

**IN THE SUPREME COURT OF INDIA**

**CIVIL ORIGINAL JURISDICTION**

**SUO MOTU WRIT PETITION (CIVIL) NO.3 OF 2021**

**IN RE: DISTRIBUTION OF ESSENTIAL SUPPLIES AND  
SERVICES DURING PANDEMIC**

**FURTHER AFFIDAVIT DATED 26.06.2021**

**ON BEHALF OF THE UNION OF INDIA**

PAPER-BOOK

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**ADVOCATE FOR THE UNION OF INDIA: BV BALARAM DAS**

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**IN THE SUPREME COURT OF INDIA**

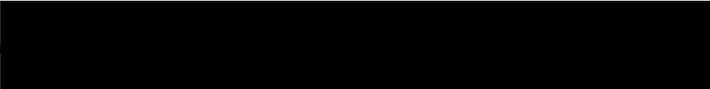
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**ON BEHALF OF THE UNION OF INDIA**

I, Dr. Manohar Agnani, s   
working as Additional Secretary in the Ministry of Health & Family Welfare, Government of India, the deponent herein, do hereby solemnly affirm and state on oath as under:-

1. I am filing this Affidavit to place further developments on record and also in respectful compliance of the order dated 31.5.2021 passed by this Hon'ble Court and also to place on record factual developments on record.

2. As pointed out hereinafter in this Affidavit, the vaccination programme is an evolving programme seeking to meet with situations as they arise. In view of the fact that the vaccination policy has been reviewed by the Central Government [as explained hereunder], some of the issues flagged in the order dated 31.5.2021 may not engage any further attention of this Hon'ble Court. The Central Government, therefore, seeks to place the following facts on the question of vaccination and the also on the question of use of *Co-WIN* platform and other issues.

## VACCINATION PROGRAMME – DEVELOPMENTS SO FAR

### *Evolution Of National Covid-19 Vaccination Program*

3. It is submitted that the National COVID-19 Vaccination Program is the largest vaccination program of its kind in the world and is under a constant and systematic review to take into account emerging scientific evidence, vaccine availability, experience on the ground and global best practices.

I respectfully submit that by its very nature such a humungous task of vaccinating the second largest country in the world poses several challenges. Such vaccination program has several peculiar features as compared to earlier vaccination programs, for example-

- (i) the pandemic and its related issues are faced not only by just one country but by the whole world;
- (ii) the nature of the virus was and continues to be novel;
- (iii) the period in which pro-active steps were taken deciding to go for vaccination, the vaccines were under process of being developed world over.
- (iv) considering the aforesaid factors, the availability of vaccines, once it was developed and the manufacturing activities started, was expected to be limited;
- (v) the vaccination drive was / is to be contemplated simultaneously to deal with the pandemic itself, requiring rational utilization of health care workers and other resources, so that one activity does not hamper another activity both of which are equally crucial.

(vi) Unlike earlier vaccination drives, which did not have any time limit constraints, this time maximum reach in shortest time is the goal.

4. In the aforesaid context, it was absolutely necessary to formulate a policy document based upon which further vaccination process can commence and continue while leaving sufficient room for required changes in course of time depending upon the emerging situations.

It is submitted that the first such document is dated 26.12.2020 which provided for a *broad vision* of the Central Government for vaccines subsequent to which, the detailed policy document came to be prepared and published on 28.12.2020 under the title “***Covid-19 Vaccine Operational Guidelines***”. A copy of the first broad policy document is a part of the aforesaid “Covid-19 Vaccine Operational Guidelines” dated 28.12.2020 as Annexue-9.

A copy of the policy document titled as “Covid-19 Vaccine Operational Guidelines”, is attached herewith and marked as **ANNEXURE R - 1**. It is submitted that this document has been uploaded on the website of the Central Government from the date it is made.

5. It is submitted that by the very nature of the ever-changing challenges being faced by the country, some of which are reflected hereinunder, the said document has always been treated as a non-static document capable of suitable modifications as the vaccination programme proceeds and is under implementation.

It is submitted that as per the aforesaid policy document itself, it is not intended to be static, the decisions are taken after elaborate consultations with experts and stakeholders and keeping in mind the

larger intent of maximising the speed, reach and width of vaccination as the criteria.

The issues are first discussed in the meeting of ‘National Expert Group on Vaccine Administration of Covid-19’ [hereinafter referred to as “NEGVAC], [the composition of which is mentioned in the Annexure-9 to the document annexed as Annexure R-1].

6. It is submitted that in each of the NEGVAC meetings, various relevant issues are discussed comprehensively and such discussions are duly minuted. The decisions taken and recommendations made by NEGVAC are thereafter discussed in the Central Government’s meetings in the Union Ministry of Health & Cabinet Secretariate etc., which are also subsequently discussed, debated and considered in meetings chaired by the highest competent authority of the Central Government being the political executive, as per requirements.

7. It is submitted that the vaccination program has concluded three phases as detailed hereunder:

PHASE	DATE	KEY FEATURES
<b>Phase 1</b>	16.01.2021 to 28.02.2021	<ul style="list-style-type: none"> <li>• Vaccination permitted for HCWs and FLWs</li> <li>• Procurement: 100% of vaccine doses procured by GoI and provided free of cost to State/UT Governments for being administered.</li> </ul>

<b>Phase 2a</b>	01.03.2021 to 31.03.2021	<ul style="list-style-type: none"> <li>• Vaccination permitted for persons above the age of 60 years and those above 45 years with defined co-morbidities.</li> <li>• Procurement: same as Phase 1</li> </ul>
<b>Phase 2b</b>	01.04.2021 to 30.04.2021	<ul style="list-style-type: none"> <li>• Vaccination permitted for all persons above the age of 45 years.</li> <li>• Procurement: same as Phase 1</li> </ul>
<b>Phase 3 (Liberalized Pricing and Accelerated National COVID Vaccination Strategy)</b>	01.05.2021 to 20.06.2021	<ul style="list-style-type: none"> <li>• Vaccination permitted for persons aged 18-44 years in addition to priority groups (HCWs, FLWs, persons above the age of 45 years)</li> <li>• Procurement: <ul style="list-style-type: none"> <li>○ 50% vaccine doses to be procured by GoI for being administered by States/UTs to priority groups.</li> <li>○ 50% vaccine doses to be procured by State Govts and Private Hospitals to be administered to persons between 18 to 44 years of age.</li> </ul> </li> </ul>

8. As shown above, under the National COVID Vaccination Program, from 16.01.2021 to 30.04.2021, 100% of vaccine doses were procured by Government of India and provided free of cost to the State/UT Governments, who in turn, would administer vaccination free of cost through Government CVCs to the defined priority groups. To increase the pace of vaccination, private hospitals were also enlisted as CVCs, where individuals could also choose to get vaccinated by paying Rs 150/- as cost of vaccine and paying service charges up to a maximum of Rs 100/-.

9. At this juncture, it may be relevant to note that in any public health program – be it vaccination or otherwise, involvement of private hospitals is always found desirable. It is respectfully submitted that as per the statistics available, approximately, 55 per cent of the population of the country seeks and gets medical care / health services from private hospitals and 45 per cent gets health care services from government hospitals.

The Central Government also kept in mind, while considering this broad classification of the health care facilities in two compartments namely – ‘out-patient care’ and ‘indoor-patient care’. The said figures also suggested that more percentage of population takes advantage of private hospitals in case of ‘out-patient care’ [which is the relevant factor for vaccination as it does not require hospitalization] and less on ‘indoor-patient care’. The said figures are as under:-

In case of ailments care (both out patient & in patient), about 33% ailments in rural areas and 26% ailments in urban areas were treated in Government hospitals / clinics, while in Private hospitals/ Private doctors/ clinics, 62% ailments in rural areas and 71% ailments in urban areas were treated and remaining 5.2% ailments in rural areas and 2.2%

ailments in urban areas were treated in Informal health care provider and Charitable/trust/NGO-run hospitals.

10. It is submitted that this was the reason of involving private hospitals in the process from the beginning of the vaccination programme so as to give wider reach to vaccination and lessen the stress on government facilities considering the very magnitude of the task ahead viz. vaccinating second largest country in the world.

11. It is submitted that during the aforesaid period of Phase I and Phase II of vaccination drive, the Central Government was actively discussing and supervising its implementation with the State Governments. Such meetings between the Centre and State Governments would take place not just at bureaucratic level but also at the level of the political executives both at the Centre and in the States.

12. During this period and during such meetings, several State Governments, mostly through their Hon'ble Chief Ministers, repeatedly suggested and requested for flexibility / autonomy to the State Governments in procurement of vaccine. The requests were received both in writing and also during video conference attended to by the Hon'ble Chief Ministers of the States. As the same is not relevant for the purpose at this stage, I am not annexing those written requests received from the State Governments. The State Governments were seeking variation in this drive broadly on the following counts-

- (i) the State Governments wanted autonomy on the ground that health is a state subject under the Constitution of India;
- (ii) many State Governments were desirous of expanding vaccination to the groups beyond the priority groups identified by the Central

Government and wanted to simultaneously vaccinate persons of 18 to 44 years of age group;

- (iii) the State Governments were insisting for being permitted to procure vaccines doses directly from manufacturers and administer such doses as per their respective prioritization based on local situations.

13. It is submitted that simultaneously, the Central Government was receiving views from the experts about capping charges of private hospitals. Various experts expressed concerns through articles, interviews and other mediums; expressing to continue involving private hospitals in the drive while permitting the manufacturers to decide their charges to be supplied to private hospitals at arm's length basis and based on mutual agreement. The opinion expressed by experts was based upon the rationale and logic that manufacturers would not have any incentive to augment their manufacturing potential and manufacture more vaccine doses, unless they have an incentive of selling some defined portion of their manufactured vaccines at the rates decided by them, so that they can sell vaccines to the Central Government after cross subsidization.

14. It is submitted that the factual position is that there are handful of vaccine manufacturers in the world. It is submitted that so far, there are only two vaccine manufacturers producing vaccines under EUA in the country. It also cannot be disputed that unless the vaccine manufacturers have an incentive or financial ability, they may either not have the capacity to augment their potential or may not sense the viability to do so. The executive policy decisions are taken, under such circumstances, keeping the unprecedented circumstances being dealt with by the world in general and by India in particular, in mind. Any static or delayed decision without factoring the pulse of the ground realities and changes taking

place, would defeat the very object and purpose and may prove to be counter-productive.

15. In response to these suggestions, with effect from 01.05.2021, Government of India revised the Guidelines under the 'Liberalized Pricing and Accelerated National Covid Vaccination Strategy' in such unprecedented circumstances.

Under this strategy, the manufacturers would supply 50% of their monthly Central Drug Laboratory released Vaccine doses to Government of India and these doses were provided to States/UTs free of cost for administration to priority groups viz. Health Care Workers (HCWs), Front Line Workers (FLWs) and persons above 45 years of age.

The State Government and private hospitals were also empowered to directly procure the remaining 50% monthly Central Drugs Laboratory released vaccine doses from Vaccine manufacturers in the ratio of 25% : 25%. Copy of the Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy dated 21.4.2021 [which came into effect from 1.5.2021] is annexed herewith and marked as **ANNEXURE R - 2**.

16. It is submitted that this decision was also taken deliberations in after the meetings of NEGVAC which are duly minuted, subsequent meetings at bureaucratic level as well as political executive level and thereafter formalised on file based upon which the aforesaid new Strategy is issued by the Ministry of Health and Family Welfare.

17. It is pertinent to note that even under this strategy, as advised by experts and as considered advisable by the Central Government, the priority groups identified by Government of India continued to remain the primary target for vaccination, inasmuch as 50% of vaccine doses

would be procured by the Government of India and distributed to States/UTs for free to vaccinate this priority group.

It is only with a view to accommodate the requests of State Governments, so that they continue to be completely focussed and committed as equal stakeholders to the mission of National Vaccination and considering the expert opinions as stated above, that an option was made available to States/UTs to expand their vaccination drives beyond the priority groups [identified by Government of India] and directly procure vaccine doses from manufacturers, should they consider the same to be necessary in light of the local needs of their State/UTs. It was considered prudent for ensuring overall success of the National Vaccination Policy, in the face of constraints of vaccine awareness and hesitancy, that strategy has to factor in requests of the States.

18. While varying the policy w.e.f. 1.5.2021, the Central Government, however, ensured [as stated in the earlier Affidavit] that –

- (i) One State does not / cannot compete with other State based upon difference in their respective financial / bargaining strength; and
- (ii) The quantity of vaccine receivable by each State also remained the same applying the principles of pro-rata population of 18 to 44 age group.

This was to ensure that one State may not buy vaccines at a higher price at the cost of another State, all States pay the same price to the manufacturer and also to ensure that the quantity of vaccine to each State is distributed equitably.

***Review Of National Vaccination Policy***

19. It is submitted that the Liberalized Pricing and Accelerated National Covid Vaccination Strategy referred above was reviewed after receiving feedback from various stakeholders including State/ UT Governments, private hospitals and vaccine manufacturers. It is submitted that the States/ UTs communicated various difficulties being faced in managing the funding, procurement and logistics of vaccines which was clearly impacting the pace of the National COVID Vaccination Program. It was also noted that smaller private hospitals, especially in remote towns and cities were facing issues in securing and ensuring timely vaccine supply.

20. Keeping in view the aforesaid aspects, the experience gained from 01.05.2021 and the requests received from the State Governments to review the Strategy, the Guidelines for National COVID Vaccination Program have been reviewed. The revised guidelines were announced by the Hon'ble Prime Minister on 07.06.2021 and has come into effect from 21.06.2021. The said decision to review the Strategy was taken after receipt of letters from 13 Hon'ble Chief Ministers as well as Health Ministers of various States and after debating and deliberating the pros and cons of such decision. The said letters were received from 15.5.2021 to 2.6.2021. In other words, such requests were received after implementation of the new revised Strategy from 1.5.2021 [which was revised as per the request of the State Governments as stated above]. The Government of India, therefore, decided to review the Strategy to factor in the problems highlighted by the State Governments and keeping in mind the main objective of maximising vaccination in the minimum possible time under the most extraordinary and unprecedented circumstances

which is being faced by the humanity in general and by India in particular.

21. It is submitted that immediately on receipt of these representations from the State Government and experience on the ground as per the daily supervision by the Central Government, it started reviewing the Strategy so that the problems faced by the State Governments may not hamper the vaccination drive and citizens also do not suffer in any manner.

As a part of the said process of review, two meetings were conducted at the level of highest political executive of the country on 15.5.2021 and 21.5.2021. It is submitted that similarly, these issues were also flagged, discussed and debated in the meeting of NEGVAC

After the Strategy which came into effect on 1.5.2021, was reviewed, the decisions were taken after deliberations in the meetings of NEGVAC and the Central Government, and the new revised Guidelines were prepared on 8.6.2021. The citizens were made aware about the same on 7.6.2021. A copy of the Revised Guidelines for Implementation of National COVID Vaccination Program dated 08.06.2021 are attached herewith and marked as **ANNEXURE R - 3**.

