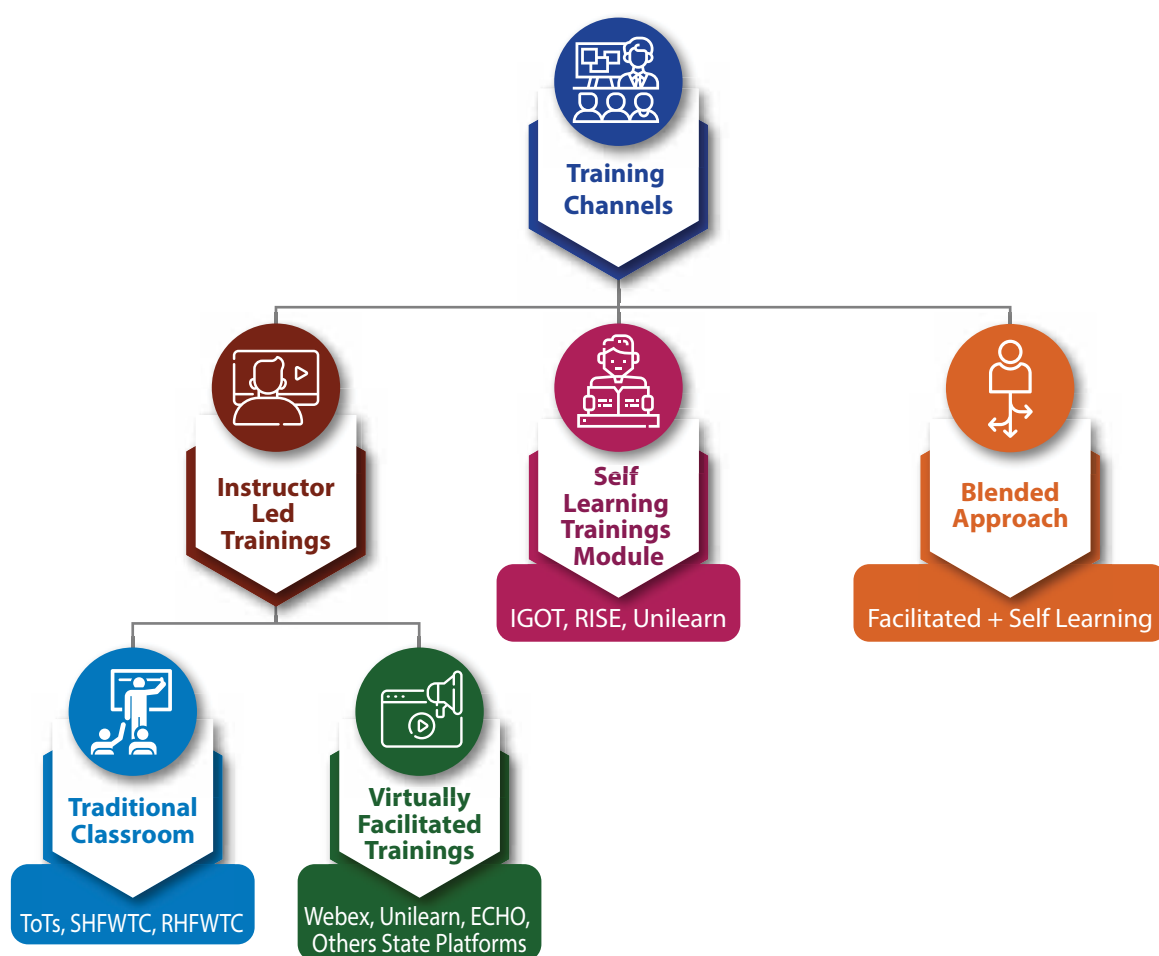


Figure. 5.1: Modalities of training

### BASIC PRINCIPLES FOR TRAININGS

- Prefer virtual trainings methods.
- Traditional classroom trainings in case virtual is not feasible.
- Follow infection prevention measures in all traditional trainings.
- Self-learning module to complement instructor led training.
- Dry runs to rehearse the methods/skills learnt.



## 5.1 VIRTUAL PLATFORMS FOR COVID-19 VACCINE INTRODUCTION TRAININGS

Virtual trainings may be conducted using Government platforms like NIC, ECHO, Integrated Government Online training' (iGOT) portal on digital infrastructure for knowledge sharing (DIKSHA) platform of Ministry of Human Resource Development (MHRD), educational satellite (EDUSAT) (in use in Madhya Pradesh), or other available online training platforms. Developmental partners will support state and districts in organizing trainings using virtual platforms.

### STATE LEVEL TRAININGS

States may conduct virtual trainings for COVID-19 vaccine introduction using available platforms like national informatics centre (NIC), any other state specific platforms. Virtual training platforms available with state level immunization partners may also be used for these workshops. Government of India may also be requested for support in conducting state level virtual trainings through the ECHO-India platform by sending email to [pdas@echoindia.in](mailto:pdas@echoindia.in) or [sbaskar@echoindia.in](mailto:sbaskar@echoindia.in) **at least two to three days in advance**, mentioning details including name of training, date and time as well as expected number of participants that will log in. Upon confirmation, the ECHO team will share a link with the facilitators, who can further share it with the participants. The participants can log in to the training by clicking on the given link. The facilitator has an option to request ECHO-India for added security through enabling pre-registration, need for a password and a waiting room.

### DISTRICT LEVEL TRAININGS

District level trainings for COVID-19 vaccine roll out are expected to be conducted as early as possible after the State level training of trainers has been completed. Districts should assess the availability of reliable internet connectivity with the intended participants and plan trainings accordingly. In case of good internet connectivity, districts may conduct trainings using any government platforms like NIC or other platforms like WebEx, Microsoft teams, Google meet etc. WHO-NPSP field units have been equipped with one or more of these platforms with a capacity to host a virtual meeting for up to 500 participants. Districts may conduct face to face meetings in case of poor internet connectivity, taking all COVID appropriate precautions that include small batch size, well ventilated venue, hand hygiene, use of mask/face cover and physical distancing of 2 Gaz between the participants.

Instructions for attending virtual trainings should be shared in advance with all participants which include:

#### Do's & Don'ts for Virtual trainings/ meetings

- |  |   |
|--|---|
| <ul style="list-style-type: none"><li>✓ Join the meeting before time to check your audio and video connection</li><li>✓ Keep your video switched off unless requested otherwise to ensure better connectivity</li><li>✓ Dress appropriately</li><li>✓ Focus on the participants speaking</li><li>✓ Identify yourself before speaking. Be close to the microphone</li><li>✓ MUTE your MIC when not actively participating, using Mute/unMute icon</li><li>✓ Post your questions in Q&amp;A or chat box so that panelists can understand the question well</li><li>✓ Disconnect once the meeting is Over</li></ul> | <ul style="list-style-type: none"><li>✗ Avoid using cordless phones to join over audio as they tend to introduce noise</li><li>✗ Avoid using mobile phone while on conference call</li><li>✗ Do not place mobile phone near Mic or Speaker. It may generate static noise</li><li>✗ Avoid side conversations as it may cause distraction</li><li>✗ Do not interrupt other speakers</li><li>✗ Do not move/drag / tap any objects/papers close to the microphones</li><li>✗ Avoid rapid movements in front of the camera</li><li>✗ DO Not annotate on screen/desktop shared by the speaker</li></ul> |
|--|---|

Training materials such as operational guidelines, presentations, trainings videos may be accessed online using the following link.

<https://1drv.ms/u/s!AkBbVf-3aw3o50QY1IHJqk4MZm84?e=NVzNNf>

## SELF-LEARNING MODULES

iGOT: Government of India has launched 'Integrated Govt. Online training' (iGOT) portal on MoHRD's DIKSHA platform for the capacity building of frontline workers on COVID-19. The platform will host training resources which may be accessed by health staff in case they were unable to access the training session or if they want to revisit the training resources. The portal website link is <https://igot.gov.in/igot/>

Please note that the portal works only in Chrome and Mozilla browsers. Users have to register/ login to access the courses. The portal can also be accessed through the DIKSHA app available for Android.

RISE: Rapid Immunization Skill Enhancement (RISE) is a blended-learning knowledge and skill-building package to complement the standard classroom training, developed by JSI under the stewardship of the Ministry of Health and Family Welfare (MoHFW). It can be accessed through the website link [www.risemohfw.in](http://www.risemohfw.in) after using the login credentials provided by the course coordinator in selected states.

## 5.2 TRAININGS FOR BENEFICIARY LISTING

Human resources from various line ministries will be sourced for this purpose by the States/ UTs. The identified manpower will be trained on the electronic beneficiary listing module of Co-WIN through virtual or face to face trainings.

## 5.3 TRAININGS FOR VACCINATION ACTIVITIES

As for any new vaccine introduction, healthcare providers will be responsible for handling and administering the vaccine as well as be a major source of information for the community.

Health-care personnel including state and district programme managers, medical officers (MOs), vaccinator officers and alternate vaccinator officers, IEC officer, cold chain handlers, supervisors, data managers, Accredited Social Health Activist (ASHA) coordinators, Mahila Arogya Samitis, NGOs, CSOs and other frontline health workers from health and line ministries will be engaged through cascaded trainings.

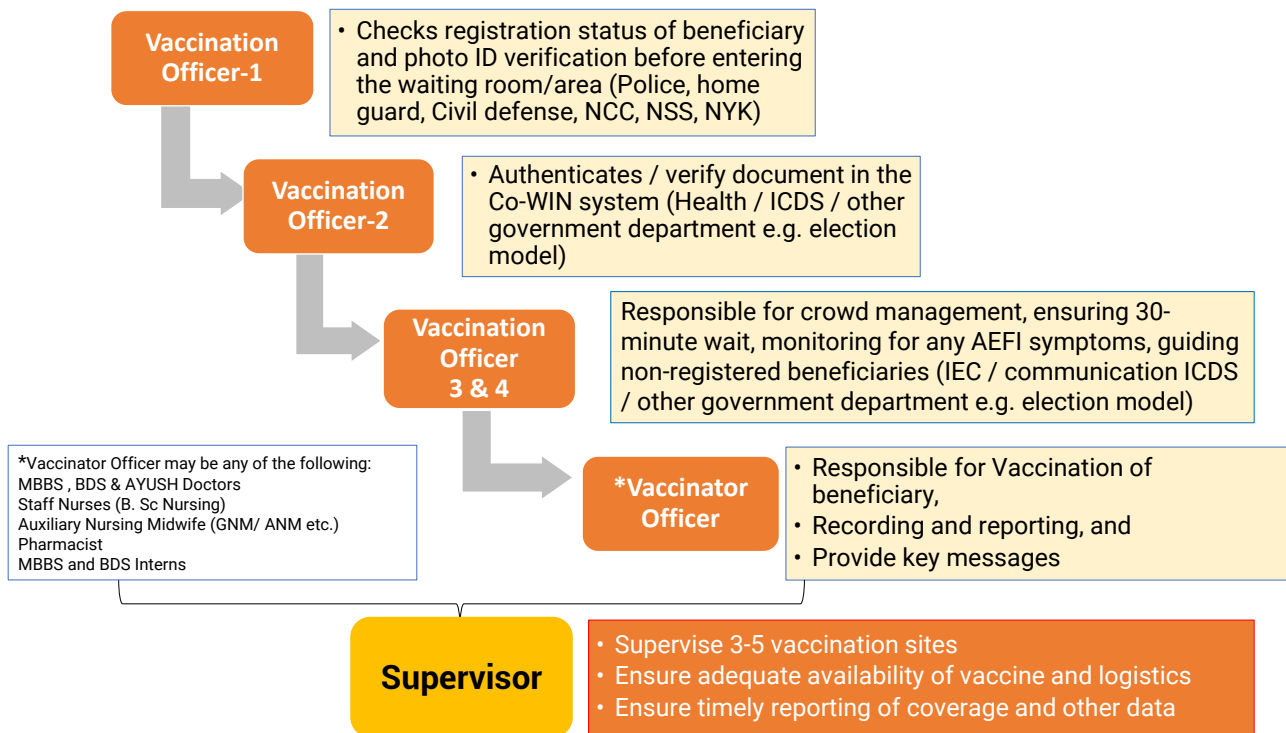
### Remember

- COVID-19 vaccine introduction training should be conducted as per guidelines;
- Standardized training package to be used during the trainings;
- All trainings will have some common and some cadre-specific messages; and
- Key tips/messages for participants incorporated in respective agenda.

Enough supervisors, vaccinators and mobilisers need to be identified prior to vaccination drive. In case of shortage, alternate vaccinators may be arranged from recently retired staff, medical and nursing colleges, private hospitals and other organizations like Defense, Railways, ESI etc.

Separate training sessions will be organized for ASHAs, Anganwadi Workers (AWWs), Mahila Arogya Samitis and volunteers for effective community mobilization. The officials and staff of the Department of Women and Child Development will also be oriented at the same time.

The various categories of staff that will be deployed at the COVID-19 vaccination site will be trained as per their roles:



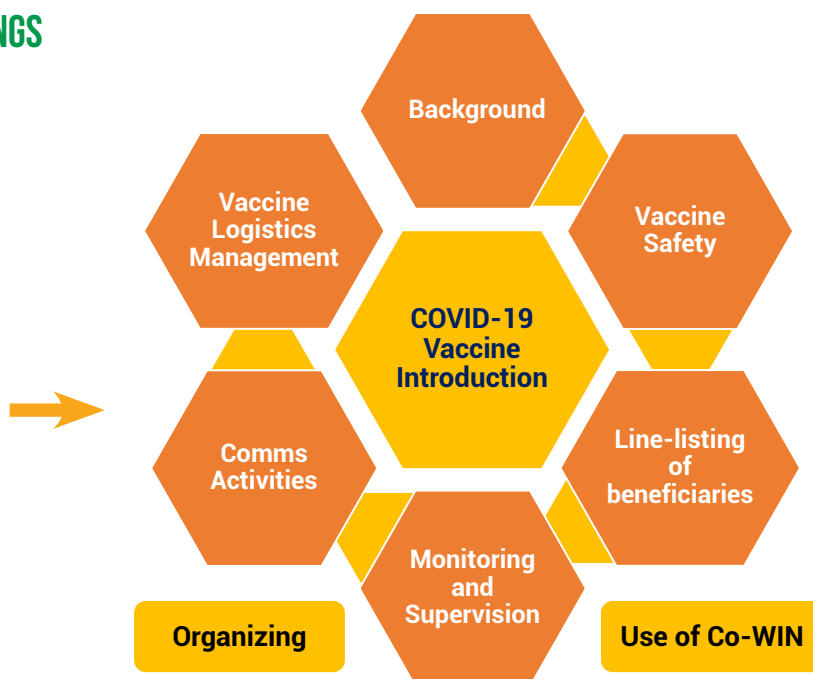
**Figure.5.2:** Training of vaccination team according to their roles

In addition, plans would be drawn up to orient the faculty of Preventive and Social Medicine departments in medical colleges as well as professional bodies such as Indian Medical Association, Indian Academy of Pediatrics, Indian Public Health Association (IPHA), Trained Nurses Association of India (TNAI) etc. involved in immunization service delivery.

COVID-19 vaccine will only be introduced once all trainings are completed in the district/block/planning unit.

### 5.3.1 THEMATIC AREAS OF TRAININGS

Trainings will be conducted for following groups
A. Vaccination Officer 1,2,3 and 4
B. Vaccinator Officer
C. Supervisors
D. Cold Chain Handlers
E. Data Entry Operators
F. Medical Officers
G. Program Managers



All training sessions will be interactive and will use the adult learning methodologies such as PowerPoint presentations, instructive videos, role plays, exercises and interactive discussions. Recent trainings of health workforce on infection prevention and control and modalities for sustaining immunization coverage during COVID-19 pandemic across the country were undertaken using virtual platforms without any major issues in reaching block level programme managers, although some limitation of IT access was observed in training of frontline workers.

### 5.3.2 ROLLOUT OF CAPACITY BUILDING

Learning from expansion of Pneumococcal Conjugate Vaccine (PCV) in Uttar Pradesh and Goa and September 2020 Sub-national Immunization days (SNID) in selected states shows that National and State training of trainers (ToTs) may be conducted on virtual platforms and cascaded at district and sub-district levels using a mix of face to face and virtual mechanisms. While training on virtual platforms is recommended at all levels, states and districts may conduct face to face trainings in situations where virtual trainings are not feasible, as in the case of limited internet availability or inadequate familiarity of trainees with the online platforms. In such cases, trainings may be conducted in small batches of 20-25 participants, following all adequate recommendations for infection prevention and control in the context of COVID-19.

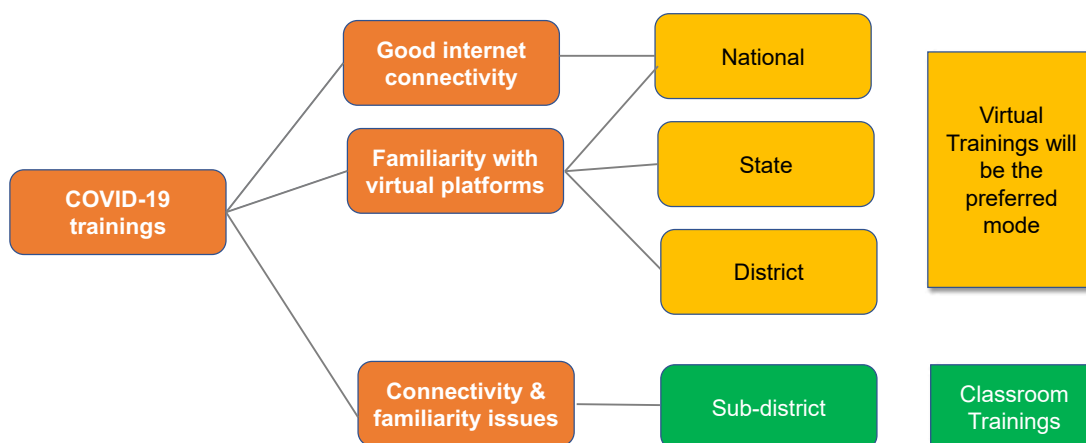


Figure.5.3: Rollout of capacity building



Capacity building of such a diverse group during COVID-19 pandemic will require extensive planning and adequate advance timing. The trainings will need to be fast-tracked, and unlike vaccine introductions earlier where cascade trainings from national to sub-district level took about 3 to 4 months, trainings for COVID-19 vaccine rollout will be aimed to be completed within 3-4 weeks.

### 5.3.3 DETAILS OF DIFFERENT TRAININGS FOR COVID-19 VACCINE INTRODUCTION

Cascade Training Framework for COVID 19 Vaccine					
S.No	Training	Target audience			
		National	State	District	Sub-District
1	<b>Orientation Meeting on Co-WIN</b>	PS and MD (NHM) from all states			
		Central Health Institutes & other Nodal Ministries			
		SEPIO, Partners and other stakeholders	CMO, District Immunization Officer, District Programme Managers (NHM), Corp. Health Officer, Urban Nodal Officers, Supervisors	District Level Officers, M. Corporations, Block Medical Officer, Block Programme Managers, NUHM, Block Supervisors	Surveyors, FLWs
2	<b>Programme Orientation on vaccine roll out (Operational &amp; Administrative)</b>	PS and MD (NHM) from all States, State Programme Managers, State Finance officers, District Magistrate / District Collector/ Municipal Commissioners, CMO, District Programme Mangers, District Finance officers and other administrative officers			
3	Operational Guidelines (Medical Officer/ Vaccinator Module, Cold Chain, AEFI, Data Management, Communication, Intersectoral coordinations)	State Senior Official, SEPIO, State Cold Chain Officers, State IEC officer, State data in-charge, Partners, National representatives of IMA, IAP, AEFI Nodal officers	CMO, District Immunization Officer, Urban Nodal Officers, Corp. Health Officer, District Programme Managers (NHM), District AEFI Nodal Officer, District Data Managers	District Level Officers, Block Medical Officer, M. Corporations, Nodal of Municipal health institutes, Block Programxme Managers, NUHM, Block Supervisors, Cold Chain Handlers, Data Entry Operators, District IAP societies, ICDS and other stakeholders	
4	<b>Media Orientation</b>	Media House	Media House	Media House	
5	<b>Medical Colleges &amp; Private Practitioners (Orientation on Program)</b>		State IMA , IAP societies, Nodal officers of Medical colleges		
6	<b>Cold Chain Handler Module</b>			Cold Chain Handlers	

Cascade Training Framework for COVID 19 Vaccine					
S.No	Training	Target audience			
		National	State	District	Sub-District
7	Alternate Vaccinator Module			Identified Alternate Vaccinators (IT Platform)	ANMs, Identified Alternate Vaccinators (Classroom Training)
8	Social Mobilization				MAS, ASHA, AWW, SHGs, Youth Groups like NCC, NSS and NYK, CBOs, PRIs (Classroom Training)

## TRAINING TIMELINES

S.No	Training	Timeline	Time Duration	Training Platform
1	Orientation Meeting of partners (At National, State, District Levels)	5th-6th December	"2 half days (Total time 8 Hrs)"	Virtual
2	Orientation of Administrators	8th December	2Hrs	Virtual
3	National ToT Workshop (OG)	9th -10th December	"2 half days (Total time 8 Hrs)"	Virtual
4	State ToT (OG)	Completed within 2 days of National ToT	"2 half days (Total time 8 Hrs)"	Virtual
5	District ToT (OG)	Completed within 2 days of State ToT	"1 Day (Total time 6 Hrs) "	Virtual / Traditional Classroom
6	"Training for Alternate Vaccinators (At District Level)"	To be decided	6 Hrs	Virtual / Traditional Classroom
7	"Vaccinator Trainings (At Sub-District Level)"	Completed within 3 days of District ToT	6 Hrs	Traditional Classroom
8	"Social Mobilisation (At Sub-District Level)"	Completed within 3 days of District ToT	4 Hrs	Traditional Classroom

COVID-19 vaccine roll-out in urban areas would require orientation of urban officials, municipal corporations' members, urban local bodies, counselors, corporators RWA members, Mohalla samitis and representatives of Youth bodies etc. Mahila Aarogya Samiti (MAS), swachagrahis and self-help groups also need to be oriented and engaged in addition to existing resources such as ASHA and AWW.

Training materials such as operational guidelines, presentations, trainings videos may be accessed online using the following link.

<https://1drv.ms/u/s!AkBbVf-3aw3o50QY1IHJqk4MZm84?e=NvzNNf>





## 6. COVID-19 VACCINE INTELLIGENCE NETWORK (CO-WIN): THE DIGITAL PLATFORM

Co-WIN (COVID -19 Vaccine Intelligence Network) has been developed as an extension of the existing electronic Vaccine Intelligence Network (eVIN) module for it to be a comprehensive cloud-based IT solution for planning, implementation, monitoring, and evaluation of COVID-19 vaccination in India. The Co-WIN system is an end to end solution that has utilities for the entire public health system from national up to the vaccinator level. The system allows for creation of users (admins, supervisors, vaccinators), registration of beneficiaries (bulk upload and individual registration), facilities/planning unit and session sites followed by planning and scheduling sessions and implementation of vaccination process. Co-WIN system on a real time basis will track not only the beneficiaries but also the vaccines, at national, state and district level. This will allow the system to monitor the utilization, wastage, coverage of COVID-19 vaccination at National, State, District and Sub-District level. The Co-WIN system has the following components (Figure 1a and 1b):

**1. The website [www.cowin.gov.in](http://www.cowin.gov.in) will be used by the National, State and District Level administrators, the key features of the website are:**

- a. Creation of State and District level admins;
- b. Creation of facility/planning unit databases;
- c. Creation of vaccinator, and supervisor databases;
- d. Manage material relevant to COVID-19 Vaccination and its allocation;
- e. Creation of session sites;
- f. Bulk upload of beneficiary data for registration;
- g. Self-registration by general population;
- h. Session management for linking session sites, vaccinators, supervisors, and beneficiaries;
- i. Rights for viewing sessions and beneficiary allocated to these sessions for Block Admin and Facility Medical Officer In charge; and
- j. Monitoring and Reporting.

**2. The application [www.app.cowin.gov.in](http://www.app.cowin.gov.in) will be for the following:**

- a. Registration of individual beneficiaries by facility/planning unit level users; and
- b. For authentication/verification of beneficiaries and recording the successful vaccination at time of conducting the session.



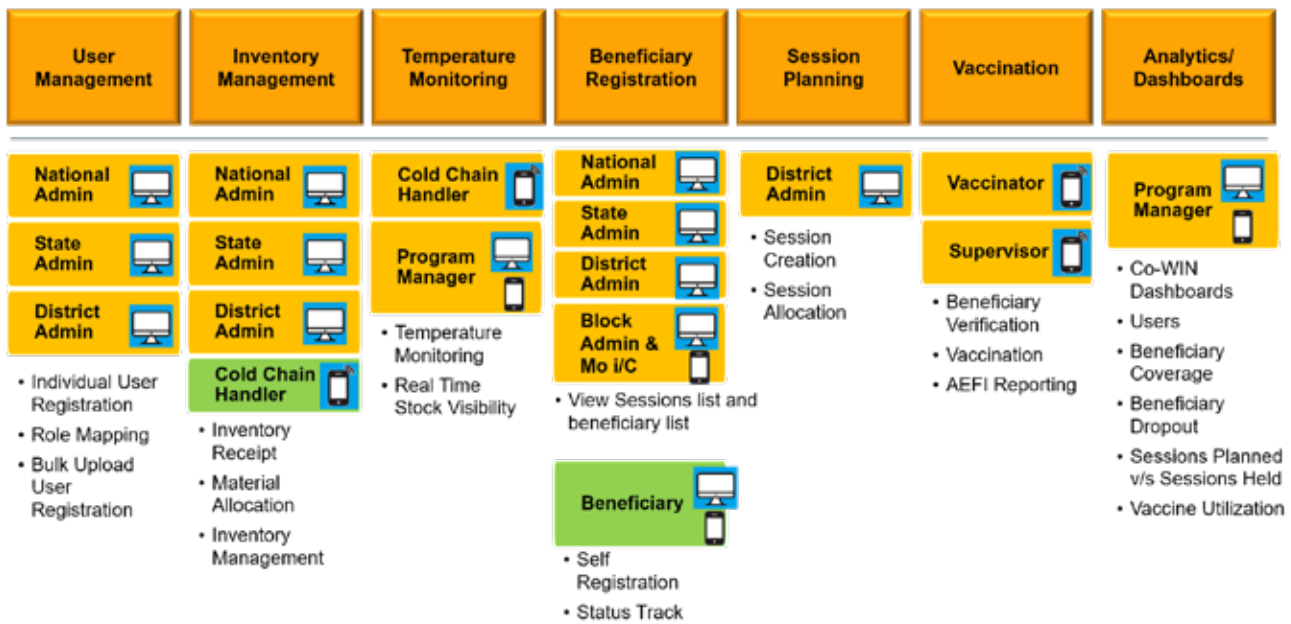


Figure 1a: Key Features of Co-WIN system

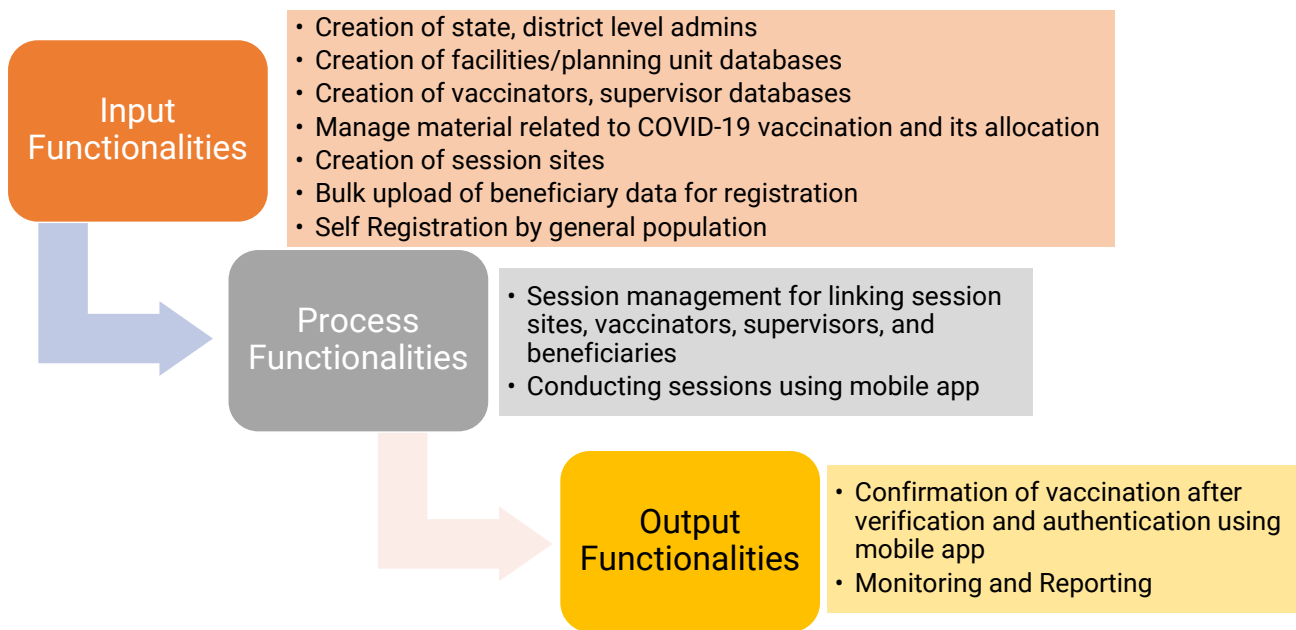


Figure 1b: Process flow of Co-WIN

## 6.1 FEATURES OF CO-WIN WEBSITE

### 6.1.1 CREATION OF NATIONAL, STATE, DISTRICT LEVEL ADMINS

- For MoHFW and State Departments of Health and Family Welfare** - The National level Administrators (National Admins) will be created by National COVID-19 Vaccine Cell of MoHFW. National Admins will create the State Admins and subsequently State Admins will create District Admins (District Magistrate/District Collector/Deputy Commissioner, supported by District Immunization Officer). New users in the application can be created by using the **Add User** tab on the **Manage User** screen or by bulk upload using the relevant template form the **Download Template** tab (Figure 2a and 2b).
- For the Central Ministries that have HCWs and FLWs** – The Level 1 Nodal Officers identified for each central ministry will be National Administrator for respective ministry. The Level 1 Nodal Officers will then create Level 2 and Level 3 admins (whichever is applicable) in the www.cowin.gov.in.