22. The main elements of the Revised Guidelines which are effective from 21.6.2021 are as follows –

- Government of India will procure 75% of the vaccine doses being produced by the manufacturers in the country. The vaccines so procured will to be provided free of cost to States/UTs.
- These doses will be administered by the States/UTs free of cost to all citizens above 18 years of age as per priority through Government Vaccination Centres.

- In respect of the vaccine doses provided free of cost by Government of India to the States/UTs, vaccination will be broadly prioritized by the State Governments / UTs as the following:
  1. Health Care Workers
  2. Front Line Workers
  3. Citizens more than 45 years of age
  4. Citizens whose second dose has become due
  5. Citizens 18 years & above
- Within the population group of citizens more than 18 years of age, States/UTs may decide their own prioritization factoring in the vaccine coverage in the State/UT, vaccine supply schedule and other local State specific factors.
- It is submitted that the methodology of computing the quantity to be allocated to States / UTs is also reviewed. The Government of India would continue to allocate vaccine doses to the States / UTs based on pro-rata population of 18 years and above age group. However, apart from pro-rata allocation, two more factors will also be taken into consideration while making the allotment i.e. –
  - (i) the disease burden i.e. the number of active cases in each State/UT; and
  - (ii) progress of vaccination in each State/UT.

23. It may be pointed out at this juncture that there is a robust and transparent administrative mechanism put in place since commencement

of the vaccination drive under which the Central Government receives, on daily basis, the figures of number of active cases in each State/UT, the number of vaccine doses administered group-wise, State-wise etc.

This is formulated into a chart by the Government of India on daily basis which is put on Government's website daily so that other States / UTs and everyone can find out daily position under each of the heads as well as the position of other States. Every citizen can also see these figures collected on daily basis. I beg to annex herewith a copy of the two charts namely –

- (a) a chart showing daily statistics of active cases from each State/UT; and
- (b) daily position of the progress of vaccination in each State/UT.

A copy of such specimen charts for dated 25<sup>th</sup> June 2021 are annexed herewith and are marked as **ANNEXURE R - 4** and **ANNEXURE R - 5**.

These are only representative charts of a particular date. It is submitted that such charts are put on the website daily.

24. It is reiterated that the Central Government not only receive these figures from the State Governments on daily basis, the position of each day in the format of the said chart is displayed on the website of the Ministry of health and Family Welfare as a “homepage” to ensure transparency and with a view to see that anyone in the country can know about the daily position. The following factors may be noted :

- The Government of India has also decided that it will provide States/UTs one month in advance the information of vaccine doses to be supplied to them. States/UTs should similarly

further allocate doses well in advance to districts and vaccination centers.

Each State is also directed to put in the public domain the information about the vaccine availability at district and vaccination center levels, and widely disseminate it amongst the local population, so as to maximize the visibility of vaccine availability and the convenience of citizens.

- The new revised policy which came into effect from 21.6.2021 permits domestic manufacturers to provide vaccines to the private hospitals only to the ceiling and upto of 25 per cent of their monthly production.
- The rationale and the object behind this policy decision is the same as it was earlier i.e. permitting private supply of vaccines by the manufacturers to private hospitals so as to widen the reach, reduce stress on public facilities, reducing crowding in public utilities and incentivising manufacturers to augment their production capacity and thereby cross subsidize the price at which they are supplying 75 per cent of their manufactured vaccines to the Central Government.
- With a view to ensure that one private hospital cannot get more doses merely by offering higher prices, the vaccine manufactures are mandated to declare the price of their vaccines [for supply to private hospitals] in advance and any subsequent change shall also be required to be notified which shall be the same for the whole country.

Most importantly, with a view to ensure that there is no exploitation by private hospitals, the Central Government has

mandated that no private hospital can charge more than Rs.150/- per dose from the individuals choosing to get vaccinated in a private facility over and above the price paid by private hospitals to the manufacturers which will always be in public domain.

Thus, there will be a uniform price throughout the country for sale of vaccine to private hospitals and no private hospital will be able to charge more than Rs.150/- as service charges per person / dose.

- During the course of implementing the vaccine drive so far it was found that initially large number of private hospitals were involved in the process of vaccination. The Central Government received these statistics on a real-time basis. Over a period of time, it is found that the number of private hospitals which are procuring vaccines from private manufacturers is decreasing. On a closer scrutiny, it was found that big hospitals / hospital chains account for maximum procurement of vaccines from manufacturers and other smaller hospitals were lagging behind.

This situation is now rectified so as to ensure that all hospitals and particularly the hospitals situated in remote parts of the States also get equitable access to the vaccines from this 25 per cent procurement earmarked for private hospitals.

With a view to ensure this equitable distribution, each State/UT Government is required to arrive at “an aggregate demand of private hospitals” within the State/UT. Based upon this aggregate demand, the Government of India will facilitate supply of these vaccines to the private hospitals and their payment would be sent by the respective private hospitals to the

manufacturers only through the electronic platform of Government of India viz. the “National Health Authority”. This would ensure that –

- (a) All private hospitals including smaller hospitals and hospitals situated in remote areas of State can procure an equitable share; and
- (b) The manufacturer do not charge nor any hospital can pay any amount more than amount publicly declared by each vaccine manufacturer.

The method of aggregating the demand is uniform throughout the country and each State/UT will have to follow the same.

25. Therefore, it is most respectfully submitted that under the Revised Guidelines, Government of India will procure vaccine and supply free of cost to the States/ UTs to vaccinate all persons above 18 years of age from 21.06.2021 and this will ensure that 18-44 years persons will also receive free vaccine from Government Covid vaccination centers. Furthermore, all citizens irrespective of their financial status are entitled to free vaccination.

In other words, at the cost of repetition, all eligible persons irrespective of age group or capacity to pay, shall be entitled for free vaccination.

Only those who have the ability to pay and who voluntarily chose to pay, are encouraged to use private hospital’s vaccination centers so that the stress and crowding on / in the on public utilities can be reduced to the extent possible. The sum total of above referred revised / reviewed vaccination programme is that Government of India will procure vaccine

and supply free of cost to States /UTs to vaccinate all persons above 18 years of age.

In other words, even for vaccinating the persons belonging to 18 to 44 years of age group neither the State Government will have to pay nor the recipient of the vaccine will have to pay. In other words, all persons above 18 years of age throughout the country are entitled to get free vaccination irrespective of their financial position.

To put the same position differently, a person below poverty line and a multi-millionaire are equally entitled for the very same vaccine in the age group of 18 years and above free of cost.

26. It is submitted that though the vaccination at all government vaccination centres is free of cost for all citizens, a new concept is introduced in the reviewed policy to make private vaccination centres accessible to economically weaker sections of the society also by use of “*Non Transferable Vouchers*”. Any person / institution / industry / NGO having the financial ability can purchase such “non-transferable electronic vouchers” and give it to their staff / other economically weaker sections of the society.

27. It is submitted that such pre-paid vouchers can be redeemed by the recipient of the voucher on presentation of the same at private vaccination centres and can get free vaccination in private hospitals. Many industries or others can use this for their staff and any NGOs / voluntary organisations can give such vouchers to economically weaker sections.

However, at the cost of repetition, it is reiterated that all persons above the age of 18 years of age are entitled to free vaccination at government vaccine centres and the aforesaid electronic voucher is only an alternative mode.

28. In view of the revised / reviewed policy which came into effect from 21.6.2021, it is neither permissible nor required either for the State/UT Governments or any other local body or anyone else to procure vaccines on their own either through global tenders or through direct negotiations with vaccine manufacturers [whether domestic or foreign]. The entire procurement of 75 per cent would be done by the Central Government from the manufacturers [local manufacturers as on date]

***Future Availability of Covid-19 Vaccines***

29. It is humbly submitted that Government of India has made every effort possible to ensure that the people of India have access to safe and effective vaccines at the earliest. Two vaccines (Covishield & Covaxin) have been a part of the vaccination program since January 2021. Another COVID-19 vaccine, Sputnik V developed by M/s Gamaleya Institute, Russia, has received Emergency Use Authorization by the DCGI, India in April 2021 and is now being administered in India.

30. In addition, some other domestic vaccines such as those from Biological E and Zydus Cadila are in the late stages of clinical trials and subject to the regulatory approvals, will further increase the availability of vaccines. The production capacity of the vaccines under the vaccination drive is being ramped-up as much as possible and as fast as possible and expected to further increase in the next few months.

31. In order to further increase vaccine availability and incentivising the foreign manufacturers, the regulatory process for use of foreign vaccines within India has been accelerated and simplified. It is submitted that NEGVAC, after comprehensive deliberations, recommended that vaccines for COVID-19, which have been developed and are being manufactured in foreign countries and which have been granted

emergency approval for restricted use by United States, European Union [EU], United Kingdom, Japan or which are listed in WHO (Emergency Use Listing) may be granted emergency use approval in India. It may be noted that this recommendation is a well-considered, and unprecedented policy intervention, made in light of the global experience of these foreign vaccines which have now been administered to millions of individuals and have proven safety across populations of different ethnicities. This recommendation has been accepted by the Government of India.

32. It is submitted that simultaneously production of indigenous vaccine at other units is also an option which is being encouraged and facilitated on a war footing.

33. It is submitted that as pointed out in the earlier Affidavit, due to the initial assistance provided for developing Covaxin, the Government has ensured a price of Rs.150 per dose for Covaxin as it is not possible to reduce the said price any further. This price is the lowest procurement price in the world.

34. It is submitted that the only available document in public domain which reflects the price of other vaccines available in other parts of the world is "UNICEF COVID19 Vaccines Market Dashboard", a copy of which is annexed herewith and marked as **ANNEXURE R - 6** to the said document is in public domain and is, therefore, placed on record.

35. It is submitted that foreign manufacturers while selling their vaccines to others, do not share their price structure either with Government of India or anybody else in the world relying upon the confidentiality clause in each of their respective contracts.

36. It is submitted that the Central Government has procured a total of:

- 34.6 crore doses of Covid-19 vaccine (Covishield: 26.6 crore doses, Covaxin: 8 crore doses) and
- additional 1 crore doses as commodity assistance under COVAX facility,

taking the total availability of vaccine doses to 35.6 crore doses as on date of filing this affidavit. Apart from these supplies, it is expected that around 16 crore doses will also be available during the period of May 2021 & July 2021 across the country.

37. It is submitted that from January 2021 to 31<sup>st</sup> July 2021, a total of 51.6 crore doses will be available as delineated hereunder:

QUANTITY (IN CRORE)	COST (IN CRORE)	STATUS
6.6 (Covishield - 5.6 & Covaxin - 1)	INR 1,392.825 {Covishield @ INR 200 +GST, Covaxin @ INR 295+GST(30% as free)}	Received and Utilized
1 (Covishield)	Commodity assistance	Received and Utilized
12 (Covishield -10 & Covaxin -2)	INR 1,890 (Both @ INR 150+GST)	For supply from Mar-May'21 - 96.83% received
16 (Covishield -11 & Covaxin -5)	INR 2,520 (Both @ INR 150+GST)	For supply from May-Jul '21

16 (Covishield – 11, Covaxin – 3 & Sputnik V - 2)	-	31.5 lakh doses of 1st component and 60 thousand doses of 2nd component of Sputnik V received.
<b>51.6</b>		

38. It is most respectfully submitted that as per the projected midyear population for 2020, the total population of the country aged 18 years and above is approximately 93-94 crore. As such, administering two doses to these beneficiaries would require an estimated 186 to 188 crore vaccine doses. As shown in the table above, out of this requirement, 51.6 crore doses will be made available for administration by 31.07.2021 leaving a requirement of approximately 135 crore vaccine doses for complete vaccination to the eligible population. The above figure of 186 crore includes the aforesaid figure of 135 crores [break-up of which is given hereunder] for which necessary arrangements have been made [subject to the approval for the vaccination at item no. 3 and 4 which will come in near future]. It is submitted that this figure of 186.6 crore does not include other vaccines which are at various stages of development as on date within the country and may come and become available.

39. The details of projected availability of Covid -19 vaccines from August 2021 to December 2021 are as follows:

S NO	VACCINE	QUANTITY THAT MAY BE RECEIVABLE THROUGH ALL SOURCES
1	Covishield	50 Crore
2	Covaxin	40 Crore
3	Bio E Sub unit vaccine	30 Crore
4	Zydus Cadila DNA vaccine	5 Crore
5	Sputnik V	10 crore
	<b>Total</b>	<b>135 Crore</b>

40. It is submitted as stated above that the vaccination drive would obviously get a boost if the Government of India succeeds in its attempts to procure vaccines available outside India such as vaccines of Pfizer, Johnson & Johnson, Moderna etc. It is submitted that for the purpose of procurement of these vaccines from abroad, efforts are ongoing at the level of the highest political executive in the Country and also at the highest diplomatic level. It is submitted that since these efforts are at a very advanced stage, it is neither desirable nor possible to give comprehensive details of these facts. As and when these efforts materialise, the speed of vaccination will be further augmented and enhanced.

41. It is submitted that as stated above it is expected that there would be availability of vaccine to vaccinate the entire eligible population and the only thing required is a structured and scientific administration of these vaccines by all stakeholders which is already in place and this biggest vaccination drive in the history is going on with full swing, reaching even remotest areas of the country by constructive and cooperative collaboration of Central Government, State/UT Governments, local authorities, human resources in medical sectors and the citizens of India.

***Status Of Covid-19 Vaccine Availability for Children***

42. It is humbly submitted that as of now, the companies manufacturing COVID-19 vaccination in India have only been given 'Emergency Use Authorization' for vaccinating people of 18 years age and above. Therefore, COVID-19 vaccines are not recommended for persons/children less than 18 years of age and is due to the fact that the clinical trial cohort during Phase 1, 2 & 3 did not cover the children below 18 years of age. It is humbly submitted that on 12th May 2021, the Drugs Controller General of India has permitted Bharat Biotech to conduct clinical trials on the healthy volunteers between 2 years to 18 years of age, for its vaccine i.e. Covaxin and the enrolment process for this trial has also begun.

43. It is submitted that Zydus Cadila which is developing DNA vaccines has concluded its clinical trial for between the age group of 12 to 18 years of age and subject to the statutory permissions, the same may be available in near future for children of the age group of 12 to 18 years of age.

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**Co-WIN PORTAL**

***Walk-in [on-sight registration] vaccination is permissible for all and – digital divide is not a constraint for access to vaccination.***

44. It is respectfully submitted at the outset that registration of vaccinated persons on Co-WIN platform is necessary and essential for more than one reasons detailed hereunder. However, self-registration through mobile phone or any other internet enabled device is only an

option available for convenience and is not a mandatory requirement for vaccination.

In other words, if a person having an access to internet and having digital device/s, chooses to self-register himself, he will go to the allocated vaccination centre at an allocated time slot requiring no further registration on-sight. However, if a person having no access to either internet or digital device/s or does not wish to self-register wants to be vaccinated, he can visit nearest vaccination centre where the health worker of the centre would register him in the device of the respective centre in Co-WIN platform and he would be vaccinated. There is, therefore, no impediment on vaccination based on availability or otherwise of digital device or internet.

45. Having clarified the aforesaid position at the outset, I beg to place the following facts-

- It is submitted that the Central Government is aware that though the extent of availability of computers, internet, smart phones and mobile phones, has improved significantly in the recent years, lack of these digital devices / internet may pose barriers to the citizens. It submitted that keeping the aforesaid factors in mind, and being cognizant of the said situation, the Central Government has been continuously and dynamically taking steps in order to widen the reach and accessibility of the vaccine.
- It is submitted that the Co-WIN system is an inclusive platform / system and has been designed keeping these limitations and challenges in mind. It is submitted that all the necessary features, to ensure that every eligible individual has the access to vaccination, regardless of any of physical, digital or socioeconomic barriers to access, have been incorporated in Co-WIN

- It is submitted that “onsite registrations” [also known as walk-in registration] and vaccinations have been permitted for all the beneficiaries vide the Circular dated 23<sup>rd</sup> May 2021 *DO no. 1940407/2020/Imm*, which was, till that date, available only for 45 plus age group .

Therefore, on and from 23.05.2021, any person above the age group of 18 years can visit any vaccination centre and get vaccinated without himself / herself pre-registering on Co-WIN platform.

### ***Need for registration***

46. At the outset, it is necessary to point out as to why a separate and singular digital platform and registration of vaccination on one / common platform is absolutely necessary to record vaccination data and ensure transparency and accountability. Registration on this common portal will capture and maintain a digital footprint and ensure inter-alia:

- (a) There is a verifiable data available as to a particular number of citizens vaccinated;
- (b) To ensure that a person who has been given first dose of a particular vaccine, receives the second dose of the very same vaccine and not another vaccine;
- (c) The time limit prescribed between the first does and the second dose is maintained;
- (d) Only the specified number of doses are administered, in other words, due to wrong perception, a person may not go for a third dose under misconception of getting better immunity;

- (e) The persons to whom vaccinations are administered, are given vaccination certificates;
- (f) Such digitalization through common portal throughout the country ensures that each vaccine does is administered to an identifiable individual leaving no room for any pilferage at any level or to prevent any unauthorized person / agency administering fake vaccines.
- (g) These digital data can be scientifically used in future, if required, to track and trace the spread, manner and method of virus for not only future pandemic planning but for further research and development.
- (h) Further, the digital footprint of vaccination data enables the administrators and Programme Managers to -
  - a. Monitor the overall progress of vaccination throughout the country or any specific State/District/Group through the data available through the digital recording system on real time basis.
  - b. Monitor the extent of vaccine availability and their utilization for enabling further planning of vaccination efforts.
  - c. Assess the extent of Vaccine wastages and take measures to minimize wastages.
- (i) Further, it is submitted that digital records offer ease of reference and shall facilitate future interventions based on emerging evidence, guidance and newer vaccines, such as administration of booster doses etc., if and when the same are recommended and also, for policy formulations at micro and macro levels.

- (j) Complete transparency of a singular national public portal promotes awareness, leaving little room for myths, thereby addressing the issue of vaccine hesitancy also.

47. It is submitted that, “facilitated registration”, i.e. individual beneficiaries or groups of beneficiaries going to their nearest Common Service Centers or Near-to-House vaccination facilities, to get registered on Co-WIN, is another such mode of registration on Co-WIN. In the said mode, a person, who may be digitally inept or even out of his free volition [despite having digital access], can get himself/herself registered through the registration process offered “on-site” at the vaccination centers [i.e. walk-in registration] showing a valid identity card. Further, health workers or ASHAs, mobilize people for on-site registration [i.e. walk-in registration] and vaccinate directly at the nearest vaccination centers either specially set up for that area or already existing. The facility for assisted registrations through the 1075 Help Line has also been operationalized and is functioning effectively.

48. It is submitted that these “on-site” registrations, “near to home registrations” etc. initiatives are not only ideas on paper but are in fact very proactively implemented as the figures of vaccination mentioned hereafter would demonstrate.

49. It is submitted that the vaccination sessions are planned and published on Co-WIN and other modes by the District Immunization Officers of each district of each State as per the policy and State specific requirements of the respective State/UT Government. The session planning module of Co-WIN provides full flexibility for planning and publishing vaccination sessions by the State authorities as the on-ground vaccination is done by the State authorities and fact situation may vary

from State to State and even within the State. The vaccination by the State / UTs can be based on the schedules of–

- Online slots
- On-site slots
- Slots reserved for 2<sup>nd</sup> dose
- Flexible session timings

Moreover depending upon the local context and situation of each State–

- Vaccination Sessions can be fully for 45+ population or
- Fully for 18-44 age group population; or
- Vaccination Sessions can be fully reserved for online or
- Fully reserved for on-site vaccination; or
- Sessions can also be fully reserved for 2<sup>nd</sup> dose vaccination.

50. It is submitted that this flexibility is required for wider reach of vaccines and as there may be circumstances, either due to infrastructural issues or otherwise, for the State Government to plan its vaccination sessions in a particular manner. Considering the population such flexibility always results into more effective vaccination drive and less inconvenience to the citizens. The State Governments are regularly sensitized to ensure that citizens are kept informed about the vaccination sessions plans so that less inconvenience is caused to the citizens resulting into maximum vaccination.

51. The above facts are for individual citizens needing vaccination. There are group vaccinations also which are elaborated hereunder which

is not only more effective in terms of wider reach of vaccination drive but is proving to be more effective in terms of the coverage as explained hereunder.

52. It is submitted that, at the cost of repetition, online registration [i.e. digital mode] and prior self-registration and booking of appointment on Co-WIN is not mandatory to avail vaccination services. Apart from online registration and walk-in [on-site] registration and appointments, Co-WIN offers the following modes for registration and vaccination of beneficiaries:

- a. Assisted registration of individuals and groups of individuals through Common Service Centers (CSCs)
- b. Assisted registration through 1075 helpline/Call center available in each state.
- c. Special sessions for facilitating vaccination of people who don't have any of the specified identity cards, [migrants, seers, nomads etc.] where 100% vaccination is done through on-site registration by the vaccinator under a special procedure.
- d. Facility for organizing special session for Near-to-Home vaccination sessions , wherein all vaccination is done through on-site registration by the vaccinator.
- e. Features for reserving vaccinations slots for second dose to ensure that people do get the second dose of vaccination within the recommended period after the first dose.
- f. Any person, who has been registered on Co-WIN through online mode, can also avail on-site vaccination.

53. It is submitted that, because of the above inclusive features, on the ground, on-site registrations mode has been the predominant mode of registration of beneficiaries on Co-WIN since the launch of the National Vaccination Drive on 16.01.2021. It is submitted that, as on **23.06.2021**, out of the **32.22 crore** beneficiaries registered on Co-WIN in the country, **19.13 crore (59%)** beneficiaries have been registered in the on-site [walk-in / Non digital] mode.

54. It is submitted that the system of vaccination is so flexible that even if a person has registered himself digitally through on-line mode, he can still approach the vaccination centre on-site and walk-in for vaccination and can get vaccination subject to the availability of vaccine at that particular centre at that particular time when he walks in.

55. It is submitted that it is understandable that the rural and tribal areas in the country have lower access to digital mediums and the internet and the Central Government is fully cognizant of the same. It is submitted that the Central Government, being aware of the situation, has adopted various other modes to provide the citizens with the vaccine in such areas as stated above and hereafter. The following aspects will clarify that the digital divide, if any, is not hindering the vaccination drives across even the remotest locations in the country.

56. It is submitted that, a majority of the Gram Panchayats in the country, have Common Service Centers (CSCs). It is submitted that CSCs facilitate access through following means -

- a. CSCs can offer the services of registration to individual beneficiary for COVID vaccination. Up to 4 registrations can be done through a single mobile number.

- b. In the mobile phone deficient areas the CSCs put up their computers with internet connectivity at vaccination centers for on-site registration and vaccination.
- c. CSCs provide the services of generating provisional vaccination certificate after 1<sup>st</sup> dose and final vaccination certificate after the beneficiary have received both the doses.

The concept of such registration in rural areas through CSCs of Gram Panchayat is not a concept just on paper but as per the Annual Report for 2019-20, of the CSC E-Governance Services India Limited, the organization responsible for implementation of the initiative of Common Service Centers, 2,68,385 number of CSCs (74% of a total of 3,60,873 CSCs as on 31.03.2020) are already functional throughout the country and are being used by the rural population for vaccination.

57. It is submitted that however, CSCs are merely additional facilitators, as all State/UT Governments are conducting Nearer to Home Vaccine Sessions, to cover all rural areas where on-site registration is equally permitted. This is a fully functional mechanism where the paramedical staff at the session-site registers the person who comes for vaccination.

58. Though, this fact is clarified in earlier Affidavits, it needs to be reiterated that for a period from 1.5.2021 to 23.5.2021, the on-site registration was not made available only to the newly added beneficiaries between 18-44 years age group, in view of the imperative of maintaining strict COVID appropriate protocol during the second surge of the pandemic going on at that stage and a large number of newly eligible beneficiaries leading to a rush for vaccines during that period of about 3 weeks.

In any case, now in view of on-site registration being permissible for all and 'Near to Home' vaccination drive being undertaken even in remote rural areas, dependence of CSC is also minimum

59. At the cost of repetition, after 23.5.2021, there has been no difference between on-site registration and digital registration for any eligible beneficiary. Both modes are permissible for all age groups of 18 years and above.

60. ***Vaccine administration in rural areas*** -- It is submitted that the National COVID-19 Vaccination Programme is implemented on the ground by the respective States/UTs. Although, the Co-WIN portal does offer the convenience of online registrations and appointments for beneficiaries with access to internet, in rural areas the vaccination programme is implemented on the same lines as the Universal Immunization Programme (UIP), the only difference being requirement of registration on Co-WIN as a tool for digital recording of vaccination data.

61. It is submitted that just as in the UIP, the staff at the Primary Health Centers and the Sub-Health Centers, including Medical Officers, Community Health Officers at the Health & Wellness Centers, nurses and health workers including Auxiliary Nurse Midwives (ANMs), prepare the village wise schedule for vaccination. The beneficiaries of a village then are informed by the health staff with the help of ASHAs workers and Panchayat representatives and officials, about the vaccination center/s, where the vaccination is planned to be provided and the date and time of vaccination. The States have also been requested to and do proactively mobilize the people in villages and also provide transportation assistance for the same wherever necessary which is being done.

62. It is submitted that once a beneficiary comes for vaccination, the vaccinator does the on-site registration, allocates the beneficiary to an ongoing session, administers the vaccine dose to the beneficiary, records the vaccination data in his own Co-WIN device which remains connected digitally and provides the vaccination certificate to the beneficiary after 30 minutes of mandatory observation, all on-the-spot on the same day. There is no need for prior registration or pre-booking of an appointment for vaccination in such cases. As reported by the states on Co-WIN, in the period from 01.05.21 till 23.06.21, out of the total 1,31,204 COVID Vaccination Centers [CVCs] providing vaccination services,

- 33,342 are operated at the Sub-Health Centers,
- 28,168 at the Primary Health Centers and
- 9,932 at the Community Health Centers, amounting to 54.45% of the total vaccination centers.

The CVCs at the Sub-Health Centers, the Primary Health Centers and the Community Health Centers are in rural areas.

63. It is submitted that a feature for tagging the vaccination centers as rural/urban has been introduced in Co-WIN w.e.f. 05/06/21. Out of the total 1,24,969 vaccination centers so far classified by the State Governments on Co-WIN as rural centre or urban centre,

- 93,044 vaccination centers, i.e. 74.45%, are located in rural areas.
- Out of the 17,10,18,010 total doses administered through these 1,24,969 vaccination centers in the period from 01.05.21 to 23.06.21, 9,61,84,637 (56.24%) doses have been administered at the rural vaccination centers.

The state-wise details of the rural/urban vaccination progress are attached herewith and marked as **ANNEXURE R - 7**.

64. It is submitted that the above stated provisions and features in Co-WIN address the concerns centering around any possible exclusion of people without computers, internet, smart phones or mobile phones or any digital device, and those living in rural areas, is evident from the facts that –

- a. As on 23.06.2021, out of the 32.22 crore beneficiaries registered on Co-WIN, 19.12 crore (59%) beneficiaries have been registered in the on-site mode.
- b. As per the data available on Co-WIN as on 23.06.2021, out of the total 29.68 crore vaccine doses recorded on Co-WIN, 23.12 crore doses (nearly 78% of all vaccine doses) have been administered through onsite/ walk-in vaccination.
- c. The feature for on-site registration and vaccination for beneficiaries in the 18-44 age group, has been enabled on 23.05.21. 3.22 crore beneficiaries have been registered through on-site registration in this age group in the months of May 2021 and June 2021 (up to 23.06.21). 3.40 crore doses have already been administered in the 18-44 years age group in the same period through on-site registration and vaccination.
- d. It is submitted that as on 23.06.2021, 1,50,988 persons without ID Cards have been vaccinated as per the prevailing system.
- e. 39,01,126 beneficiaries have been vaccinated through the functionality of Near-to-Home vaccination sessions, introduced recently.

- f. 1,15,85,71 vaccine doses have been administered at government workplaces and 64,73,24 at private sector workplaces.
- g. The coverage of vaccination in tribal area – As per the data available on Co-WIN as on 23<sup>rd</sup> June, 2021 –
- i. Vaccination per million population in tribal coverage is better than the National average.
  - ii. 97 out of 176 Tribal Districts are performing better than all India vaccination coverage.
  - iii. More walk-in vaccinations are happening in Tribal Districts as compared to National average.
  - iv. Gender ratio for people vaccinated is better in the tribal districts.

	<b>National</b>	<b>Tribal districts</b>
Doses per million population	2,13,244	2,19,762
Male : Female ratio	54 : 46	53 : 47
Walk-in : Online vaccination	78 : 22	84: 16

- v. That, the Co-WIN includes all the necessary features for enabling access to vaccinations, is also evident from exceptional coverage of vaccination observed even in districts with the most difficult and remote areas and with a higher proportion of tribal populations. Details of vaccination in such districts are reproduced below –

State/UT	District	Percent age of ST population	No. of persons at least one dose	Population	% age at least one dose
Ladakh	Leh	More than 50% ST	115447	1,33,487	86.5
Lakshadweep	Lakshadweep	More than 50% ST	52818	64,429	82.0
Himachal Pradesh	Kinnaur	More than 50% ST	62861	84,121	74.7
Sikkim	South Sikkim	Between 25 & 50	105154	1,46,850	71.6
Himachal Pradesh	Lahaul Spiti	More than 50% ST	20859	31,528	66.2
Sikkim	East Sikkim	Between 25 & 50	182268	2,83,583	64.3
Ladakh	Kargil	More than 50% ST	88289	1,40,802	62.7
Sikkim	West Sikkim	Between 25 & 50	83490	1,36,435	61.2
Sikkim	North Sikkim	More than 50% ST	26376	43,709	60.3
Tripura	Dhalai	More than 50% ST	216283	3,78,230	57.2

65. It is submitted that the Co-WIN system is inclusive and has been designed to provide the necessary features and the required flexibilities to states/UTs and their officials to overcome the challenges posed by various

State specific problems and barriers to access. There is no question of any person being left out due to any digital divide. Thus, it is may not be correct to conclude that the technology or methodology adopted is resulting in exclusion some persons or any particular class. The facts, in fact, show otherwise.