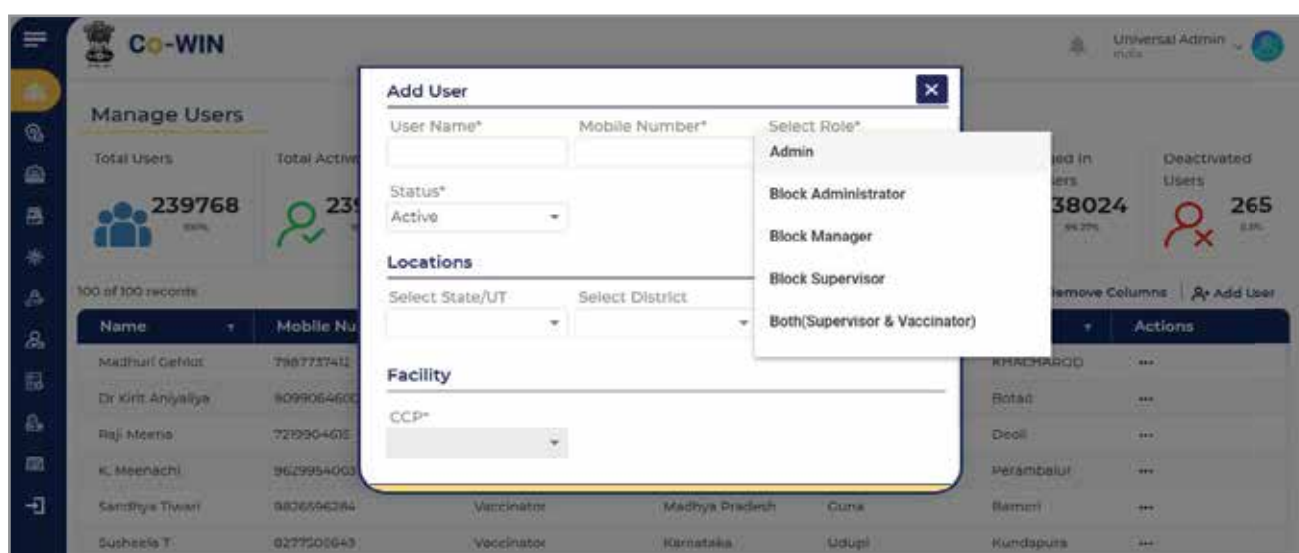


Figure 2a – Creation of New Admin and Users using Add user

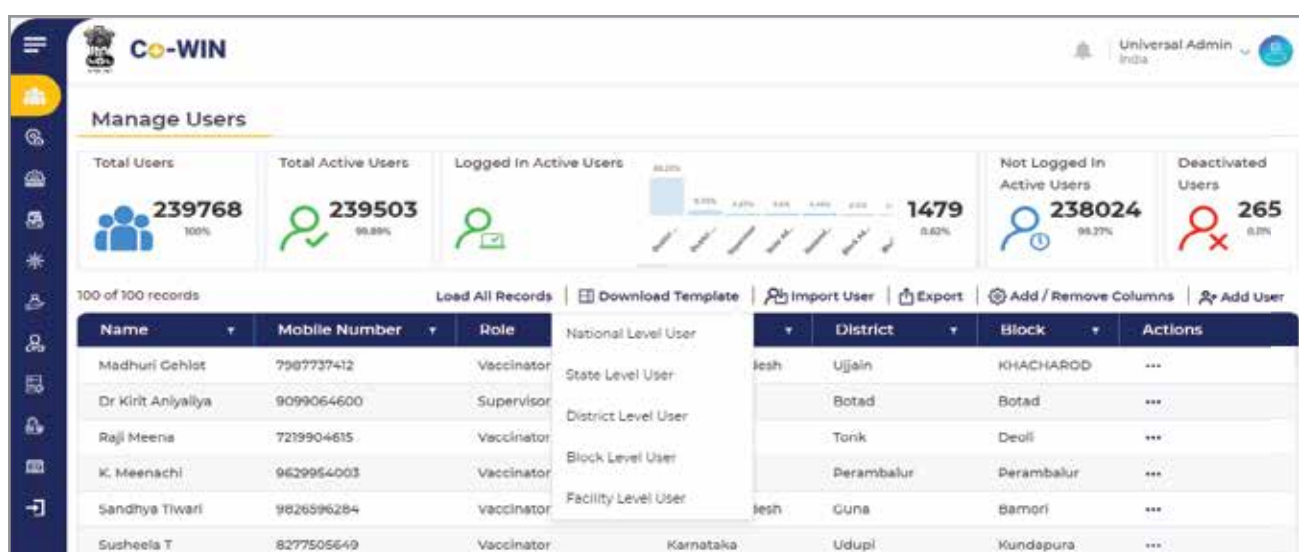


Figure 2b – Creation of New Admin and users using Bulk Upload

## 6.1.2 CREATION OF FACILITY/PLANNING UNIT DATABASES

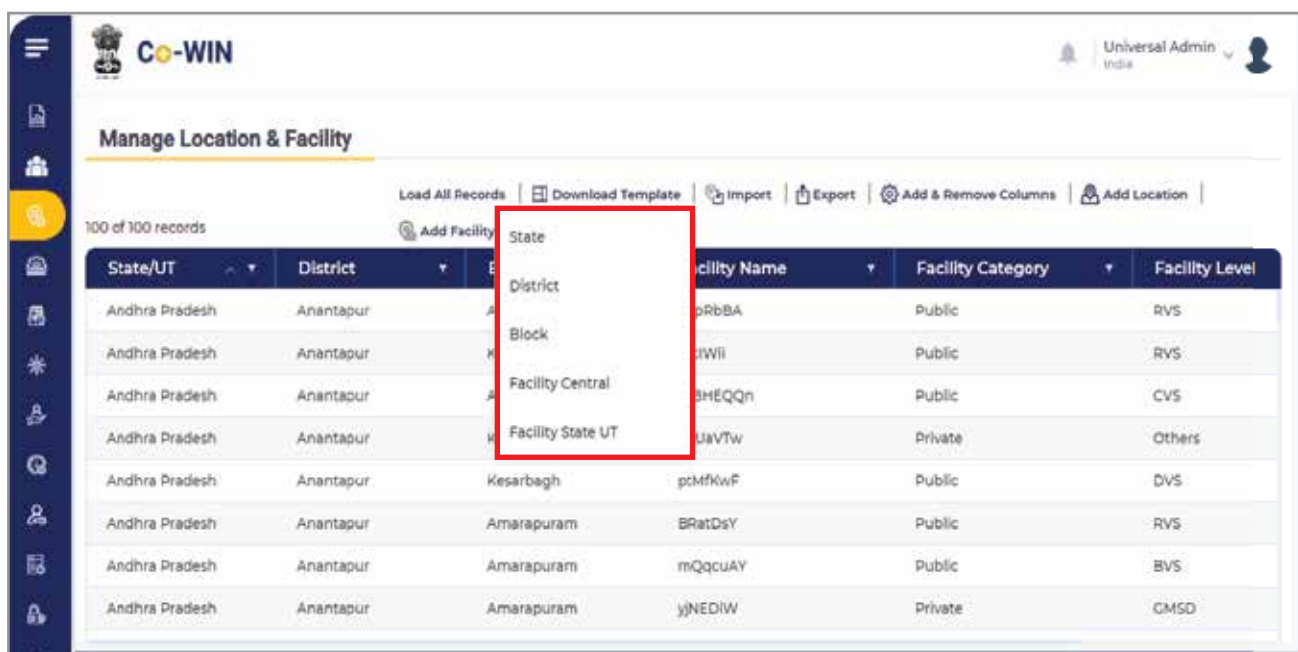
- a. **State Departments of Health and Family Welfare** – State and District Admins will create a database of the health facilities under respective heads of state departments of Health and Family Welfare HCWs data will be required to be linked to these health facilities.
- b. **Central Ministries having HCWs** – Central ministries which are compiling the data of HCWs as per the guidelines circulated, will be required to create a database of health facilities (Level 2 or Level 3 which ever applicable) under their respective ministries. These health facilities will be linked to the HCWs being uploaded.
- c. **Central Ministries having FLWs** – The Central ministries which are compiling the data of FLWs as per the guidelines circulated, will be required to create a database of Planning Units (Level 2 or Level 3 which ever applicable) as per which the FLWs data is being compiled.

The Creation of facility/planning unit database can be done by the following methods:

- a. **Add facility and session site** – District Admins/Level 2/Level 3 Admins can create each facility/ planning unit and site one by one by clicking on Add Facility tab in [www.cowin.gov.in](http://www.cowin.gov.in). (Figure 3a).
- b. **Facility and Site template** – District Admin can download the Facility/Site Template from [www.cowin.gov.in](http://www.cowin.gov.in), populate the data of each facility/planning unit and site in the template and upload it back into [www.cowin.gov.in](http://www.cowin.gov.in). (Figure 3b).

State/UT	District	Category	Facility Level
Andhra Pradesh	East Godavari	Others	Others
Andhra Pradesh	East Godavari	Others	Others
Andhra Pradesh	Sri Potturu	CCP	CCP
Andhra Pradesh	East Godavari	Others	Others
Andhra Pradesh	Krishna	CCP	CCP
Andhra Pradesh	West Godavari	Others	Others
Assam	Jorhat	Others	Others
Bihar	Katihar	Others	Others
Bihar	East Champaran	Sugauli	PHYSIOTHERAPY CLINIC
Bihar	East Champaran	Sugauli	Private

Figure 3a – Creation of Facilities/Planning Units using Add facility



**Figure 3b** – Creation of Facilities/Planning Units using Bulk Upload

### 6.1.3 CREATION OF VACCINATOR, AND SUPERVISOR DATABASES

District Admins (District Magistrate with support from District Immunization Officer) will create a database of vaccinators, and supervisors within the facilities in the districts. The users can be created by two methods:

- a. **Add User** - District Admin can create the users one by one by clicking Add User” tab in “Manage User” screen after logging into [www.cowin.gov.in](http://www.cowin.gov.in). (Figure 2a).
- b. **Bulk Upload** - District Admin can download the Facility Level User Template from [www.cowin.gov.in](http://www.cowin.gov.in), populate the data of each user in the Template and upload it back into [www.cowin.gov.in](http://www.cowin.gov.in). (Figure 2b).

### 6.1.4 CREATION OF SESSION SITES

Session sites will include the traditional routine immunization sites as well as additional outreach session sites for reaching out to the HCWs and FLWs beyond the department of health and family welfare. District Magistrate will use DTFI platform to create additional outreach session sites in consultation with relevant departments.

District Admins will be able to create the session sites in Co-WIN website by two methods:

- a. **Add Site** - District Admin can create sites one by one by clicking on “Add Site tab” in “Manage Site screen” after logging to [www.cowin.gov.in](http://www.cowin.gov.in). List of facilities and vaccinators will appear in drop down within the add site screen and District Admins will use these drop downs to link each session site to a facility and a vaccinator. (Figure 4a).
- b. **Bulk Upload** - District Admin can download the Site Template from [www.cowin.gov.in](http://www.cowin.gov.in) and populate the data of each site with respect to the facility and vaccinator details to which the session site will be tagged and then upload it back into [www.cowin.gov.in](http://www.cowin.gov.in). (Figure 4b).



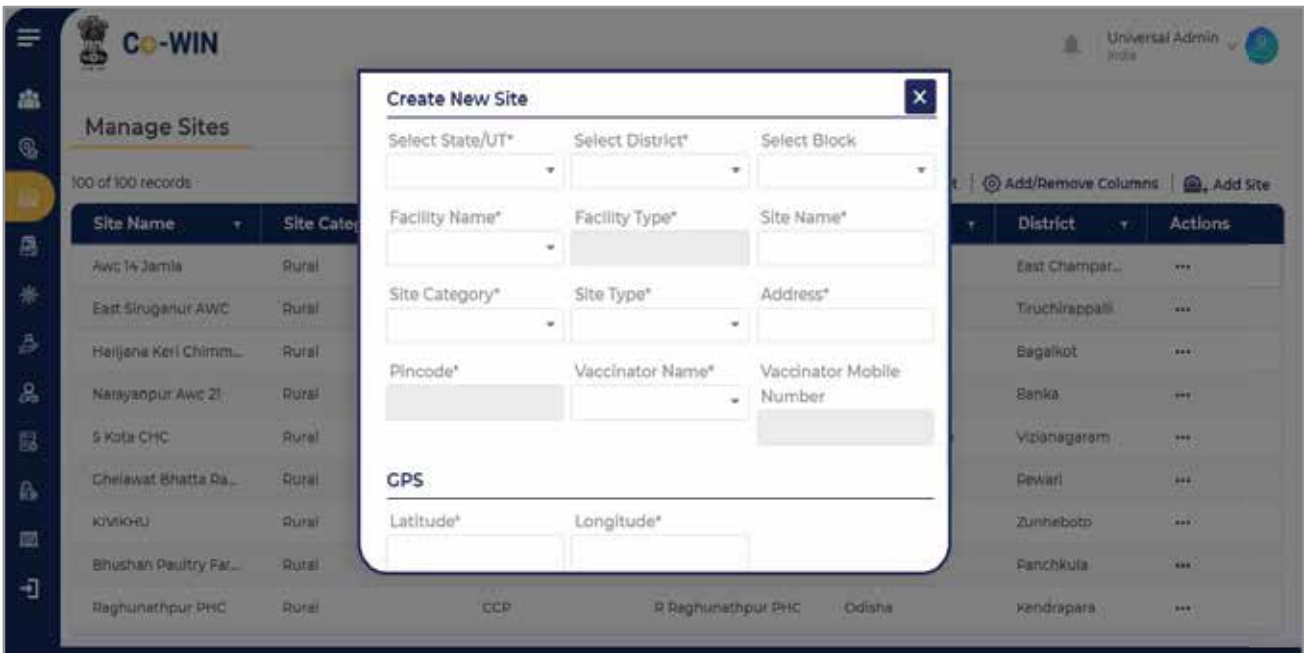


Figure 4a – Creation of Session Sites using Add Site

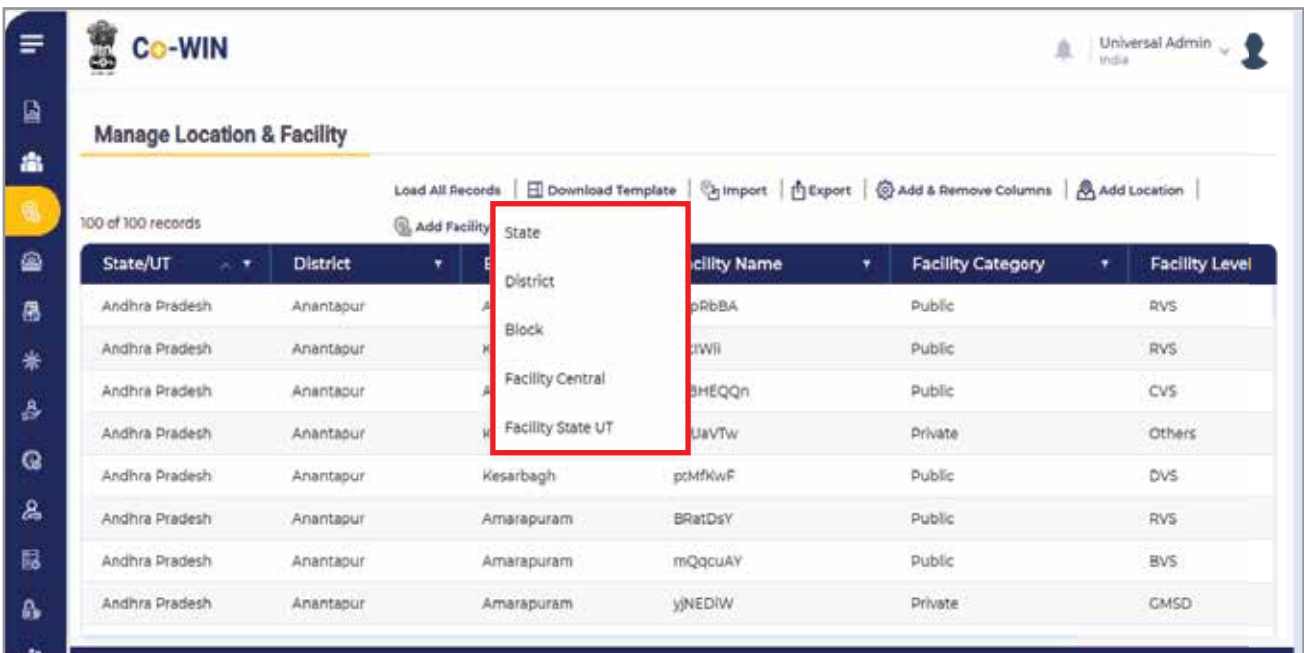


Figure 4b – Creation of Session Sites using bulk upload

## 6.1.5 MANAGE MATERIAL RELEVANT TO COVID-19 VACCINATION AND ITS ALLOCATION

- a. **Manage Material (Figure 5a)** - National Admin will create a master of all types of COVID-19 vaccine and other relevant logistics (i.e. syringes, droppers etc.) in the “Manage Material” screen. For each vaccine type National Admin will provide the following details
  - i. Manufacturer Details;
  - ii. Batch Number;
  - iii. Doses per vial; and
  - iv. Schedule of the Vaccine.
- b. **Manage Material Allocation (Figure 5b)** – Once Master of all the materials are created, National Admin will be able to allocate vaccines to states similarly states to district and districts to facilities.
- c. Districts will enter the number of doses of every vaccine type received from the states under the **receipt tab** of the application.
- d. States must ensure allocation of one type of vaccine to one geography for example a district.

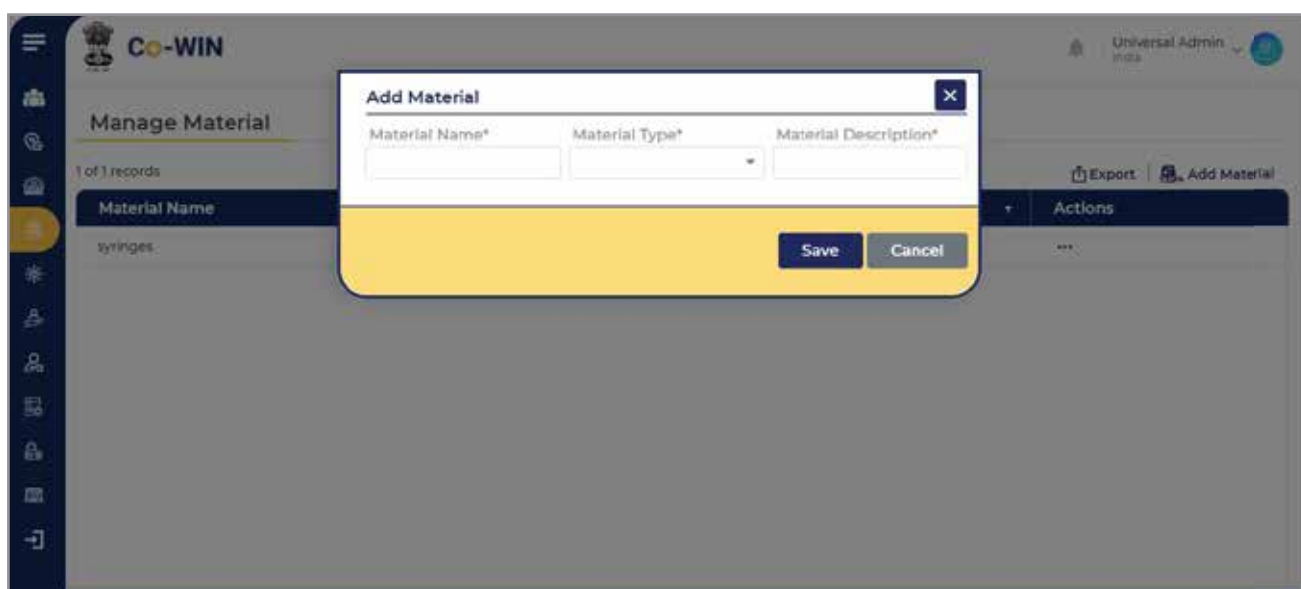


Figure 5a - Manage Material

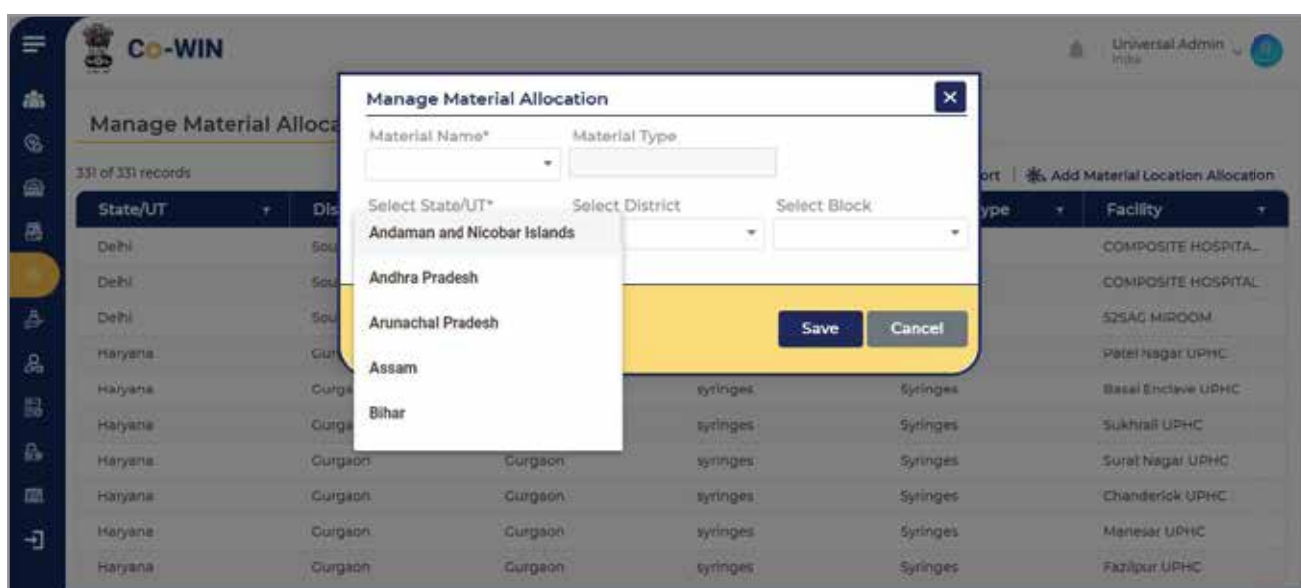


Figure 5b - Manage Material Allocation

## 6.1.6 BULK UPLOAD OF BENEFICIARY DATA FOR REGISTRATION

COVID-19 vaccine will be provided only to beneficiaries pre-registered in Co-WIN ([www.cowin.gov.in](http://www.cowin.gov.in)).

- Registration of HCWs and FLWs will be required to be done in Co-WIN by bulk upload using a standard excel template available from [www.cowin.gov.in](http://www.cowin.gov.in).
- Bulk upload will be done by District /Level2/Level 3 Admins by downloading the relevant templates using the download template utility in **Manage Beneficiary** screen of Co-WIN.
- Templates are specially designed excel sheets with pre-defined file names. District /Level2/Level 3 Admins will download these templates and share these with their respective Facility/Planning Units. Facility/Planning Units are defined as the points of beneficiary database collection. For Health Care Workers, these facilities/Planning Units will be the preferred sites of vaccination. (Figure 6a)
- Each Facility/ Planning Unit will be required to populate the template with the data of the beneficiaries working/reporting under them. The detailed SOPs for filling the templates are available in Annexures. After populating the templates, the Facilities/Planning Units will share the same with their respective Districts/Level2/Level 3 Admins by email only.
- District/Level2/Level 3 Admins will compile the templates from all facilities/Planning Units and will be responsible for quality as well as authenticity of data. Templates will then be required to be uploaded on Co-WIN website by clicking on **Import Beneficiaries** tab (Figure 5a). The software will check each entry in template for correctness. While correct entries will be successfully uploaded, the erroneous entries will be filtered out as a separate template with reasons for failure to upload. This template will be required to be sent back to the respective facility/Planning Unit for correction. Corrected template will then be uploaded back on the above website. A detailed SOP for uploading templates is provided in Annexure (Figures 6b and 6c)

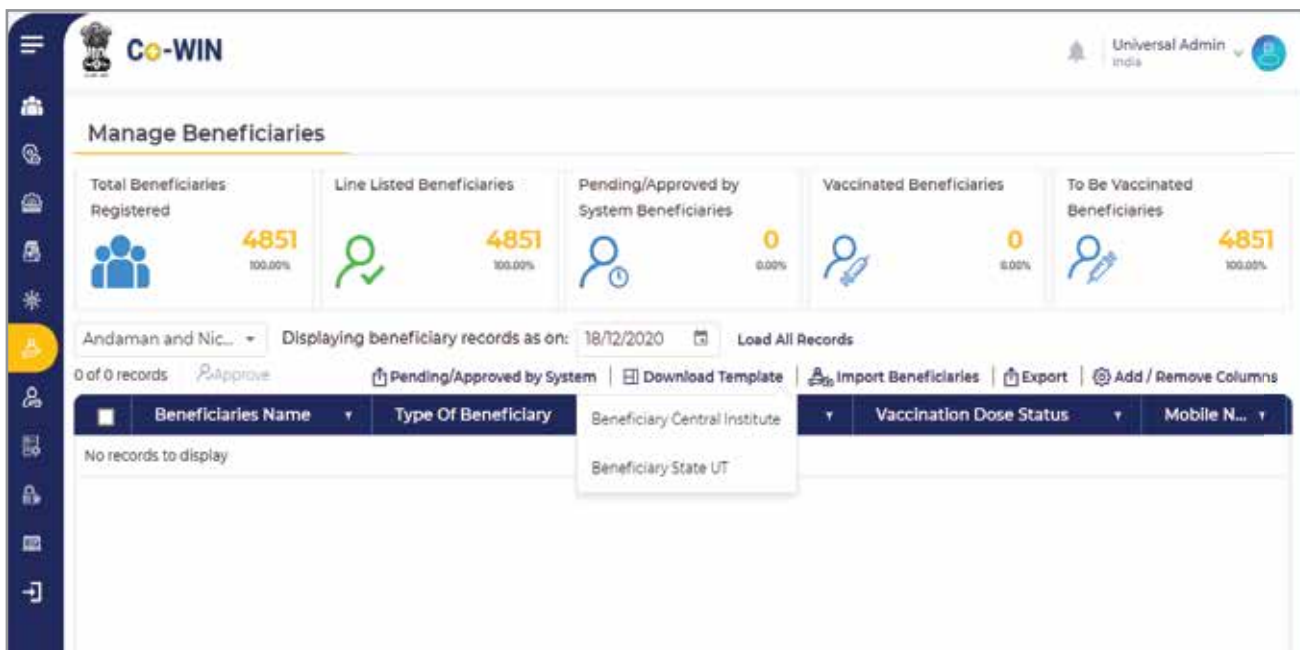


Figure 6a – Downloading template for bulk uploading of beneficiaries

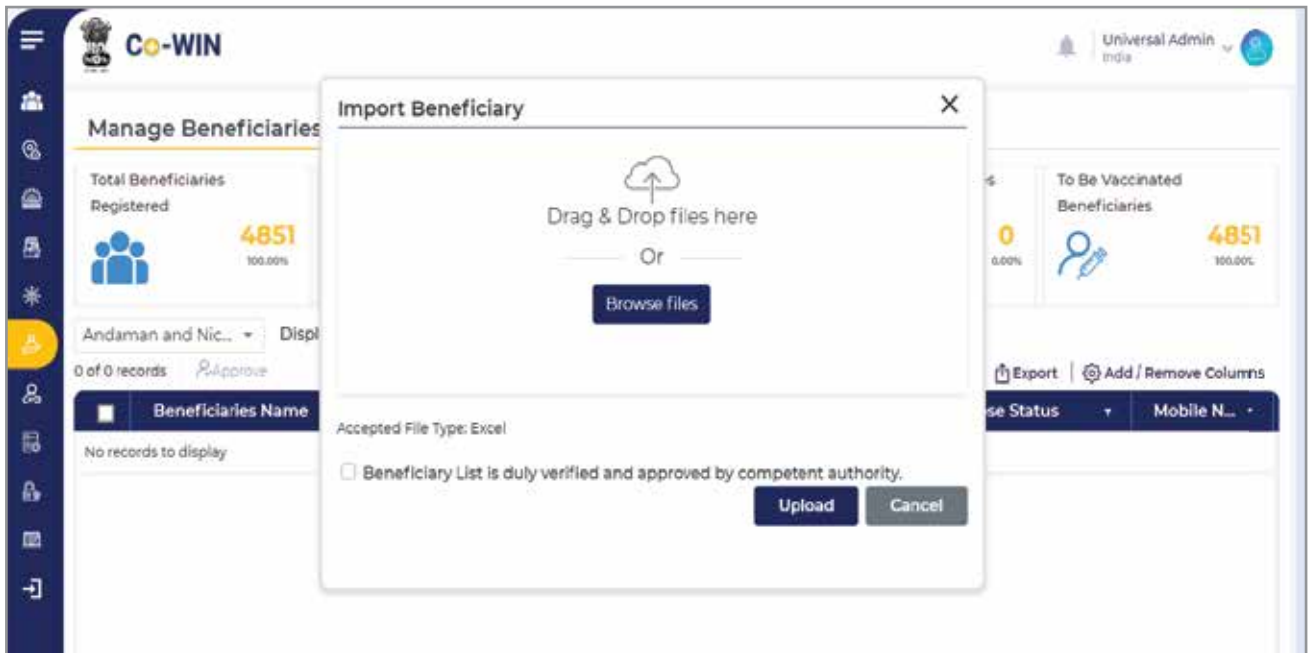


Figure 6b – Uploading of filled template

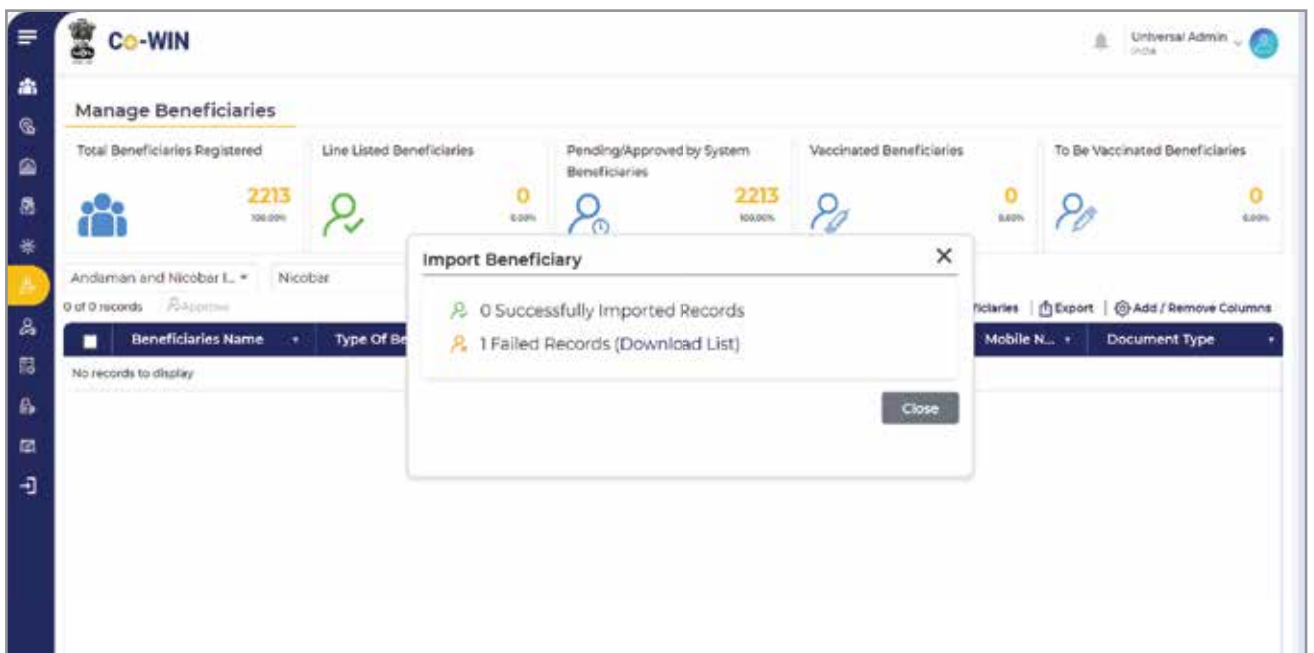


Figure 6c – Message regarding successful and failed records



## 6.1.7 SELF-REGISTRATION BY GENERAL POPULATION (FIGURE 7)

Self-registration link on Co-WIN website is essentially meant for the general population wherein an individual can register himself/herself by providing her/his basic demographic details like name, Date of Birth, permanent and current address and details of co-morbidities, if any. An individual interested to register her/himself will be required to provide her/his photo identity from one of the following:

- a. Aadhaar Card;
- b. Driving License;
- c. Health Insurance Smart Card issued under the scheme of Ministry of Labour;
- d. MNREGA Job Card;
- e. Official identity cards issued to MPs/MLAs/MLCs;
- f. PAN Card;
- g. Passbook issued by Bank/Post Office;
- h. Passport;
- i. Pension Document;
- j. Service Identity Card issued to employees by Central/State Govt./PSUs/ Public Limited Companies;
- k. Smart Card issued by RGI under NPR; and
- l. Voter ID.

Photo identity can either be uploaded on Co-WIN system (in PDF, JPG or PNG file formats) or can be pulled from the existing Digi Locker account of the individual. In case an individual chooses to provide Aadhaar as Photo ID, Co-WIN system will perform an Aadhaar authentication. Individual can select the method of authentication from one the following methods:

- a. **Biometric** - If a biometric device is available then a biometric scan/finger- print scan can be done for authentication. Once the biometric authentication is successful, demographic details of the individual i.e. Name, DoB, Gender, Permanent Address as per the Aadhaar will auto-populate.
- b. **OTP Authentication** - Click on OTP authentication to send an OTP to registered mobile number. Individual will then enter the OTP received on registered mobile number and click on verify. If the OTP authentication is successful, demographic details of individual i.e. Name, DoB, Gender, Permanent Address as per the Aadhaar will auto-populate.
- c. **Demographic Authentication** - If biometric device is not available or the individual does not have registered mobile number in Aadhaar handy, s/he can enter the demographic details i.e. Name, DoB, gender and select Demo Authentication. If the Demographic authentication is successful, a green tick will appear confirming the same.

Common Service Centres may be utilized for self-registration, wherever need. Self-registration module will be made available in the later phases of implementation.