66. It is submitted that, in order to further improve access for citizens as well as field functionaries operating the Co-WIN portal, the multilingual citizen and user interfaces are now available in 12 languages on Co-WIN. These languages are - Hindi, Marathi, Malayalam, Telugu, Kannada, Oriya, Gurumukhi, Bengali, Assamese, Tamil, Gujarati and English.

#### **ENABLING FEATURES FOR VISUALLY CHALLENGED**

67. It is submitted that in some of the IAs, some genuine concerns are raised by some of the applicants. These concerns are also continuously being addressed before and after filing of the IAs. These facts are placed hereunder.

68. It is submitted that in order to improve access for those who are visually challenged, following measures have already been taken –

- The feature for text Captcha has been removed and an alternative safety mechanism is being used.
- Text resizing options have been included on the Co-WIN webpages to improve accessibility to the content for visually challenged persons.

- It has been ensured that table headers correspond to associated cells while determining the number of available vaccine slots on corresponding dates.
- Keyboard support for navigating the Co-WIN website has been made available.
- 15 minutes session time has been provided for everyone to schedule their online appointment without the possibility of being automatically logged off.

Additionally, all visually challenged persons can always avail either on-site registration mode in which it is always someone else who undertakes registration or Co-WIN platform.

It is submitted that, further improvements are also being done, as per the “Guidelines for Indian Government” websites - “<https://web.guidelines.gov.in>”.

### ***Persons with Disabilities***

69. In this regard, it may be noted that with a view to further enhance the inclusivity of the vaccination programme, the State/UT Governments have been advised to take the following steps:

- (a) District level officer of Disability/Social Welfare department should be made nodal officers for the purpose of dealing with redressal of grievances of differently abled persons in connection with obtaining treatment for COVID-19 on real time basis. He will work in close co-ordination with CMO of the district. Necessary advisory in this regard is issued to the States.
- (b) State government are advised to properly orient 104 helpline personnel to take necessary care for differently abled persons and

to facilitate their proper care and vaccination. States have been asked to make special arrangements for their vaccination through Near to Home Covid Vaccination Centres (CVCs) (details at **ANNEXURE R - 8**).

- (c) Directions are given to all district level officers for providing assistance to differently abled persons for matter related to COVID-19. The District/City Control & Command Centres can facilitate this process. Necessary advisory in this regard is issued to the States.
- (d) Directions are issued to the States/UTs that differently abled persons should be provided hospital beds on priority basis.(e)  
Through public health system, it is difficult to achieve home vaccination. However, the State Government must provide ambulance transport to persons with 40% or more disability. State government must also arrange home vaccination of fully disabled persons on production of a certificate of a qualified medical practitioner.
- (f) In addition, the Union Ministry of Health & Family Welfare has recently issued directions to States/UTs to facilitate differently abled persons & senior citizens in Covid vaccination.
- (g) The Ministry of Health & Family Welfare, received representations from various organizations where it was submitted that there should be door-to-door vaccination of differently abled persons and elderly. However, door-to-door vaccination has so far not been provisioned under National COVID-19 Vaccination Pogramme due to valid scientific and germane reasons which are stated below:

- (i) It would be difficult to timely address Adverse Event Following Immunization (AEFI) in an adequate manner in a home setting.
- (ii) There will be delay in reaching health facility resulting into the derailment of time schedule of vaccination programme defeating the purpose.
- (iii) The protocol of observation of each beneficiary for 30 minutes post vaccination cannot be maintained as the vaccinated staff, if waits for 30 minutes can hardly vaccinate few individuals.
- (iv) There would be high chances of break in cold chain of the vaccine due to frequent opening of vaccine carrier (for storage of vaccines at required temperature at vaccination sessions) at every household, which may adversely affect vaccine efficacy & potentiate AEFIs.
- (v) Chances of vaccine wastage would be high due to increased time involved in visiting beneficiaries from door to door.
- (vi) Door to door vaccination also poses risk to the vaccinator as it involves exposure to multiple household environment and substantial time spent indoors.

70. It is submitted that however, being cognizant of the issues faced, an Expert Committee was constituted to examine the matter, comprising technical medical and domain experts, which recommended a community-based approach of Near to Home COVID Vaccination Centres (NHCVCs) should be used for the differently abled and elderly citizens. The recommendation and guidance document was also presented to the National Expert Group on Vaccine Administration for COVID-19

(NEGVAC) on 25<sup>th</sup> May 2021 which endorsed the decision of the Expert Committee for Near to Home COVID Vaccination Centres (NHCVC).

71. It is submitted that the NHCVCs follow a community-based approach where sessions can be conducted in non-health facility-based settings and are nearer to homes e.g. in a community centre, RWA centre/office, housing complexes, panchayat ghars,, school buildings, old age homes etc. home required homes, hostels for disabled persons etc, Directives are issued to facilitate entry and exit of elderly and differently abled citizens including provision of wheelchair, seating arrangement, drinking water and toilet facilities. Signages are to be ensured in the facilities to guide beneficiaries to the vaccination site and due assistance would be provided for differently abled people.

72. To make the vaccination process convenient and seamless, the beneficiaries are to linked to a helpline number by the State Governments to avail support for pickup and drop to the NHCVC. Any unregistered beneficiary can be registered on-site or facilitated cohort registration facility can be utilized. Each NHCVC **will be backed** up by an Advanced Life Support ambulance/Basic Life Support ambulance/transport vehicle for shifting beneficiaries to the linked AEFI management center, if required.

73. It is submitted that for availing COVID-19 vaccination, the Central Government has listed Nine prescribed photo identity documents which can be used by a beneficiary for registering on Co-WIN [either for self-registration or on-site registration] and also for verification at the time of vaccination. These photo identity documents include:

1. Aadhaar card
2. Electoral Photo Identity Card (EPIC)- Voter ID

3. Passport
4. Driving License
5. PAN Card
6. NPR Smart Card
7. Pension Document with Photograph
8. Unique Disability Identification Card (UDID)
9. Ration Card with photo

74. It is submitted that in order to further facilitate the access to vaccination for persons with disability, the Unique Disability Identification Card (UDID), issued to persons with disability by the Department of Empowerment of Persons with disabilities, M/o Social Justice & Empowerment, has also been included on 7<sup>th</sup> June 2021 in the list of prescribed Photo ID for COVID-19 vaccination. The letter regarding inclusion of Unique Disability Identification Card (UDID) in the list of the prescribed photo IDs while registering for COVID-19 vaccination is at **ANNEXURE R - 9**. Also, keeping in view that the UDID is a recent initiative of the Government, and therefore that, some of the persons with disabilities may not possess the UDID Card as of now, the States/UTs have also been advised that the Disability Certificates issued to the persons with disabilities, by the respective competent authorities of the States/UTs, may also be accepted as valid photo identity document in lieu of the UDID Card.

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**OTHER ASPECTS ON VACCINATIONS*****Students - Relaxation of COVID-19 vaccine dose interval for individuals going abroad for higher education or employment prospects***

75. It is submitted that the dose interval between the two doses of Covishield vaccine under the COVID-19 vaccination drive has undergone a series of revision based on the available & emerging scientific evidence with overall guidance of the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC). From 4 weeks at the start of vaccination drive to a gap of 6-8 weeks, currently, the interval between the 1<sup>st</sup> and 2<sup>nd</sup> dose of Covishield is at 12-16 weeks interval in view of emerging evidence documenting higher seroconversion and protection offered at longer dose interval. The matter was deliberated by the National Technical Advisory Group on Immunization (NTAGI) which recommended to increase the interval between the two doses of Covishield to 12-16 weeks.

76. It is submitted that MoHFW has received several representations from students as well as State Governments, like Kerala, regarding relaxation for administration of 2<sup>nd</sup> dose of Covishield before the currently stipulated 84 day interval for students going abroad for higher studies. The various representations request for allowing administration of 2<sup>nd</sup> dose of Covishield for such persons who have only taken the first dose Covishield and are seeking to undertake international travel for educational purposes or employment opportunities or as part of India's contingent for Tokyo Olympic games, but whose planned travel dates fall prior to completion of the currently mandated minimum interval of 84 days from the date of first dose.

77. It is submitted that this matter was taken up in the meeting of Empowered Group- 5 (EG- 5), on COVID-19 Vaccination, which has recommended on administration of 2<sup>nd</sup> dose of Covishield vaccine prior to the prescribed time interval (after 28 days but before 84 days) to provide full coverage of vaccination and facilitating international travel in the following cases:

- Students who have to undertake foreign travel for the purpose of education
- Persons who have to take up jobs in foreign countries
- Athletes, sportspersons and accompanying staff of Indian contingent attending International Olympic Games to be held in Tokyo

78. It is submitted that the Letter communicating the relaxation in 2<sup>nd</sup> dose interval for Covishield vaccine in special cases and the Standard Operating Procedure on the same is placed at **ANNEXURE R - 10**. The SOPs have also been uploaded on MoHFW website. The requisite facility in Co-WIN for administration of 2<sup>nd</sup> dose in such exceptional cases will be made available shortly.

### ***Vaccination Of Crematorium Workers and Panchayat Workers***

79. It is submitted that Crematorium workers (regardless of employment status of being permanent, contractual, outsourced or manpower working with contractor with or without any designation) who are engaged in working in cremation grounds are already included under “municipal workers group” under the “Frontline Workers category”. Similarly, panchayat workers in rural areas involved in COVID-19

activities are also included in Frontline Workers category. All these workers are under the broad category of Municipal workers and Panchayat workers (which are included in “Frontline workers”] therefore their exact numbers cannot be ascertained through the Co-WIN platform. The State Governments can further provide the said data.

***Utilization of Funds for Vaccine Procurement Till Date***

80. It is submitted that the reference to the amount spent for procuring vaccines by the Central Government in the order dated 31.5.2021 was in the context of the earlier regime in which the Government was procuring only 50% of vaccines. It is submitted that now, in view of the change / review of the policy as stated above where procurement is by the Central Government, the said aspect no longer remains relevant. However, in view of the order dated 31.5.2021, the details of funds utilization for procuring vaccines prior to 21.6.2021 are as under:

QUANTITY (IN CRORE)	DATE OF PURCHASE ORDER	COST (IN CRORE)	TIMELINE OF SUPPLIES	SUPPLY STATUS
6.6 (Covishield -5.6 & Covaxin - 1)	10 Jan '21- (Covishield 1.1 & Covaxin 0.55) 3 Feb '21 – (Covishield 1.0 & Covaxin 0.45) 10 Feb '21- Covishield 1.5 24 Feb '21- Covishield 2.0	INR 1,392.825 {Covishield @ INR 200 + 5% GST, Covaxin @ INR 295+ 5% GST(30% as free)} Out of the total 1.0 Crore doses procured from M/s Bharat Biotech, 30 Lakh doses was provided	Jan-Mar '21	Received and Utilized

QUANTITY (IN CRORE)	DATE OF PURCHASE ORDER	COST (IN CRORE)	TIMELINE OF SUPPLIES	SUPPLY STATUS
		free of cost.		
12 (Covishield - 10 & Covaxin - 2)	12 <sup>th</sup> Mar 2021	INR 1,890 (Both @ INR 150+ 5% GST)	Mar-May'21	18,36,840 doses of Covaxin remain as on 12 <sup>th</sup> June '21
16 (Covishield - 11 & Covaxin - 5)	5 <sup>th</sup> May 2021	INR 2,520 (Both @ INR 150+ 5% GST)	May-Jul '21	Covishield supplied 3.47 cr ,balance 7.53 cr. Covaxin yet to start supply
44 (50% of anticipated production between Aug'21-Dec'21 i.e. Covishield - 25, Covaxin - 19)	4 <sup>th</sup> June '21	30% Advance paid i.e. INR 2079 (Both @ INR 150+ 5% GST)	Aug-Dec'21	Supplies would commence in August'21
<b>78.6 (Covishield - 51.6, Covaxin - 27.0)</b>				
<b>30 (Corbevax by Bio E)</b>	<b>2<sup>nd</sup> June '21</b>	<b>INR 1500 (Partial payment @ INR 50/dose)</b>	<b>Sep -Dec '21</b>	
<b>108.6 (Covishield - 51.6, Covaxin-27.0 &amp; Corbevax - 30.0)</b>		<b>INR 9381.825*</b>		

***Cold Chain Capacity***

81. It is submitted that there are more than 29,000 Cold Chain Points (CCPs) across the country in States/ UTs, where the vaccines are stored at recommended temperatures. Of the above CCPs, 4 national level stores i.e. Government Medical Store Depot (GMSD) are managed by the Govt. of India and the remaining are managed by the respective State/UT Governments. There are 37 State Vaccine Stores, 114 Regional Vaccine Stores, 723 District Vaccine Stores and 28,268 sub-District vaccine stores.

82. It is submitted that based on the programme requirement of both Universal Immunization Programme and COVID-19 vaccination, Government of India has centrally procured and supplied the Cold Chain Equipment (CCE) to the States/UTs. Further, funds are allocated to the States/UTs under the National Health Mission- Programme Implementation Plan (NHM-PIP) for maintenance of CCEs and also for provisioning the Cold Chain Technicians (CCTs) for undertaking the repair and maintenance of CCEs.

83. There are 29,116 CCPs located from National to sub-District level across India, which have CCEs like Walk-in Cooler (WIC), Walk-in Freezer (WIF), Ice Lined Refrigerator (ILR), Deep Freezer (DF), Cold Box for storage of vaccines and freezing of icepacks. The capacity of these CCPs has been augmented for the COVID-19 vaccination drive. The present numbers of CCEs and comparison with the numbers prior to March 2020 are mentioned in the table below:

<b>NAME OF CCE</b>	<b>STATUS AS ON MAR 2020</b>	<b>PRESENT STATUS AS ON 8.6.2021</b>
Walk-in Cooler (WIC)	243	280
Walk-in Freezer (WIF)	73	103
Ice Lined Refrigerator (ILR)	41,985	50,529
Deep Freezer (DF)	39,036	54,101
Cold Box	60,405	69,650

84. The cold storage equipment procured by Govt. of India through domestic budget is indigenously manufactured. The cold storage equipment supplied as aid by the donors i.e. UNICEF constitutes both indigenously manufactured equipment and imported equipment.

85. At present two vaccines (Covishield & Covaxin) which are currently being used are required to be stored at 2-8 degree centigrade. The country also has the capacity to store vaccines which may require lower temperature in the range of -15 to -20 degree centigrade. Sputnik V vaccine requires storage at -18 degree centigrade.

86. It is submitted that the requirement for cold storage may change with the arrival of other COVID-19 vaccines in the future. The Government of India is well aware of the challenges posed by such requirements and is fully prepared to take appropriate steps as and when such vaccines are available.