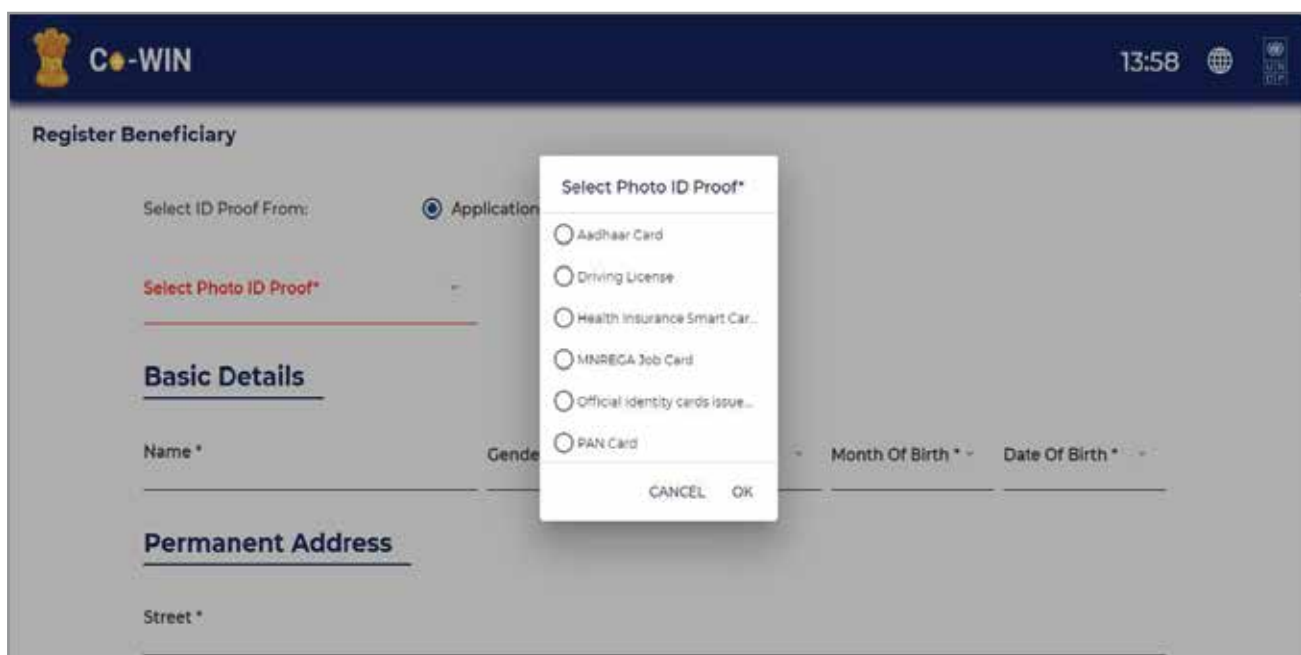


Figure 7 – Self registration screen

## 6.1.8 SESSION MANAGEMENT FOR LINKING SESSION SITES, VACCINATORS, SUPERVISORS AND BENEFICIARIES

District Admin will be responsible for the session management for both State and central ministries/ department beneficiaries in the Co-WIN system. For this, District Admin will be required to link the session sites, vaccinators, supervisors, and beneficiaries and decide the dates and time for conducting the vaccination session. The steps for scheduling a session are as follows:

- a. District Admin will go to **“Manage Beneficiaries”** and approve the registered beneficiaries for session site allocation. Approved beneficiaries will now be seen under **“Line Listed”** tab of the **“Manage Beneficiary screen”**. (Figure 8a)
- b. The District Admin will then go the receipt screen and add the details of the vaccine received by the district (Figure 8b)
- c. Further, District Admin will go to **“Manage Material Allocation”** screen and allocate the vaccines to the facilities (Figure 8c)
- d. District Admin will then go **“Session Site Allocation”** screen and select the vaccine and batch type according to which the relevant session sites will appear (Figure 8d)
- e. District Admin will then click **Next** by selecting the sites where session is to be scheduled and fill in the following (Figure 8e):
  - a. Dates of sessions;
  - b. Days of session;
  - c. Time of session;
  - d. Session load per vaccinator;
  - e. Type and categories of beneficiaries to be vaccinated; and
- f. Once the sessions are allocated, they will be under draft stage, District Admin can then schedule, cancel or edit sessions as per the requirement and opt to send details of sessions on SMS to vaccinators and beneficiaries. (Figure 8f)

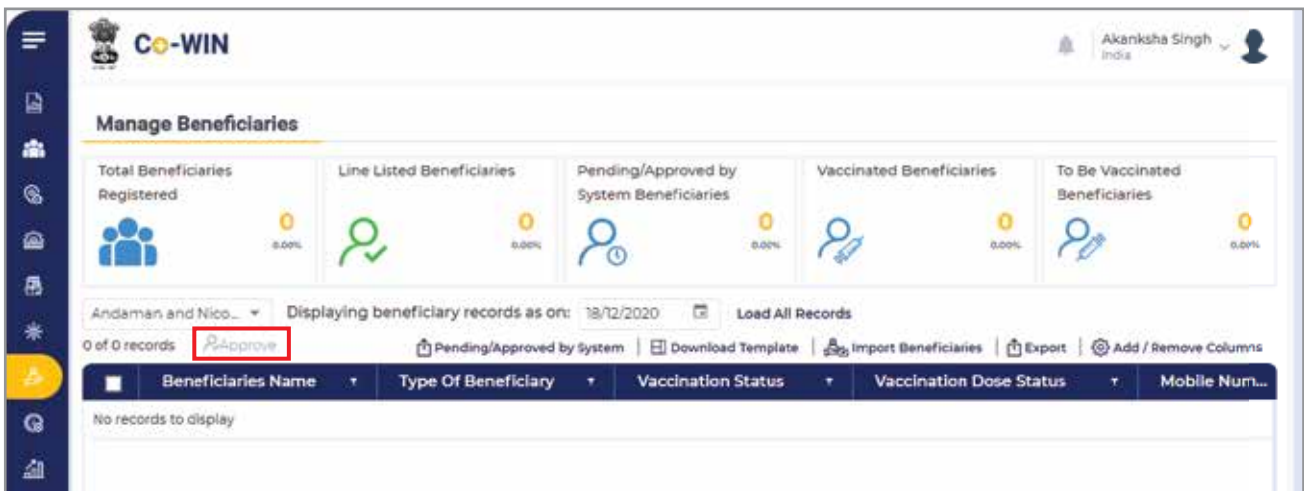


Figure 8a – Approving registered beneficiaries for line listing and session allocation

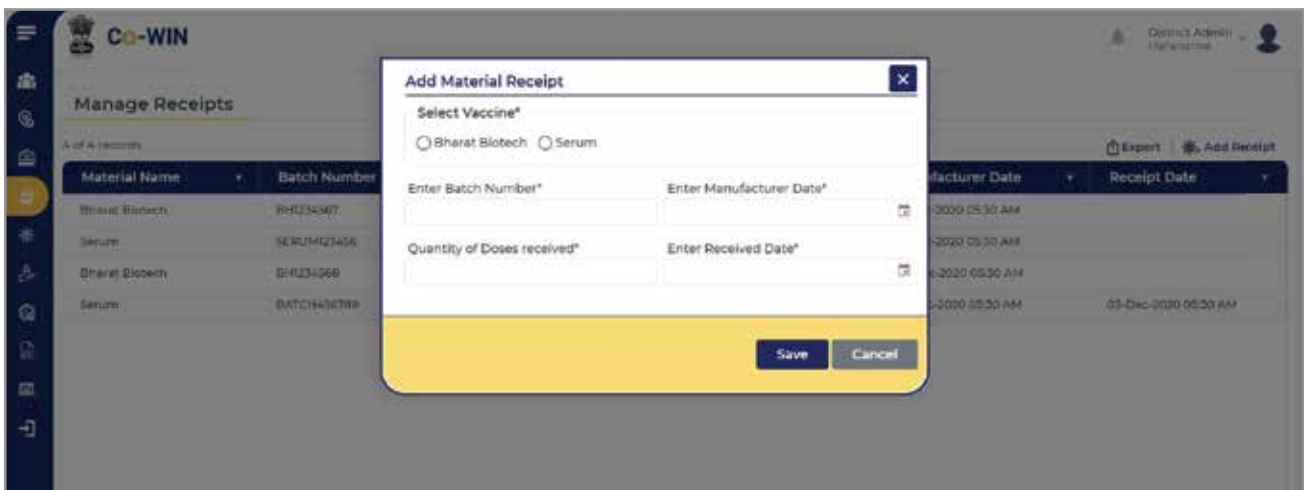


Figure 8b – Receipt of Vaccines by District Admin

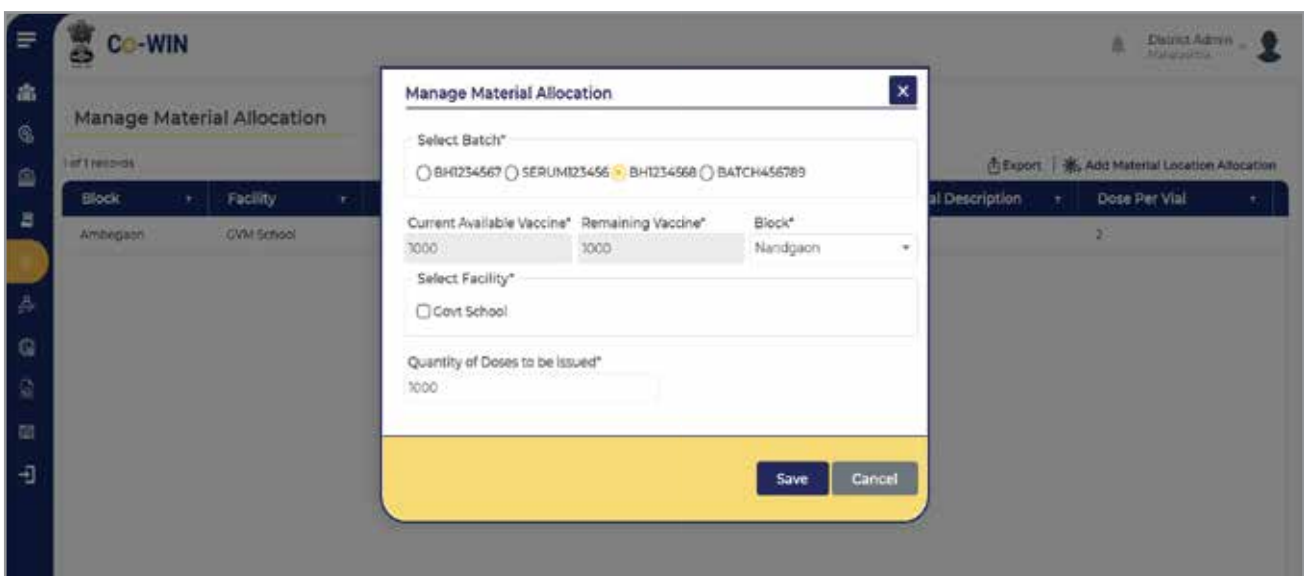


Figure 8c – Allocating vaccines to facilities

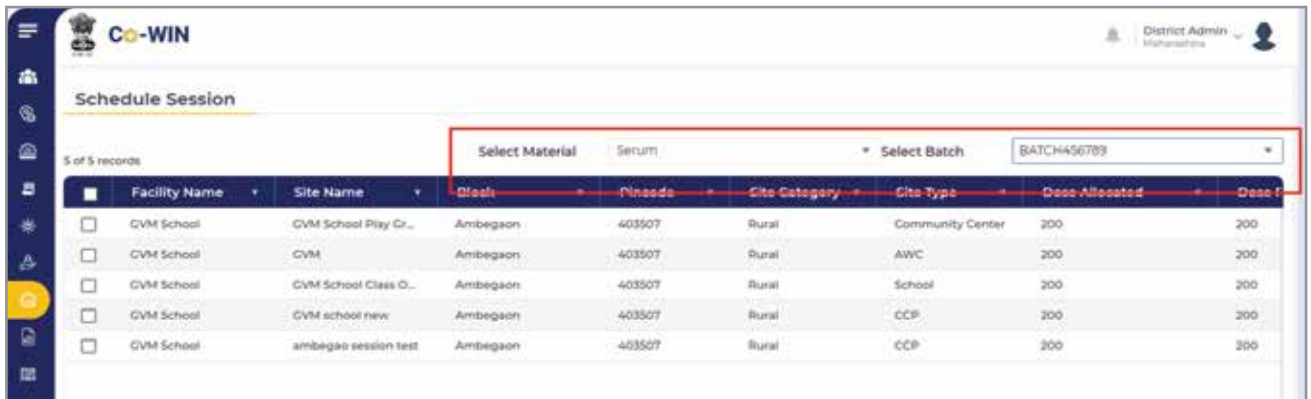


Figure 8d – Selecting session site for allocation based on vaccine type and batch number

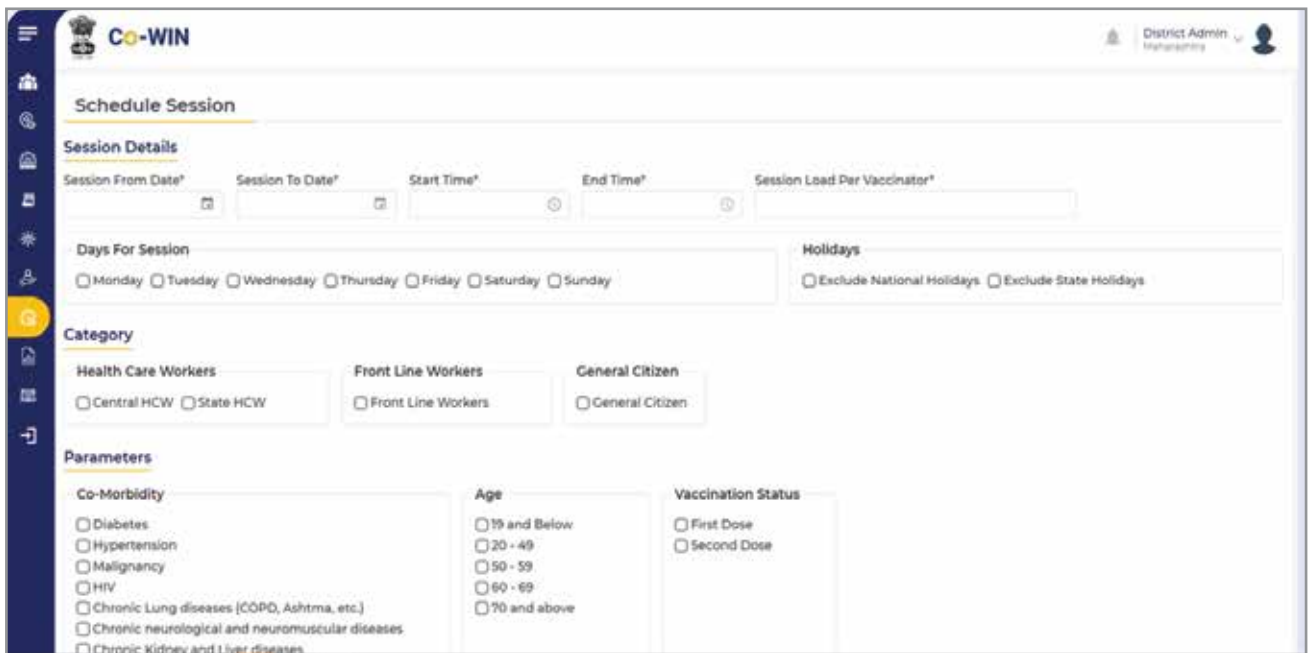


Figure 8e – Scheduling of Session

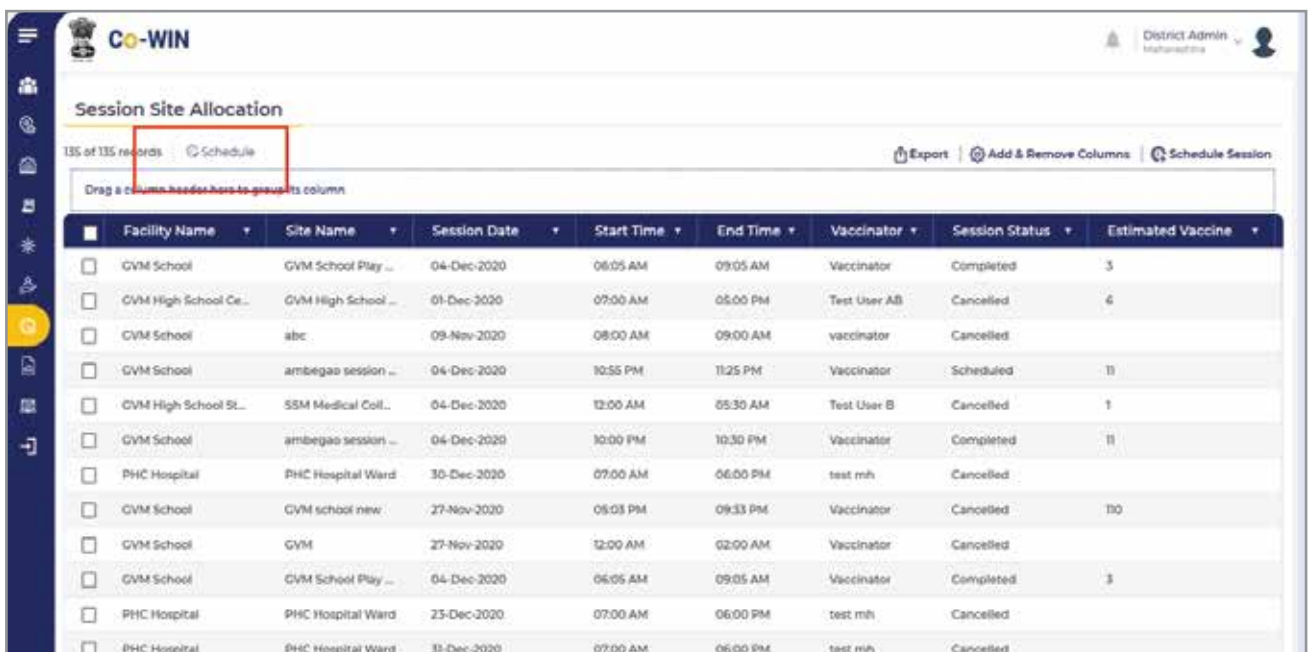


Figure 8f – Scheduling Draft sessions



Each vaccination session will be expected to cater to maximum of 100 beneficiaries, however, in case of remote and sparsely populated areas the state could organize session for lesser number of beneficiaries ensuring that there is no vaccine wastage. If the number of beneficiaries at a session are less, then such session site will be clubbed with other sessions. Each session must be planned for 100 beneficiaries per day. If the session site has adequate logistics and space available for waiting room and observation room along with arrangement for crowd management, one more vaccinator officer can be added to create a session for 200 beneficiaries. A full team of a vaccinator Officer and four vaccination officers needs to be deployed, if a session is expected to cater to more than 200 beneficiaries.

## 6.1.9 MONITORING AND REPORTING

The Co-WIN system will have an inbuilt mechanism of monitoring and reporting which will include some key performance indicators like:

- a. Beneficiaries registered against baseline;
- b. Sessions planned vs sessions held;
- c. Beneficiaries vaccinated for each dose against Beneficiaries registered for vaccination;
- d. Beneficiaries who completed the schedule of COVID-19 vaccination against beneficiaries registered for vaccination;
- e. Dropout rates for dose 2 against dose 1 and dose 3 against dose 2 whichever is applicable;
- f. Left out rates in terms of registered beneficiaries who have not received even one dose of vaccine after session allocation; and
- g. AEFI reported against number of beneficiaries vaccinated.

Further reports and indicators will be added as the system matures. These reports will be aggregated on a real-time basis and at National, State, Sub-State levels.

## 6.2 FEATURES OF CO-WIN APPLICATION

### 6.2.1 VACCINATOR MODULE

Vaccination module in the Co-WIN system will be used by Vaccinator Officer and Vaccination officer 2 at the time of vaccination. At the session site, only pre-registered beneficiaries will be allowed to proceed for vaccination. Before vaccination, Vaccination Officer 2 will use the Co-WIN application to verify the beneficiaries for whom Aadhaar authentication has been done at time of registration by using Aadhaar card or other Photo IDs as per the guidelines. For the beneficiaries whose Aadhaar authentication has not been done previously, the verifiers will conduct the Aadhaar authentication, if Aadhaar card/number is available. If Aadhaar card/number is not available, then other Photo IDs will be used as per guidelines. Once the beneficiary details are authenticated/verified they will proceed for vaccination and their vaccination status will be updated to 'Vaccinated' in the application by the Vaccination Officer 2 after confirmation of the same from the Vaccinator officer (Figure 10a and Figure 10b). The supervisors will have access to the list of session sites and beneficiaries to be vaccinated on a designated day in the Co-WIN application. The supervisors will use this list to monitor and supervise the session sites on the day of vaccination. For registered beneficiaries who don't have an Aadhaar card or other Photo ID, the vaccination officer will crosscheck the demographic details from the beneficiary as per the details in application and if found correct, the beneficiary will be vaccinated.



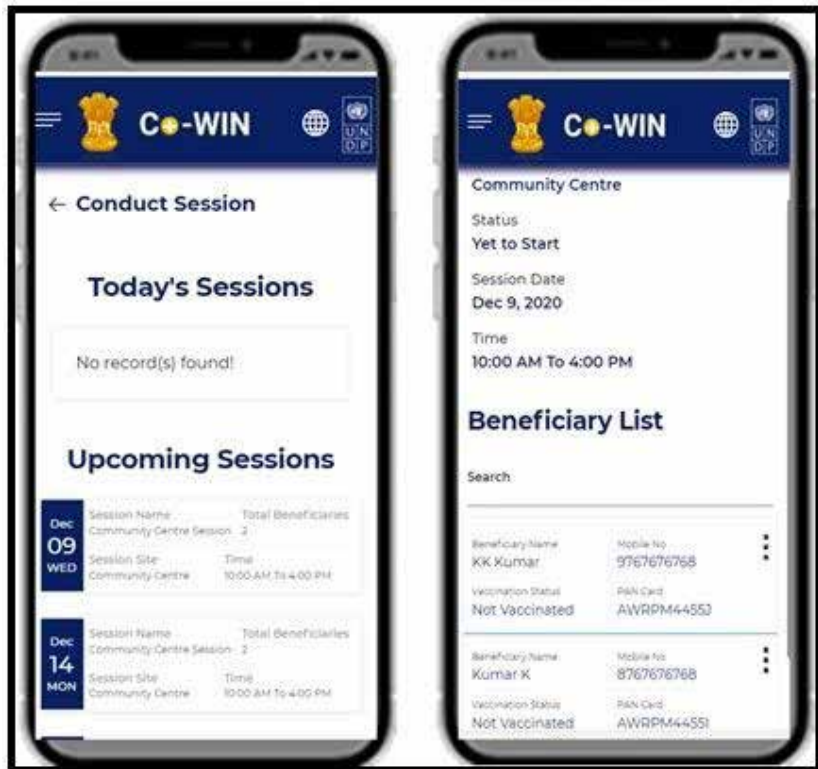


Figure 9a – Vaccination Officer's module – List of sessions and beneficiaries

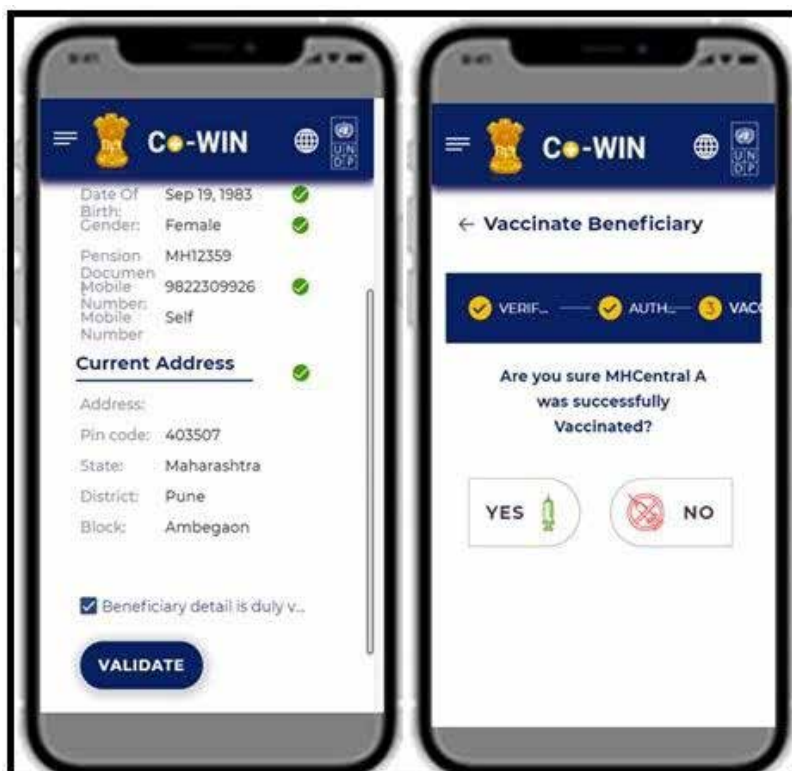


Figure 9b – Vaccination Officer's Module – Verifying and Confirmation of Vaccination





## 7. ADMINISTRATION OF COVID-19 VACCINE

The rollout of COVID-19 vaccine in a time bound manner while ensuring safety and security will require the development of a detailed operational plan following due consultation with various stakeholders. While the vaccine characteristics (including efficacy, safety, cold chain requirements, number of doses, interchangeability, herd immunity etc.) will be known with the availability of vaccine, the overall operational plan can be streamlined and prepared for quick roll out of COVID-19 vaccine whenever available.

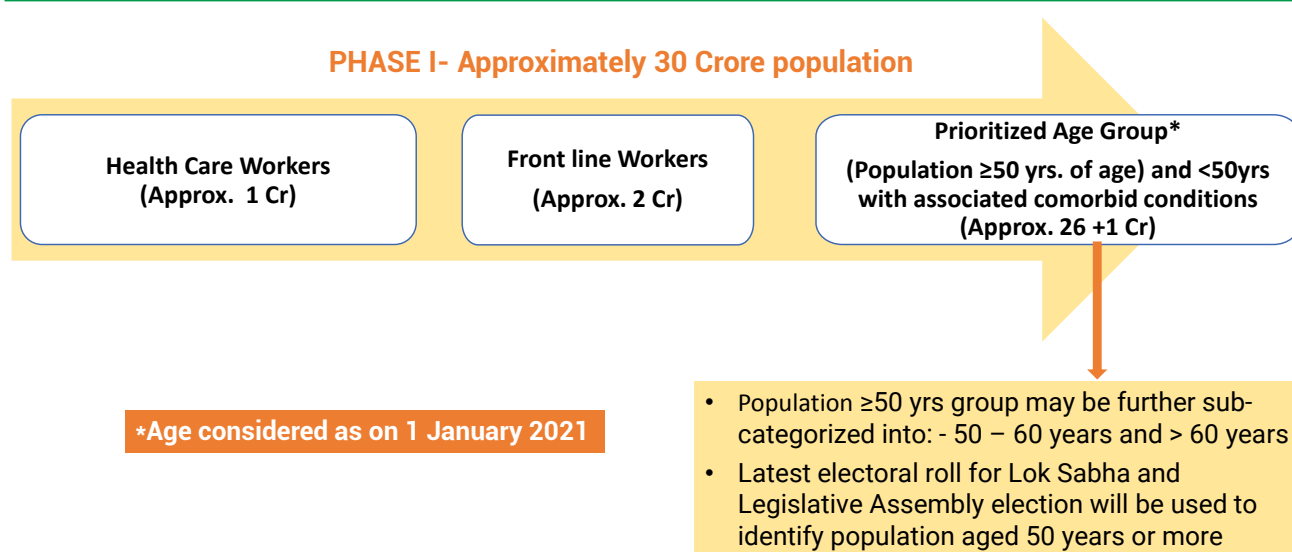
### 7.1 PRIORITIZATION OF BENEFICIARIES FOR COVID-19 VACCINE

Based on the guidance from NEGVAC, COVID-19 vaccine will be introduced in a phased manner with first phase focusing on health care workers, frontline workers and population at higher risk. The prioritization of groups will depend upon the disease incidence and prevailing pandemic situation.

Timing for rollout of vaccination in these three-priority groups will be tailored based on vaccine availability and is not necessarily sequential. In phase-1 of the vaccination, it is planned to vaccinate nearly 30 crore population:

- 1. Health Care Workers (HCWs):** Health care providers and workers in health care settings (Public and Private), including ICDS workers
- 2. Frontline Workers (FLWs):** Personnel from State and Central Police department, Armed Forces, Home, Guard, prison staff, disaster management volunteers and Civil Defense Organization, Municipal Workers and Revenue officials engaged in COVID-19 containment, surveillance and associated activities.
- 3. Population  $\geq 50$  years of age and  $< 50$  years with co-morbidities like diabetes, hypertension, cancer, lung diseases etc.**

**FIGURE 7.1: PHASE-1 OF COVID-19 VACCINE INTRODUCTION**



**Goal is to protect people, minimize societal and economic impact by reducing COVID-19 mortality**

**Health Care Workers:** HCW is defined as 'health care service providers and other workers in health care settings; both in government and private sector including ICDS workers.

Health Care Workers group for COVID-19 vaccination comprise of:

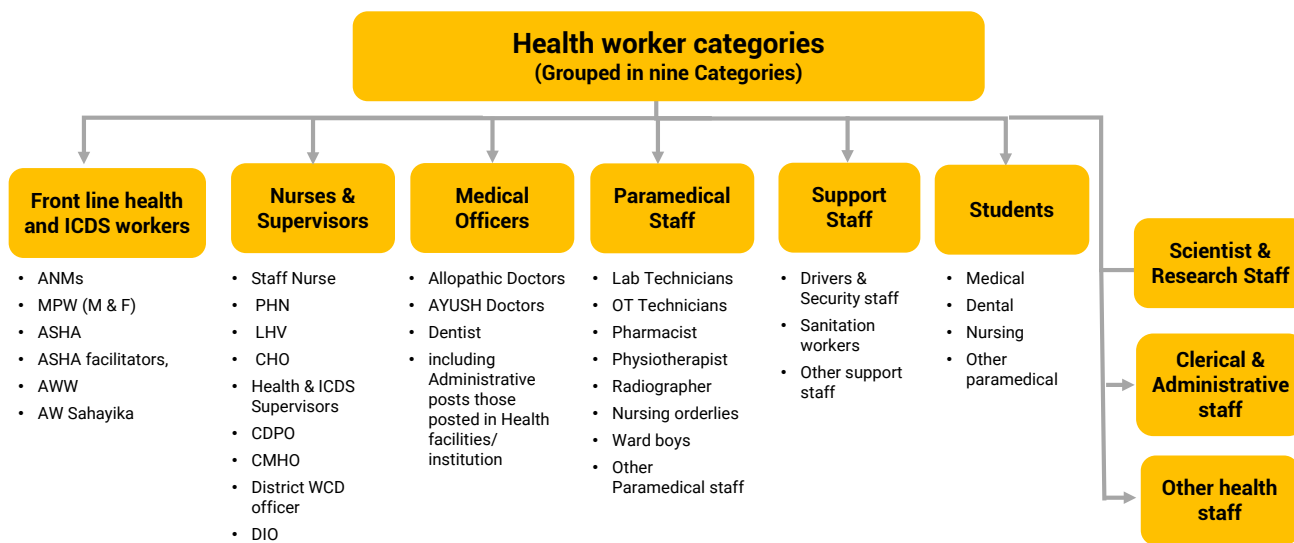


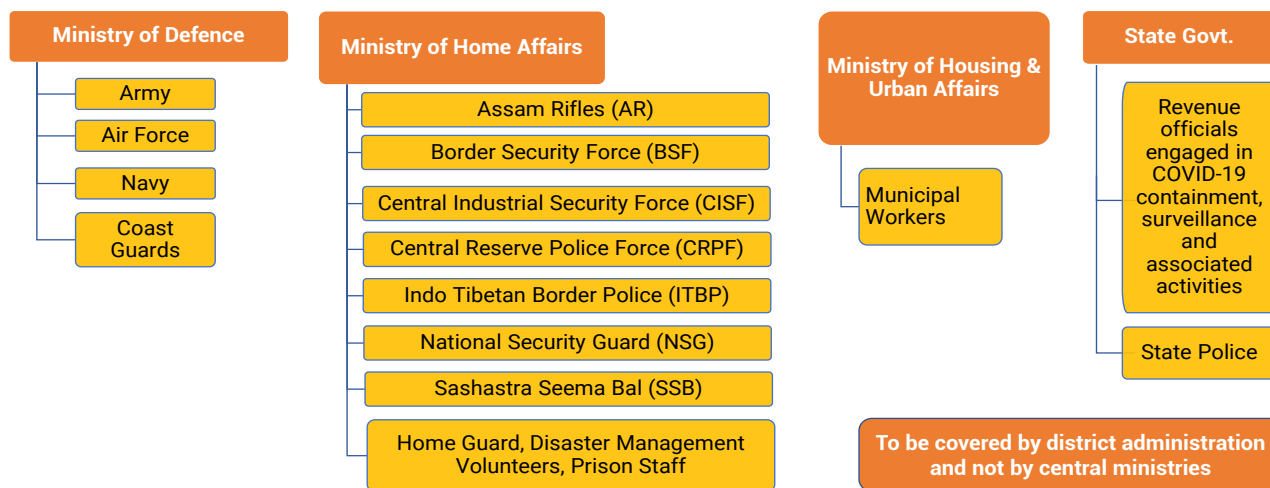
Figure 7.2: Health Care Worker categories for COVID-19 vaccination

## FRONTLINE WORKERS

Frontline Workers engaged in delivery of essential services such as police staff, defense, municipal workers etc. will be prioritized for COVID-19 vaccination and include the following groups:

### FIGURE 7.3: FRONTLINE WORKERS CATEGORIES

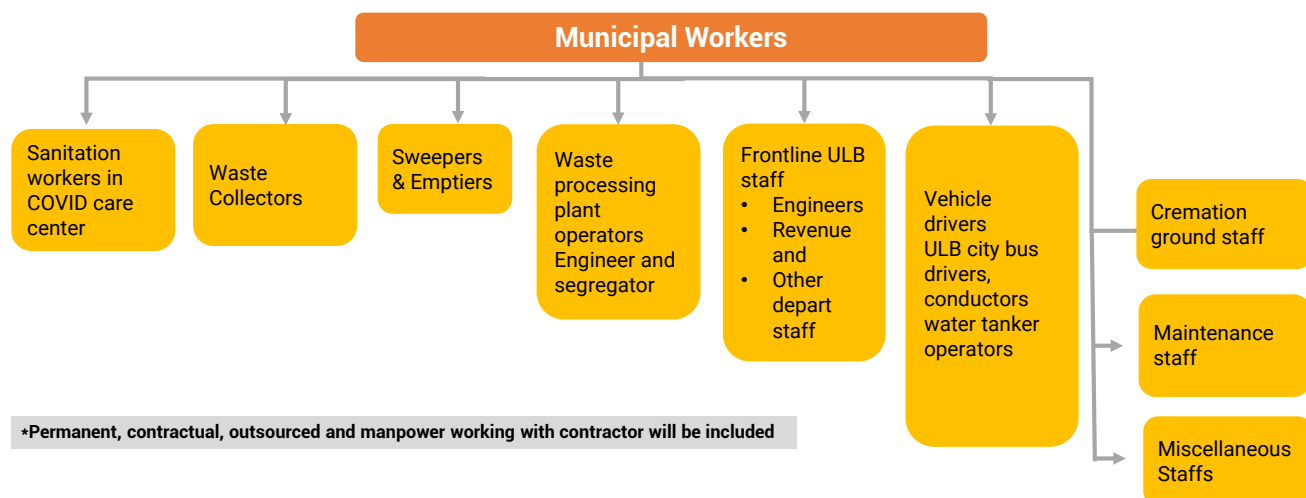
Frontline workers are personnel from following departments





**Municipal Workers:** are defined as “all workers\* who are engaged in providing any form of public health, sanitation and waste management services for the city or town”

**Municipal workers are further classified as follow:**



*Figure 7.4: Municipal worker categories for COVID-19 vaccination*

### PRIORITIZED AGE GROUP

While COVID-19 effects every age group, morbidity and mortality among elderly and people with co-morbidities is higher than other age groups. Therefore, population with age  $\geq 50$  years will be prioritized for vaccination. Priority will also be extended to  $< 50$  years population with associated comorbidities in a phased manner. The prioritization will depend upon the disease incidence and prevailing pandemic situation.

Latest electoral roll for Lok Sabha and Legislative Assembly election will be used to identify population aged 50 years or more.

Age will be calculated based on the cut off date of 1st January 2021 and anyone born on or before 1st January 1971 will fall under this category. This group will be further sub-categorized into various age groups with priority to senior citizens ( $\geq 60$  years):

- Population  $\geq 60$  years; and
- Population between 50 –  $< 60$  years of age.

### LINE LISTING OF BENEFICIARIES

Every eligible person for COVID-19 vaccination needs to be registered in the Co-WIN application and a systemic line listing mechanism has been created for different priority groups:

- 1. Health workers:** Standard template (excel sheet) provided to the states and central ministries is used to collect the data of the HCWs working in various health facilities/institutions (public and private). Once the data is collected, the template will be uploaded into the Co-WIN system at [www.cowin.gov.in](http://www.cowin.gov.in).



**2. Frontline Workers:** Customized templates will be developed in consultation with Nodal officers of the concerned Ministries for identified FLW groups. These templates will be available for downloading from Co-WIN and will be used for data compilation and bulk upload. The concerned facility/level can also register the beneficiary individually by logging in app.cowin.gov.in.

The data for frontline workers will be collected by respective ministries and departments and uploaded in the system based on the above defined two mechanisms. The states and the concerned central ministries' nodal officers have been trained by the UNDP team on how to create the HCW and FLW data base in Co-WIN. A detailed description of Co-WIN and its features are highlighted in previous Chapter 6.

**3. Prioritized Age Group:** Latest electoral roll for Lok Sabha and Legislative Assembly election will be used to identify population aged 50 years or more.

The detailed guidelines on data collection of Healthcare workers along with roles, responsibilities and coordination mechanism was shared by MoHFW vide letter dated 16th October 2020. States need to ensure completion of data collection and review of collected data in STFI and DTFI meetings.

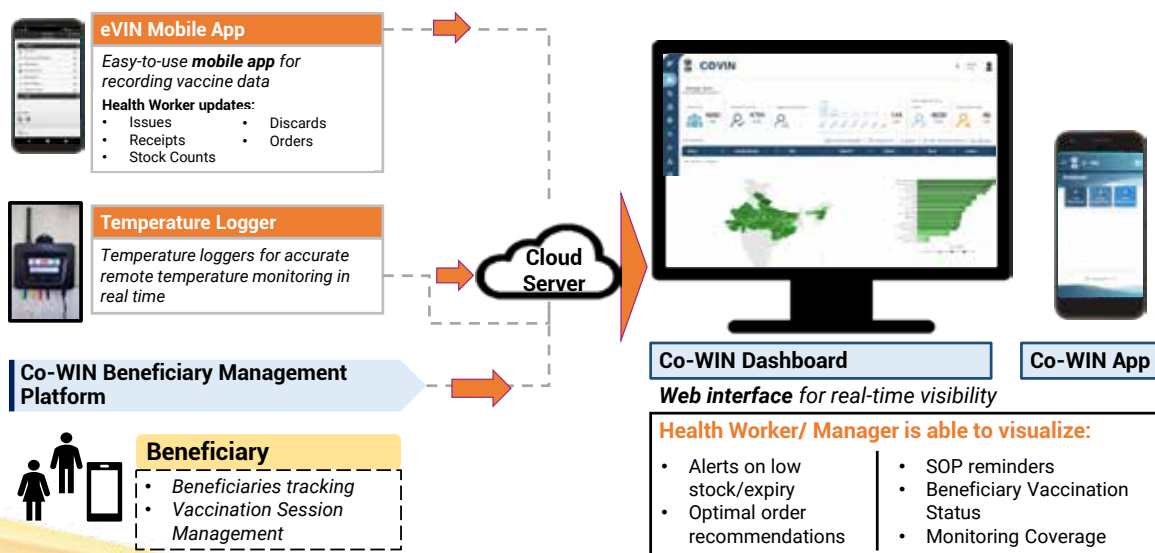
**4. Geographical Prioritization:** States/ UTs will also have the generic flexibility to do priority phasing of the roll-out for the identified priority groups (as decided by the NEGVC) in identified geographical areas where the COVID-19 infection prevalence is high.

## 7.2 SESSION SITE PLANNING AND MANAGEMENT

Once the beneficiary registration and upload process are completed by the Central and State Ministries/Departments, the Co-WIN system will be used by District Collector (DC)/ District Magistrate (DM) for session site planning i.e. allocated beneficiaries to session site which in turn will be linked to a vaccinator. For session planning, district will be taken as a unit and District Collector (DC)/ District Magistrate (DM) will plan the sessions to cover all priority groups located within the district covering State and Central ministries/departments and private sector HCWs within district. DTFI platform will be used to collaborate with various stakeholders while identifying session site and other operational planning with clear roles and responsibilities. For the same, multi-disciplinary teams should be formed at district and block levels, like in election mode, to check the adequacy of the proposed sites with respect to the necessary arrangements at a session site as mentioned in the subsequent part of this section of operational guidelines. Further, another physical inspection of the session sites a day prior to the scheduled session day will help to check that all arrangements are in place.

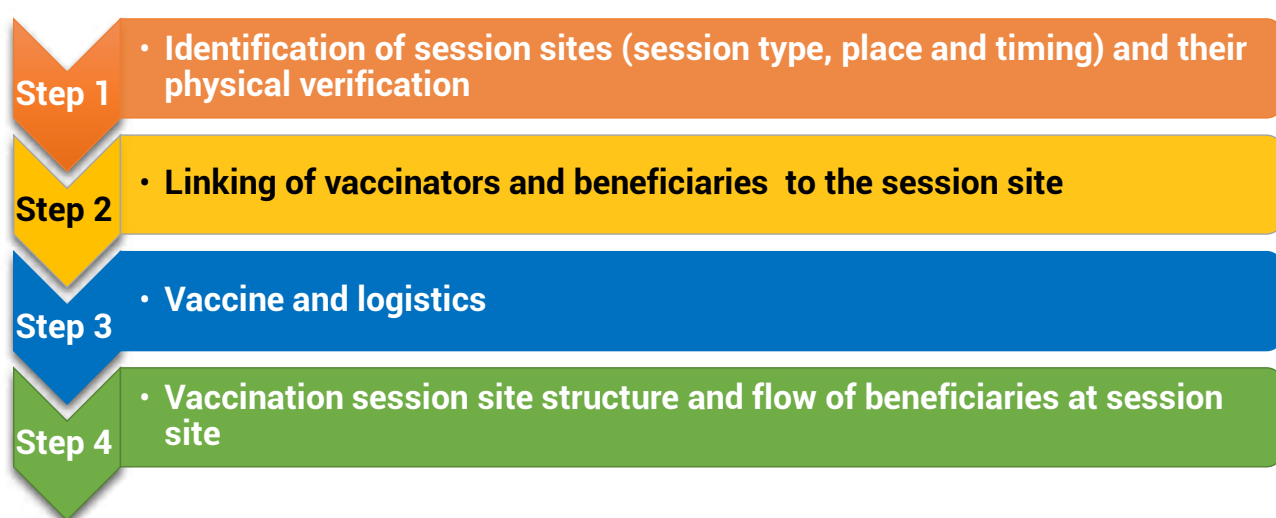
**Staggering beneficiaries will help to avoid over crowding at vaccination session site**

**FIGURE 7.5: ELECTRONIC VACCINE INTELLIGENCE NETWORK (EVIN) TO CO-WIN**



District Collector (DC)/District Magistrate (DM) with support of District Immunization Officer will link the sessions sites, vaccinators, supervisors and beneficiaries and decide the dates and time for conducting the vaccination session. Selection of session site will be at the discretion of the DC/DM, who would ensure that each session is planned for 100 beneficiaries per day (based on vaccine presentation and open vial policy). If the session site has adequate logistics and space available for waiting room and observation room along with arrangement for crowd management, one more vaccinator can be added to create a session for 200 beneficiaries.

In remote and sparsely populated areas, state / districts could consider conducting session for lesser beneficiaries, as well as having mobile vaccination teams, however, due care should be undertaken to minimize the vaccine wastage.



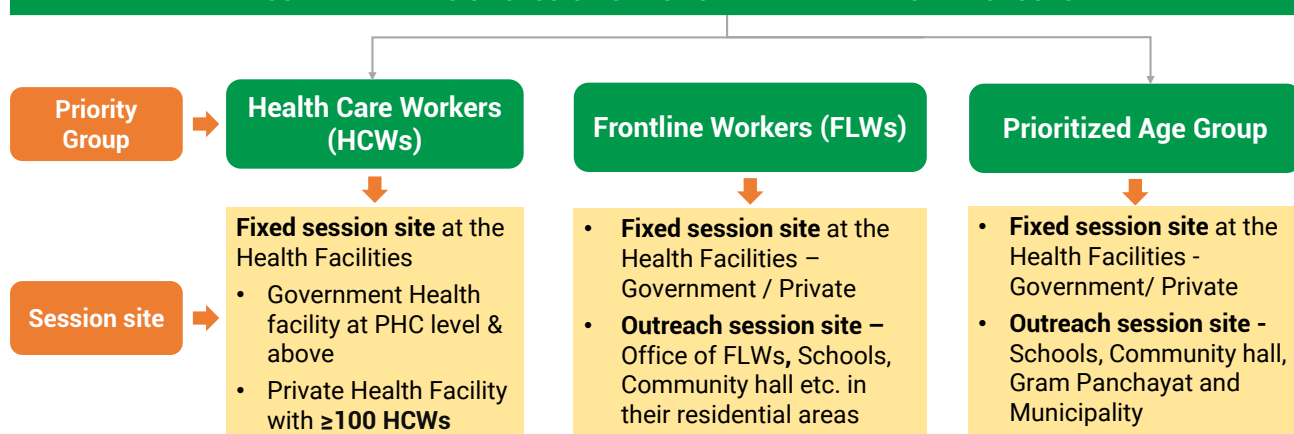
*Figure 7.6: Steps of session site planning and management*

## **STEP 1** IDENTIFICATION OF SESSION SITES (SESSION TYPE, PLACE AND TIMING) AND THEIR PHYSICAL VERIFICATION

Session sites will be identified by DC/DM for entire eligible priority groups within the district (State and Central ministries including private sector HCWs) before linking the beneficiaries to the session site. Multi-disciplinary teams should be formed at district, urban and block level, like in election mode to check the adequacy of the planned sites. The Block/Urban Task Force should check all the proposed sites and the District Task Force shall check a sample of the sites for ensuring that required space, infrastructure for making all necessary arrangements, including security arrangements, at a session site is available, and that all other preparatory arrangements are made. This physical inspection of the proposed session sites is an important aspect of preparatory activities and needs to be ensured.

In addition, the session sites and the concerned cold chain point should also be inspected a day prior to the scheduled vaccination to ensure that all preparatory arrangements have been made (checklist at annexure 6). The following strategy will be adopted for vaccination of priority groups:

**FIGURE 7.7: TYPES OF SESSION SITES FOR DIFFERENT PRIORITY GROUPS**



**Note:** Facilities with <100 beneficiaries should be clubbed in both Government & Private settings to make a injection load of 100

- Election polling booth list may be referred for identifying outreach sessions sites
- Special mobile teams for hard-to-reach areas, unserved or underserved areas, migratory populations areas, international borders or LWE areas
- Session site venue list is indicative, DTF to finalize session site as per available resources

## FIXED SESSION SITE

Vaccination conducted at the health facilities (both government and private) where medical officer/doctor is available is defined as Fixed Session Site. All government health facilities at and above the level of Primary Health Centre/Urban Primary Health Centre can be utilized as session site. Private health facilities with  $\geq 100$  HCW can be opted as session sites. For the initial phase of HCW vaccination, the facilities with lesser number of HCWs will be clubbed together under a nodal facility that could be a session site. For example, all facilities like sub health centre (SHCs) that are below PHC level can be clubbed together at the PHC or CHC level for administering the vaccine. Similarly, all private sector OPD clinics could be clubbed together at a larger Nodal facility or hospital. DC/ DM as chair of DTFI will identify and finalize session sites after taking a holistic review and in collaboration with all other stakeholders. DC/DM would be assisted by CMHO, DIO and private sector professional bodies of HCWs in finalising the vaccination sites considering vaccination load, convenience of beneficiaries and the suitability of the vaccination site such as availability of adequate space/ rooms etc. It must be ensured that there is no vaccine wastage while undertaking this planning exercise.

## OUTREACH SESSION SITE

Vaccination conducted at the site other than health facility is defined as Outreach Session Site. Various locations like schools, colleges, community hall, municipal offices, panchayat bhawan, marriage places, FLWs offices like cantonment hospitals/clinics, railway hospitals etc. can be identified as outreach session sites if they fulfil all the pre-requisite conditions for arranging a session. Election polling booth list may also be utilized for identification of outreach session sites. It will be at the discretion of DC/DM to identify and finalize session site after a holistic review and discussions with other stakeholders. Vaccination sites can also be planned in FLWs from central ministries are placed e.g. cantonment areas, encampment of the paramilitary forces, railways and other central PSU colonies. Once finalized, these session sites need to be uploaded in Co-WIN. It will be incumbent on DTF and BTF to ensure all FLWs from such Central ministries are covered.

## SPECIAL MOBILE TEAMS

For hard-to-reach areas, unserved or underserved areas, migratory populations areas, international borders or LWE areas, districts need to plan special mobile teams as part of the operational plan.

## VACCINATION DAYS

Vaccination to be planned excluding Routine Immunization days for uninterrupted routine immunization services for children and pregnant women.

## DURATION OF SESSION

All COVID-19 vaccination sessions will be conducted from 9 am to 5 pm.

All efforts need to be undertaken to ensure no overcrowding of beneficiaries / attendants are at vaccination session site. Beneficiaries should be allocated staggered time slots.

## **STEP 2** LINKING OF VACCINATORS AND BENEFICIARIES TO THE SESSION SITE

Once planning unit wise session sites are planned, vaccinators, mobilizers, security staff, support staff and supervisors are to be finalized. They are linked to the particular session and the beneficiaries are tagged to specific session. Autogenerated SMS/email intimation will be sent to the beneficiaries, vaccinators, mobilizers and supervisors about the date, time and place of the session. To observe the staggered approach, beneficiaries should be advised by mobilisers to come to session as per staggered time slot to prevent overcrowding at the sessions site.

## **STEP 3** VACCINE AND LOGISTIC PLANNING

Vaccine and logistics for the session sites need to be calculated in accordance with number of beneficiaries due for vaccination under Co-WIN. Only one type of vaccine should be planned across sessions in a day. As data on interchangeability is currently not available, every beneficiary must receive the 2nd dose of same vaccine and the same should be considered while allocating vaccine through the Co-WIN system.

Vaccine needs to be sent to every session site on the day of vaccination along with one additional vaccine carrier with conditioned icepacks using alternate vaccine delivery mechanism. Along with vaccine, each session site needs to be provided with three hard copies of registered beneficiary list due for vaccination on that session site.

Vaccination session site should be sanitized prior to vaccination.

Each session site should have the following items (refer annexure-2):

1. Three printed copies of beneficiary list (wherever feasible);
2. Vaccine carrier with ice packs and additional vaccine carrier;
3. Adequate COVID-19 vaccine;
4. Adequate numbers of AD syringes and reconstitution syringe (if needed);
5. Hand sanitizer and masks;
6. Vaccine vial opener;
7. Hub cutter;
8. Screen for privacy (if room is not separate);
9. Anaphylaxis kit;
10. Red, yellow and black bags, puncture proof blue container, waste basket;
11. Cotton wool;
12. Tally sheet and manual reporting formats;
13. IEC material; and
14. Hand washing facilities.

As mentioned before, a day before vaccination, physical inspection of session sites will be undertaken by BTF team (DTF to do a sample check) to ensure logistics arrangements (checklist at annexure 6). The detailed logistics arrangements for the session can be checked using checklist at annexure 2. BTF will review the feedback and undertake corrective measures.

## STEP 4 VACCINATION SESSION SITE STRUCTURE AND FLOW OF BENEFICIARIES AT SESSION SITE

### COVID-19 VACCINATION SESSION SITE STRUCTURE

#### Guiding principle of vaccine eligibility for the beneficiaries

Only pre-registered beneficiaries will be eligible for COVID-19 vaccination. No on the spot registration of beneficiaries at the session site. Pre-registration of the beneficiary could take place through:

1. Bulk upload of HCWs and FLWs data by respective departments;
2. From latest electoral roll for Lok Sabha and Legislative Assembly election for priority age group population aged 50 years or more; and
3. Self-registration by beneficiary.

**Guidelines on session site structure:** Vaccination session site structure should be like that of the election booth with exactly defined role of each team member. District Administration and DTF/ BTF will ensure that the vaccination session site chosen should have minimum risk of COVID-19 virus transmission ensuring proper infection prevention and control practices, identification and allocation of duties including a backup team to support in case of absenteeism due to unforeseen circumstances. The session site should have good internet connectivity. Following are the key considerations while selecting the session site:



Beneficiaries for Vaccination







Sufficient shaded space



Adequate & Safe  
Drinking water



Friendly for female, elderly  
and people with special needs



Internet connectivity

Figure.7.8: Key considerations for selection of session site

There are a range of simple steps that may be taken to protect beneficiaries from COVID-19 exposure, such as:

- Limiting the number of individuals present at vaccination session site;
- Organising scheduled times for vaccination appointments;
- Use of outdoor spaces, if possible, and adherence to physical distancing at the health care facility or site; and
- For vaccination sessions at health facility, vaccination area and waiting areas should be separated from curative services (i.e. separate times of the day or separate spaces depending on the facility).

## DETAILED SESSION PLANNING

1. Based on beneficiary listing, session site and vaccinators details, session planning and vaccine allocation will be done through Co-WIN. This will be accessible to planning unit incharge and cold chain handler
2. Block PHC / Planning unit incharge will allocate other four team members (vaccination officer 1-4) and complete planning as per COVID-19 Vaccination Planning Template (Annexure-1). Block task force will closely review the planning process. Plan will also be shared with district task force.
3. Block PHC / Planning unit incharge will inform each of the member about responsibilities. Block task force will ensure all team members reaches session site in time
4. Block PHC / Planning unit incharge will coordinate with cold chain handler to ensure vaccine and other logistics reaches the session site well before session start timings.

## LAYOUT PLAN OF SESSION SITE

An ideal session site should have three demarcated rooms/areas:

1. Waiting Room/Area;
  2. Vaccination Room; and
  3. Observation Room.
- The rooms should preferably have 2 doors one for entry & one for exit.
  - Rooms/areas should be well-ventilated. A well-ventilated area is one that can be achieved through open windows and natural ventilation.



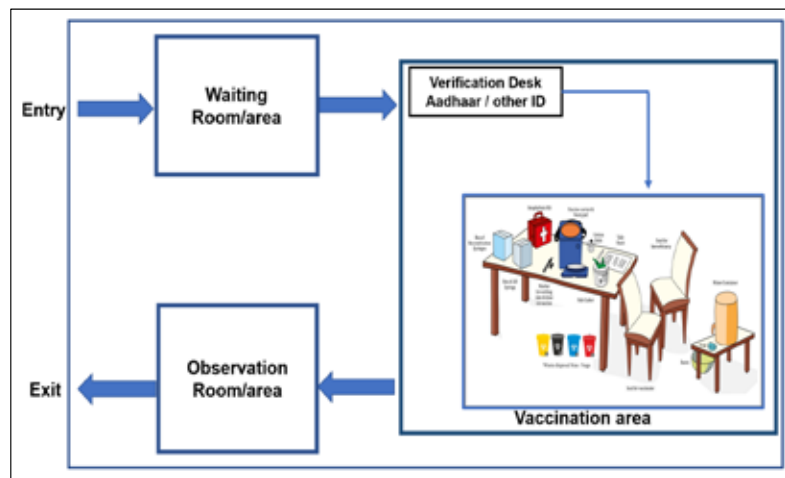
Figure.7.9: Physical distancing at session site

- Waiting area should be demarcated so that seating location should be 2 Gaz apart. Waiting area could be part indoor and part outdoor with adequate arrangement of chairs, benches, drinking water etc.
- Ensure privacy at the Injection site.
- Adequate queue management and crowd control system outside the waiting area with '2 Gaz ki Door' maintained between individuals.
- Access to the Vaccination site should enable proper access for the differently abled.
- Adequate seating arrangements should be available at the site. Waiting area should be covered to protect the beneficiaries from the vagaries of nature (Cold weather, Rains etc.). Since the priority groups include the elderly, adequate arrangements must be made for their ease and comfort.

1. **Waiting Room/Area:** This should preferably be a separate room or a clearly demarcated and covered

**FIGURE 7.10: LAYOUT PLAN OF THE VACCINATION SESSION SITE**

- Designate a **separate entry and exit** if possible
- Designate **3 separate rooms or areas**
  - ♦ Waiting room
  - ♦ Vaccination Room
  - ♦ Observation Room
- Ensure **adequate physical distance** between chairs/ seats in waiting rooms
- **Avoid criss-cross movement** of beneficiaries at session site



area. As the priority population includes senior citizens and people with co-morbidities, seating arrangement with distancing, protection from direct sun, rain or wind to be ensured. There should be preferably separate entry and exit and handwashing/sanitization facilities available at entrance.

**FIGURE.7.11: WAITING ROOM/AREA**

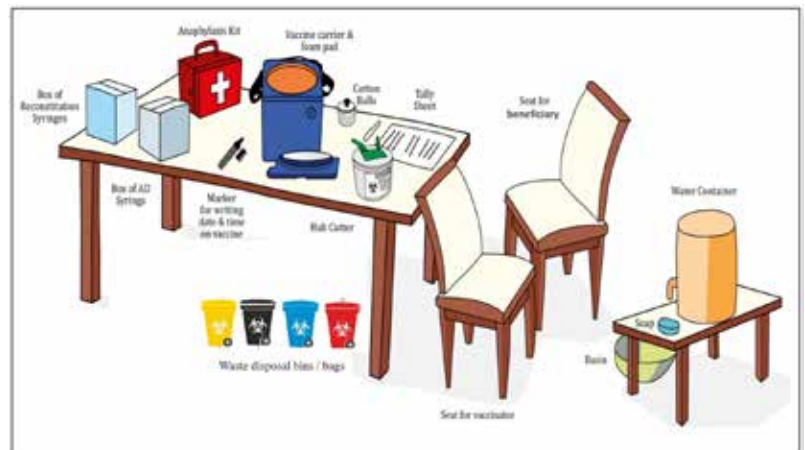
- Seating arrangement to **ensure physical distancing**
- Only **one person to enter** vaccination room at a time
- Facility for **hand washing/ sanitization** at entrance
- IEC materials on **COVID appropriate behaviour** to be displayed



2. **Vaccination Room:** There should ideally be a dedicated room for vaccination with one table (at least 4 feet x 2 feet) and two chairs, handwashing/sanitization arrangement and all other logistics mentioned above. In case of female beneficiary, it must be ensured that a female team member is present in the room while vaccinating.

**FIGURE 7.12: VACCINATION ROOM / AREA**

- Only one beneficiary enters vaccination room to ensure privacy
- Logistics to be made available
  - ◆ One table (4 feet X 2 feet), two chairs
  - ◆ Vaccine carrier with ice packs
  - ◆ Adequate COVID-19 vaccine
  - ◆ Adequate numbers of AD syringes
  - ◆ Hand sanitizer and masks
  - ◆ Vaccine vial opener
  - ◆ Hub cutter
  - ◆ Screen for privacy
  - ◆ Anaphylaxis kit
  - ◆ **Red, yellow and black bags, puncture proof blue container and waste basket**



3. **Observation Room:** This needs to be a room with adequate seating space, drinking water and toilet facility as senior citizens need to wait for 30 mins in comfortable environment.

**FIGURE 7.13: OBSERVATION ROOM**

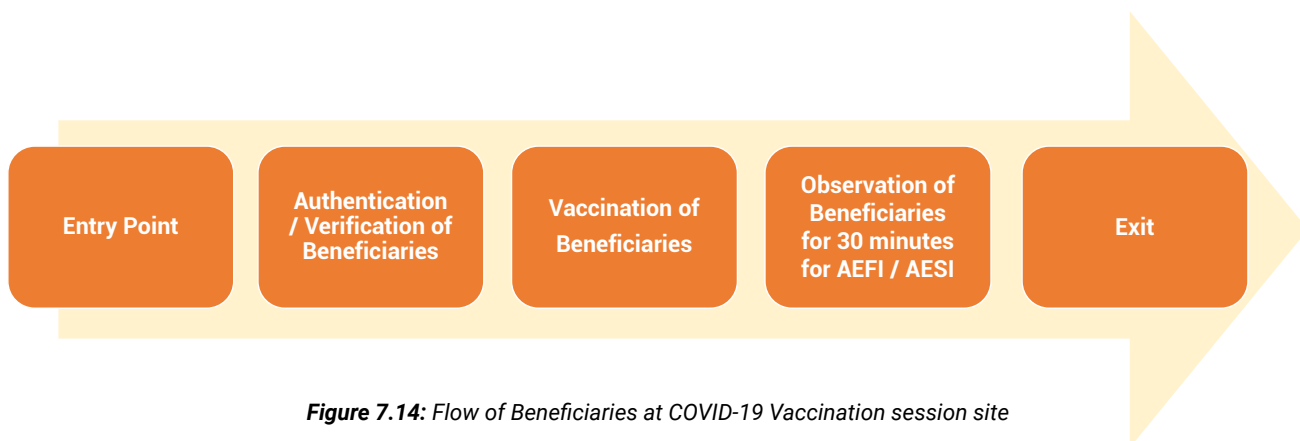
- Beneficiaries wait for 30 minutes post vaccination
- Seating arrangement ensuring physical distancing norms
- IEC materials on COVID appropriate behaviour may be displayed
- Drinking water should be available



AEFIs occurring within 30 minutes to be managed and/or referred to AEFI management centre. Recording of such events on Co-WIN software (linkage with SafeVac)

**Flow of Beneficiaries at COVID-19 Vaccination session site:**

Support Staff assigned at vaccination session site should ensure flow of beneficiaries at sessions site as per the roles and responsibilities of team members mentioned below:



**Figure 7.14:** Flow of Beneficiaries at COVID-19 Vaccination session site

## VACCINATION TEAM

Every session will be managed by a 5 membered team with defined responsibilities:

**Vaccination Officer-1:** In-charge for pre-checking registration status of beneficiary and photo ID verification before entering the waiting room/area (Police, home guard, Civil defense, NCC, NSS, NYKS) and ensures selected entry to the vaccination session. Vaccination Officer-1 will be assisting in making queues/ crowd management

**Vaccination Officer 2:** In-charge of authenticating/ verify document in the Co-WIN system (Health / ICDS / other government department e.g. election model)

**Vaccinator Officer:** In-charge of vaccinating the beneficiaries (Doctors (MBBS / BDS/AYUSH), Staff Nurse, Pharmacist, ANM, LHV). Anyone authorized to give injection may be considered as potential vaccinator.

**Vaccination Officer 3 and 4:** In-charge of crowd management, ensuring 30-minute wait, monitoring for any AEFI symptoms, guiding non-registered beneficiaries (IEC / communication ICDS / other government department e.g. election model)

- Important planning considerations:
  - ♦ If session load 100-200: another **Vaccinator Officer** will be deployed.

Based on the above team composition, adequate number of personnel need to be identified, trained and allocated to session as part of micro-planning. The team will also be supported by mobilizers (ASHA, AWW, VHSNC, SHGs, PRIs, ULB staff, MAS etc.) for support in session management.

For three to five vaccination team a supervisor will be deployed for closed supervision at session site. Allocation of teams to supervisor will depend upon distancing of vaccination session and travel time. Supervisors working in hilly and difficult to reach areas may have less teams whereas those working in congested areas may have more teams. Team supervisors will be provided with standardized checklist and guide on the job corrections / trainings to vaccination team members.

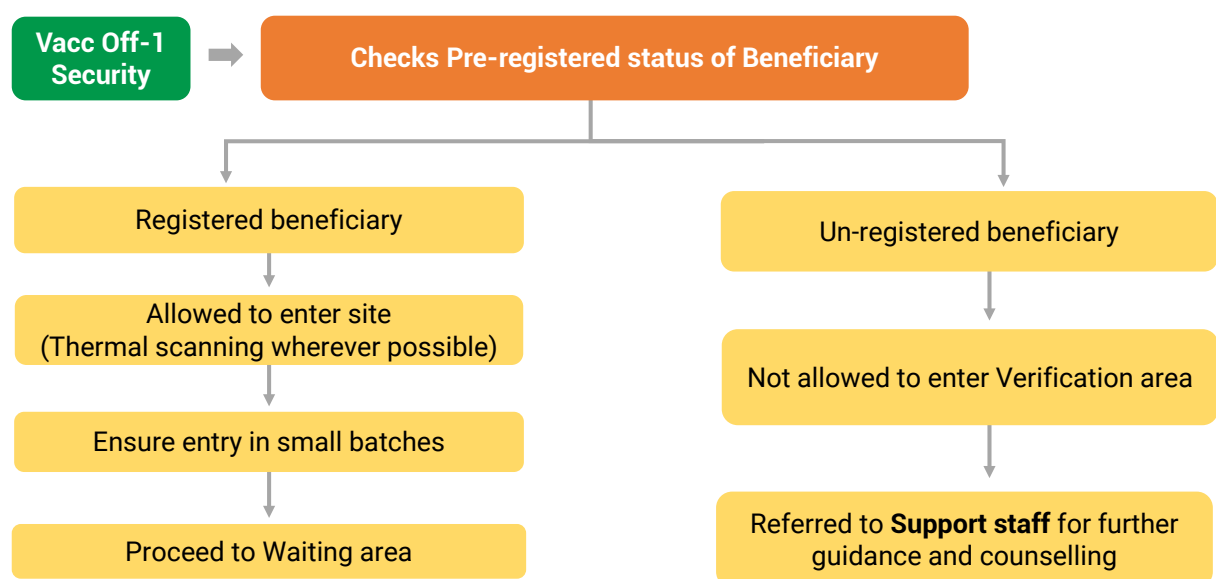


## JOB RESPONSIBILITY OF THE TEAM MEMBERS

### ROLE OF VACCINATION OFFICER-1

The Vaccination Officer-1 will be positioned at the entrance of the session site and will have a hard copy of the registered beneficiary list to be vaccinated on that day at that vaccination site. When the beneficiary comes, he will cross verify the names of the beneficiary from the list received and do a photo identity check. S/he will allow the pre-registered beneficiaries to enter the session site after thermal scanning for temperature check wherever possible. S/he will guide the beneficiary to wash hands before entry to verifier. Un-registered beneficiaries will be referred to the Vaccination Officer-4 for further guidance and counselling.

**FIGURE 7.15: ROLE OF VACCINATION OFFICER-1 AT ENTRY POINT OF SESSION SITE**

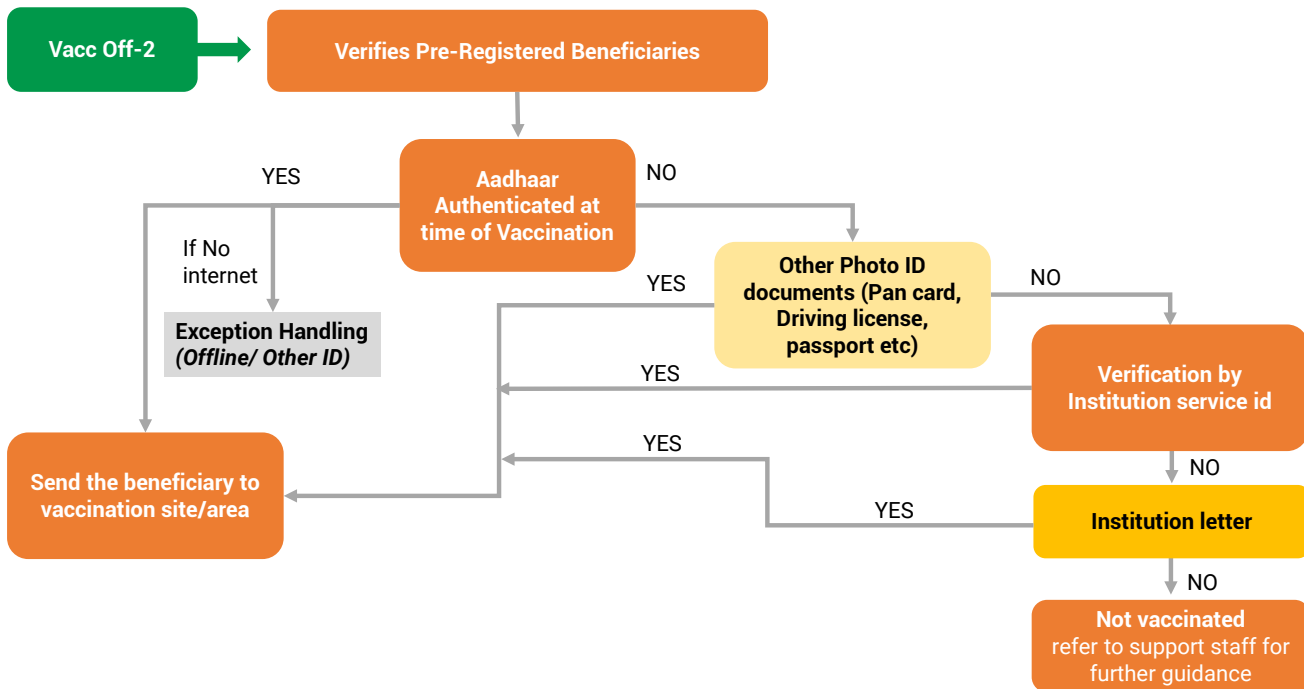




## ROLE OF VACCINATION OFFICER-2

Vaccination Officer-2 should be aware of managing smart phone / tablets and will follow the Co-WIN verification SOPs to verify the beneficiary who are authenticated at the time of registration or those who are registered but not authenticated at the time of registration (e.g.: HCWs) under the Co-WIN system.

**FIGURE 7.16: ROLE OF VACCINATION OFFICER-2 AT VERIFICATION DESK**



In case of beneficiaries authenticated at the time of registration (e.g.: frontline workers or general population above 50 years of age), they will be verified at the time of vaccination.

For those beneficiaries, who do not have Aadhar number/card, other alternate photo ID as per Co-WIN SOPs, the demographic details will be checked to verify the details. In case of HCWs, if Aadhar is not available, check for service ID, verify and vaccinate the beneficiary. If no service ID is available, check for institution letter – employment proof, if available vaccinate and if not available do not vaccinate and refer him/her to Vaccination Officer-4 for further guidance. Once the beneficiary has been verified/authenticated, the verifier will send her/him for vaccination.

If verification fails due to exceptional situations or technical problem at the time of verification/authentication, exceptional handling will be considered. Following are the reasons for exceptional handling: poor internet connectivity/no internet connectivity/ unreadable digits or information on the ID card/non availability of biometric. In such situations scan the QR code on Aadhar card where last 4-digit numbers will come on the mobile screen with details of the beneficiaries. The verifier will cross check the details with the beneficiary. If Aadhar does not have QR Code, cross verify the details manually.

Once the vaccination is completed, Vaccination Officer-2 will update the vaccination status of vaccinated beneficiary in the application.

## ROLE OF VACCINATOR OFFICER

- Vaccinator Officer will vaccinate the beneficiary who has been authenticated/verified by the Vaccination Officer-2.
- Ensure anaphylactic kits with Injection Adrenaline is available at the session site.
- Check expiry date on Injection Adrenaline.
- Mark date and timing of opening of vaccine on each vial as practiced under routine immunization programme.
- Deliver the key messages related to COVID-19 vaccine to the beneficiary.
- Follow all the guidelines of Infection Prevention and Control, injection safety and biomedical waste management as per the training provided to them.
- After providing vaccine to beneficiaries, vaccinator officer will inform Vaccination Officer-2 to update the vaccination status of the beneficiary in the application vaccinated. In case Co-WIN application is managed by vaccinator officer, he/she will update the same.