### ***Workplace Vaccination***

87. It is respectfully submitted that, Guidelines on workplace vaccination were issued to all States/UTs *vide* D.O No. 2146926/2021/Immu dated 6<sup>th</sup> April 2021, through which vaccination was allowed to employees of the work place aged 45 years or more, excluding outsiders and eligible family members. The detailed guidelines are available on MoHFW website <https://www.mohfw.gov.in/pdf/GuidelinesforCOVID19VaccinationatWorkplace.pdf>.

A copy of the letter & detailed guidelines is annexed herewith and marked as “**ANNEXURE R - 11 & R - 12**”.

88. The following amendments were made in the said guidelines in view of the provisions for Liberalised Pricing and Accelerated National COVID-19 Vaccination Strategy, wherein the following decisions have been taken and communicated to all States/UTs:

- 18-44 years of age group has been included for workplace vaccination, *vide* D.O No T-22014/12/2021-IMMUNIZATION dated 19.05.2021, which is annexed herewith and marked as “**ANNEXURE R - 13**”.
- Family members & dependents of the employees / workers are included for workplace vaccination *vide* letter dated 21.05.2021, which is annexed herewith and marked as “**ANNEXURE R - 14**”.
- Family members & dependents of employers can also be covered for COVID-19 Vaccination at Industrial **COVID-19 Vaccination Scheme (CVS)** and Workplace COVID-19 Vaccination Centers (CVC).

- For Industrial and Private CVSs, vaccine doses will have to be arranged by the industries with their tie up with the private hospitals.
- For Government Workplace CVCs, beneficiaries of 45 years or above may be covered through doses supplied through Government of India channel to the States/UTs for administration free of cost. The beneficiaries above 18, may be covered through vaccine doses of the respective States/UTs.

These guidelines continue even today, appropriately as per the extant reviewed / revised policy.

***Near To Home Covid Vaccination Centers (NHCVC) For Elderly And Differently Abled Citizens***

89. It is respectfully submitted that, under the National COVID-19 Vaccination Program, the vaccination of population aged above 60 years had started since 1<sup>st</sup> March 2021, however, there was a need to vaccinate the elderly & differently abled, who may have been left behind because of the inability to travel to COVID-19 Vaccination Centers (CVC). Therefore, in view of this need and to ensure easy access, it was felt pertinent to bring vaccination services closer to the community and nearer to homes, while maintaining all necessary precautions and safety measures, as per Operational Guidelines and Advisories issued from time to time.

90. In this regard it is submitted that, the MoHFW constituted a committee consisting of domain knowledge experts to examine this issue which recommended the strategy of Near to Home COVID Vaccination Centres (NHCVC) to cater to special needs of elderly & differently abled persons. This strategy has also been endorsed by the National Expert

Group on Vaccine Administration for COVID-19 (NEGVAC), which has both government & non-government experts.

91. It is respectfully submitted that, the strategy of Near to Home COVID Vaccination Centres (NHCVC) for elderly & differently abled citizens is flexible, people-centric and follows a community-based approach, where sessions can be conducted in non-health facility based settings and are nearer to home, e.g. in a Community Center, RWA Center/Office, Panchayat Ghar, school buildings, old age homes, Sub-Health Centres and Health & Wellness Centers with availability of adequate space etc.

92. It is submitted that under the said setup, the overall planning, review and implementation will be the responsibility of the District/Urban/Block Task Force. The NHCVC will be linked to an existing CVC for planning & execution of the vaccination session. These NHCVC will be organized specially for this target population (i.e. all individuals above 60 years of age and individuals below 60 years with disability due to physical or medical conditions) while vaccination for all other age groups will continue at the existing CVCs. The beneficiaries can either register themselves in advance, on-site or can be registered following Facilitated Cohort Registration process on Co-WIN. For management of any adverse event following immunization (AEFI), an advanced life support/basic life support/transport vehicle must be stationed at the NHCVCs for transport to nearby AEFI Management Centre. Herein, the guidelines on NHCVC was shared with all States/UTs on 27<sup>th</sup> May 2021 and is also available on MoHFW website at <https://www.mohfw.gov.in/pdf/GuidanceNearToHomeCovidVaccinationCentresForElderlyAndDifferentlyAbleCitizens.pdf>. A copy of the guidelines is annexed herewith and marked as “**ANNEXURE R - 15**”.

93. It is further stated that, the Ministry of Health and Family Welfare *vide* directive. D.O. No. 2088847/2021/Imm dated 29<sup>th</sup> May, 2021 has prohibited carrying out any vaccination drives in Star Hotels, which must be stopped immediately. Furthermore, necessary legal and administrative actions would be initiated against such erring institutions. A copy of D.O. No. 2088847/2021/Imm dated 29<sup>th</sup> May, 2021 is annexed herewith and marked as “**ANNEXURE R - 16**”.

***Facilities for disabled people***

94. It is humbly submitted that Union Ministry of Health and Family Welfare has issued advisory to the State/ UT Governments for the following actions:

- District level officer of Disability/Social Welfare department should be considered as designated nodal officer for the purpose of dealing with redressal of grievances of differently abled persons in connection with COVID-19 on real time basis. He/ She will work in close co-ordination with CMO of the district.
- Directions should be given to all district level officers for providing assistance to differently abled persons for matter related to COVID-19. The District/City Control & Command Centres can facilitate this process.
- To properly orient 104 helpline personnel to take necessary care for differently abled persons and to facilitate their proper care and vaccination, States have been asked to make special arrangements for their vaccination through Near to Home Covid Vaccination Centres (CVCs)

- Differently abled persons should be provided hospital beds on priority basis.

A copy of D.O. No. 2128363/2021/Imm dated 11th June, 2021 in this regard is annexed herewith and marked as “ANNEXURE R - 17”.

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## **VACCINATION STATUS**

### ***Number Of Videoconferences Held With States/UTS Since 1<sup>st</sup> May 2021 By MOHFW Officials***

95. It is respectfully submitted that, a total thirteen (13) virtual meetings were held with States/UTs from 1st May to 10<sup>th</sup> June 2021 by MoHFW officials. These 13 meetings were held on 4<sup>th</sup>, 11<sup>th</sup>, 19<sup>th</sup> (2 meetings), 20<sup>th</sup> (2 meetings), 23<sup>rd</sup>, 25<sup>th</sup>, 27<sup>th</sup>& 31<sup>st</sup> of May 2021 and 2<sup>nd</sup>, 3<sup>rd</sup>& 10<sup>th</sup> June 2021.

### ***Present Covid-19 Vaccination Status Across India***

96. It is humbly submitted that as on 25.06.2021 :

- more than 31 crore vaccine doses have been administered across the country.
  - This includes 1,73,35,543 doses to Health Care Workers (HCWs),
  - 2,66,36,432 doses to Frontline Workers (FLWs),
  - 9,93,05,811 doses to persons between 45 to 59 years of age,
  - 8,96,03,216 doses to persons above the age of 60 years and

- 7,84,37,353 doses to persons between 18 to 44 years of age.
- Total 44.2% of the priority population of persons above 45 years of age and 13% of the population group of 18-44 years of age have received the first vaccine dose.
- A total of 27.3% of eligible population (18 years and above) have received one dose of Covid-19 vaccine.

97. It is humbly submitted that prior to the initiation of the New Liberalized Pricing and Accelerated National COVID Vaccination Strategy on May 1<sup>st</sup> 2021; a total of 15,49,89,635 (15.49 Cr) COVID-19 vaccine doses were administered in the country from 16<sup>th</sup> January to 30<sup>th</sup> April 2021. These include a total 94,12,140 doses to Health care Workers (HCWs), 1,25,58,069 doses to Frontline Workers (FLWs), 5,27,07,921 doses to 45 to 59 years of age and 5,23,78,616 doses for people above the age of 60 years.

98. It is further stated that, in the month of May, 2021, a total of 4,03,49,830 doses were provided by Union Government to the States/UTs for vaccination of priority group of Health Care Workers (HCWs), Front-Line Workers (FLWs) and person aged 45 years + and above as supply from Government of India channel, for which no amount is collected from anyone as explained in the previous affidavit filed by UOI. In the month of May, 2021, 3,91,80,160 doses were available for the State(s)/UTs and Private Hospitals (which would be proportionate to the people of 18-45 age group in each state/UT). Therefore, in May, 2021 a total number of 7,95,29,990 (7,95 Cr) doses were available for the National COVID vaccination program. A Chart depicting supply of COVID-19 vaccine to States/UTs from January'21 to May'21 is annexed herewith and marked as **ANNEXURE R - 18**.

99. It is humbly submitted that each state is informed by the Union Government in writing about the number of vaccine doses it would receive on monthly basis. This exercise is absolutely essential so as to have uniform vaccination throughout the country. This endeavour can be successful only by treating India as one unit and considering the question on pan India Basis. This can be achieved only with each state following the discipline in letter and spirit, and be in tune with simultaneous vaccination of the country avoiding any demands by one state at the cost of other state and residents of the rest of the country.

100. As has been practice in May and June 2021, Union Government has provided advance information to States/UTs regarding vaccine doses to be supplied to them for the month of July 2021 also. A copy of the DO letter No.2088847/2021/Imm dated 19th June 2021 is attached herewith and marked as **ANNEXURE R - 19**.

101. It is humbly submitted that, allocation for the month of July 2021 for available vaccine was done amongst all States/ UTs on pro-rata basis based on population of 18 years and above. A copy of the detailed allocation sheet is attached herewith and marked as **ANNEXURE R - 20**.

102. It is most respectfully submitted that, a total of 19 Video conference meetings were held from 10<sup>th</sup> May to 28<sup>th</sup> May, 2021 with both the manufacturers i.e. M/s Serum Institute of India and M/s Bharat Biotech Ltd., has been chaired by Additional Secretary, Ministry of Health & Family Welfare (MoHFW) and other senior officials of the Central Government to streamline the delivery schedule and supply of the vaccine.

103. It is submitted that though there is no global scientific evidence of virus selecting to affect a particular age group, the Central Government has ensured that all State Governments are geared-up to deal with any such potential threat to children. Since 'health' is a State subject and 'hospitals' are under the State Governments, the Central Government has pro-actively prepared two SOPs – one for prescribing an ideal clinical treatment and second prescribing the infrastructural facilities mandated in the hospitals. A copy of the SOPs prescribing an ideal clinical treatment and second prescribing the infrastructural facilities mandated in the hospitals are annexed herewith and marked as **ANNEXURE R - 21**. The Central Government is in constant and direct touch with the State Governments to ensure that these facilities are created / augmented on war footing.

***Additional Measures being taken by Government of India regarding preparedness for future resurgence in COVID-19 cases in the country***

104. It is submitted that though the trajectory of the COVID 19 spread throughout the country is encouraging as of now, the Central Government is continuously preparing the State Governments/UTs and their infrastructure to meet with any future resurgence. It is submitted that possibility of any such resurgence would necessarily be speculative at this stage. However, the possibility of resurgence would depend upon (a) behaviour pattern of the virus and (b) behaviour of the citizens viz. whether they follow COVID appropriate behaviour or not.

105. It is humbly submitted that Government of India is in close and continuous collaboration with States/ UTs and is continuously monitoring the COVID-19 situation throughout the country up to District level on a daily basis. It may be noted that the website of the Health

Ministry displays on a daily basis, the positivity trend district wise to guide the State government to take appropriate public health response.

106. The State Governments/UTs have been cautioned to maintain a continuous vigil and plan in advance for any exigencies that may arise due to resurgence of COVID-19 in their respective States. On 29th May 2021, 10 Empowered Groups in Govt. of India have been reconstituted keeping such potential threat in mind to facilitate inter-ministerial coordination and fast track decision making on various facets of COVID-19 management. These include Empowered Groups on (i) Emergency Management Plan and Strategy, (ii) Emergency Response Capabilities, (iii) Augmenting Human Resources and Capacity Building, (iv) Oxygen, (v) Vaccination, (vi) Testing, (vii) Partnership, (viii) Information, Communication and Public Engagement, (ix) Economic and Welfare Measures and (x) Pandemic Response and Coordination.

107. It is also submitted that communications are regularly being sent out to States Governments regarding current trajectory of cases, need for adherence to Test-Track-Treat policy for containment of outbreaks, need for adherence to COVID appropriate behaviour, vaccination, and other related issues as stated above. Based on observed trajectory of cases and other relevant parameters, detailed reviews have been conducted with States/Districts at the level of Minister for Health & Family Welfare, Cabinet Secretary, Secretary (Health & Family Welfare) wherein various challenges related to COVID-19 management have been discussed and deliberated with the respective counter parts of the State Governments/UTs as this on-ground management shall have to be done by the State Governments.

108. It is submitted that States are being provided with projections on future requirements of bed capacities in COVID health care facilities

based on existing trends of Covid cases. It is also stated that all States have been provided with detailed measures on Containment, besides template for preparation of District Action Plan. The high case load Districts have been specifically reviewed and asked to present their District Action Plan for COVID-19 management during the periodical and regular Video Conferences held by the Central Government at various levels. Taking note of spread of the disease to peri-urban/semi-urban and rural areas in many Districts, Ministry of Health and Family Welfare on 16th May 2021 has issued an "SoP on Covid19 Containment and Management in Peri-Urban/Semi-Urban, Rural and Tribal Areas". It is also submitted that, advisories/protocols specifically related to clinical management have been refined & updated in expert consultation and widely circulated to optimize treatment outcomes and minimize mortality. Technical advisories have also been issued for management of Mucormycosis.

A copy of the "SoP on Covid19 Containment and Management in Peri-Urban, Rural and Tribal Areas" dated 16th May 2021, issued by the, Ministry of Health and Family Welfare issued keeping future contingencies in mind is attached herewith and marked as **ANNEXURE R - 22**.

109. It is submitted that with a view to increase the availability of trained human resources to tackle the Covid-19 pandemic situation and any potential resurgence, the States have been advised to explore avenues for utilization of services of Medical Interns, Final Year MBBS students, Final Year PG Students as well as final year super-specialty students as residents. It was also advised to utilize the services of B.Sc./GNM Qualified Nurses, Final Year GNM or B.Sc. (Nursing) students under appropriate guidance. The services of Allied Health Care professionals have also been planned based on their training and certification. States

are also being provided with requisite financial support under National Health Mission, State Disaster Response Fund and India COVID-19 Emergency Response and Health Systems Preparedness Package.

110. It is submitted that so far as oxygen requirement is concerned, fortunately there is no crisis situation in view of the recent declining trajectory of active cases. However, the Central Government has already commenced efforts to augment oxygen production as mentioned in the previous affidavit. This Hon'ble Court was pleased to constitute a National Task Force on oxygen vide order dated 06.05.2021 in the matter titled *Union of India v. Rakesh Malhotra and Ors.* The recommendations of the said Task Force have been received and most of the said recommendations were already under implementation on a war footing. The Central Government is working on all recommendations. The report of the National Task Force on oxygen and the action taken report is placed separately in the present proceedings for perusal of this Hon'ble Court.