## ROLE OF VACCINATION OFFICER 3 AND 4

The Vaccination Officer-3 and 4 will have the following key roles:

- Crowd/ Queue management at the session site entry and waiting area.
- Monitor vaccinated persons for any adverse event and immediately report to Vaccinator Officer in any such case.
- Ensuring that all the vaccinated beneficiaries wait for 30 mins in the waiting area after the vaccination.
- Support vaccinator Officer in vaccination process.
- Ensure that all COVID-19 preventive measures are followed like physical distancing (**2 Gaz ki duri**), use of mask, use of sanitisers or hand wash etc.
- Counselling of the un-registered beneficiaries on how to get themselves registered if they are eligible for vaccination.

## ROLE OF TEAM SUPERVISOR

For three to five vaccination team a supervisor will be deployed for closed supervision at session site. Allocation of teams to supervisor will depend upon distancing of vaccination session and travel time. Supervisors working in hilly and difficult to reach areas may have less teams whereas those working in congested areas may have more teams.

Team supervisors will visit teams and check for follow-up of prescribed guidelines for the session site, he/she will ensure:

- All team members are present at the session, in case any of the team member is absent supervisor will co-ordinate with medical officer in charge to arrange alternate team member.
- Availability of all logistics and in case any of the item is missing / inadequate will reimburse the same.
- Follow up of standard procedures (of verification, vaccination, post vaccination waiting, crowd management etc) at session, in case of diversion supervisor will provide on the job training / guidance to the team.
- Will participate in the evening meeting and provide feedback to MO in charge.

## COMMUNICATION MATERIALS AT SESSION SITE

Adequate IEC material should be displayed and made available at the session site including:

- IEC materials like banner, poster, leaflets about COVID-19 vaccination has to be in local language.
- Visual display alerts such as posters, with information about COVID-19 disease and reminders on individual prevention strategies; and
- Message on bringing the ID used to register her/himself will be required at session site for verification purpose: Aadhaar Card, Driving License, Health Insurance Smart Card issued under the scheme of Ministry of Labour, MNREGA Job Card, Official identity cards issued to MPs/MLAs/MLCs, PAN Card, Passbook issued by Bank/Post Office, Passport, Pension Document, Service Identity Card issued to employees by Central/State Govt./PSUs/ Public Limited Companies, Smart Card issued by RGI under NPR, Voter ID Card.

## COMMUNITY ENGAGEMENT AND MOBILIZATION FOR VACCINATION SESSION

- Engagement with community leaders / influencers and mobilizers about COVID-19 vaccination and infection prevention measures must be undertaken in all the phases of vaccination- preparatory phase, implementation phase and post-implementation phase.
- Support arrangement of logistics such as drinking water, sitting arrangements, etc.
- Support from panchayat/urban local body to be sought for identification of appropriate session site with space to practice physical distancing (at least 2 Gaz).
- Engagement with ASHAs, AWWs, panchayats, municipal corporations, NGOs, CSOs, Self Help Groups, Youth networks etc. for mobilization of eligible beneficiaries to the vaccination session. Their support should also be leveraged for sensitising the community on COVID-19 vaccination.

### 7.2.1 COLD CHAIN MAINTENANCE AT SESSION SITE

As there will be no VVM and expiry date on the vial of the vaccine that will be supplied, cold chain maintenance will be of prime importance. The following points need to be ensured at session site:

- All vaccination teams should have an extra vaccine carrier with conditioned ice packs for immediate replenishment of ice packs in the vaccine carrier with vaccine vials;
- Every session site should be monitored by a supervisor including review and checking of vaccine carrier temperature and records;
- Open vial policy will not be applicable and therefore vaccinator officer should mark date and time of opening vial, all open vaccine vials need to be discarded after 4 hours of opening or at the end of session;
- Vaccinator must ensure backup vaccine carrier and icepacks at the session site;
- Never expose the vaccine carrier, the vaccine vial or icepack to direct sunlight;
- All vaccines should be kept inside the vaccine carrier with the lid closed until a beneficiary comes to the centre for vaccination;
- Once the ice pack kept outside melts fully, another ice pack should be taken out of the vaccine carrier to keep the vaccine vial on top of the ice pack (in case the COVID-19 vaccine is very heat sensitive);
- At the end of the session, vaccine carrier with all icepacks and unopened vaccine vials should be sent back to the distributing cold chain point; and
- Intact sealed vials returned on the previous session day should be clearly marked and kept separately in the ILR on top layer so that these will be the first to be used on the following session day.

## 7.2.2 INFECTION PREVENTION AND CONTROL PRACTICES DURING VACCINATION

The team members and beneficiaries should follow proper Infection Prevention and Control Practices as mentioned below:

**Table 7.1:** Infection prevention and control practices during vaccination

	Infection Prevention & Control Actions
For Vaccination Team	<ul style="list-style-type: none"> <li>Do not come to work if you have ILI symptoms (Fever, Cough or Cold). Inform your supervisor about your illness. Isolate yourself, get tested for COVID-19 and take treatment.</li> <li>Adhere to national/state guidance and protocols for IPC measures and use recommended personal protective equipment in line with national policy.</li> <li>Perform hand hygiene before/after each beneficiary using soap and water or with a hand sanitizer that contains 70% alcohol.</li> <li>Wear a three-layered surgical mask and sanitize hands with an alcohol-based sanitizer after vaccinating every beneficiary.</li> <li>Clean and disinfect environmental surfaces often, including tabletops, chairs, light switches.</li> <li>Ensure the availability of hand sanitizer or a hand washing station with soap and water for use by beneficiaries and their companion at the entrance of vaccination sites and health facilities.</li> <li>Strictly adhere to safe waste management protocol for discarded PPE and other consumables at session site.</li> </ul>
During screening	<ul style="list-style-type: none"> <li>Always maintain 2-Gaz distance between screener and beneficiaries/companion.</li> </ul>
At the waiting areas	<ul style="list-style-type: none"> <li>Ensure seating arrangement with physical distancing of 2 Gaz.</li> </ul>
During all sessions	<ul style="list-style-type: none"> <li>Conduct sessions in well-ventilated areas if possible. A well-ventilated area is one that can be achieved through open windows and natural ventilation.</li> <li>Minimise wait times as much as possible</li> <li>Limit number of individuals present at immunization visit to avoid crowded wait rooms; schedule immunization appointments.</li> </ul>
For Beneficiaries	<ul style="list-style-type: none"> <li>Only beneficiary will be allowed to attend vaccine session, however old/ unwell and differently abled will be allowed to be accompanied by one caregiver/ family member.</li> <li>Always maintain 2 Gaz distance among recipients</li> </ul>

## 7.2.3 VACCINATION COMPLETION

After vaccination of beneficiary, Vaccination Officer-2 ticks the vaccination completion checkbox in Co-WIN system. The beneficiary will receive SMS notification with a link for the date & time of subsequent dose.

Through the link, beneficiary can download and get the certificate of COVID-19 vaccination from “Common Service Centres (CSC)” by providing Aadhar number to the CSC.

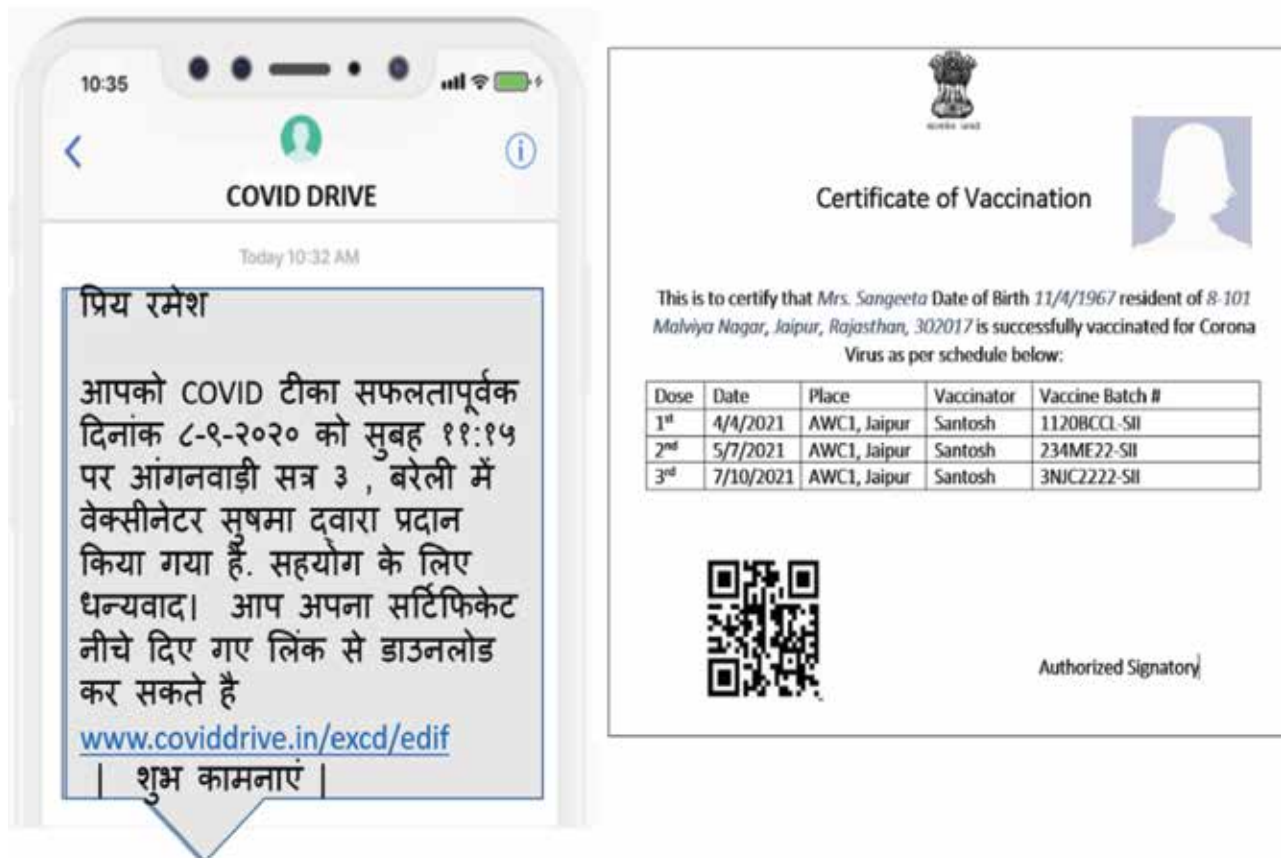


Figure 7.17: Vaccination completion SMS and certificate template

## GRIEVANCE REDRESSAL

The national helpline '1075' should be utilized to provide necessary information and guidance on COVID-19 vaccination and Co-WIN software related queries. In addition to 1075, a Technical Helpline (0120-4473222) has been established to specifically handle Co-WIN software related queries. Any technical issue which is not resolved by 1075 is directed to the Technical Helpline for resolution. The state 104 Helpline is primarily intended to provide medical assistance for several minor illnesses, ailments, and mental distresses, along with directory information, details on health schemes etc. For COVID-19 vaccination, the capacity of 104 Helpline should be augmented by States/UTs to address queries on COVID-19 vaccination including grievance redressal related to vaccination process as well as linking to concerned facilities for management of any adverse event. Grievance Redressal must also be reviewed at regular interval at the level of State Task Force, District Task Force, Urban Task Force & Block Task Force.



## 7.2.4 MANAGEMENT OF AEFI AT SESSION SITE

An adverse event following immunization (AEFI) is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine.

The adverse event may be any unfavorable or unintended sign (e.g. abscess following vaccination), abnormal laboratory finding (e.g. thrombocytopenia following measles vaccination) symptom or disease (e.g. disseminated BCG infection following BCG vaccination).

### REPORTING CATEGORIES OF AEFIs

- **Minor AEFI:** These are minor reactions which are common, self-limiting e.g. pain & swelling at injection site, fever, irritability, malaise, etc.
- **Severe AEFI:** These are non-hospitalized cases with increased severity which do not lead to long-term problems but can be disabling. Examples: non-hospitalized cases of anaphylaxis that has recovered, high fever (>102-degree F), hypotonic hypo-responsive episodes, sepsis, etc.
- **Serious AEFI:** include deaths, hospitalizations, clusters, disability, media reports/ community/ parental concern following vaccination.

### ANAPHYLAXIS KIT AND AEFI KIT

The following table will describe the usage and contents of AEFI kit and Anaphylaxis kit.

	Anaphylaxis kit	AEFI kit
Where is it used?	At outreach vaccination session site	<ol style="list-style-type: none"> <li>1. At fixed vaccination session site located at health facility (PHC/ CHC/Subdistrict/ District hospitals/ private health facility)</li> <li>2. At AEFI management centres</li> </ol>
Who will use?	Trained ANM/ vaccinator	Trained doctor
What are the contents?	Contains adrenaline (3 in no.), tuberculin/ insulin syringes (3 in no.), 24/25 G one-inch needles (3 in no.), swabs (3 in no.), guidelines/ job aid with dose calculation, certification format for expiry date of adrenaline	<ul style="list-style-type: none"> <li>• In addition to the contents of the Anaphylaxis kit, it has</li> <li>• Inj. hydrocortisone,</li> <li>• Ringer lactate/Normal saline (1),</li> <li>• 5 % dextrose (1),</li> <li>• IV cannula/scalp vein set (2),</li> <li>• IV drip set (1),</li> <li>• Disposable syringe – 5 ml with 24 / 25G</li> <li>• IM needle -3 sets,</li> <li>• Adhesive tape</li> </ul>



Content of Anaphylaxis kit



Content of AEFI kit

Updated contact information of DIO, Medical Officer(s) of PHC/CHC, AEFI management center and local ambulance services should be available with the vaccinator and supervisor

## AEFI MANAGEMENT AT SESSION SITE

**At fixed session site:** Trained medical officer/doctor in charge of the health facility must manage the AEFI.

**At outreach session site:** Vaccinator officer must ensure following steps

- For Minor AEFI like fever / pain or swelling at injection site etc:
  - ♦ As with other vaccines, minor adverse events such as mild to moderate fever, local pain and swelling at injection site, malaise etc. may be expected following COVID-19 vaccination. These should subside within 2-3 days on its own. Beneficiaries may be asked to take Tablet Paracetamol SOS with a minimum interval of 4 hours between two doses. If fever, injection site pain and swelling persist beyond 2-3 days, beneficiary may inform the vaccinator/ASHA/AWW of the respective area or a doctor may be consulted for further management. All minor AEFIs must be reported into Co-WIN and AEFI registers.
- For Serious/Severe AEFI e.g. anaphylaxis:
  - ♦ As per the age of patient, administer one dose of injection adrenaline by deep intramuscular route;
  - ♦ Don't panic & reassure the patient, parents and relatives; and
  - ♦ Suspected case should **never be left alone.**

### VACCINATOR HAS TO

- **Immediately** arrange for an ambulance/vehicle to transport the patient to the **nearest AEFI management center** (PHC/CHC/District hospital, etc.);
- **Inform medical officer/doctor (telephonically)** about the case with necessary details (name, age, date, time, site, route and dose of adrenaline administered) for further management at the health facility well equipped to manage anaphylaxis and for follow up;
- Record the anaphylaxis reaction (suspected/confirmed) in the immunization card in block letters; and
- Future vaccinations should be given in hospital settings with adrenaline and other resuscitation equipment available at hand.

Case details should also be entered into Co-WIN, recorded in AEFI register and reported in CRF as a serious/severe AEFI case by MO to the DIO.

## 7.2.5 INJECTION SAFETY AND SAFE WASTE DISPOSAL

- A safe injection is one that does not harm the recipient, does not expose the HCWs to any avoidable risks and does not result in waste, which is dangerous for the community.
- There are seven steps to giving a safe injection:
  1. Clean Workspace;
  2. Hand Hygiene;
  3. Sterile safety-engineered syringes;
  4. Sterile vial of Vaccine and diluent;
  5. Skin cleaning and antiseptis;
  6. Appropriate collection of sharps; and
  7. Appropriate Waste management.



## ENSURING SAFE INJECTION PRACTICES

A safe injection is one that does not harm the recipient, does not expose the Health care workers (HCWs) to any avoidable risks and does not result in waste, which is dangerous for the community and environment.

- Wash your hands with soap before and after the vaccination session and sanitize with 70% alcohol-based sanitizer or wash your hands with soap & water after vaccinating each beneficiary.
- Cover any small cuts on the service provider's skin.
- Avoid giving injections at the injection site where there is local skin lesion, cut or dermatitis.
- Always use Auto-disable (AD) syringes during the COVID-19 vaccination campaign. These syringes prevent person-to-person transmission of blood-borne pathogens.
- Use a new sterile packed AD syringe for each injection for each beneficiary.
- Do not use AD syringes that have damaged packaging, or have passed the manufacturer expiry date.
- Do not pre-fill syringes.
- Do not attempt to recap the needle. This practice can lead to needle-stick injuries.
- Immediately after injecting the beneficiary, the AD syringe must be cut from the hub (plastic part at base of needle) using the hub cutter and cut part of the syringe put in the red bag. Do not put the syringes on the table or on a tray after.
- **Safe disposal of injection waste:** Cut the hub of the AD syringe immediately after administering the injection using the hub cutter.
- Cut needles will get collected in the puncture proof container of the hub cutter.
- Segregate and store the plastic portion of the cut syringes in the **red bag**.
- Plastic wrapper and the cap of the syringe should be treated as Municipal general waste Use of **Hub cutter correctly**.
- Store used cotton swab in **yellow bag** after administering the injection.
- The used, unused, partially used vaccine vials should be returned to the cold chain point as per existing AEFI guidelines for proper disposal.
- Carry the segregated immunization waste generated during outreach sessions and hand these over to the PHC for further disposal.
- Wash the hub cutters properly with sodium hypochlorite before reuse. Store broken vials in the puncture proof **blue container**.





## RETURNING USED AND UNUSED SUPPLIES

All vials (used/empty, unused and partially used) must be returned through alternate vaccine delivery (AVD) to the vaccine distribution / ILR point, maintaining a reverse cold chain. Completed and signed tally form should also be returned with vaccine carrier.

It is important to ensure the following:

- Returned unopened vials must be properly marked and stored immediately at the correct temperature;
- On the next day, these discarded marked vials must be supplied and used first ensure that all used/empty COVID-19 vaccine vials at the end of the session are kept in a separate zip lock bag to return to ILR point;
- Always keep used COVID-19 vaccine vial returned from the field separately contained in a zip lock bag / box with proper cold chain till the next session or 48 hours which ever earlier. (as per existing AEFI guidelines).



Figure 7.19: Job aid for Immunization Waste Disposal (As per BMW management guidelines 2016, 2018)

**Reporting of Vaccination Coverage:** This will be through Co-WIN software, however for use in unforeseen circumstances of inability to use Co-WIN, if needed, manual reporting formats are attached as contingency. STFI will decide use of these formats.

## 7.3 ENGAGEMENT OF PRIVATE SECTOR

The private health sector will be an important stakeholder during the roll out of COVID-19 vaccination across the country and while in the initial stage of the campaign private sector providers will be vaccinated, subsequently they will be engaged in service provision. The document provides guidance on the activities that need to be undertaken at the state and district levels to facilitate the engagement of the private health sector during the current phase of the vaccination campaign.

### PROACTIVE ENGAGEMENT OF THE PRIVATE SECTOR

The states and districts need to proactively engage the private health sector providers, some of the measures that can be undertaken are enlisted.

- 1. Outreach by state and district administrations:** At both state and district levels, administration (Mission Director, NHM, District Magistrate / District Commissioner) can issue letters to private sector medical colleges and hospitals, professional associations, NGOs and CSOs representatives of Rotary Club etc. seeking their participation and support during the vaccination campaign.
- 2. Engagement with professional and hospital associations:** States and districts need to build on the existing partnerships with the associations<sup>17</sup> (for example IMA, IAP, API, FOGSI, IPHA, IAPSM, APHI, ICHA, AMA) and leverage their strength and expertise to facilitate the campaign and spread right message in case of vaccine hesitancy and vaccine eagerness among general population.
- 3. Involvement of NGOs, CSOs, Rotary International, Lions Club etc.:** Apart from the medical professionals involved with these organizations, other staff and members should be engaged as influencers, volunteers, verifiers, and other support staff in the vaccination teams.
- 4. Engage COVID-19 warriors** enlisted/created by the empowered group to combat COVID-19. They may be engaged as influencers, volunteers, verifiers, and other support staff in the vaccination teams.
- 5. Private sector representatives in Task Forces:** Representatives of private hospitals, professional associations, eminent medical professionals can be nominated as members of state, district and block task forces.
- 6. Identifying champions and influencers:** The private sector can play an instrumental role in advocating for a positive vaccine environment. State and district administrations can engage well known and respected health and allied sector professionals as brand ambassadors for the campaign.
- 7. Joint Media Briefing with IMA and other associations:** States and districts can undertake joint media briefings to facilitate a conducive environment for vaccination.

### ENUMERATION OF PRIVATE HEALTH CARE PROVIDERS

Guidelines for enlisting private health care providers have already been provided to the states, while the broad guidelines are in line with the listing of public health care providers, due to the variable nature of the private sector involving providers working across a myriad of entities ranging from single provider clinics to large multispecialty hospitals, in addition to notifying individual private facilities, following steps can be undertaken to facilitate and fast-track enumeration of private health care providers:

<sup>17</sup> IMA: Indian Medical Association, IAP: Indian Academy of Pediatrics, API: Association of Physicians of India, FOGSI: Federation of Obstetricians and Gynecologists of India, IPHA: Indian Public Health Association, IAPSM: Indian Association of Preventive and Social Medicine, AHPI: Association of Health Care Providers of India, ICHA: Indian Confederation for Healthcare Accreditation, AMA: Ayush Medical Association



1. **Collaboration with professional associations:** The vast network of associations (both allopathic and allied sciences associations) needs to be tapped into fast-track the enlisting of providers. This involves proactive engagement with national, state and district chapters of the associations. This becomes extremely important in states where the private sector landscape is dominated by single doctor / allied specialty health clinics and outposts.
2. **Partnership with CSOs / NGOs / Trust Hospitals:** Private sector also includes services rendered by CSO, NGOs, and trust hospitals. While they might not include a significant proportion of service providers, they often are a major source of service delivery in the rural hinterland and need to be included in the vaccination cohort. It is envisaged that while reaching out to individual units / entities can be a major challenge, partnerships with NGO / CSO associations and mother-NGO networks can be explored.
3. **Involving Private Medical Colleges:** Private medical colleges are important stakeholders and employ a host of doctors, nurses and other cadre of providers. States are advised to proactively engage with the private sector medical colleges managements' and facilitate the vaccination process including enumeration of the HCWs, vaccinators, roll out of the vaccination etc.
4. **Leveraging national hospital and health care institutions (NABHHP and NABL):** Centralized institutions can be used to obtain the list of private health care facilities which will facilitate the enumeration process.
5. **Utilizing the Clinical Establishment Act (CEA):** State where CEA is in place, list of facilities can be sourced from its data base.

Above all, states should reassure private sector institutions and providers that the data base will only be used for facilitating the vaccination campaign. While CO-WIN unique identifier system will ensure that duplicity of individuals is avoided, a manual review of lists of private care institutions needs to be done in case they are sourced from different avenues.

**As enumeration process involves identification of potential vaccinators, more comprehensive and robust enumeration process is, bigger will be the pool of vaccinators. The pool will capture all eligible in-service and superannuated staff in private sector.**

## TRAINING OF PRIVATE HEALTH CARE PROVIDERS

The vaccination campaign will engage vaccinators from the private sector. To ensure this the following steps need to be undertaken by the states:

1. **Time bound completion of enumeration:** Listing of potential vaccinators from the private health facilities / unit needs to be completed on time to ensure that they participate in the vaccinator trainings organized at the district or block levels.
2. **Engaging private sector providers as master trainers:** States can also identify eminent private health care providers to be trained as master trainers during national and state trainings.
3. **Inclusion in vaccination teams:** As most of the private sector providers will be introduced to universal immunization programme (UIP) guidelines for the first time, these vaccinators can be used as second vaccinators at session sites with beneficiary load of more than 100. Lead vaccinator must be from the public health care system. States are also advised to build in screening mechanisms to ensure that the vaccinators engaged from the private sector are qualified and competent.
4. **Skill building trainings of vaccinators:** States and districts should ensure appropriate skill building of these vaccinators on all aspects including management of AEFI.

## PRIVATE HEALTH FACILITIES AS VACCINATION SITES

With private facilities with a staff strength of  $\geq 100$  being identified as session sites, it is imperative that the facilities follow the national guidelines for setting up and managing a vaccination session site. However, states are advised to ensure that the session sites identified fulfill the following essential criteria:

- 1. Linking of all session sites to Co-WIN:** All session sites identified in the private sector should be tagged through Co-WIN
- 2. Accessibility, acceptability, and awareness of the session site:** Sites should be easily accessible and acceptable to all members of the community. Also, the beneficiaries need to be aware of the session site and adequate communication material should be available at the site.
- 3. Allocate well demarcated area** for COVID-19 vaccination separate from routine health services in the health facilities.
- 4. Ensure pre-sanitization of session sites:** It is of utmost importance that private sector facilities / institutions identified as session sites maintain and follow the universal COVID-19 precautions and adequate cleanliness. On site sensitization is recommended a day prior to vaccination.
- 5. Adequate provision of AEFI management:** Session sites should mandatorily have provision to manage any AEFI as per national guidelines, also identify private sector facilities that can function as AEFI referral management centers.
- 6. Rationalization of session sites:** District administration should rationalize number of sites to prevent any unnecessary burden on the health system.
- 7. Identification of nodal person:** Each session site should have a nodal official identified to ensure accountability and function as a point of contact for the district health administration and vaccination team. Administrative head of the facility should by default be the accountable person for program.

Both vaccines and logistics need to be delivered to the session sites as per guidelines. It is recommended that vaccines need to be delivered daily, as most of the private health facilities might not be adequately equipped to store vaccines as per UIP guidelines. Used vials and other immunization waste should be returned to the cold chain points as per national guidelines.

In the event of vaccines being distributed at one go to a private facility organizing multiple sessions, the facility needs to have appropriate vaccine storage facilities. In addition, facilities will need to adhere to the national Central Pollution Control Board (CPCB) guidelines for immunization waste disposal. Overall vaccine, logistics and cold chain management practices at private health facilities will be extremely critical to avoid any adverse event, thereby, compromising quality of vaccination campaign. It is therefore suggested that facility readiness assessment be undertaken for private health facilities functioning as either storage points or session sites or both. Daily on-site and off-site monitoring should also be ensured during the campaign.

Constitution of vaccination team at the session site will be an important consideration for private sector engagement. For private facilities functioning as session sites, the vaccination team can either be internal to the facility or derived from the cohort of vaccination teams created at the district level. In case the team is internal to the facility, the training of such teams will be very important and the campaign at such facilities will need to be closely monitored.

It is also advocated that if infrastructure permits, district IMA / IAP / FOGSI chapters can be operationalized as session sites for ensuring vaccination of other private sector health care providers, such a site can be provided with a dedicated team and the campaign can be conducted smoothly over a defined period.

States and districts should ensure that the following details are available from each of the session sites:

- Administrative Head – Contact details
- Nodal Officer for program - Contact details
- Doctor responsible for management of AEFI:
- Number of expected beneficiaries-
- Date of sanitization of vaccination site

In addition, a day before vaccination, district authorities may undertake a random inspection of private sector session sites with help of IMA, Medical College faculty and district level officers to assess preparedness.

## ENGAGING PRIVATE SECTOR DURING VACCINATION OF FLWS AND GENERAL POPULATION

While the priority right now is vaccinating private health care providers, preparations for the subsequent phases need to be undertaken by the states. This will involve engaging **private facilities to function as vaccination sites**.

With the cohort of beneficiaries increasing, multiple private facilities might need to function as vaccination sites. One facility can be identified as a nodal facility, where HCWs from the nearby facilities can be mobilized to come for vaccination. It should be ensured that the beneficiary load is enough at a vaccination site so that there is minimal wastage of vaccines and resources including human resources. Hence enlisting of such facilities with readiness assessment planning needs to be initiated. This in turn, will help in mapping out vaccine logistics and requirements and estimating the training load.

## COLLABORATING ON AEFI

With AEFI, AESI and safety surveillance being important determinants, and as per the guidance on expansion of AEFI committees to include specialists cutting across domains, private sector facilities and providers will be important stakeholders in monitoring such events. The following are suggestive options:

- 1. AEFI referral sites:** States should undertake steps to identify private sector facilities as referral / management centers for AEFI management.
- 2. Involving private health facilities in national AEFI surveillance:** COVID-19 vaccination campaign provides an opportunity to expand the national AEFI surveillance program and districts should ensure that private facilities are mandated to report AEFI to them on a monthly basis. This effort will require coordination and training at multiple levels and can be rolled out over a defined period.
- 3. AEFI / AESI sentinel surveillance:** In line with previous experiences, few identified private health facilities may be engaged as centers for AEFI / AESI surveillance post vaccine roll out. Service providers at these facilities should be adequately trained to facilitate this process.

## INVOLVEMENT IN PROGRAM COMMUNICATION AND SOCIAL MOBILIZATION

National communication plan for the COVID-19 vaccine roll out lays out a comprehensive framework and the private health care institutions and providers will be important stakeholders to manage and address both vaccine eagerness and hesitancy.

- 1. Private providers as advocates and influencers:** With the private health sector providers getting vaccinated in the first phase, they will become advocates and champions for the next cohorts. Further, being direct touch points with the community at large both formal and informal private health care providers can function as positive influencers for the vaccine roll out and contribute to social listening efforts. Effort should be made to include general practitioners to be included as advocates for the immunization program as well.
- 2. Engagement of professional associations:** Associations need to be engaged in various community engagement and social mobilization efforts.

Hence states and districts are advised to undertake capacity building of private health care providers on these aspects.

## COLLABORATION ON POST INTRODUCTION EVALUATIONS (PIE)

Once the vaccine is rolled out, private sector will be an important stakeholder in monitoring roll out and contributing to PIEs. The modalities of this need to be worked upon and can be initiated in a time bound manner at national and state levels.

## 7.4 SOP FOR PREVENTION OF PILFERAGE OF COVID-19 VACCINES

### SOP FOR PREVENTION OF PILFERAGE OF COVID-19 VACCINES

#### BACKGROUND

Government of India is planning to roll out COVID-19 vaccine in the country. With the high demand and limited availability of COVID-19 vaccine, system should be geared up to prevent any attempts of theft, pilferage or misuse of COVID-19 vaccine.

#### OBJECTIVE

The objective of this SOP is to support States and Districts in setting up adequate policies and procedures in place to ensure safety and security of COVID-19 vaccine.

#### THE DRUGS AND COSMETICS ACT 1940 AND THE RULES, 1945

All COVID-19 vaccines supplied by the Central Government are intended to be used only under the National COVID-19 Vaccination Programme. As per The Drugs and Cosmetics Act 1940 and the Rules, 1945, any unauthorized storage/distribution/purchase or sale of COVID-19 vaccine under Government Supply is a punishable offence and needs to be immediately reported to the Drugs Controller as well as other appropriate authorities. To ensure compliance and immediate action:

- A Representative from the office of State Drugs Controller should be included in the State, District Task Force and Block Task force.

- Community awareness and community-based event reporting systems to be created to report any such activities with clear reporting mechanism (phone numbers/email IDs). State 104 Call Centers could also be considered for such reporting from the public. The Call Centre should have a system to forward the complaint to the State Drugs Controller/District Drug Inspectors for immediate verification and action.
- State and District to identify nodal person for reporting any misuse of COVID-19 vaccine and associated follow up action.

### VACCINE TRACKING

The Co-WIN system of Ministry of Health and Family Welfare is designed for end-to-end tracking of COVID-19 vaccines and linking every dose to individual beneficiary. As part of the Co-WIN system, details of COVID-19 vaccine (name of vaccine, batch, manufacturing date) will be entered in the electronic database and vaccine doses along with batch number will be allocated to each site using the electronic system only. This will support in tracking every COVID-19 vaccine vial up to last mile. While initial COVID-19 vaccine vials might not have labels indicating Govt. supply in the initial phases, the following protocols need to be maintained to ensure stringent track-and-trace mechanism:

1. Physical verification (counting) of all vaccine vials at the time of receiving or issuing stock. This includes counting of the incoming/outgoing stock and the existing stock and reconciling it with the stock in Co-WIN system. Any mismatch in available physical stock with the Co-WIN stock should be immediately reported to State Immunization Officer/District Immunization Officer for necessary enquiry and appropriate action.
2. An event of broken or damaged vaccine vial/s need to be immediately reported to the Medical Officer/Store in-charge and should be physically examined, counted, photographed and certified by the Medical Officer in-charge. The officer in-charge should also ascertain the reason for damage to avoid any such further incidence. Breakage of vaccine vials also need to be reported in the Co-WIN system.
3. Any damage of more than 10 vials should be reported to State Immunization Officer/District Immunization Officer along with photo documentation.
4. Accountability for damage to vaccine vials during transportation will reside with the supply store in-charge. The supply store should ensure proper packing of cold boxes as per standard defined protocols and proper stacking of cold boxes in vaccine vans to prevent any risk of vaccine vial damage during transportation.

### PREVENTING MISUSE OF EMPTY/PARTIALLY USED COVID-19 VACCINE VIALS

All partially used/empty COVID-19 vaccine vials need to be brought back to the cold chain point and matched with the total vials issued for a particular session, taking into consideration the unopened vaccine vials. All empty/partially used vaccine vials to be disposed off in accordance with the Central Pollution Control Board (CPCB) guidelines while ensuring that empty vials with intact labels cannot be accessed by any person to prevent its misuse. The facility in charge of the cold chain point needs to directly supervise and ensure safe disposal of unusable and empty vaccine vials immediately after return of the vaccine carrier from the session site.