***Media Report regarding Fake Vaccination Camps***

111. It is further submitted that recent media reports regarding incidents of unauthorized or fake vaccination drive has come to the notice of Govt. of India. Veracity of these reports is being verified by the State governments and the Central Government is also requiring details. The States/ UTs have been directed vide letter dated 25<sup>th</sup> June 2021 to promptly investigate any alleged irregularities and take suitable action, wherever necessary. It is submitted that any valid vaccination can only be through Co-WIN platform. Necessarily the vaccination will have to be undertaken by the State authorities and therefore, they must ensure that in case of near to home or any such mode of vaccination only permitted vaccination centres undertake the drive and each vaccination is registered and accounted for in the Co-WIN platform. The State authorities must

ensure most stringent criminal actions with regard to any breach in this behalf and must exercise constant vigil through the District Administration, the Taluka Administration, and Police Administration to ensure that such unauthorized vaccination does not take place. A copy of the letter dated 25<sup>th</sup> June 2021 issued by MoH&FW is attached herewith and marked with **ANNEXURE R - 23**.

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### **DRUG AVAILABILITY FOR MUCORMYCOSIS**

112. It is submitted that the drug *Amphotericin* is available both through domestic production and by imports and both sources have been ramped up. The capacity and supply has had to be increased manifold in a very short period of time to cope with the surge in demand seen for the first time in May and June 2021. Further, allocation is being made as an interim measure to enable equitable distribution across states, using patient data of Mucormycosis as reported on the portal created for this purpose by MoHFW. MoHFW has also issued guidance on the judicious use of the drug and States and UTs have been required to put in place transparent arrangements for allocation to private and government hospitals within their states / UTs. A copy of the guidance on the judicious use of the drug and States and UTs by Department of Pharmaceuticals is annexed herewith and marked as **ANNEXURE R - 24**.

It is submitted that every state government must have a structured plan for judicious use of the said drug which must percolate to every hospital with a protocol of administering the said drug. As the administration of this drug has to be at the State level, the Central Government is monitoring the same and the State Government can place their respective systems on record.

***The steps taken for increasing the production and imports***

113. It is submitted that in order to augment domestic manufacture, the Union of India is continuously engaging with manufacturers to resolve issues related to raw materials. In this regard, the Ministry of External Affairs (MEA) is playing a critical role in reaching out to various manufacturers abroad. With the active participation of MEA, several important and critical steps have been taken to augment both, domestic production and imports. It may be noted that vide OM dated 16.05.2021, Ministry of Health and Family Welfare had requested the Ministry of External Affairs to explore all possibilities of sourcing Amphotericin B/Liposomal Amphotericin B injection from abroad through Indian Mission. Accordingly, MEA has also instructed Indian Missions all over the world to immediately identify additional sources of the drug and alternative drugs for treatment of Mucormycosis. The said exercise is in process at war footing.

114. It is submitted that MEA has also been working on ensuring supplies of key excipient HSPC [raw material for manufacture of a drug which can be administered/consumed] from sources abroad for production of Liposomal Amphotericin B in India. It may be noted steps have also been taken to facilitate import of the other key excipient namely DSPG-Na.

115. As regards the import of Liposomal Amphotericin B by Mylan Labs from Gilead Inc. USA, the Department of Pharmaceuticals and the Indian Embassy in the USA are working continuously with the Mylan Labs and Gilead to increase the imports and for early delivery. The import position is as follows:

S. No.	Particulars	Number of Vials
	Total Orders placed with Gilead	905,000
	Stocks received till date by Mylan	5,33,971 As on 25 <sup>th</sup> June, 2021

The remaining deliveries are being expedited and are likely to reach on 26.06.2021.

116. It is submitted that in order to augment domestic production, Department of Pharmaceuticals and the Drug Controller General of India has actively coordinated with the industry for identification of manufacturers, alternate drugs and expeditious approvals of new manufacturing facilities.

117. It is submitted that regular Monitoring of production is being carried out by The Union of India. Meeting was held with manufacturers on 22<sup>nd</sup> May, 29<sup>th</sup> May, 2<sup>nd</sup> June, 5<sup>th</sup> June, 12<sup>th</sup> June and 19<sup>th</sup> June, 2021 to identify and address the issues faced by the manufacturers in the augmentation of the production and such issues are being resolved.

118. It is submitted that companies manufacturing APIs have been contacted by DOP/ DCGI and have been asked to ensure increased and continuous supplies vide discussions held with API manufacturers on 22<sup>nd</sup> May, 25<sup>th</sup> May, 29<sup>th</sup> May, 5<sup>th</sup> June 12<sup>th</sup> June and 19<sup>th</sup> June 2021 for augmenting production.

119. It is submitted that the manufacturing of liposomal formulation involves a complicated process and can only be manufactured by industries having advanced technology. The DCGI after consultation with the association of Drugs manufacturers has recently issued manufacturing / marketing permission of Amphotericin B Liposomal Injection to eleven

companies so as to augment the production which would be available. Some of such 11 companies have already started producing and some are commencing production from July 2021.

120. It is submitted that on 17.5.2021, the Central Drugs Standard Control Organisation (CDSCO) has also issued a circular whereby it reiterated its resolve to expeditiously process all applications of stakeholders wanting to manufacture drugs keeping in mind the emergent need of such drugs in the pandemic. The CDSCO called upon all State/UT Drug Controllers to bring the said circular to the attention of all the stakeholders. A copy of the Central Drugs Standard Control Organisation (CDSCO) circular dated 17.05.2021 is attached herewith and marked as **ANNEXURE R - 25**.

121. It is submitted that all applications submitted by companies for permission to manufacture Amphotericin-B have been considered expeditiously, keeping in mind the safety and efficacy of the drug to be manufactured by facilitating permissions to new manufacturers as tabulated below:

<b>Number of Manufacturer</b>	<b>Production Capacity (vials/month)</b>	<b>June Production</b>
<b>6</b>	141,500	112,748

In addition to the above, CDSCO has granted manufacturing licences to 5 new manufacturers and one importer in the second week of June. It is relevant to state that an import license has also been granted to import Liposomal Amphotericin B from Taiwan in about 2 days of applying in the month of May, 2021.

122. The existing manufacturers have also been called upon to increase production of Amphotericin-B. The DCGI vide letter dated 07.05.2021 has

issued letters to individual firms to enhance the production capacity of Amphotericin B Liposomal Injection to cater to the current and future requirement in this pandemic situation. The Central Government is constantly following it up with the manufacturers so as to ensure that they augment their capacities as fast and technically feasible.

123. It is submitted that the supply by domestic manufacturers of Amphotericin B has been enhanced to 3,75,688 vials. The domestic production capacity of Amphotericin B Liposomal Injection (in vials) has progressed as follows—

MONTH	QUANTITY
April, 2021	62,000
May, 2021	1,63,352
June, 2021	3,75,688

124. It is submitted that the Ministry of Health and Family Welfare vide its letter dated 7<sup>th</sup> June, 2021 has circulated to all States/UTs, the advisory of The National Task Force on COVID-19 for treatment and management of Covid related Mucormycosis (CAM). The advisory explains in detail, the manner and conditions under which various Mucormycosis drugs like Amphotericin B lipid complex, liposomal Amphotericin B, Amphotericin deoxycholate form (Conventional Amphotericin), Posaconazole etc. are to be used. A copy of the Ministry of Health and Family Welfare vide its letter dated 7<sup>th</sup> June, 2021 is attached herewith and marked as **ANNEXURE R - 26**.

125. It is submitted that projected production of L-Amphotericin B in July and August from domestic manufacturers is as below:

	Projected Production in units injections (in lacs)	
	Jul-21	Aug-21
<b>Total</b>	4.785	5.525

### ***Allocation of L-Amphotericin-B***

126. It was noted that in the month of May, the demand exceeded the supply that was available from the domestic manufacturers and importers. The supply position is expected to improve with further imports of this drug and increase in production. Therefore, after reviewing the position with the manufacturers/ importer, the Department allocated the supply of this drug amongst the states/UTs as an interim measure in consultation with MoHFW till supply position improves. Between 11<sup>th</sup> May and 23<sup>rd</sup> June, a total of 7,89,165 vials of Amphotericin B have been allocated to the states, where the cases of Mucormycosis have been reported. In addition, 91,600 vials of Conventional Amphotericin B were also allocated to States / UTs between 14<sup>th</sup> June and 18<sup>th</sup> June. With this available supply, the situation on the ground is reasonable stable with judicious use of the drug.

127. It is pertinent to mention herein that the primary concern of the Central Government is to ensure that the drug in question is distributed in the country in such a way which prevents inequitable distribution and hoarding of the drug in question. From 14<sup>th</sup> June, allocation for Conventional Amphotericin B was also started and total 91,600 vials of Conventional Amphotericin B have been allocated to States / UTs between 14<sup>th</sup> June and 18<sup>th</sup> June.

***Present system of distribution of L-Amphotericin-B for various states***

128. It is humbly submitted that in order to maintain equitable distribution, distribution is being done to the States in accordance with the proportion of their reported case load. It is submitted that the number of patients in a particular state is derived from the portal of Ministry of Health and family welfare, in which States themselves enter the figures of patient load in their respective States.

129. It is submitted that this distribution mechanism is an interim arrangement till the supply of the drug stabilises vis-a-vis the demand.

It is also to be submitted that once the particular number of vials are distributed amongst the States based upon the system referred to above, it is for the State Governments to ensure equitable distribution internally.

-----

**ADDITIONAL DRUG AVAILABILITY**

***Availability of Remdesivir***

130. It is submitted that looking to the sudden increase in demand for the patented drug, Remdesivir in April 2021, the Central Government had made efforts to augment the production by the 7 licensed domestic manufacturers. The domestic production capacity was augmented from 38 lakh vials per month to nearly 122 lakh vials per month with the accelerated approval of 40 additional manufacturing sites by the DCGI (Drug Controller General of India) taking the number of sites to 62. Government also undertook allocation of the drug to all the States/UTs of

the country in a move to ensure fair and equitable distribution across the country for an interim period till production was ramped up and the drug becomes adequately available in the market. Beginning with the first distribution to States/UTs on 21st April, 2021 to the last allocation made on 23rd May 2021, the total cumulative allocation of 98.87 lakh vials of Remdesivir was made to all States/UTs and Central Health Institutions covering the period from 21st April to 30th May 2021. It is submitted that about 93 lakh vials have been supplied till date by the manufacturers against the distribution to the States and UTs. It is submitted that some States have cancelled their purchase orders worth 4.63 lakh vials in last few days, indicating adequate availability of the drug with them.

131. It is submitted that meanwhile, noting the slowdown in the demand of Remdesivir from the States/UTs owing to decrease in the number of active cases and sufficient availability of the drug with States/UTs, allocation by Government of India has been discontinued in the end of the May, 2021, and states / UTs can purchase as per their requirement from the manufacturers. Further, in June 2021, Government of India has also started providing the drug to the States through the central procurement, to build adequate stocks for future contingencies. Moreover, close coordination continues to be maintained with manufacturers to maintain adequate stocks of drug and raw materials to enable quick ramp up of production in case of any future sharp surge in demand.

### ***Availability of Tocilizumab***

132. It is submitted that *Tocilizumab* is listed in the treatment protocol issued by the Joint Monitoring Group of MoHFW for management of COVID 19 patients. Since the drug is not manufactured in India it is sourced from a company Roche in Switzerland and marketed by Cipla Ltd in India. Till about March, 2021 the demand of Tocilizumab by various

hospitals across the country was adequately being met until the sudden spike of COVID cases April, 2021 onwards whereby the demand for the drug went up hugely.

133. It is submitted that Government of India coordinated with manufacturer and importer to expedite and increase imports including donations and commercial supplies. Government also made distributions to States/UTs and Central Govt Hospitals based on the number of active cases to ensure a fair and equitable distribution of stocks till supply increased. As of 20<sup>th</sup> June, 9,900 (400 mg) vials and 65000 (80 mg) vials have been allocated from the commercial supplies. In addition, 1000 (400mg) vials and 50024 (80 mg) vials have been allocated to states / UTs and central Health Institutions from stocks received through donations.

134. It is submitted that States/UTs have always been advised to use the drug in a very judicious and efficient manner. They have been also advised to widely publicize in their respective States/UTs the mechanism to obtain the drug from the State Health Departments.

The demand for the drug seems to have come down relatively in June 2021 and supply demand gap is largely overcome. However, all efforts are being made at the diplomatic level to source more drug for the country to meet possible future demand. Further, CDSCO has also given approval to one domestic manufacturer to conduct Clinical Trials to develop a biosimilar, which if successful can reduce dependence on imports for the drug.

**Commercial supplies charts**

<b>Tocilizumab</b>	<b>Allocation date</b>	<b>Total allocation (No of vials)</b>	<b>Supply as on 20<sup>th</sup> June, 2021</b>
400 mg vial	30 <sup>th</sup> April 2021 to States	9,900	9,548
	4 <sup>th</sup> May 2021 to Central Govt Institutions		
	5 <sup>th</sup> May 2021 to UTs		
80 mg vial	11 <sup>th</sup> May 2021 to States/UTs and Central Health Institutions	65,000	44,136
	7 <sup>th</sup> June 2021 to States/UTs and Central Health Institutions		

**Donations**

<b>Tocilizumab</b>	<b>Allocation date</b>	<b>Total allocation (No of vials)</b>	<b>Supply completed</b>
400 mg (Oman)	13 <sup>th</sup> May, 2021 to States/UTs and Central Health Institutions	1,000	1,000
80 mg (Roche)	10 <sup>th</sup> May, 2021 to States/UTs and Central Health Institutions	50,024*	25,211
*On 27 <sup>th</sup> May, MoHFW decided to supply only 50% of it and remaining reserved for supply in future depending upon active case load.			

135. The present affidavit is bonafide and in the interest of justice.



**DEPONENT**

(डा. मनोहर अगनानी)  
(Dr. MANOHAR AGNANI)  
अपर सचिव / Addl. Secretary  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
Ministry of Health & F.W.  
भारत सरकार / Govt. of India  
नई दिल्ली / New Delhi

**VERIFICATION**

I, the deponent abovenamed, do hereby verify that the contents of Para 1 to 135 of my above affidavit are prepared on the basis of instructions received by me from respective ministries i.e. Ministry of Health and Family Welfare, Department of Pharmaceuticals, Ministry of Home Affairs, Ministry of Chemicals and Fertilizers, Department of Industrial Policy and Promotion, Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry etc. and on the basis of legal advice received and no part of it is false and nothing material has been concealed there from to the best of my knowledge.

Verified at New Delhi on this the 22.06.2021.