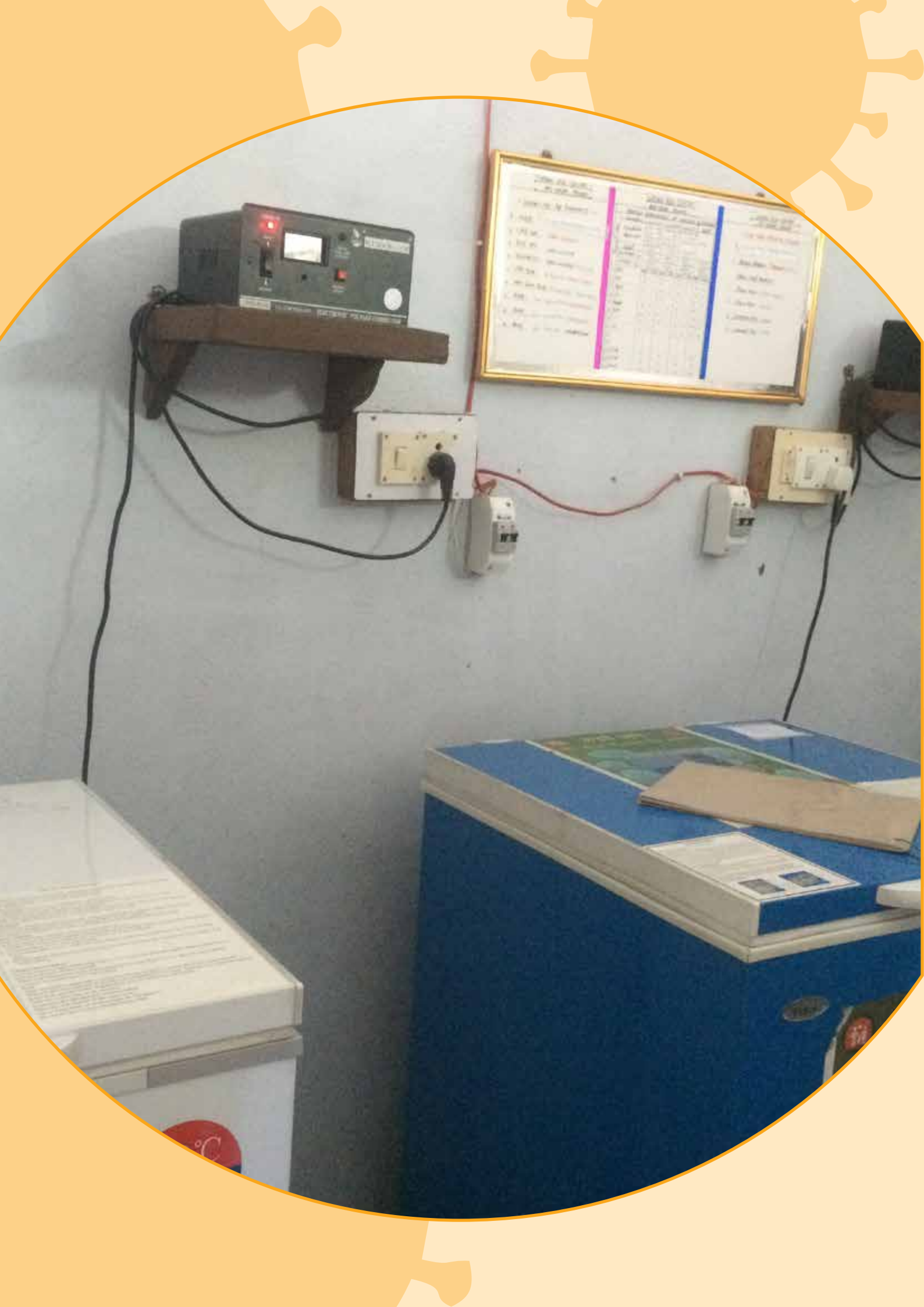


## VACCINE SECURITY

With the limited vaccine availability in the initial phases, adequate security arrangements need to be in place for safety of vaccine at storage site, during transportation and at session site.

- State and District administration need to make adequate arrangement for 24\*7 security of cold chain points at all location and appropriate arrangement during transportation of vaccines with sufficient security.
- Access to cold chain rooms to be restricted to authorized personnel only.
- Vehicles carrying COVID-19 vaccine between districts/states should be sealed before leaving the cold chain point and should be opened only in front of the facility in-charge.
- Proper logbook to be maintained for any access of vaccine storage points.

States/Districts may further explore and add relevant steps as per local need to ensure safety and security of COVID-19 vaccine and to prevent any misuse. States also need to orient all cadres involved in vaccine logistics (State Immunization Officer, State Cold Chain Officer, District Immunization Officer, Store in-charge, Cold Chain Handlers, Vaccinator etc.) on these guidelines along with roles and responsibilities at the earliest.



DATE	TIME	TEMPERATURE	PH	CONDUCTIVITY
1/1/2020	10:00	25.0	7.0	150
1/1/2020	11:00	25.0	7.0	150
1/1/2020	12:00	25.0	7.0	150
1/1/2020	13:00	25.0	7.0	150
1/1/2020	14:00	25.0	7.0	150
1/1/2020	15:00	25.0	7.0	150
1/1/2020	16:00	25.0	7.0	150
1/1/2020	17:00	25.0	7.0	150
1/1/2020	18:00	25.0	7.0	150
1/1/2020	19:00	25.0	7.0	150
1/1/2020	20:00	25.0	7.0	150
1/1/2020	21:00	25.0	7.0	150
1/1/2020	22:00	25.0	7.0	150
1/1/2020	23:00	25.0	7.0	150
1/1/2020	00:00	25.0	7.0	150
1/1/2020	01:00	25.0	7.0	150
1/1/2020	02:00	25.0	7.0	150
1/1/2020	03:00	25.0	7.0	150
1/1/2020	04:00	25.0	7.0	150
1/1/2020	05:00	25.0	7.0	150
1/1/2020	06:00	25.0	7.0	150
1/1/2020	07:00	25.0	7.0	150
1/1/2020	08:00	25.0	7.0	150
1/1/2020	09:00	25.0	7.0	150



## 8. VACCINE, LOGISTICS AND COLD CHAIN MANAGEMENT

COVID-19 vaccine introduction is a unique landmark in the history of vaccination campaigns in public health in terms of the immunization cohort covered and the scale of operations involved, hence requiring focused planning and implementation of immunization activities.

Considering the scale of operations, management of cold chain, vaccine and other logistics will be critical for reach and quality of the campaign.

Accordingly, this section of the operational guidelines has been broadly categorized into an initial planning component before the actual campaign followed by the activities required during the campaign itself.

### 8.1 PLANNING FOR COVID-19 VACCINE INTRODUCTION

This section will focus on the relevant preparatory activities for introduction of COVID-19 vaccine.

#### 8.1.1 VACCINE ESTIMATION

The COVID-19 vaccine management will be fully integrated in the eVIN platform and will work in synchronization with the Co-WIN (beneficiary module). The vaccine requirement will depend on the phase of vaccination and will also be impacted on the type of vaccination used in each phase for next dose, considering the non-interchangeability of multiple vaccine types. The standard calculations in use for estimation of all UIP vaccines will support in vaccine estimation:

COVID-19 vaccine required for 1 month = [(Total population to be covered in the relevant catchment area (state/ district/ block/ sector) x % of population to be covered in this catchment area/no. of months of the campaign) x 2 doses x WMF

WMF = Wastage Multiplication Factor = 1.11 for the COVID-19 vaccine, assuming an allowable programmatic wastage of 10% [WMF = 100/ (100 – wastage) = 100/ (100-10) = 100/90 = 1.11)

#### 8.1.2 ELECTRICAL COLD CHAIN EQUIPMENT ESTIMATION

If the recommended temperature range for the COVID-19 vaccine is between +2° to +8°C, it should be stored in the WIC at State/ Regional Vaccine Stores and in ILRs at the District Vaccine Stores and Last Cold Chain Points.

However, in case of a COVID-19 vaccine requiring storage at a temperature range of -15° to -25°C, it should be stored in WIFs at State/ Regional Vaccine Stores, in DFs at District Vaccine Stores and in ILRs at the Last Cold Chain Points.



The additional cold chain equipment requirement for COVID-19 vaccine at all levels of the immunization supply chain can be estimated through the following steps should follow this:

### STEP 1

#### Calculation of existing CC space requirement for current UIP vaccines

Existing monthly CC space requirement = [(annual UIP target/12) x CC volume per FIC x1.25]

### STEP 2

#### Additional cold chain space requirement for COVID-19 vaccine

Additional CC space requirement = [monthly number of doses required x number of months of supply x unit cold chain space per dose (3.6 ml)]

### STEP 3

#### Net additional cold chain space required for UIP and COVID-19 vaccine

Net additional CC space required = [(CC space required for current UIP + CC space required for COVID-19 vaccine) – Available CC space] (The available CC space at every level is accessible from the NCCMIS)

### STEP 4

#### Additional cold chain equipment requirement

Additional CCE required = net additional CC space required/ unit storage volume of respective CCE (rounded up to the next higher number)

An indicative list of average units CCE net storage volume for the different types of CCE is provided below for reference:

**ILR:** ILR(L) – 200 liters; ILR(S) – 75 liters

**DF:** DF(L) – 250 liters; DF(S) – 80 liters

**For Example:** If the unit cold chain space per dose of COVID-19 vaccine is 3.6ml, then 1 liter of CC space can store 278 doses of vaccine. Assuming an ILR of 100 liters will be able to store 27800 doses of COVID-19 vaccine which is adequate for immunizing 25045 beneficiaries (WMF = 1.11)



## 8.1.3 NON-ELECTRICAL COLD CHAIN EQUIPMENT ESTIMATION

In addition to electrical cold chain equipment, passive cold chain equipment like cold boxes and vaccine carriers will also be required for the campaign. Cold boxes will be required for two categories of activities during the campaign:

### ACTIVITY 1: USE OF COLD BOXES FOR ROUTINE IMMUNIZATION

Cold boxes will continue to be used for routine immunization during vaccine transport and contingency storage. States will be required to ensure adequate availability of cold boxes for routine immunization at every cold chain point through a rapid assessment and redeployment of available cold boxes across the state.



### ACTIVITY 2: USE OF COLD BOXES FOR THE COVID-19 CAMPAIGN

Cold boxes may be required during the COVID-19 campaign for vaccine distribution and storage at temporary vaccine storage and distribution sites for effective population coverage. All such sites should be identified in the campaign micro plan and requirement of cold boxes should be calculated based on vaccine estimation for the population covered. An inventory update of all cold boxes should be undertaken. Cold boxes requiring minor repair and maintenance like thorough cleaning, fixing of metal clasps and handles, etc., should be identified and included in the cold chain crash repair. The calculation for cold box requirement can be done as follows:

Number of cold boxes required at temporary storage sites =

Estimated cold chain space requirement based on estimated vaccine doses required/ unit cold chain storage volume of one cold box

[A large cold box has an average net vaccine storage capacity of 20 liters and a small cold box has a net storage capacity of around 5 liters.]

**Similarly, vaccine carriers will be required for the following**

**Activity 1:** Continued use for routine immunization activities as per routine immunization (RI)s micro plan. This will involve an assessment of requirement for vaccine carriers as per the latest updated RI micro plan. Generally, one vaccine carrier offers a net storage space of around 1.7 liters and can accommodate 16-20 vaccine vials.

**Activity 2:** Use of vaccine carriers for vaccine transport to additional session sites for the COVID-19 campaign. The requirement will depend on exact micro plan for the COVID-19 campaign. In case the additional sessions are organized on non-RI days, the existing vaccine carriers can be utilized for campaign session site vaccine transport. In case the campaign sessions are planned on RI days, the additional requirement of vaccine carriers can be calculated on the micro plan-based requirement of vaccine vials, as given below:



Number of vaccine carriers required for campaign sessions = Number of COVID-19 vaccine vials required as per micro plan/ 20 vials per vaccine carrier

States should plan for repair and maintenance of existing vaccine carriers, including the vaccine carriers used for the IPPI rounds, like thorough cleaning, repair of torn or damaged straps, etc., during any planned crash repair.

## 8.1.4 COLD CHAIN SYSTEM STRENGTHENING

Anticipating the flexible nature of the COVID-19 vaccine supply in terms of mixed products with different storage temperature ranges, plans for supply of additional cold chain equipment by the Government of India are already in place for implementation.

States will play a crucial role in ensuring that these initiatives are implemented timely and with quality to ensure adequate cold chain system capacity for the COVID-19 vaccine campaign. The major activities to be ensured for effective strengthening of the cold chain network include the following:

- Identification of sites for WIC/WIF installation, as per the distribution plan of Government of India.
- Ensuring site readiness for installation of WIC/WIF at the designated sites, as per standard site readiness checklists. (*Annexure – WIC/ WIF installation site readiness checklist*).
- Identification of district and sub district stores requiring additional cold chain equipment, based on population cohort-based vaccine estimation and additional cold chain space requirement, as detailed above.
- Rapid supply of the additional cold chain equipment received to the identified stores with installation and functionalization.
- Data entry of all the newly received cold chain equipment in NCCMIS.

## 8.1.5 IMMUNIZATION SUPPLY CHAIN SYSTEM PREPAREDNESS

Before implementation of the COVID-19 vaccine campaign, every state needs to ensure preparedness of the supply chain system. All available cold chain equipment (CCE) inventory details need to be updated in national cold chain and vaccine management resource centre (NCCMIS) to enable accurate estimations and calculations with ensuring of all WICs/ WIFs in functional status with standby generators and access to adequate fuel.

COVID-19 vaccine and associated logistics needs to be clearly segregated from vaccines under routine immunization to avoid any programme error. It is preferable to store COVID-19 vaccine in a separate cold chain equipment, if available at the cold chain point. If separate cold chain equipment is not available, clear demarcation of cold chain space dedicated for COVID-19 vaccine inside the equipment needs to be ensured. Similarly, dedicated dry storage space for syringes and other logistics required for COVID-19 vaccination session needs to be created. In case of availability of freeze dried COVID-19 vaccine requiring diluent, clear protocols need to be created to avoid any mix with diluent of vaccines under routine immunization.

As far as possible, state should allocate vaccine from one manufacturer to a district, this will avoid mixing of different COVID-19 vaccine in the field.

Tool kits should be assessed at district level and replenished locally. (*Annexure – Standard tool kit component checklist*). All standby CCE should be mobilized and made functional for installation before undertaking the final estimation of CCE requirement for COVID-19 vaccine introduction. Standby and buffer equipment are to remain functional, in case immediate deployment is required due to breakdown events.

Alternate vaccine storage sites should be identified at the state and regional level based on the estimation of cold chain space and equipment required, and any anticipated delay in supply or installation of WICs/

WIFs. This could include exploring and engaging with both the available public sector and private sector cold chain facilities available locally. The following critical issues should be kept in mind before engaging with the non-health sector cold chain service providers:

- Storage equipment available with operating temperature range of +2° to +8°C / -15° to -25°C;
- Continuous remote temperature monitoring or periodic manual monitoring of temperature possible with existing HR at the store;
- Functional alternate power source with auto-start facility available in case of mains electricity failure;
- Vaccine storage area is clean and dry and is not used for storage of products with potential for water leakage;
- Store and equipment have adequate security measures in place for safe vaccine storage;
- Basic stock record maintenance for the duration of vaccine storage is possible with existing HR and resources;
- Acoustic or any other functional alarm system present in equipment to signal critical temperature excursions; and
- Shelves or pallets available for stacking without any contact of tertiary packaging with floor of equipment.

Detailed contingency plans for vaccine storage should be available at all levels of vaccine stores. Crash repair drive may be undertaken by states to ensure optimum functional status of all available CCE. One round of planned preventive maintenance should be completed for all cold chain points in the state by the cold chain technicians to ensure optimum function of available cold chain equipment and identification of any equipment requiring repairs. CCE beyond economic repair should be included in the condemnation process for disposal. All vaccine and cold chain handlers (VCCH) should be reoriented on the VCCH module.

There should be availability of adequate standard vaccine stock registers at all cold chain points and the state should ensure availability of functional mobile phones with the eVIN app installed for all VCCH in states with eVIN rolled out. All eVIN remote temperature monitors should be checked for functionality and replacements should be ensured wherever required. Vaccine distribution plans for every cold chain point should be updated and reviewed for feasibility and efficiency.

All the effective vaccine management (EVM) recommendations, as per the latest EVM assessment for the state or the National EVM 2018 recommendations, need to be followed and steps are to be taken to ensure compliance to these recommendations, as far as possible.

Two rounds of preparatory reviews should be conducted at district and state level. The first review should be conducted immediately after the ToT and will focus on identifying gaps as per the indicative list of activities mentioned above. The second review will be conducted at least 1 week before the campaign to assess the preparedness and undertake immediate corrective actions, wherever required.

- Deficient stock management practices including updating of vaccine registers, monitoring of vaccine transactions, standard formats for vaccine transactions, Pre-Delivery and Pre-collection notification system, recording of vaccine wastage, vaccine demand forecasting and physical count of vaccine stocks
- Lack of adequate knowledge/ practice of shake test, open vial policy, vaccine requirement and wastage calculations, immunization waste management
- Inadequate number of supportive supervision visits by supervisors and lack of documentation of SS visits

- Absence of standard temp log books and non-compliance to standard practices
- Temperature log books and alarm events were not being reviewed
- Ice pack freezers did not have sufficient storage capacity in most of the SVS
- Emergency contingency plan was not available in most of the upper level stores
- Vaccine distribution plan not available at most of the stores
- PPM checklist for equipment not universally followed

## 8.2 MANAGEMENT DURING COVID-19 VACCINATION CAMPAIGN

### 8.2.1 AT CAMPAIGN SESSION SITES

All measures should be taken to avoid exposing the vaccine carrier, vaccine vials or icepacks to direct sunlight. Vaccines and diluents should be kept inside the vaccine carrier with the lid closed until a beneficiary comes to the center for vaccination.

There may not be VVM and date of expiry on the label of COVID-19 vaccine, this should not discourage vaccinators from using the vaccine. The vaccinator should take out one ice pack from the vaccine carrier to place the COVID-19 vaccine on the ice pack (in case the COVID-19 vaccine is very heat sensitive) or keep the COVID-19 vaccine on the table (in case the vaccine is not very heat sensitive). At the end of the session, vaccine carrier with all icepacks and unopened vaccine vials should be sent back to the distributing cold chain point.

Intact sealed vials returned on the previous session day should be clearly marked and kept separately in the ice lined refrigerator (ILR) on the top layer so that these will be the first to be used on the following session day.

### 8.2.2 AT LAST COLD CHAIN POINTS

Vaccine carriers need to be clean and dry before packing with 4 conditioned ice packs and vaccine vials inside a zipper pouch. The VCCH should ensure that the correct number of vials with syringes, tally sheets and hub cutter is handed over to the AVDS volunteer/ vaccine transporter.

There will be vaccine specific guidance provided by MoHFW on open vial policy. If the vaccine is not eligible for reusing open vial, discard the remaining vaccine and vaccine vial as per standard procedures outlined in the latest open vial policy guidelines.

Immunization waste should be disposed as per the latest immunization waste management guidelines of the Government of India after return of all immunization waste from session sites to the cold chain points after the session.

Data entry of the session day vaccine distribution should be recorded in eVIN/ standard stock registers on the session day itself. The VCCH and MO I/C should review temperature records, available either through the eVIN RTM and/ or manual twice daily recording to identify potential damage to vaccines due to temperature excursions. Details of discarded vaccines due to any event should be recorded in eVIN and/ or standard stock registers.

Weekly vaccine stock reviews should be conducted by the MO I/C and VCCH with appropriate official communication to the supplying store in case of any requirements for the succeeding week's campaign activity. Contact details of the cold chain technician should be available with all VCCH for immediate communication of any technical defect or breakdown of cold chain equipment. Planned preventive maintenance of equipment should be performed by the VCCH as per guidelines in the VCCH module

### 8.2.3 AT DISTRICT LEVEL

Vaccine transport to sub district stores should take place in insulated vaccine vans with all vaccines stored in cold boxes packed with the required number of conditioned ice packs. Vaccine stock records should be updated on the day of transaction in eVIN and/ or standard stock registers.

District vaccine store (DVS) keeper should regularly monitor the DVS equipment temperature through eVIN RTM and/ or manual twice daily temperature recordings. The cold chain technician should implement the



approved preventive maintenance plan to cover all cold chain points in the district per quarter during the duration of the campaign. The cold chain technician should follow the recommended norms for response time (less than 2 days from intimation) and down time of equipment (maximum of 7 days in normal areas & 21 days in hilly areas).

DIO should undertake weekly reviews of the district for the following:

- Vaccine stock position and adequacy across the DVS and all LCCPs in the district for the upcoming week;
- Temperature monitoring of all equipment in the district with follow up action on any identified temperature excursion;
- Cold chain equipment breakdown events during the week with required follow up action;
- Review of vaccine stock records and cold chain inventory information; and
- Availability of VCCH at all LCCPs in the district with alternate plans for contingencies.

All district supervisors should undertake regular, planned monitoring and supportive supervision of cold chain points and session sites for immunization supply chain (ISC) management and quality using the available standard GoI monitoring checklists on the SS mobile app.

## 8.2.4 AT STATE LEVEL

Vaccine transport to regional and district stores should take place in insulated vaccine vans with all vaccines stored in cold boxes packed with required number of conditioned ice packs. Vaccine stock records should be updated on the day of transaction in eVIN and/ or standard stock registers. SVS/ RVS storekeeper should regularly monitor the state vaccine store (SVS)/ regional vaccine store (RVS) equipment temperature through eVIN RTM and/ or manual twice daily temperature recordings.

In case private sector or non-health public sector cold chain is utilized for vaccine storage, SEPIO along with the state team should ensure periodic monitoring of vaccine storage to ensure essential storage quality standards.

The SEPIO, along with the state team, should conduct weekly/ biweekly/ monthly review meetings of the ISC, including the following points:

- Review of stock position at district level and identifying specific needs for replenishment;
- Review of temperature monitoring and equipment performance information with required follow up actions;
- Review of supportive supervision data with follow up feedback and recommendations to districts;
- Financial review of ISC expenditure for the campaign with appropriate follow up actions to ensure uninterrupted activity; and
- ISC HR status review with identification of critical gaps and follow up action.

All state supervisors should undertake regular, planned monitoring and supportive supervision of DVS for ISC management and quality using the available standard GoI monitoring checklists on the SS mobile app.

## 8.3 VACCINE SAFETY AND SECURITY

Safety and security of each dose of COVID-19 vaccine is of paramount importance and States must undertake adequate safety and security measure at location of vaccine storage, during transport and at session site. State/District administration needs to ensure adequate security arrangement for vaccines at:



1. All cold chain points;
2. During vaccine transport at all levels; and
3. At session site.

Stringent vigilance mechanism must be in place to protect pilferage and theft. Any such activity should be immediately reported, and prompt police action should be initiated with clear accountability.

## **8.4 OPERATIONAL MANAGEMENT OF COVID-19 VACCINES UNDER SPECIAL CIRCUMSTANCES (NO VVM AND EXPIRY DATE ON VACCINE VIALS)**

### **8.4.1 AT SESSION SITE**

All vaccination teams should have an extra vaccine carrier with conditioned ice packs for immediate replenishment of ice packs in the vaccine carrier with vaccine vials. Every session site should be monitored by a supervisor including review and checking of vaccine carrier temperature and records.

### **8.4.2 AT THE COLD CHAIN POINT**

Any temperature excursion beyond 30 minutes should be responded with alternate storage of vaccines in the short term and repair of the affected cold chain equipment as soon as possible on an emergency basis. The VCCH should undertake inspection and recording of storage temperature at least twice every day during the campaign period from the eVIN RTM.

Proper conditioning of ice packs during vaccine distribution should be ensured with monitoring of every vaccine distribution during campaign days. Open vial policy guidelines may not be applicable to the COVID-19 vaccine depending upon the type of vaccine supplied. Details of open vial policy applicability will be communicated by the Gol.

Issue of vaccine doses should match with the registered list of beneficiaries (rounded off to the nearest higher whole number of vials) without any adjustment made for vaccine wastage in terms of the WMF and vaccine vials with earlier manufacturing dates should be prioritized for issue first.

### **8.4.3 AT DISTRICT VACCINE STORES**

Vaccine distribution should be planned in small quantities (e.g. on a weekly basis to all cold chain points) to avoid any additional risk of temperature excursions during transport on larger vaccine quantities. All cold boxes used for transport of COVID-19 vaccine should contain a 30 DTR. In case there is evidence of any temperature excursion during transport, the receiving store should first store the vaccine as per standard protocols in the equipment and immediately inform the DIO. Further decision on use of these vaccines will be taken on a case to case basis based on available information, with support from the SEPIO, CCO and other development partners.

Vaccine doses issued should be equal to the number of registered beneficiaries for each cold chain point (rounded up to the nearest higher number of vaccine vials) without adjustment for vaccine wastage in terms of the WMF. The issue quantity will depend on the supply frequency (e.g. weekly estimate of registered beneficiaries at cold chain points in the district) and vaccine batches with earlier manufacturing dates should be prioritized for issue first.

All COVID-19 vaccines should be stored in separate ILRs/ DFs from other RI vaccines (as per recommended temperature range of the specific vaccine) and the lid should only be opened during vaccine distribution.

Continuous temperature monitoring should be ensured with the eVIN RTM with recording of half hourly temperatures for review. DIO should undertake daily temperature review of equipment with COVID-19 vaccines and monitor every vaccine distribution event. Any temperature excursion beyond 30 minutes should be responded with alternate vaccine storage for vaccines with repair of affected equipment as soon as possible on emergency basis.

#### 8.4.4 AT STATE/ REGIONAL VACCINE STORES

All WIC/WIF should have functional autostart facility with adequate fuel for seamless power during power cuts. WIC/WIF doors should only be opened and staff entry permitted during vaccine packing for distribution. Vaccine distribution plans should ensure minimum time for vaccine delivery to district stores and vaccine vials with earlier manufacturing dates should be prioritized for issue first.

All cold boxes used for transport of COVID-19 vaccine should contain a 30 DTR. In case there is evidence of any temperature excursion during transport, the receiving store should first store the vaccine as per standard protocols in the equipment and immediately inform the SEPIO. Further decision on use of these vaccines will be taken on a case to case basis based on available information, with support from the national level working group. All equipment for vaccine storage should have functional eVIN RTM with daily monitoring of mobile alerts by SEPIO and CCO.

Alternate vaccine storage sites (including private sector and non-health public sector) should be identified in advance of vaccine arrival including all contractual arrangements and site inspections. State level monitors should supervise every vaccine arrival and distribution event to ensure quality process in vaccine receipt and distribution.

### STATE WISE COLD CHAIN EQUIPMENT

National Cold Chain MIS (NCCMIS) Data

S. No.	State	Cold Chain Points	Walk in Coolers	Walk in Freezers	Ice Lined Refrigerator	Deep Freezers	Solar Units
1	Andaman & Nicobar Islands	40	1	0	53	56	6
2	Andhra Pradesh	1650	9	6	2307	2109	0
3	Arunachal Pradesh	193	2	0	282	249	49
4	Assam	792	5	2	1186	1033	26
5	Bihar	678	19	4	1655	931	5
6	Chandigarh	51	1	0	69	58	0
7	Chhattisgarh	630	5	2	908	1017	18
8	Dadara & Nagar Haveli	19	0	0	30	33	0
9	Daman & Diu	2	0	0	26	16	0
10	Delhi	629	1	0	817	478	0
11	Goa	41	1	0	77	61	0
12	Gujarat	2291	9	2	2597	2467	1
13	Haryana	682	8	2	1089	887	0
14	Himachal Pradesh	416	5	1	565	579	4
15	Jammu and Kashmir	681	5	1	1032	831	16
16	Jharkhand	275	5	3	686	699	5

S. No.	State	Cold Chain Points	Walk in Coolers	Walk in Freezers	Ice Lined Refrigerator	Deep Freezers	Solar Units
17	Karnataka	2870	9	5	3776	3495	0
18	Kerala	1251	6	1	2106	1832	0
19	Lakshadweep	5	0	0	26	15	0
20	Madhya Pradesh	1214	11	5	2311	2164	14
21	Maharashtra	3257	18	6	4408	4199	12
22	Manipur	123	2	0	109	99	27
23	Meghalaya	189	3	0	207	230	15
24	Mizoram	85	1	0	131	111	1
25	Nagaland	120	1	0	122	124	20
26	Odisha	1224	13	2	1793	1712	18
27	Puducherry	56	0	0	77	76	0
28	Punjab	750	6	3	1149	1042	0
29	Rajasthan	2405	14	3	3522	3472	18
30	Sikkim	34	0	0	107	88	6
31	Tamil Nadu	2599	18	3	2785	2677	0
32	Telangana	897	7	3	1201	1139	0
33	Tripura	160	2	1	191	217	0
34	Uttar Pradesh	1308	30	10	3574	4060	17
35	Uttarakhand	373	5	1	698	609	16
36	West Bengal	942	18	4	2554	1927	0
<b>India</b>		<b>28932</b>	<b>240</b>	<b>70</b>	<b>44226</b>	<b>40792</b>	<b>294</b>

As per the National Cold Chain Management Information System (NCCMIS) accessed on 6th December 2020







## 9. COMMUNICATION AND SOCIAL MOBILIZATION

As the country stands on the cusp of COVID 19 vaccine administration, certain challenges are foreseen that needs to be countered well in time. These may include the challenge of ensuring over 135 crores people in India receive factual and timely information and updates on vaccine rollout progress and benefits, public's anxiety and queries regarding government's decision for prioritization of vaccine administration, apprehension about the vaccines introduced after a short trial raising safety concerns, and fear of adverse events, misconception about vaccine efficacy, rumours and negative narrative in the media / social media space and laxity observed in public adherence to COVID Appropriate Behaviors.

To address these probable challenges, an integrated 360-degree comprehensive advocacy communication and social mobilization strategy is implemented to adequately include mechanisms by which four key areas around vaccination introduction, vaccine eagerness, vaccine hesitancy can be handled along with continuance and sustenance of COVID Appropriate Behaviors. The communication approach will be that of a *Jan Andolan* or a people's movement where people's engagement and participation will be the center point.

Objectives of the COVID 19 Communications Strategy:

- To provide **Prompt, Simple and Focused communication** (on vaccine availability, safety and timelines);
- **Ensure understanding and acceptance** of the **phased & prioritized approach** to overcome concerns of population waiting for vaccination;
- To **build public confidence** on the safety and efficacy of the new vaccine; and
- **To maintain and sustain the key preventive behaviors:** prompt testing on developing symptoms, wearing masks, maintaining physical distance and hand washing with soap during and after vaccination.

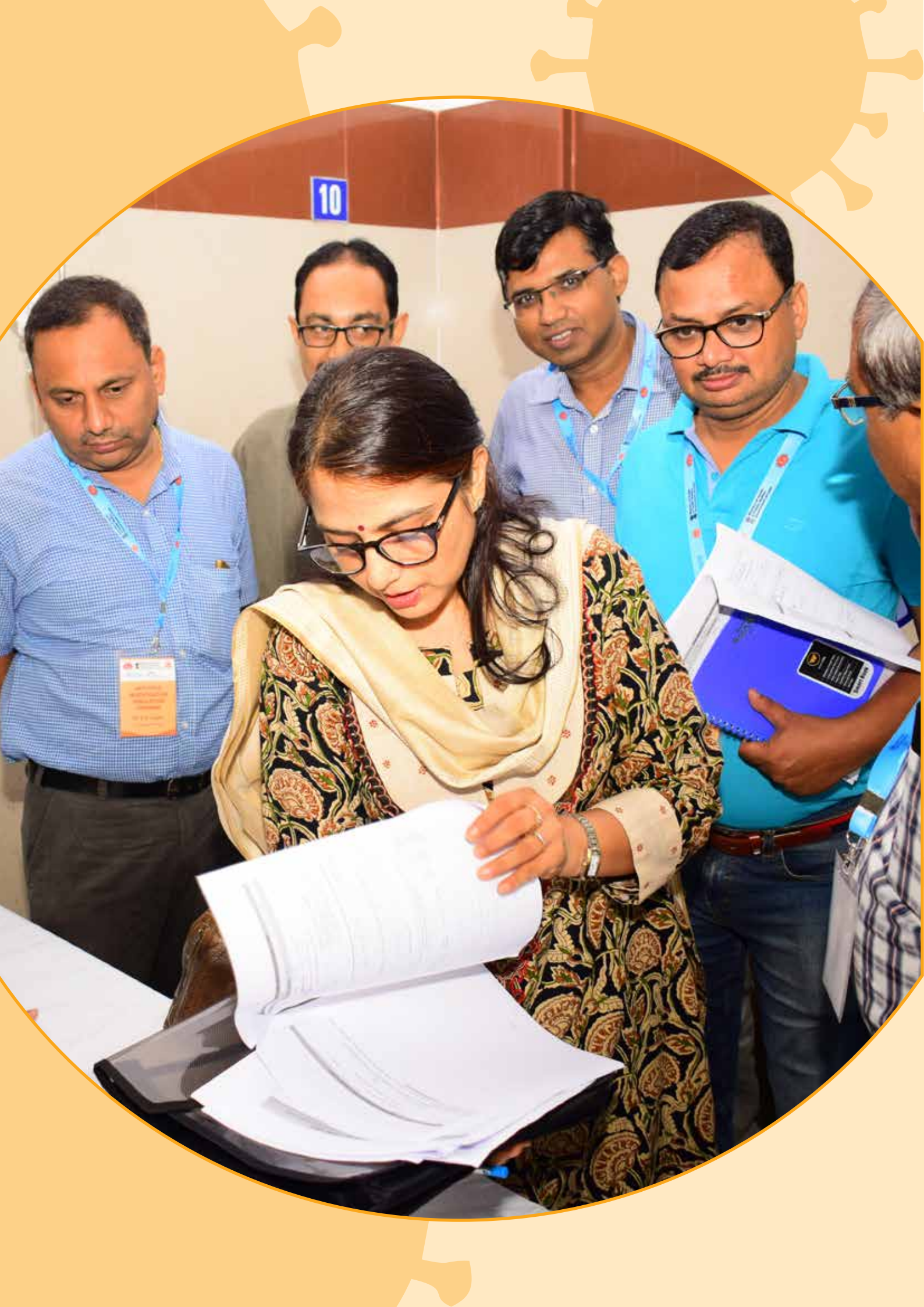
**Information on COVID 19 vaccine and vaccination process must also explain the implementation plan and facilitate in maintaining transparency.**

**BASED ON THE LEARNINGS OF THE PREVIOUS IMMUNIZATION CAMPAIGNS (MI/IMI/MR), FIVE STRATEGIES WILL GUIDE THE INTRODUCTION OF COVID-19 VACCINE AT THE NATIONAL AND STATE LEVEL.**

- **Advocacy:** To gain commitment and garner support for roll out of new COVID-19 vaccine.
- **Capacity Building:** To enhance capacities and communication skill of target audiences.
- **Media Engagement and Social media:** To promote balanced, evidence-based discourse on COVID-19 Vaccine and vaccination process. Engage media to address Vaccine Eagerness, Vaccine Hesitancy, build trust, manage misinformation/rumors.
- **Social Mobilization and Community Engagement:** To provide prompt, simple and Focused communication to community members; and address eagerness and hesitancy concerns.
- **Crisis Communication including AEFI:** To be prepared for rapid response and managing any crisis situation arising from Vaccine Eagerness and Vaccine Hesitancy.

A robust monitoring and evaluation framework, methods and tools will support the implementation of communication and demand generation strategies and guide mid-course corrective actions of the communication interventions.

**A DETAILED COMMUNICATION STRATEGY DOCUMENT WILL BE SHARED SEPARATELY**



10

Dr. [Name]  
[Title]  
[Institution]

[Logo]  
[Text]





# 10. ADVERSE EVENTS FOLLOWING IMMUNIZATION

## 10.1 INTRODUCTION

COVID-19 vaccines have limited safety data. Therefore, it is important to monitor the safety of these vaccines when administered to a large population. A robust AEFI surveillance system would enable us to monitor adverse events and better understand the safety profile of the vaccines. During COVID-19 vaccinations, AEFIs must be rapidly detected and promptly responded to or else it can undermine confidence in the vaccine and immunization programme. All AEFIs should be reported as per the National AEFI Guidelines.

**Programme managers should be aware of the following:**

- COVID-19 vaccination will involve vaccination of large population over a short period of time. This may lead to increased reporting of AEFIs;
- During mass campaigns, there can be chances of anxiety reactions and occurrence of programme errors, especially if it involves reconstitution of vaccines using diluents; and
- Immunization errors which might lead to AEFI must be prevented at all costs through proper training, regular and intensive monitoring and supervision, and strict adherence to proper vaccine / diluent handling procedures and injection practices.

COVID 19 vaccines may be administered to persons belonging to high risk groups such as health care workers, other front line workers such as those in the police, municipal workers, etc. who are more at risk of contracting the disease and the elderly and persons with co-morbidities as they are more likely to have higher mortality and morbidity rates as compared to healthy individuals. Many of the deaths, and hospitalizations following COVID19 vaccinations in these high-risk groups may be coincidental. However, it is important that all deaths, hospitalizations, any event occurring in clusters following COVID19 vaccination, or any event felt by health workers and medical staff to be due to COVID 19 vaccines or vaccinations should be reported and investigated immediately.

## 10.2 AEFI SURVEILLANCE SYSTEM

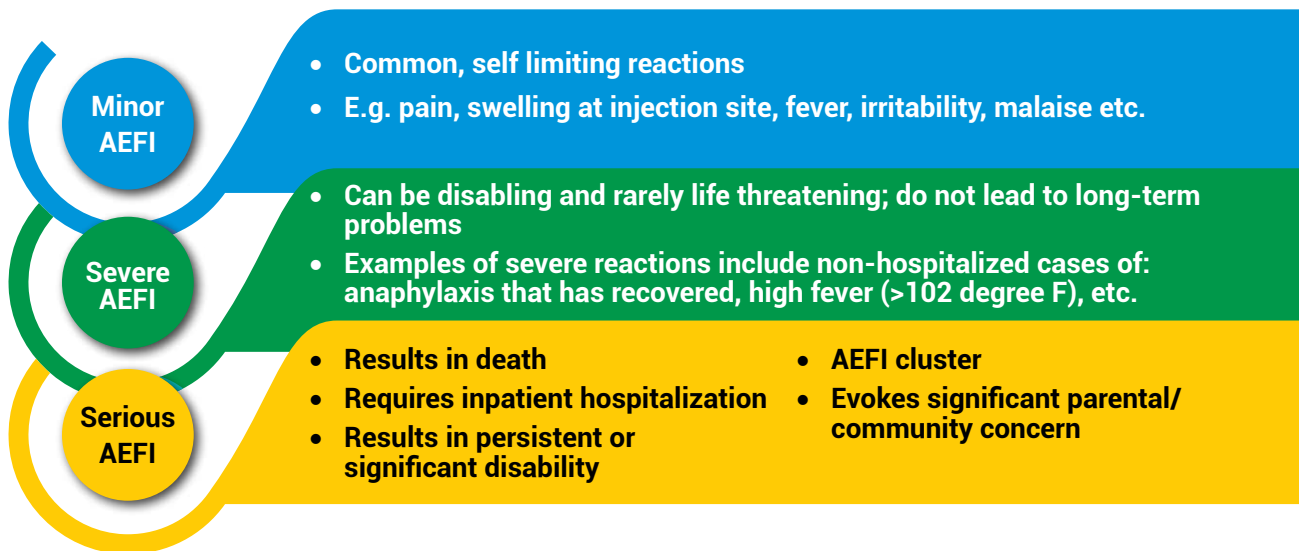
The overall goal of AEFI surveillance is to ensure that vaccines are administered safely to the recipients and the trust in vaccines is sustained. The specific objectives of AEFI surveillance are to:

- Promptly detect, report and respond to AEFIs;
- Promptly identify programmatic errors and implement corrective measures;
- Document the rates of AEFI for a specific vaccine lot / brand in a specific region/population;
- Estimate serious AEFI rates in the population and compare these with local and global data;
- Identify signals of unexpected adverse events that would need further confirmation and planned studies; and
- Sustain confidence of the public, health functionaries and professionals on the vaccines and immunization program.

## 10.3 ADVERSE EVENTS FOLLOWING IMMUNIZATION

An adverse event following immunization (AEFI) is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended disease, symptom, sign or abnormal laboratory finding. Reported adverse events can either be true adverse events, i.e. really a result of the vaccine or immunization process, or coincidental events that are not due to the vaccine or immunization process but are temporally associated with immunization.

For purposes of reporting, AEFIs can be classified as minor, severe and serious



### 10.3.1 PREVENTION OF AEFIs

Injectable COVID-19 vaccines are expected to be given in a campaign mode and these vaccines may have different modalities of administration. Appropriate measures need to be taken to avoid possibilities of anxiety reactions in individuals and clusters. Programme managers and implementers must plan to prevent and minimize chances of occurrence of preventable AEFIs. Beneficiaries should be observed at the session site for at least 30 minutes post-vaccination to detect, manage and treat immediate adverse reactions.

### 10.3.2 PREVENTING ANXIETY REACTIONS

Session sites should be planned in such a way that there is a separate area for those waiting for vaccination, site of actual vaccination and post-vaccination observation area.

- Ensure vaccinations occur in comfortable, well-ventilated and airy settings. Beneficiaries who seem anxious or nervous should be identified and made to calm down or their attention diverted from the process and the pain. After vaccination, they should be asked to remain seated for some time and observed. If they feel light-headed or giddy, they should be asked to lie down for some time.

### 10.3.3 PREVENTING PROGRAMME ERRORS

Ensure guidelines for safe injection practises are followed at the session site. Special attention should be on the following:

- Ensure nothing other than vaccines / diluents are stored in ILRs;
- If reconstitution is required, separate reconstitution syringes should be used for each vial and diluent;



- Proper cold chain management of the vaccines at the session site;
- Screening for contraindications of the vaccine; and
- Other specific precautions as per guidelines issued or as mentioned in the vaccine product insert.

## 10.4 AEFI MANAGEMENT

Vaccinators and supervisors at the vaccination site will provide primary treatment of all AEFIs. If needed, cases should be immediately referred to the nearest AEFI management centre/ health facility and reported to the appropriate authority.

COVID 19 vaccination sessions may be at fixed sites such as at government health facilities such as PHCs, urban PHCs, CHC, Sub divisional hospitals, district hospitals, medical college hospitals and identified private hospitals and nursing homes, etc. or in outreach.

- All beneficiaries must be counselled about adverse events which may occur after COVID-19 vaccine. These are expected to be minor events such as local pain and swelling and mild to moderate fever, etc. However, the list of expected events could be different based on the safety profile of the COVID19 vaccine(s) which finally gets approved for use.
- In case of any type of discomfort or illness following COVID vaccination, the vaccine recipient should visit the nearest health care facility for treatment.
- At fixed session sites, an AEFI management kit or an emergency tray should be available for use. The contents of the AEFI kit are: Inj. Adrenaline (1:1000) (3), Inj. Hydrocortisone (3), Ringer lactate/Normal saline (2), 5% dextrose (2), IV drip set (2), scalp vein sets or IV cannula (2), disposable syringes – 5 ml with 24/25G IM needle (3 sets), adhesive tape and blank Case Reporting Formats (CRF).
- Outreach session sites should have an Anaphylaxis kit
- Contents of Anaphylaxis Kits

- All vaccinators must be trained to suspect signs and symptoms of anaphylaxis and to use the contents of the anaphylaxis kit to provide a single, age-appropriate dose of injection Adrenaline and arrange transportation of the patient to the nearest AEFI management centre/hospital for further treatment.

- Job aid for recognizing anaphylaxis
- Dose chart for adrenaline as per age
- 1 mL ampoule of adrenaline (1:1000 aqueous solution) - 3 nos.
- Tuberculin syringes (1 mL) OR insulin syringe (of 40 units, without fixed needle) – 3 nos.
- 24G/25G needles (1 inch) – 3 nos.
- Swabs – 3 nos.
- Updated contact information of DIO, Medical Officer(s) of PHC/CHC, referral center and local ambulance services
- Certification by Medical Officer for expiry dates of contents



This is crucial for saving lives in case of rare but life-threatening anaphylactic reactions.

- Ensure that is enough stock / supply of injection adrenaline during the campaign, keeping in mind the short expiry period of the adrenaline.
- Each outreach session site should be linked to an identified AEFI management centre to provide immediate treatment for serious AEFI cases.
- Adequate transportation should be available to transfer persons with serious adverse reactions to nearest identified AEFI management centre or health facility. The vaccinators at the session sites must be aware of all relevant contact numbers like ambulance services (108 or 102), AEFI management centres, higher health care facilities, etc.

## 10.4.1 AEFI MANAGEMENT CENTRES

- States and UTs should identify **at least** one AEFI management centre in each block.
- During vaccination campaign, AEFI management centres must be identified near the vaccination sites. PHCs, CHCs, UPHCs, DHs or any other fixed health facilities with medical officers and paramedical staff should be identified as AEFI management centres. Private health facilities may also be made AEFI management centres.
- Every session site should be linked to a designated AEFI management centre. Contact details of medical officer, and address of AEFI management centre should be mentioned in the micro plans and should be known to staff of the session site.
- Adequate mobility support/ambulance services (102, 108) must be available to transport any person with AEFI from session sites to AEFI management centres.
- All MOs acting as supervisors will carry an AEFI management kit.
- All AEFI management centres should have an AEFI management kit and AEFI reporting forms.
- BMO and PHC MOIC should have mobility support to respond to AEFI investigation and management.
- AEFI management centres will report the AEFI as per laid out procedures in the national guidelines.
- If required, arrangements should be made to transfer the patient to a secondary or tertiary care hospital for specialist management.

## 10.5 REPORTING AND RECORDING

Any adverse event following COVID-19 vaccination must be reported. There is no time limit (between vaccination and onset of symptoms) for reporting AEFIs. If the health worker or the treating physician or anyone suspects the event to be due to vaccination, it should be reported.

**State and district authorities (DIO/CMO or the Block MO) should proactively reach out to all health care service providers such as medical colleges, hospitals (public, autonomous and private) and individual practitioners and sensitize them to report any adverse event following COVID-19 vaccine as per guidelines.**

Doctors should ask and record history of COVID-19 vaccination in OPD prescriptions, casualty records, clinical treatment sheets, etc. Patients with history of COVID-19 vaccination (any duration) in which onset of symptoms has occurred AFTER COVID-19 vaccination should be considered as AEFIs and reported by the treating doctor to the nearest PHC doctor or District Immunization / RCH Officer in Case Reporting Format or telephonically. During investigations conducted by the DIO/district AEFI committee, all treatment records of the patient must be shared for causality assessment.

Professional bodies like IAP, IMA, IPHA, partner agencies like WHO-NPSP, UNICEF, UNDP, USAID, PATH and others should also be encouraged to support AEFI surveillance.

Blank copies of Case Reporting Formats (CRF) should be available with potential reporters to capture AEFI details. The reporter should also know whom to report and how to report. Thereafter, the case should be investigated by the district health authorities (DIO with support of the district AEFI committee members) as per national AEFI guidelines.

## 10.5.1 IMMEDIATE REPORTING OF SERIOUS AND SEVERE AEFIs

A serious or severe AEFI case needs to be reported immediately to the concerned Medical Officer or the appropriate health authorities. Soon after the identification / notification of a serious and severe AEFI, a two-step process must be initiated.

**STEP 1** Report serious and severe AEFI to the appropriate authority (DIO or the nearest government health facility) in Case Reporting Format.

**STEP 2**

- Investigation of all reported serious and severe AEFI by District Immunization Officer or District AEFI Committee.
- All serious and severe AEFIs should be treated as a medical emergency and priority should be given to its management followed by its reporting and investigation on the standardized AEFI formats. All serious and severe AEFIs should be documented on a CASE REPORTING FORM (CRF).

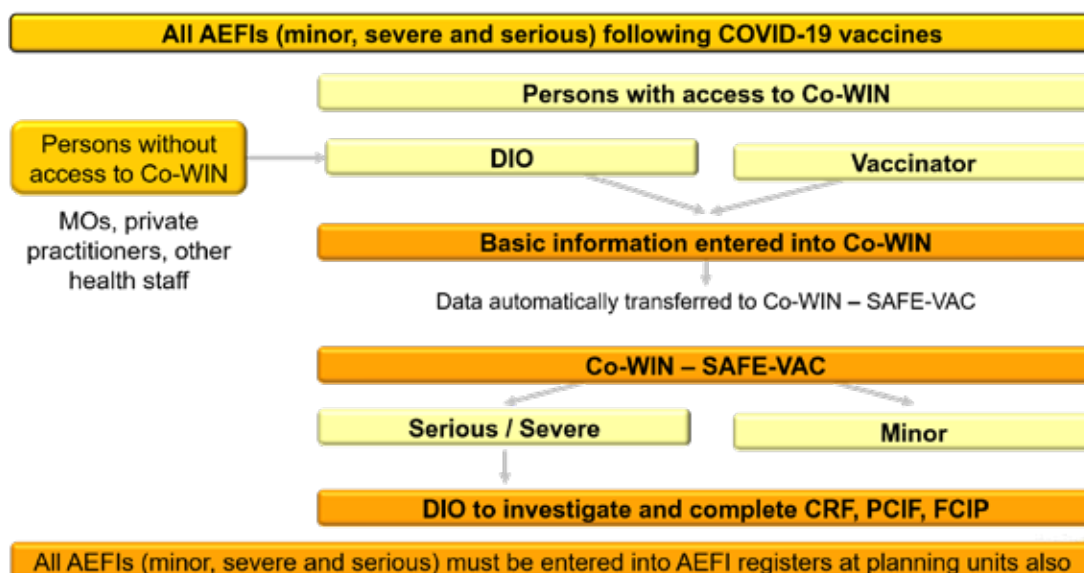
All serious and severe AEFIs should be treated as a medical emergency and priority should be given to its management followed by its reporting and investigation on the standardized AEFI formats. All serious and severe AEFIs should be documented on a CASE REPORTING FORM (CRF).

## 10.5.2 ROUTE OF REPORTING

### Reporting through Co-WIN

Co-WIN is a web-based application developed for management of COVID-19 vaccination process including AEFI reporting. In the beneficiary module of Co-WIN, there is a provision for reporting of AEFI cases following COVID-19 vaccines.

- All adverse events (minor, severe and serious) following COVID-19 vaccination must be reported in Co-WIN by
  - The vaccinator through vaccinator's module
  - The DIO through district login in Co-WIN
- Immediately inform severe and serious AEFI cases telephonically by vaccinator to supervisor/medical officer/DIO.



- Only basic information is entered in Co-WIN, which is automatically transferred to SAFE-VAC.
- Once the basic case details are entered through Co-WIN, DIO can generate CRF for a serious / severe case. DIO, using a single sign-on through Co-WIN, can access SAFE-VAC for AEFIs related to COVID-19 vaccines and can enter information into CRF, PCIF, FCIF and can upload the documents

**AEFI registers at PHC/block/planning unit levels:** ANMs at block/planning unit should notify all AEFIs (serious, severe and minor) of their respective areas on weekly basis and document them in the AEFI register which is being maintained at the centre. Medical Officer In-charge of the block or planning unit (PHCs, CHCs etc.) should analyse the information regularly to look for any pattern or preventable programme errors and inform to District Immunization Officer.

**Reporting and investigation of cluster AEFI cases:** Cluster of AEFI cases is a specific condition which warrants immediate investigation because of its nature and seriousness. Each case of an AEFI cluster should be separately reported and investigated as per national AEFI guidelines.

For known anxiety clusters, separate CRFs should be filled for each case of a cluster. In confirmed anxiety clusters ONLY, if symptoms, clinical sequence of events, treatment and outcome are similar in all cases, a single, completely-filled PCIF and FCIF with all critical information recorded can be submitted. In addition, a summary report of the district AEFI committee certifying that this is an anxiety cluster should also be submitted along with the CRFs, PCIF, FCIF, hospital records, etc. of the cluster.

**If cases of a cluster are showing different clinical pictures, separate PCIFs, FCIFs need to be filled for each case.**

## 10.6 INVESTIGATION OF AEFI CASES

All serious and severe AEFI cases after COVID-19 vaccines must be investigated as per the National AEFI Guidelines. The process of investigation must be expedited in order to collect accurate and complete clinical and epidemiological facts so that causality assessment can be completed as soon as possible. Following actions are required in advance as preparation for investigation of cases:

- District AEFI committee meetings must be held at least one month prior to the start of COVID-19 vaccination. All members of the committee must be sensitized, and their services should be utilized, if needed, to investigate the cases.
- The district AEFI committees must include drug inspectors and ensure their support in the investigations.
- Medical Officers of government and private health care facilities, where serious AEFI cases are expected to reach for treatment, must be informed and sensitized about AEFI surveillance for immediate reporting and cooperation in investigations. Their support is also crucial for ensuring availability of medical records and clinical details of the cases which are required for causality assessment of the cases.

If a death following vaccination is reported, and the case was not hospitalised or clinical records are not available, relatives should be motivated to give consent for post mortem. Post mortems should be conducted to find the pathological cause of death. Any samples sent for laboratory tests should be followed up for obtaining results as soon as possible.

If consent for post mortem is refused, the AEFI verbal autopsy form should be administered as soon as possible.



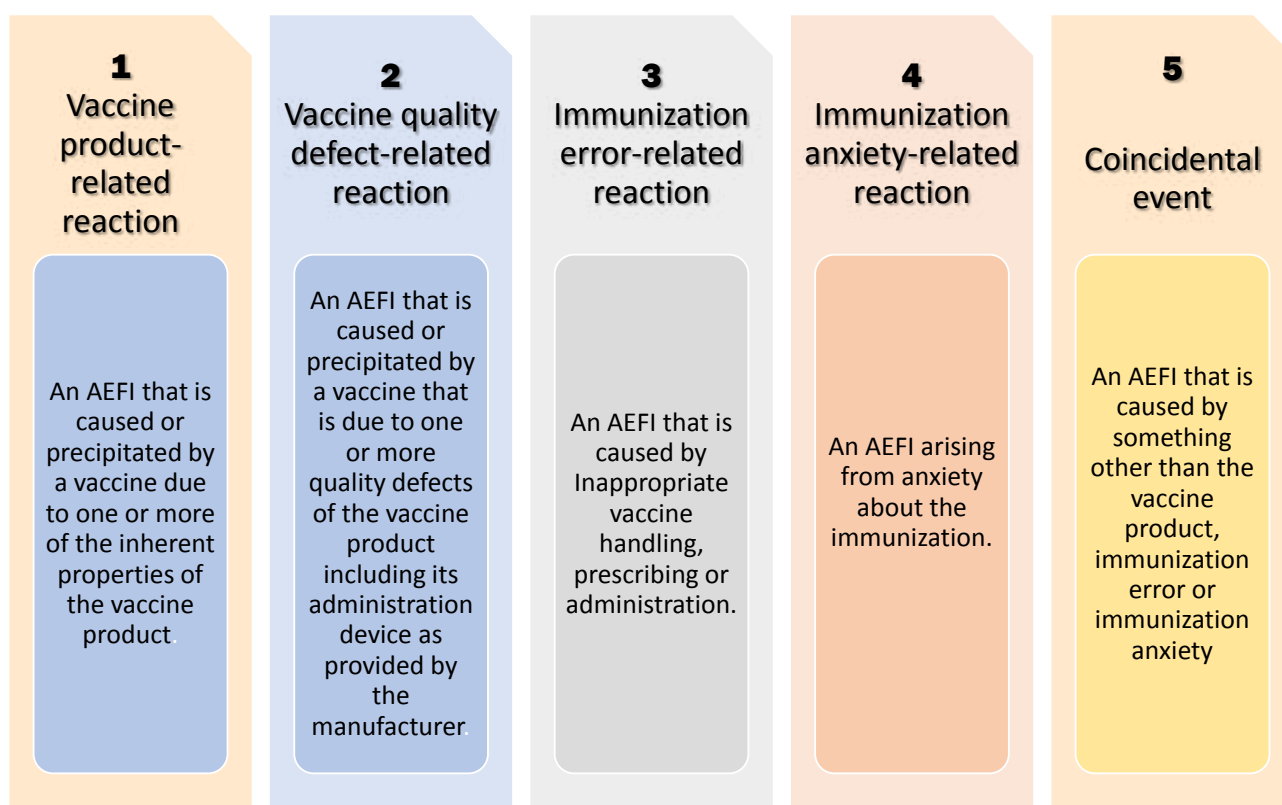
## 10.7 TESTING OF VACCINE SAMPLES

The testing of vaccine samples is done very rarely. It should not be done unless there is a specific reason to doubt vaccine quality. Decision for testing will be taken by the district AEFI committee and the DIO should consult the state for this. Necessary guidelines and procedures for testing of COVID 19 vaccine samples available at that time should be followed.

## 10.8 CAUSALITY ASSESSMENT

Once investigations are complete for a serious/severe AEFI case and all supporting documents are available (hospital records, post mortem reports, final outcome), trained experts of the state and national AEFI committees assess the case as per globally accepted causality assessment protocol and available evidence of safety profile of the vaccine to classify it as follows:

### WHO cause specific definition of AEFIs



## 10.9 CAPACITY BUILDING ACTIVITIES

Training on AEFI surveillance will be a part of overall training package for COVID-19 vaccine implementation. Cascaded trainings will be conducted till the level of vaccinators. The content will provide information on AEFI surveillance system in the country with roles and responsibilities and specific information on AEFIs related to COVID-19 vaccines. All personnel involved in vaccination and AEFI surveillance including those in the private sector should be sensitized for identification and reporting of AEFIs.

## 10.9.1 ROLES AND RESPONSIBILITIES

### Session site

Vaccinator Officer–vaccinator at the session site will be responsible for administering COVID19 vaccines safely as per guidelines and conveying appropriate messages to each beneficiary regarding management of AEFIs. S/he will also be responsible for reporting all AEFIs informed to her through recommended channels.

- a. Inform the beneficiaries about the possible minor adverse events following COVID-19 vaccination
- b. Ask beneficiaries to wait at vaccination sites for 30 minutes after vaccination
- c. If any adverse event happens at the session site, manage appropriately
  - i. Primary treatment to all AEFIs
  - ii. Inj. Adrenaline for suspected anaphylaxis
  - iii. Inform to MO / DIO
  - iv. Arrange transport to refer, if required
  - v. Enter the AEFI information in beneficiary module of Co-WIN
- d. If any person reports about adverse event after 30 minutes following vaccination
  - i. Ask beneficiary to contact nearest health care facility for prompt management
  - ii. Enter the AEFI information in beneficiary module

### SUPERVISOR

Supervisor will ensure that the trained vaccinators at sessions are following all guidelines for safe administration of vaccines, conveying correct messages regarding adverse events and their management and ensure availability of anaphylaxis kits at the session site.

### PHC / AEFI MANAGEMENT CENTRE

Medical Officer – The medical officer at the PHC will ensure that all session sites are tagged to an AEFI management centre with AEFI management kits. S/he should be trained in managing emergencies following COVID19 vaccination and ensures adrenaline ampoules at the session sites are within expiry dates.

### DISTRICT LEVEL

- a. DIO should ensure all health personnel involved in the COVID19 immunization programme are trained, cold chain is adequate, and processes are in place to manage AEFIs following vaccination.
- b. DIO should network with all large hospitals and medical colleges (government, PSU, autonomous and private) and doctors to report minor, serious and severe AEFIs using the recommended processes.
- c. District AEFI Committee - DIO will expand the committee to include neurologists, cardiologists, respiratory medicine specialists/medical specialists and obstetrician & gynaecologist. These specialists will support DIOs in investigation of the case and establishing a diagnosis for causality assessment. District AEFI committee shall meet at least 15 days before the campaign to familiarise itself regarding preparations for vaccination, potential vaccine issues, is available to conduct urgent serious AEFI investigations and assesses investigation reports to give probable diagnosis.

d. If any serious/severe AEFI case is reported

- ♦ Arrange for clinical management at secondary or tertiary care hospitals
- ♦ Investigate the case
- ♦ If the case information has not already been entered in Co-WIN by vaccinator, enter the basic information through district log-in (information is automatically transferred from Co-WIN to SAFE-VAC)
- ♦ Complete CRF, PCIF and FCIF in SAFE-VAC
- ♦ Entry of all AEFIs (minor, severe and serious) reported directly to DIO by persons not having access to Co-WIN (MOs, private practitioners, other healthcare staff etc.)

**Preparatory**

- Expansion of District AEFI Committee
- Sensitization of District AEFI Committee members
- Expansion of reporting network – medical colleges, private practitioners

**AEFI Management**

- Arrange for clinical management
- Investigate the case
- Enter the basic information into Co-WIN
- Complete CRF, PCIF and FCIF in SAFE-VAC

**Reporting**

- Entry of all AEFIs (minor, severe and serious) reported directly to DIO by persons not having access to Co-WIN (MOs, private practitioners, other healthcare staff etc.)

**STATE LEVEL**

- **SEPIO**–Ensure all districts are using trained vaccinators for session sites, and they are aware of procedures for managing, reporting and investigating AEFIs as per guidelines. He/she ensures state AEFI committee and district AEFI committee members are oriented on COVID19 vaccination and are aware of their roles and responsibilities.
- **State AEFI Committee**–SEPIO will expand State AEFI Committee to include neurologists, cardiologists, respiratory medicine specialists/medical specialists and obstetrician & gynaecologist. State AEFI committee meets at least 7 days before the campaign to familiarise itself regarding preparations for vaccination, potential vaccine issues, be available to conduct urgent serious AEFI investigations and assess causality of AEFI cases following COVID19 vaccinations within recommended timelines.

**NATIONAL LEVEL**

- a. **MOHFW (including AEFI Secretariat)** – Coordinates with partners to ensure preparations are in place for COVID 19 vaccination. Reported and investigated AEFIs are causally assessed and database analysed for potential signals. Consultative meetings with experts are held for further management of potential signals.

**b. National AEFI Committee** – National AEFI Committee will be expanded to include neurologists, cardiologists, respiratory medicine specialists/medical specialists and obstetrician & gynaecologist. The national AEFI committee monitors the progress and analysis/ assessment of AEFIs reported and investigated in the districts, conducts and approves causality assessment results, assesses causality assessment data and active surveillance data for better understanding of the safety profile of COVID19 vaccines.

## 10.10 ADVERSE EVENTS OF SPECIAL INTEREST (AESI) SURVEILLANCE FOR COVID 19

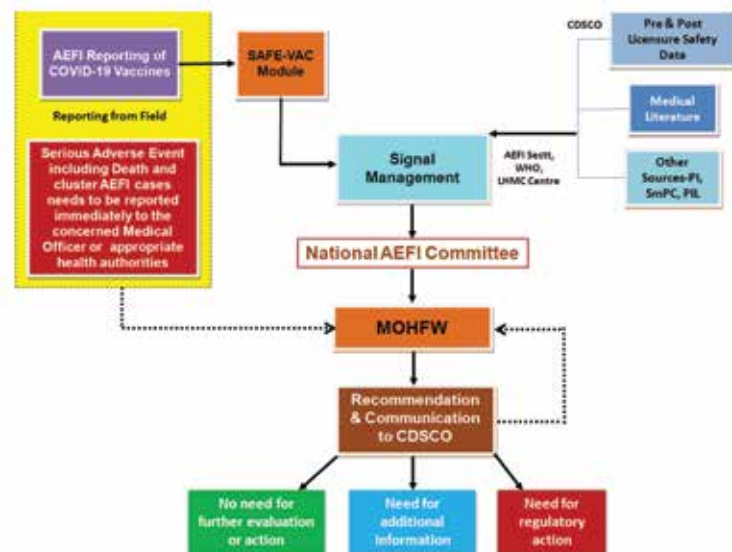
When a new vaccine is approved for use, there is a theoretical possibility of occurrence of some events based on available data for existing and new vaccines. Such Adverse Events of Special Interest (AESI) should be monitored

- To ensure these are not occurring at a rate more than the background or expected rate and
- To elicit safety issues related to these as early as possible and take appropriate action

An active AESI sentinel surveillance, which is one of the ways to assess these AESIs, will complement the regular passive AEFI surveillance system. The combined evidences from routine AEFI surveillance and active AESI surveillance will further help in generating sound evidence to characterize the safety profile of the new vaccine. A few sentinel sites across the country will be chosen for this AESI surveillance as part of separate project.

## 10.11 SIGNAL MANAGEMENT AND SAFETY MONITORING

The evaluation of safety signals identified through reported AEFIs is part of vaccine vigilance and is essential to ensure that regulatory authorities and immunization programme have the most up-to-date information on benefits and risks. Database of AEFI cases reported from the districts, can be analysed for safety signals by integrating automated data-mining and appropriate statistical methodologies. The evidences generated by the system will equip decision makers to take important decisions to ensure vaccines administered under the programme are safe.



### KEY POINTS

1. Expand committees at various levels to include neurologists, cardiologists, respiratory medicine specialists/medical specialists and obstetrician & gynaecologist
2. Expand reporting network through sensitizing medical colleges, private practitioners and medical officers
3. Expedite investigation and causality assessment of cases
4. Prompt case management / referral of AEFI cases
5. Vaccinators at the session sites and DIOs at district level can directly enter basic information of AEFIs following COVID-19 vaccines, which will be transferred automatically to SAFE-VAC for further processing.







# 11. MONITORING AND SUPERVISION

**A** robust mechanism is needed to identify, mitigate and manage challenges at various steps of vaccine introduction. Close monitoring and supportive supervision will help to identify bottlenecks and challenges at all levels.

At national level National Expert Group on Vaccine Administration (NEGVAC) has been constituted to provide guidance.

At state, districts and block levels following mechanisms are functional:

- State Steering Committee under the chairpersonship of the Chief Secretary;
- State Task Force under the chairpersonship of the Principal Secretary (Health);
- District Task Force at district level under DC/DM;
- Urban Task Force under Municipal Commissioner; and
- Block Task Force under SDM / Tahsildar / BDO.

Additionally, State, district and Block core groups are constituted to ensure implementation.

## 11.1 SUPPORTIVE SUPERVISION

Supportive Supervision is active support by the vaccine programme managers during the preparation phase and implementation phase of COVID 19 vaccine roll out at every level. The objective of supportive supervision is confidence and capacity building of team members to ensure that Standard Operating Procedures are being followed. State and districts will deploy supervisors specially for high risk / poor performing districts and blocks.

For three to five vaccination teams, a supervisor will be deployed for close supervision at session site. Allocation of teams to supervisor will depend upon distancing of vaccination session and travel time. Supervisors working in hilly and difficult to reach areas may have fewer teams whereas those working in congested areas may have more teams.

Team supervisors will be provided with standardized checklist (Annexure-3) and guide on the job corrections / trainings to vaccination team members. Team level supervision checklist is an important tool for supportive supervision.



## 11.2 TRACKING PROGRESS OF INTRODUCTION ACTIVITIES AIMS TO IDENTIFY AREAS WITH SLOW PROGRESS AND GUIDE CORRECTIVE MEASURES. ACTIVITIES REQUIRE TRACKING WOULD INCLUDE

- a. Monitoring progress of database of beneficiaries on Co-WIN
- b. Identification of human resources,
- c. Planning and Mapping of vaccination sessions through Co-WIN
- d. Quality and participation in trainings at various levels
- e. Monitoring of communication activities
- f. Procurement of logistics
- g. Status of review mechanisms – identification and deployment of monitors, meeting of task forces

## 11.3 DRY RUN FOR COVID-19 VACCINATION

The unique feature of COVID-19 vaccine deployment as compared to Universal Immunization Programme are pre-identified populations of specified groups, use of Co-WIN application, engagement of session sites, vaccinators and other team members beyond routine immunization platforms. The objective of dry run includes:

- Assess operational feasibility of using Co-WIN application in field environment;
- Test linkages between planning, implementation and reporting mechanisms;
- Identify challenges and guide way forward prior to actual implementation; and
- Provide confidence to programme managers at various levels

The dry run will be planned in one or two districts of the states and sessions will be organized at District hospital / Medical College, CHC / PHC, Private health facility, outreach sites at urban and rural areas. The dry run will test all major steps for COVID-19 vaccination process (excluding message to beneficiary and actual vaccination) in field environment:

- Planning & preparations including prerequisites for the vaccine introduction as per the Operational Guidelines
- Creation of Facilities & Users on CoWIN application
- Session site creation, & mapping of sites
- HCW beneficiary data upload on Co-WIN
- Receipt of Vaccines by the District and vaccine allocation using Co-WIN
- Session planning, vaccinator deployment
- Deployment of team members
- Vaccine and logistics mobilization at session site
- Mock drill of beneficiary vaccination and reporting
- Review meetings at block, districts and state and provide feedback to guide actions for COVID-19 vaccination
- Standard operating procedure to conduct dry run is included as annexure 8.

## 11.4 READINESS ASSESSMENT PRIOR TO VACCINE INTRODUCTION

Efficient roll out of COVID-19 vaccine will require a high quality of preparedness at all levels. India has ensured successful roll out of new vaccines in the recent past, namely measles rubella (MR) vaccine and pneumococcal conjugate vaccine (PCV) using a preparedness assessment framework before the introduction. A similar preparedness assessment will be conducted in context to COVID-19 vaccine introduction. Assessment will be carried out at National, State and District level and field network of immunization partners will assist the readiness at process. Task forces at state, district, urban and block will review the observations and undertake corrective measures to ensure completion of preparedness prior to vaccination.

### **State, district, urban and block readiness assessment checklists:**

Preparedness will be assessed for all state, district, urban and block planning units using standard checklists (attached as annexure 7), Assessment will capture status of key preparedness activities for COVID-19 vaccine introduction:

- Planning and coordination;
- Identification of resources;
- Prioritization of beneficiaries and COVID-19 surveillance;
- Microplanning;
- Training and supervision;
- Monitoring and evaluation;
- Vaccine/logistic calculations and cold chain plan;
- Safety surveillance (AEFI surveillance); and
- Demand generation and communication activities.

## 11.5 CONCURRENT MONITORING OF VACCINATION ACTIVITIES

Over the years, immunization programme has put in place a robust framework for rigorous monitoring. This framework facilitate reach of over 97% beneficiaries during Polio SIAs or recently conducted MR vaccination campaigns and Mission Indradhanush. Partners such as WHO, UNICEF and UNDP support MoHFW on immunization monitoring. Mechanism has been put in place for real time collation and analysis of data to provide guidance for corrective actions.

The independent external monitors will be from national, state, district level – both Government and nongovernment partners (externally hired field monitors by WHO / UNICEF, UNDP, other developmental partners).

Depending on availability of resources, concurrent monitoring will be prioritized in high risk / hard to reach areas and areas with low performance. Monitor will observe the management and operation practices during the campaign.

Monitoring formats will be designed to capture various aspects such as availability of vaccine and logistics, cold chain management at session, adherence to standard vaccination protocols etc.

Existing routine immunization monitoring platform will be used to collate monitoring data which will have availability of monitoring data up to block level on real time basis. This data will be used during



evening review meetings to guide corrective actions. Such methods were used extensively during Mission Indradhanush campaign successfully. Monitoring feedback will guide corrective actions through on job capacity building and strengthening the programme further.

## 11.6 POST INTRODUCTION EVALUATION

WHO recommends that all countries which have introduced any new vaccine should conduct a Post-Introduction Evaluation (PIE) to evaluate the impact of the vaccination processes. PIE following the introduction of a new vaccine helps with timely identification of problems and can highlight strengths of introducing a new vaccine into the EPI system.

Such a review will be planned within 6–12 months following introduction of the new vaccine by a group of independent national and international public health experts. The objectives will be as follows:

- Identify, evaluate and rectify programmatic and logistical challenges; and
- Document and share lessons learned to improve planning for introduction of additional vaccines in the future.



# ANNEXURE 1: COVID-19 VACCINATION PLANNING TEMPLATE

Name of District: \_\_\_\_\_ Block / Planning Unit: \_\_\_\_\_  
 Name of MO I/C: \_\_\_\_\_ Date of Vaccination: \_\_\_\_\_  
 Name and Designation of Supervisor: \_\_\_\_\_ Mobile Number of Supervisor: \_\_\_\_\_

Team Number	Session Site Location	No. of Beneficiaries	Details of Vaccination of Team Members			AEFI Management Center
			Name	Designation	Mobile Number	
			Vaccinator Officer			
			Vaccination officer-1			
			Vaccination officer-2			
			Vaccination officer-3			
			Vaccination officer-4			
			Vaccinator Officer			
			Vaccination officer-1			
			Vaccination officer-2			
			Vaccination officer-3			
			Vaccination officer-4			
			Vaccinator Officer			
			Vaccination officer-1			
			Vaccination officer-2			
			Vaccination officer-3			
			Vaccination officer-4			



# ANNEXURE 2: LOGISTIC PLANNING TEMPLATE

Name of District: \_\_\_\_\_ Block / Urban Area: \_\_\_\_\_

Planning Unit: \_\_\_\_\_ Cold Chain Point: \_\_\_\_\_

Session Site Details	For Supervisors			Team logistics														AVD Details			Transport for mobile teams for Hard to Reach Areas			
	Micro plan	Supervisory checklist	Reporting formats	Team Micro plan	Beneficiary list	Masks	Hand sanitizers	Soap for hand washing	Vial Openers	Vaccine Carrier with Vaccine	Syringes	Anaphylaxis Kit	Tally sheet	IEC Material	Hub Cutter	Waste bags (red / yellow / black, blue puncture proof container)	AVD Person Name	AVD Person Contact Details	Type of Vehicles needed	Type of Vehicle required	Vehicles Details	Specify type		
<b>Total</b>																								



# ANNEXURE 3: COVID-19 VACCINATION – SESSION SITE SUPERVISION CHECKLIST

Name of Supervisor: \_\_\_\_\_ Designation: \_\_\_\_\_ Contact No: \_\_\_\_\_  
 Name of Block/Urban Area: \_\_\_\_\_ Session Site details: \_\_\_\_\_ Date: \_\_\_\_\_

Booth No.	No:	No:	No:
Time of visit →			
Is the booth easily accessible to the beneficiaries?	Y/N	Y/N	Y/N
Does the booth have IEC materials (like banners or posters) displayed prominently?	Y/N	Y/N	Y/N
No. of beneficiaries present at the booth? a) <5 (b) 6 - 10 (c) 11 - 15 (d) > 15	a / b / c / d	a / b / c / d	a / b / c / d
Is a printed list of beneficiaries available at the entry of the vaccination booth?	Y/N	Y/N	Y/N
Vaccination officer-1 checking the registration status of beneficiaries at entry?	Y/N / NA	Y/N / NA	Y/N / NA
Vaccination officer 2 verifying / authenticating beneficiary details adequately?	Y/N / NA	Y/N / NA	Y/N / NA
Vaccination officer 3 & 4 managing crowd, monitoring 30 min period and supporting vaccinator?	Y/N	Y/N	Y/N
Number of team members found working	0 / 1 / 2 / 3 / 4 / 5 / 6	0 / 1 / 2 / 3 / 4 / 5 / 6	0 / 1 / 2 / 3 / 4 / 5 / 6
Number of team members not same as in micro plan (i.e. replaced team members)	0 / 1 / 2 / 3 / 4 / 5 / 6	0 / 1 / 2 / 3 / 4 / 5 / 6	0 / 1 / 2 / 3 / 4 / 5 / 6
Team members found wearing face mask/ face cover	All / Some / None	All / Some / None	All / Some / None
Hand washing facility with soap and water / alcohol-based hand sanitizer available	Y/N	Y/N	Y/N
Arrangements for drinking water for beneficiaries at session site?	Y/N	Y/N	Y/N
Vaccinator sanitizing / washing hands at regular intervals	Y/N / NA	Y/N / NA	Y/N / NA
Beneficiaries following physical distancing of at least 2 Gaz?	Y/N	Y/N	Y/N
Did the vaccinator attend training on COVID-19 vaccination?	Y/N / NA	Y/N / NA	Y/N / NA
Provision of privacy in vaccination area (separate room/curtain/ screen)	Y/N	Y/N	Y/N
Did the booth receive enough vaccine supply as per listed beneficiary	Y/N	Y/N	Y/N
No. of beneficiaries observed while COVID-19 vaccine was administered	_____ / NA	_____ / NA	_____ / NA
No. of observed beneficiaries vaccinated with correct dose / technique?	_____ / NA	_____ / NA	_____ / NA
Does the number of used vials tally with the number of beneficiaries vaccinated?	Y/N	Y/N	Y/N
Is the va Vaccinator mentioning date and time on each vial before opening the vial for use?	Y/N	Y/N	Y/N
Separate area for observation of beneficiaries after vaccination available?	Y/N	Y/N	Y/N
Any Other observations:	Supervisor's Signature		





# ANNEXURE 4: COVID-19 VACCINATION REPORTING FORMATS

S. No.		Supervisor/ Team No.	Sessions Planned	Sessions Held	Target / Achievement	Dose	Beneficiaries												No. of Vials Issued	No. of Vials utilized	No. of Vials balanced			
							Health Care Providers						Front Line Workers			Elderly Population and comorbidity						Total Beneficiaries		
							Public		Private		Total		M			F						T		
							M	F	T	M	F	T	M	F	T	M	F	T				M	F	T
1	Target	1st																						
		2nd																						
	Achievement	1st																						
		2nd																						
2	Target	1st																						
		2nd																						
	Achievement	1st																						
		2nd																						
3	Target	1st																						
		2nd																						
	Achievement	1st																						
		2nd																						
4	Target	1st																						
		2nd																						
	Achievement	1st																						
		2nd																						
5	Target	1st																						
		2nd																						
	Achievement	1st																						
		2nd																						
Total	Target	1st	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
		2nd	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
	Achievement	1st	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
		2nd	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					





**State Reporting Format: COVID-19 Vaccination Campaign 20\_\_**  
**COVID-19 Vaccination Campaign**

Name of State:		Date:																							
		Beneficiaries										Total Beneficiaries													
		Health Care Providers					Front Line Workers					Elderly Population and comorbidity					Total Beneficiaries								
		Public		Private			Total		M		F			T		M		F			T				
S. No.	Name of District	Sessions Planned	Sessions Held	Target / Achievement	Dose	M		F			T		M		F			T		No. of Vials Issued	No. of Vials utilized	No. of Vials balanced			
						M	F	T	M	F	T	M	F	T	M	F	T								
1				Target	1st																				
				Achievement	2nd																				
2				Target	1st																				
				Achievement	2nd																				
3				Target	1st																				
				Achievement	2nd																				
4				Target	1st																				
				Achievement	2nd																				
5				Target	1st																				
				Achievement	2nd																				
Total				Target	1st	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				Achievement	2nd	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0





## COVID-19 VACCINATION: 2021 PHYSICAL INSPECTION OF COLD CHAIN POINT



# ANNEXURE 5: PHYSICAL INSPECTION OF COLD CHAIN POINT

Name of the Cold chain point:	Setup (encircle): PHC / CHC / DH / UPHC/ Private hospital		
Planning Unit:	Date of assessment: ___ / ___ / ___		
Block/Urban Area: _____	District: _____		
_____	State: _____		
Name of monitor: _____	Designation: _____		
_____	Organization: _____		
Visit session site one day prior to COVID-19 vaccination to assess readiness of the session site in the prescribed format. After assessment, provide specific recommendations to the Block/District team. Monitor to enter data from the checklist in excel sheet and share with DIO / SMO (NPSP).			
S. No	Activities	Status	Actions suggested
1	Micro plan for sessions available at cold chain point	Yes / No	
2	Session wise availability of vaccination planning template for details of team members	Yes / No	
3	Availability of vaccine delivery plan at cold chain point	Yes / No	
4	AVD person identified for vaccine and logistic supply	Yes / No	
5	Transportation available for vaccine and logistic supply	Yes / No	
6	Availability of session wise list of beneficiary in hard copy (set of three for each session)	Yes / No	
S. No	Activities	Status	Actions suggested
7	Is the vaccine stored at correct temperatures	Yes / No	
8	Whether proper method of freezing icepacks is being followed	Yes / No	

9	Mustering (Bundling) of following logistics as per planned sessions	Completed/Ongoing/ Not started
10	Availability of logistics in proportion to sessions planned	
a	Mask for team members per session ( n*5)	Yes / No
b	Hand sanitizer / Soap ( encircle what is available )	Yes / No
c	Vial Openers one per vaccinator	Yes / No
d	Vaccine carriers	Yes / No
e	Hub Cutters one per session	Yes / No
f	AD Syringes according to beneficiaries including wastage	Yes / No
g	Anaphylactic kits with Inj. Adrenaline for each session planned	Yes / No
h	AEFI management drugs availability at facility	Yes / No
i	Availability of android phone/ tab per session	Yes / No
j	Reporting Format	Yes / No
k	Tally Sheet	Yes / No
l	Biomedical Waste bags ( red/ yellow/ black bags and blue color puncture proof container)	Yes / No
m	Is safety available at facility	Yes / No
n	IEC material availability per session	Yes / No

## COVID-19 VACCINATION: 2021 PHYSICAL INSPECTION OF SESSION SITE



# ANNEXURE 6: PHYSICAL INSPECTION OF SESSION SITE

Name of the session site:	Setup (encircle): Government / Private		
Place of Session site (Encircle):	Health facility / Private hospital / School / Municipality premises / Community hall / FLWs office/Other		
Planning Unit:	Date of assessment: ___ / ___ / ___		
Block/Urban Area: _____	District: _____	State: _____	
_____	_____		
Name of monitor: _____	Designation: _____	Organization: _____	
_____	_____		
<p>Visit session site one day prior to COVID-19 vaccination to assess readiness of the session site in the prescribed format. After assessment, provide specific recommendations to the Block/District team. Monitor to enter data from the checklist in excel sheet and share with DIO / SMO (NPSP).</p>			
S. No	Activities	Status	Actions suggested
1	Is booth easily accessible to the beneficiary	Yes / No	
2	Is the in-charge of set up aware of scheduled vaccination for COVID-19	Yes / No	
3	Sanitization of session site prior to vaccination	Completed / Planned / Not planned	If planned: mention time/date,
	If planned, mention date and time		
4	Is the manpower accountable for sanitization identified	Yes / No	
	Availability of space: three designated rooms / demarcated area	Yes / No	
	If No, need of tent	Yes / No	
	If Yes, Order in place for renting and availability of tent	Yes / No	
5	Premises cleanliness	Yes / No	
	Hand washing facility with soap and water / alcohol-based hand sanitizer available	Yes / No	
6	Arrangements for drinking water for beneficiaries at session site?	Yes / No	
7	Internet access availability	Yes / No	

8	Availability of ramp for physically disabled persons Logistics availability at session site:	Yes / No	
9	At least one table for vaccination room	Yes / No	
	Chairs (at least two) in the vaccination room	Yes / No	
	Chairs for beneficiaries in waiting area	Yes / No	
	Provision of privacy in vaccination area (screen/curtain/room)	Yes / No	
<b>S. No</b>	<b>Activities</b>	<b>Status</b>	<b>Actions suggested</b>
10	No of vaccination team members contacted in person / virtually on following points*:	5 / 4 / 3 / 2 / 1 / 0	
	No of team members aware of session site	5 / 4 / 3 / 2 / 1 / 0	
	No of team members aware of session timings	5 / 4 / 3 / 2 / 1 / 0	
	Vaccinator aware of AVD person assigned for vaccine & logistic supply to session site	Yes / No	
	Vaccinator aware of other team members assigned at session site (name / mobile no)	Yes / No	
11	IEC material displayed/arrangement for display at session site	Yes / No	



## COVID-19 VACCINATION: 2021

### READINESS ASSESSMENT FOR COVID-19 VACCINATION - STATE LEVEL

State: \_\_\_\_\_ Total Number of districts: \_\_\_\_\_ Date of assessment: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Name of Monitor: \_\_\_\_\_ Designation: \_\_\_\_\_

**NOTE: Checklist should be completed and shared with STF at least 5 days prior to start of vaccination campaign.**

Activities	Achieved (Y/N)	Actions suggested during the assessment
1	Y / N / Meeting held but not chaired by CS	Date of last SSC meeting
2		Date of last STFI
3	Y / N	
4	Y / N	
5	Y / N	
6	Y / N	
7		
8	— of — monitors	

Planning and Coordination



Activities		Achieved (Y/N)	Actions suggested during the assessment
Trainings	9	Y / N /Planned (mention date) / Yet to be planned	
	10	Y / N /Planned (mention date) / Yet to be planned	
	11	Y / N /Planned (mention date) / Yet to be planned	
	12	Y / N /Planned (mention date) / Yet to be planned	
Co-WIN Update	13	Y / N	
	14		
	15	Y / N	
	16	Y / N	
Logistics	17	Y / N	
	18	Y / N	
	19	Y / N	

Activities		Achieved (Y/N)	Actions suggested during the assessment
AEFI	20	Y / N	Is the State AEFI committee expanded to include neurologists, cardiologists, respiratory medicine specialists/medical specialists?
	21	Y / N	State AEFI committee met at least once prior to COVID-19 vaccination? If Yes, date of last State AEFI Committee meeting:
Communi- cation	22	Y / N	Does the State have key communication and demand generation strategies in place on COVID-19 vaccination?
	23	Y / N / In progress	Any communication material printed by State for COVID-19 vaccination
	24		Number of completed districts assessment checklist available with state?
	25		Number of districts conducted 3-4 DTFs in last 30 days
			Number of districts conducted 1-2 DTFs in last 30 days
			Number of districts with no DTFs conducted in last 30 days
	26		Number of districts completed trainings on CoWIN app
	27		Number of districts completed trainings on Operational guidelines
	28		Number of districts completed sensitization of media
	29		Number of districts completed cold chain handlers training
30		Number of districts with AEFI committee met at least once prior to COVID-19 vaccination	
	31	Number of vaccinators (as per Co-WIN) trained	— out of — Vaccinators
Readiness assessment findings apprised to Additional Chief Secretary/Principal Secretary (Health)		YES / NO	Date Assessment Findings shared
WHO to facilitate readiness assessment feedback to national level			

**COVID-19 VACCINATION: 2021**  
**READINESS ASSESSMENT FOR COVID-19 VACCINATION - DISTRICT LEVEL**

State: \_\_\_\_\_ Districts: \_\_\_\_\_ No. of Blocks: \_\_\_\_\_ Date of assessment: \_\_\_\_/\_\_\_\_/\_\_\_\_

Name of monitor: \_\_\_\_\_ Designation: \_\_\_\_\_ Organization: \_\_\_\_\_

**NOTE: Checklist should be completed and shared with DTF at least 6 days prior to start of vaccination campaign. A copy of completed checklist to be shared with state.**

Activities	Achieved (Y/N)	Actions suggested during the assessment
1		Date of last DTFI
2	Y / N	
3	Y / N	
4	Y / N	
5	Y / N	
6		
7		
8	— out of — monitors	

Planning and Coordination

Activities		Achieved (Y/N)	Actions suggested during the assessment
9	District team estimated number of sessions required to vaccinate all HCW in district ?	Y / N	If Yes, mention numbers:
	Has the district team estimated the human resources needed to conduct the vaccination in the session sites and the required number of days	Y / N	"Vaccinators required (numbers): Vacc Officer-1 (Security person) required (numbers): Vacc Officer-2 (Verifiers) required (numbers): Vacc Officer 3 & 4 (Mobilisers) required (numbers):"
	District identified sufficient vaccinators for vaccination?	Y / N	
	District identified sufficient team members (VO 1-4) required	Y / N	
10	District Workshop for COVID-19 vaccine introduction conducted	Y / N	
	Orientation of Vaccinators (as per Co-WIN) conducted	Y / N / Partial	If Yes, No of participants expected v/s attended
	% of Vaccinators oriented		
	Orientation of other team members (vaccination officer 1-4) conducted	Y / N / Partial	If Yes, No of participants expected v/s attended
11	% of team members (vaccination officer 1-4) oriented		
	Orientation of cold chain handlers conducted	Y / N / Partial	If Yes, No of participants expected v/s attended
	% of Cold Chain handlers oriented		
	Orientation for members of Professional bodies (like IMA, IAPSM, Med College)	Y / N / Partial	If Yes, No of participants expected v/s attended
12	District Media Workshop conducted	Y / N ? Planned	
	HCWs database upload completed	Y / N / Partial	If partial, mention the name of the blocks pending for uploading database
	FLWs database upload reflected	Y / N / Partial	
	Session allocation through Co-WIN started	Y / N	
13	Status of vaccine allocation for session using Co-WIN	started/ planned	
	DTF reviewed microplans with details of team members by blocks (COVID-19 Vaccination Planning Template)?	Y / N	



Activities		Achieved (Y/N)	Actions suggested during the assessment
Logistics	25	Y / N	District has sufficient cold chain space to store COVID-19 vaccine?
	26	Y / N / Partial	"District arranged all required logistics for vaccination (mention if incomplete): Hand sanitizer and masks, Vaccine vial opener, Hub cutter, AEFI/Anaphylaxis kit, Red and yellow bags, blue puncture proof container, bag for municipal waste"
AEFI Surveillance	27	Y / N	Is the district AEFI committee expanded to include neurologists, cardiologists, respiratory medicine specialists/medical specialists?
	28	Y / N	Has the district AEFI committee met at least once?
AEFI Surveillance	29		Number of AEFI management centers identified
	30	Y / N	Whether AEFI management logistics including Inj adrenaline available / procured
Communication	31	Y / N	District has key communication and demand generation strategies in place on COVID-19 vaccination?
	32		Mention communication challenges identified by district:
Block Progress Assessment	33	Y / N / Expected	Communication / IEC material for display at COVID-19 vaccination session site distributed to blocks? (Mention details)
	34		Number of completed block assessment checklist available with district?
	35		Number of block conducted 3-4 BTFs in last 30 days
			Number of block conducted 1-2 BTFs in last 30 days
			Number of blocks with no BTF conducted in last 30 days
			Number of blocks completed trainings on CoWIN app
37		Number of blocks completed trainings on Operational Guidelines	
38		Number of blocks procured AEFI kit for all session site	
Readiness assessment findings appraised to District Magistrate / District Collector		YES / NO	Date Assessment Findings shared
Preparedness assessment findings shared with state		YES / NO	Date Assessment Findings shared

**COVID-19 VACCINATION: 2021**  
**READINESS ASSESSMENT FOR COVID-19 VACCINATION - BLOCK LEVEL**

State: \_\_\_\_\_ Districts: \_\_\_\_\_ No. of Blocks: \_\_\_\_\_ Date of assessment: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Name of monitor: \_\_\_\_\_ Designation: \_\_\_\_\_ Organization: \_\_\_\_\_

**NOTE: Checklist should be completed and shared with BTF at least 7 days prior to start of vaccination campaign. A copy of checklist to be shared with district.**

Activities	Achieved (Y/N)	Actions suggested during the assessment		
Planning and Coordination	1	Number of Block Task Force (BTF) meeting conducted during last 30 days (should be conducted weekly basis)?	Y / N	Date of Last BTF held
	2	Last BTF chaired by SDM / Tehseeldar / BDO ?	Y / N	
	3	All stakeholders participated in last BTF meeting (Mention who did not participated): SDM/Tehsildar/BDO/BMO/CDPO/ Medical Officer/Data manager/Block Education Officer/ Representative of local bodies/Representatives of NYK,NSS, representative from any other relevant department like Panchayati Raj, Education, PWD, Animal Husbandary, NGOs working at health sector, Development partners, CSO and local influencers	Y / N	
	4	Minutes of last BTF shared with participants and relevant stakeholders?	Y / N	
	5	"BTF identified multi-disciplinary team to check the planned/identified session sites for adequacy of space and other arrangements?	Y / N	
	6	"BTF identified adequate monitors to undertake session site readiness a day prior to vaccination?	Y / N	
Co-WIN	12	Has block shared the details on vaccinators & identified session sites with district?	Y / N / Partial	
	13	Block aware of number and details of sessions allocated by district?	Y / N / Partial	
	14	Block completed microplans with details of team members/ supervisors using COVID-19 Vaccination Planning Template?	Y / N / Partial	
Trainings	15	Microplan (COVID-19 Vaccination Planning Template) shared with district?	Y / N / Partial	
	16	Block Workshop for COVID-19 vaccine introduction been completed	Y / N	
	17	Orientation of Vaccinators (as per Co-WIN) completed	Y / N / Partial	If Yes, No of participants expected v/s attended
	18	% of Vaccinators oriented		
	19	% of Supervisors oriented		
	20	% of Team members oriented		

Activities	Achieved (Y/N)	Actions suggested during the assessment
Session Site Preparations	21	Number of planned session sites reviewed by BTF/Multidisciplinary team for adequate space/ logistics
	22	Number of session sites with adequate space available for 3 designated areas
	23	Number of sessions with adequate seating space available / arranged
	24	Number of sessions with adequate table chair for vaccinator available/arranged
	25	Number of sessions with hand wash facilities available / arranged
	26	Number of sessions with internet facilities available / arranged
	27	Number of sessions for which three printed copies of beneficiary list will be provided
Vaccine / Logistics	28	Whether the block has sufficient cold chain space to store COVID-19 vaccine? Y / N
	29	"Block has all required logistics for vaccination (mention if incomplete): Hand sanitizer and masks, Vaccine vial opener, Hub cutter, kit, Red and yellow bags, blue puncture proof container, bag for municipal waste" Y / N
	30	Session site vaccine / logistics distribution plan available (as per template) Y / N
AEFI	31	AVD person/ vehicle identified Y / N
	32	Vaccinators oriented on AEFI management Y / N
	33	Anaphylaxis kit with adrenaline and syringe available for all sessions? Y / N
	34	AEFI management centers identified Check the list
	35	AEFI management centers equipped with AEFI kits
	36	No of ambulances / vehicle identified for AEFI referrals
Communication	37	Does the block have key communication and demand generation strategies in place on COVID-19 vaccination Y / N
	38	Mention communication challenges identified by block
	39	Communication / IEC material for display at COVID-19 vaccination session site available at blocks? (Mention details) Y / N/ Expected
Readiness assessment findings discussed with SDM / Tahseeldar/ BDO		YES / NO Date Assessment Findings shared
Readiness assessment findings shared with District		YES / NO Date Assessment Findings shared

**COVID-19 VACCINATION: 2021**  
**READINESS ASSESSMENT FOR COVID-19 VACCINATION - URBAN CORPORATION**

State: \_\_\_\_\_ Districts: \_\_\_\_\_ No. of Blocks: \_\_\_\_\_ Date of assessment: \_\_\_\_/\_\_\_\_/\_\_\_\_

Name of monitor: \_\_\_\_\_ Designation: \_\_\_\_\_ Organization: \_\_\_\_\_

**NOTE: Checklist should be completed and shared with UTF at least 7 days prior to start of vaccination campaign, a copy of checklist to be shared with district**

Activities	Achieved (Y/N)	Actions suggested during the assessment
1	Y / N	Date of Last BTF held
2	Y / N	
3	Y / N	
4	Y / N	
5	Y / N	
6	Y / N	
7	Y / N	
8	Y / N	
9	Y / N	
10	Y / N	

Identification of resources

Activities		Achieved (Y/N)	Actions suggested during the assessment
Co-WIN	11	Y / N / Partial	Has urban area shared the details on vaccinators & identified session sites with district?
	12	Y / N / Partial	Urban facility aware of number and details of session allocated by district?
	13	Y / N / Partial	Urban facility completed micro plans with details of team members/ supervisors using COVID-19 Vaccination Planning Template?
Trainings	14	Y / N / Partial	Micro plan (COVID-19 Vaccination Planning Template) shared with district?
	15	Y / N	Urban Workshop for COVID-19 vaccine introduction completed
	16	Y / N / Partial	Orientation of Vaccinators (as per Co-WIN) completed
Session Site Preparations	17		% of Vaccinators oriented
	18		% of Supervisors oriented
	19		% of Team members oriented
	20		Number of planned sessions reviewed by UTF for adequate space/ logistics
	21		Number of sessions with adequate space available for 3 designated areas
	22		Number of sessions with adequate seating space available / arranged
	23		Number of sessions with adequate table chair for vaccinator available/arranged
24		Number of sessions with hand wash facilities available / arranged	
25		Number of sessions with internet facilities available / arranged	
26		Number of sessions for which three printed copies of beneficiary list will be provided	
Vaccine / Logistics	27	Y / N	Urban has sufficient cold chain space to store COVID-19 vaccine?
	28	Y / N	"Urban has all required logistics for vaccination (mention if incomplete): Hand sanitizer and masks, Vaccine vial opener, Hub cutter, kit, Red and yellow bags, blue puncture proof container, bag for municipal waste"
	29	Y / N	Session site vaccine / logistics distribution plan available (as per template)
	30	Y / N	AVD person/ vehicle identified
			If Yes, No of participants expected v/s attended
			Details of logistics arrangement incomplete



Activities		Achieved (Y/N)	Actions suggested during the assessment
AEFI	31	Y / N	
	32	Y / N	
	33		Check the list
	34		
	35		
Communication	36	Y / N	
	37		
	38	Y / N/ Expected	If expected , mention date
Readiness assessment findings discussed with Municipal Commissioner?		YES / NO	Date Assessment Findings shared
Readiness assessment findings shared with District		YES / NO	Date Assessment Findings shared



# ANNEXURE 8: STANDARD OPERATING PROCEDURE TO CONDUCT DRY RUN

## BACKGROUND

The Universal Immunization Programme (UIP) has experience of conducting nationwide multiple wide-age range injectable vaccination campaigns such as measles-rubella (MR) and adult Japanese Encephalitis (JE) campaign (carried out in 35 endemic districts). However, for the first time programme will vaccinate pre-identified beneficiaries from specified groups supported by Co-WIN, an electronic application. The dry run will exercise end to end testing of COVID-19 vaccination process and will include:

- Planning & preparations including prerequisites for the vaccine introduction as per the Operational Guidelines
- Creation of Facilities & Users on CoWIN application
- Session site creation, & mapping of sites
- HCW beneficiary data upload on Co-WIN
- Receipt of Vaccines by the District and vaccine allocation using Co-WIN
- Session planning, vaccinator deployment
- Deployment of team members
- Vaccine and logistics mobilization at session site
- Mock drill of beneficiary vaccination and reporting
- Review meetings at block, districts and state and provide feedback to guide actions

## OBJECTIVE

**Primary objective of dry run includes:**

- To assess operational feasibility of using Co-WIN application in field environment;
- To test linkages between planning, implementation and reporting mechanisms;
- To identify challenges and guide way forward prior to actual implementation; and
- To provide confidence to programme managers at various levels

## SCOPE OF DRY RUN EXERCISE

To begin with dry run is proposed to be conducted in 4 states, namely Andhra Pradesh, Assam, Gujarat, Punjab. Each state will identify one or two districts for this activity, and the district will, in turn, plan it in one district hospital/medical college and one block. The dry run is to be planned at 5 types of session sites, preferably one each at:

- District hospital / Medical College
- CHC / PHC
- Private health facility
- Urban outreach
- Rural outreach

The **test link of Co-WIN** ([www.uat.co-vin.in](http://www.uat.co-vin.in)) has been made ready for the dry run. For the activity, user ids are to be created by state administrators a day prior to the dry run. The district administrators will create the same for the vaccination teams. For each of the five session sites, the concerned medical officer in-charge will identify 25 test beneficiaries (healthcare workers) at each session site for the dry run. The data of these identified test beneficiaries is to be uploaded on the Co-WIN test link by the district administrator. These test beneficiaries will also be at the session sites for session site simulation. In order to avoid any confusion due to SMS generated during the dry run, it is advised that phone number of only the concerned medical officer in-charge is used against the mobile numbers of beneficiaries in his/her team. Also, the test beneficiaries & the selected sites' in-charge are to be clearly instructed that this is a dry run and any SMS generated or received is for the purpose of dry run only. The Call Centre/Helpline (104/1075) could also be tested by making one or two calls to the Call Centre for queries redressal.

Dry run will be a two-day exercise at district followed by review at State Task Force on Immunization:

- Day 1: Planning of session and deployment of logistics team and members
- Day 2: Implementation of vaccination plan

## PREREQUISITE FOR DISTRICTS TO CONDUCT DRY RUN

- Complete the trainings on Operational Guidelines & Co-WIN for the team dealing with the dry run.

## TIMING OF DRY RUN

To be conducted for two days between 28th and 29th December 2020

## RESPONSIBILITY TO UNDERTAKE DRY RUN

- District Collector, with engagement of Block Task Force of blocks where sessions are being planned during this exercise, will be responsible to undertake the dry run. WHO along with UNDP and UNICEF will support this exercise.
- After state administrator creates user id for districts, the district administrator of Co-WIN will be responsible to upload the beneficiary data on test link and also create user ids for the teams.
- State Task Force will review the feedback to guide further actions. State to provide feedback to MoHFW.

## Activities to be undertaken during dry run

<b>Conducting Dry Run for COVID-19 Vaccination</b>			
On test link of Co-WIN ( <a href="http://www.uat.co-vin.in">www.uat.co-vin.in</a> ) and ( <a href="http://www.app.uat.co-vin.in">www.app.uat.co-vin.in</a> ) for Vaccinator			
Day	Time	Activity	Responsibility
DAY - 0		State Administrator to create user id for district	State Administrator of Co-WIN
		District Administrator to create facilities & user id for teams	District Administrator of Co-WIN
		Test beneficiaries to be kept identified by the District	DIO & concerned MO I/C
DAY - 1	9:00 AM	Session site creation, mapping of sites	District Administrator of Co-WIN
	9:00 AM	Beneficiary data upload on Co-WIN test portal	District Administrator of Co-WIN
	10:00 AM	Session site allocation (beneficiary / vaccinator)	District Administrator of Co-WIN
	11:00 AM	Allocate vaccine and inform Cold Chain Point (CCP)	District Administrator of Co-WIN
	11:00 AM	Inform Vaccinator(s) about session site date / timing	District Administrator of Co-WIN
	11:00 AM	Allocate responsibilities to Vaccination Officer 1-4 and Supervisor	BTF / MO I/C, DTF
	12:00 PM	Inform Vaccination Officers 1-4 and Supervisor	BTF / MO I/C, DTF
	1:00 PM	AVD planning completes at CCP	MO I/C, DTF
	2:00 PM	Mustering (bundling) of vaccine logistics at CCP	CCH, MO I/C
	2:00 PM	Arrange beneficiary mobilization (25 HCWs) for session site	BTF & DTF
	4:00 PM	Session site logistics arrangements	BTF / Supervisor
	5:00 PM	Evening review meeting at Block	BTF
6:00 PM	Evening review meeting at District	DTF	

### Conducting Dry Run for COVID-19 Vaccination

On test link of Co-WIN ([www.uat.co-vin.in](http://www.uat.co-vin.in)) and ([www.app.uat.co-vin.in](http://www.app.uat.co-vin.in)) for Vaccinator

Day	Time	Activity	Responsibility
DAY - 2		Vaccine / logistics distribution starts from CCP	CCH
	8:15 AM	Team members / Supervisors reaches session site	Team Members / Supervisor
	8:15 AM	AVD deliver vaccine / logistics to session site	AVD
	9:00 AM	Session site prepared to receive beneficiaries	Team Members / Supervisor
	9:00 AM	Session starts	Team Members / Supervisor
		Assess session flow with dummy beneficiaries (HCW): 25 HCWs visit session site in 2 hour time slot VO-1: Matches beneficiary names from list and allows entry VO-2: Verifies beneficiary using Co-WIN application Vaccinator officer follows SoP of vaccination (without vaccinating) Vaccinator officer inform VO-2 about vaccination VO-2 report vaccination in the Co-WIN app VO-3 & 4: Manage crowd, IPC messaging, support Vaccinator, 30 min wait following vaccination VO-2 report 2-3 AEFIs in Co-WIN application at session site	Team Members
	10:00 AM	Visit by monitor - concurrent monitoring	Partners
	1:00 PM	Review meeting at Block	BTF
	2:00 PM	Review meeting at District	DTF
	5:00 PM	Prepare Feedback to be shared with State	DTF
STFI - Feedback sharing to guide roll out actions			
Feedback shared with MoHFW			