**DEPONENT**

(डा. मनोहर अगनानी)  
(Dr. MANOHAR AGNANI)  
अपर सचिव / Addl. Secretary  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
Ministry of Health & F.W.  
भारत सरकार / Govt. of India  
नई दिल्ली / New Delhi



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)  
[www.mohfw.gov.in](http://www.mohfw.gov.in) | [www.cowin.gov.in](http://www.cowin.gov.in)



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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



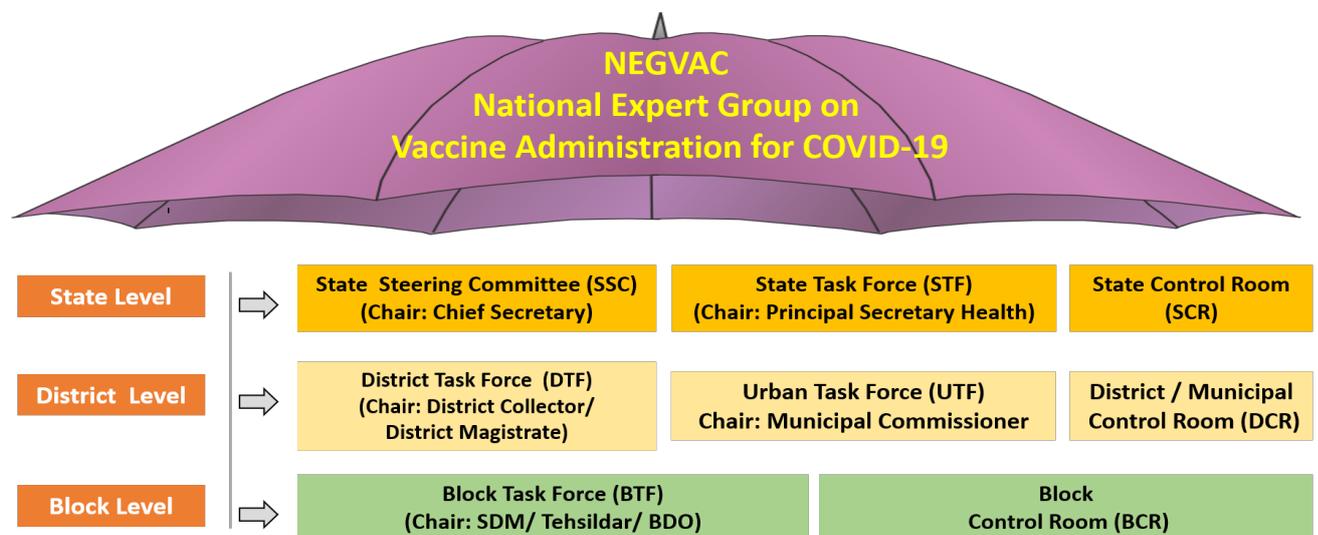


# 1. EXECUTIVE SUMMARY

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-lshstm.shinyapps.io/ncov\\_vaccine\\_landscape/](https://vac-lshstm.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.

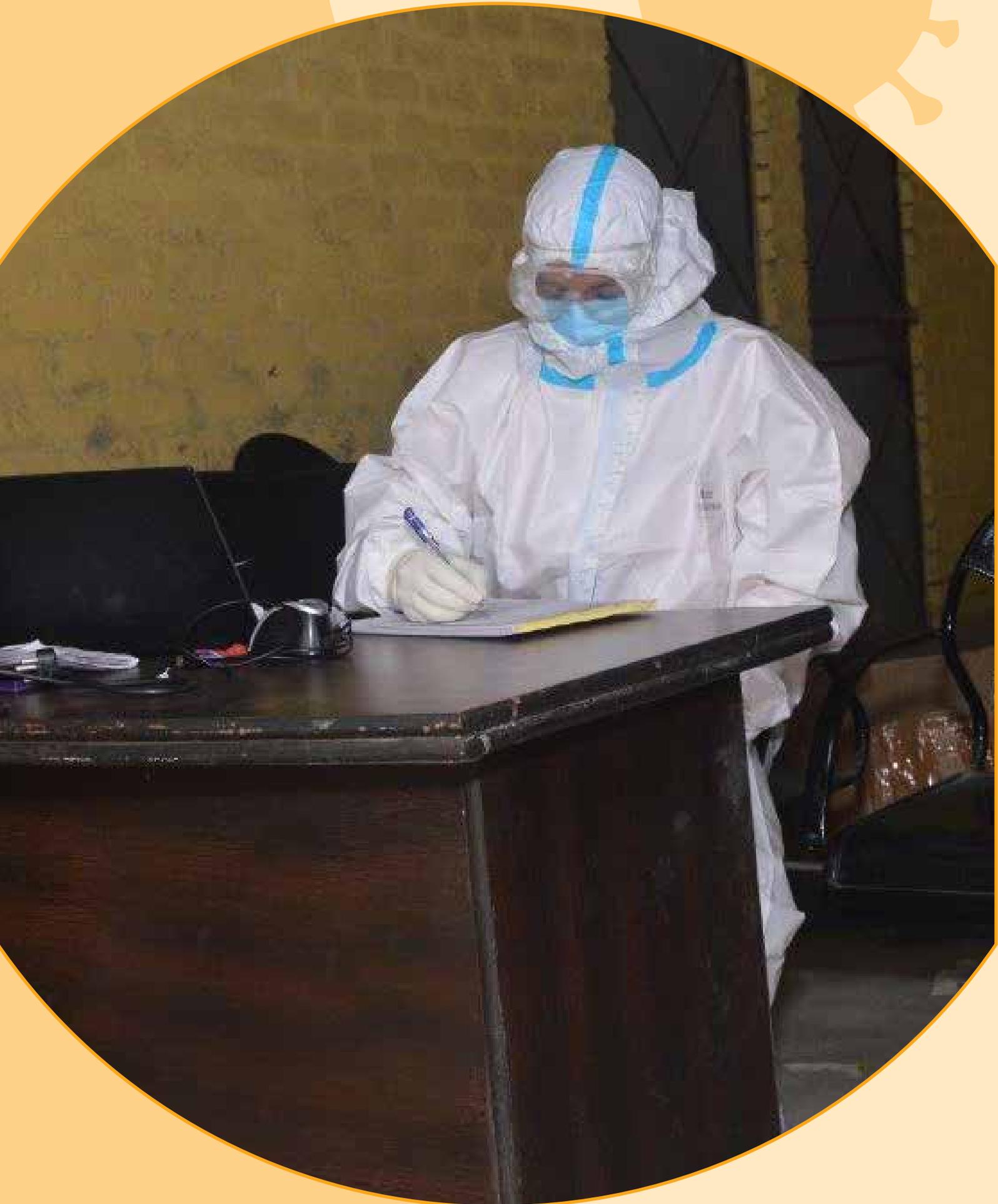
**Safety precautions**, including infection prevention and control practices, safe injection practices and waste disposal, will be followed during vaccination sessions. As large population groups will be vaccinated over a short period with a new vaccine, monitoring the safety of these vaccines will be 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.

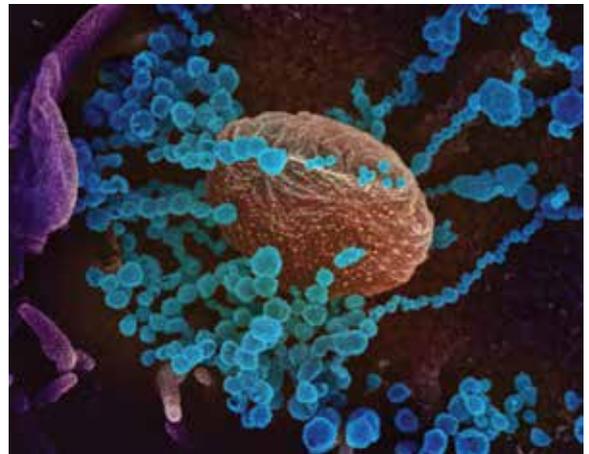


Figure 2.1: Novel Coronavirus SARS-CoV-2.  
Credit: NIAID-RML, NIH Image Gallery.

**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-gfeneral-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))

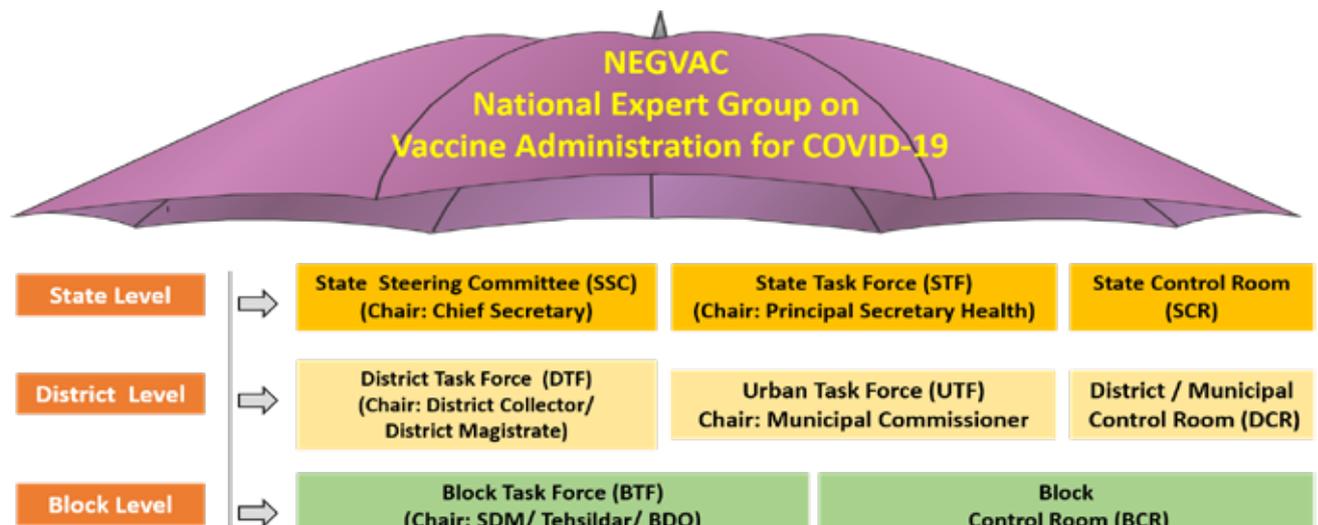




## 3. MULTILEVEL GOVERNANCE MECHANISMS

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:

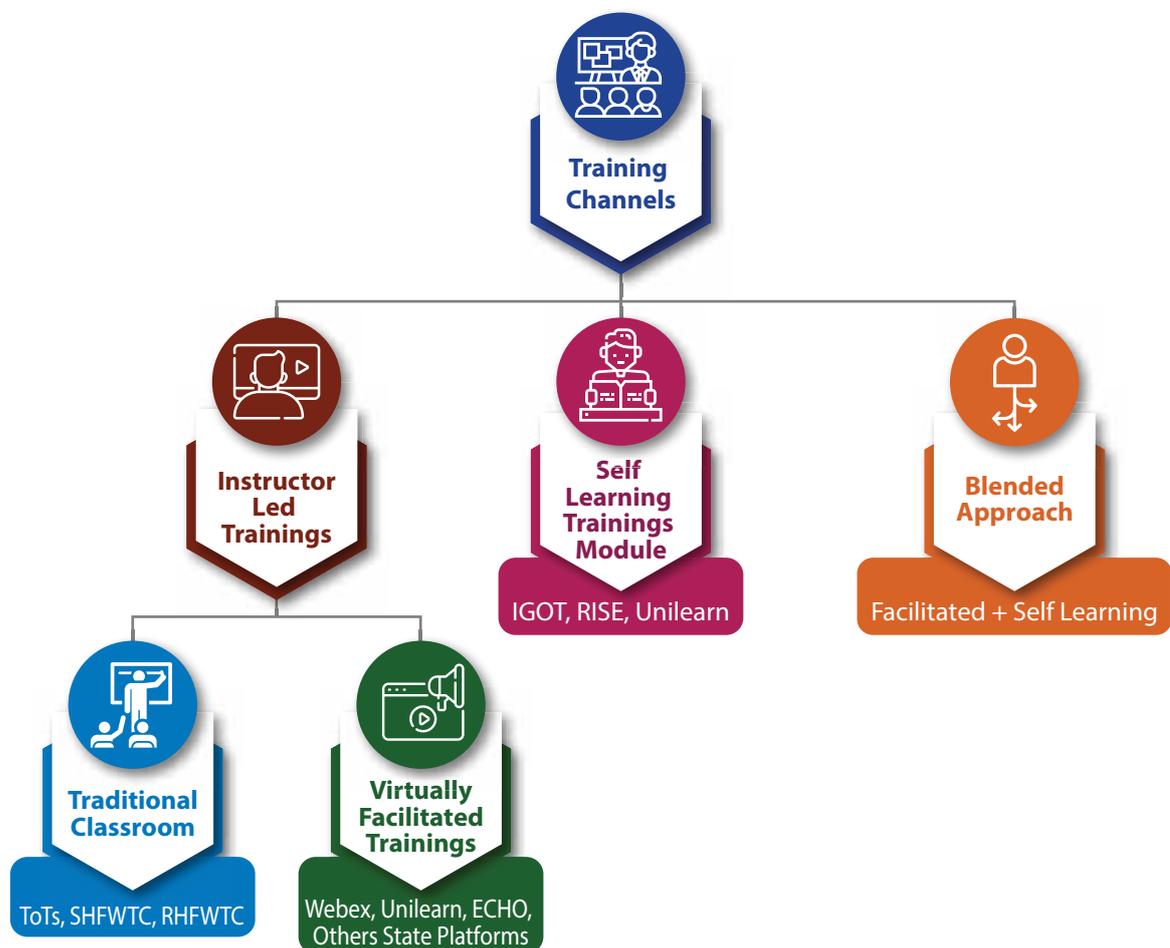


Figure 5.1: Modalities of training

### 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.

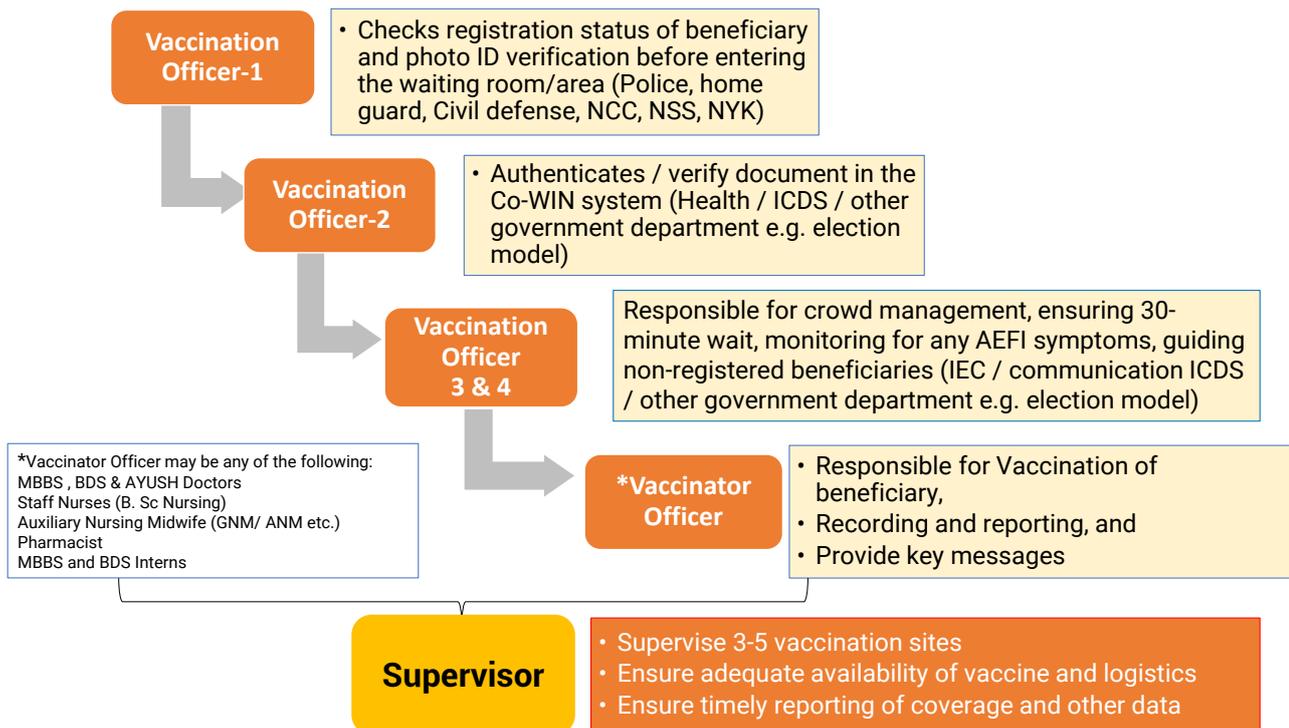
### Remember

- 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:



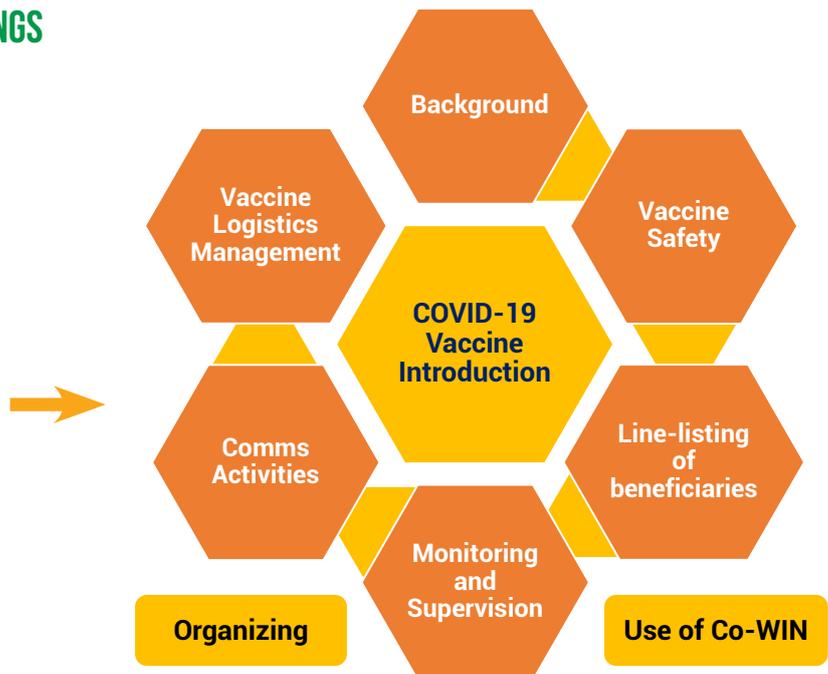
**Figure.5.2:** Training of vaccination team according to their roles

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.

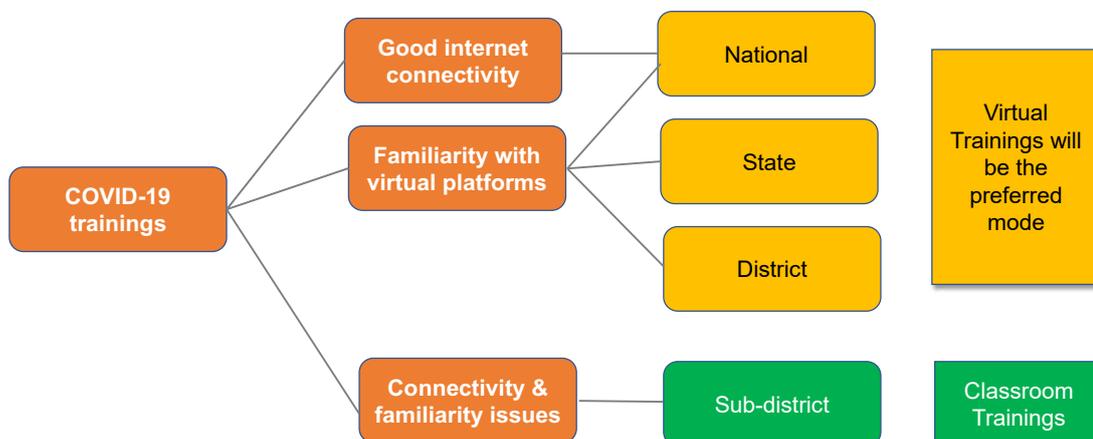


Figure.5.3: Rollout of capacity building

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

**C**o-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.

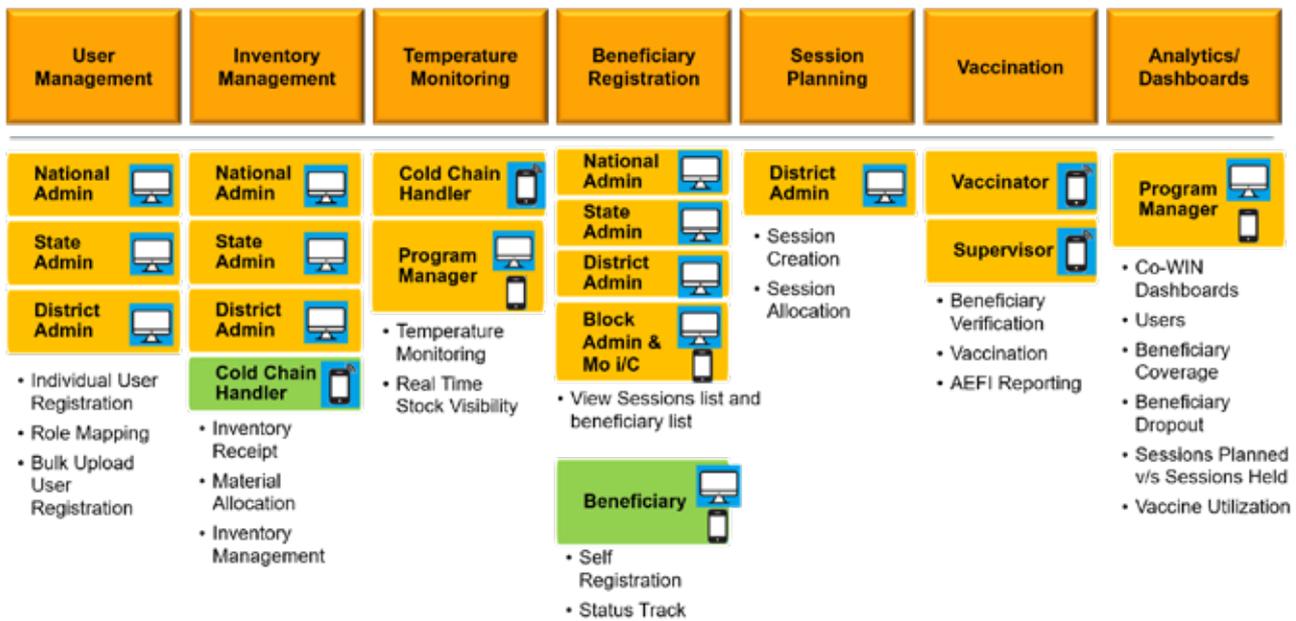


Figure 1a: Key Features of Co-WIN system

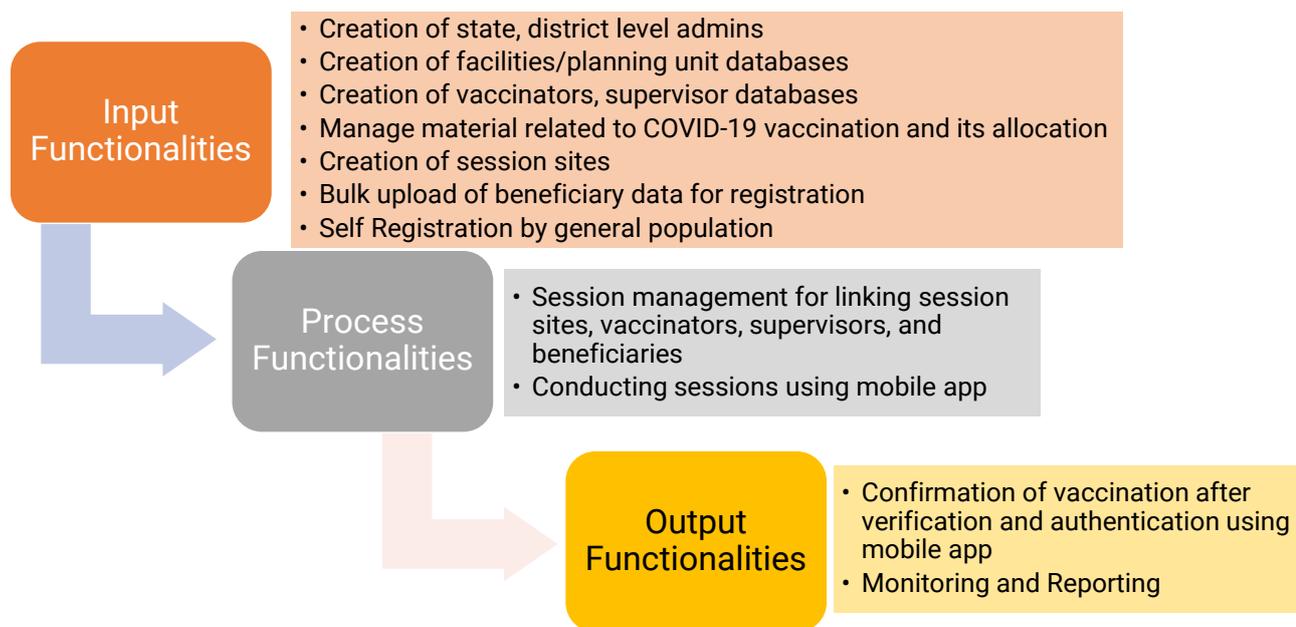


Figure 1b: Process flow of Co-WIN

## 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.

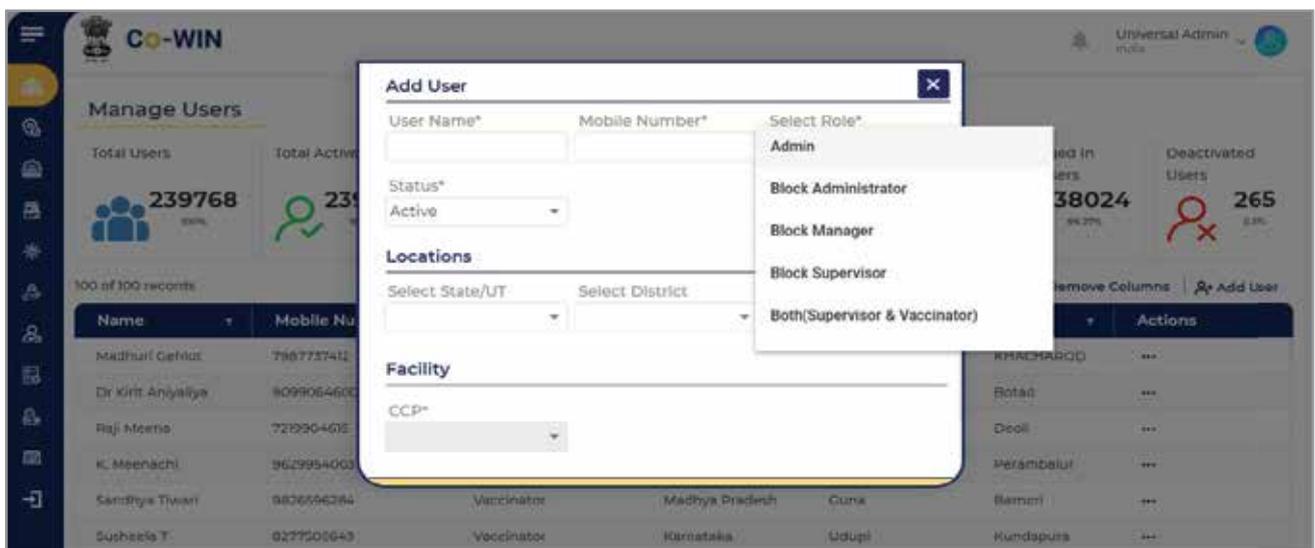


Figure 2a – Creation of New Admin and Users using Add user

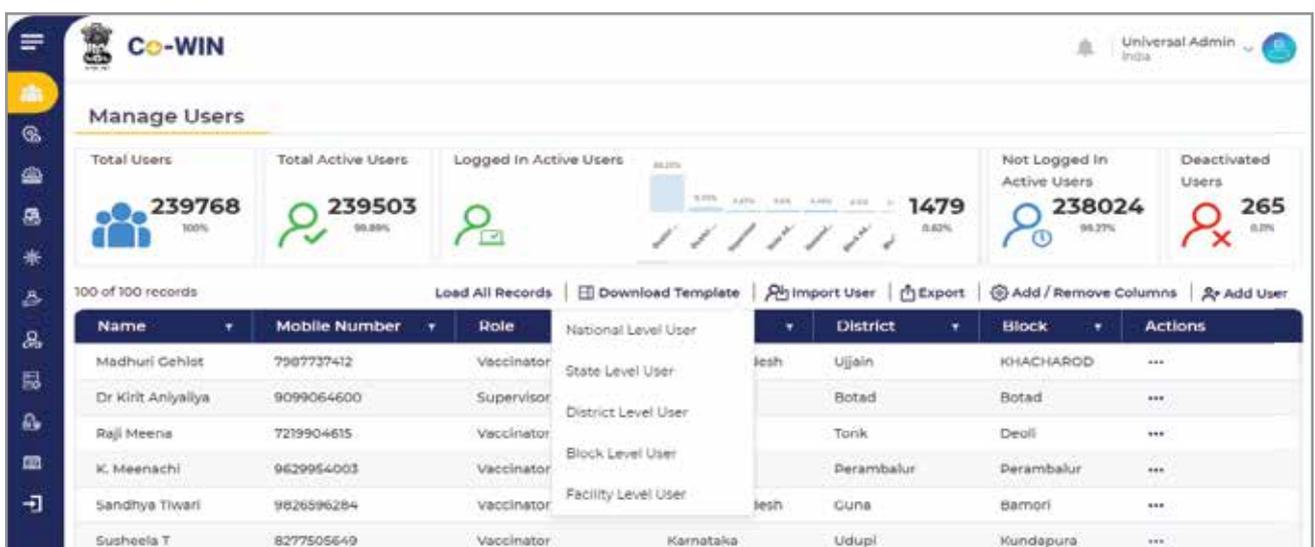


Figure 2b – Creation of New Admin and users using Bulk Upload

## 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).

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

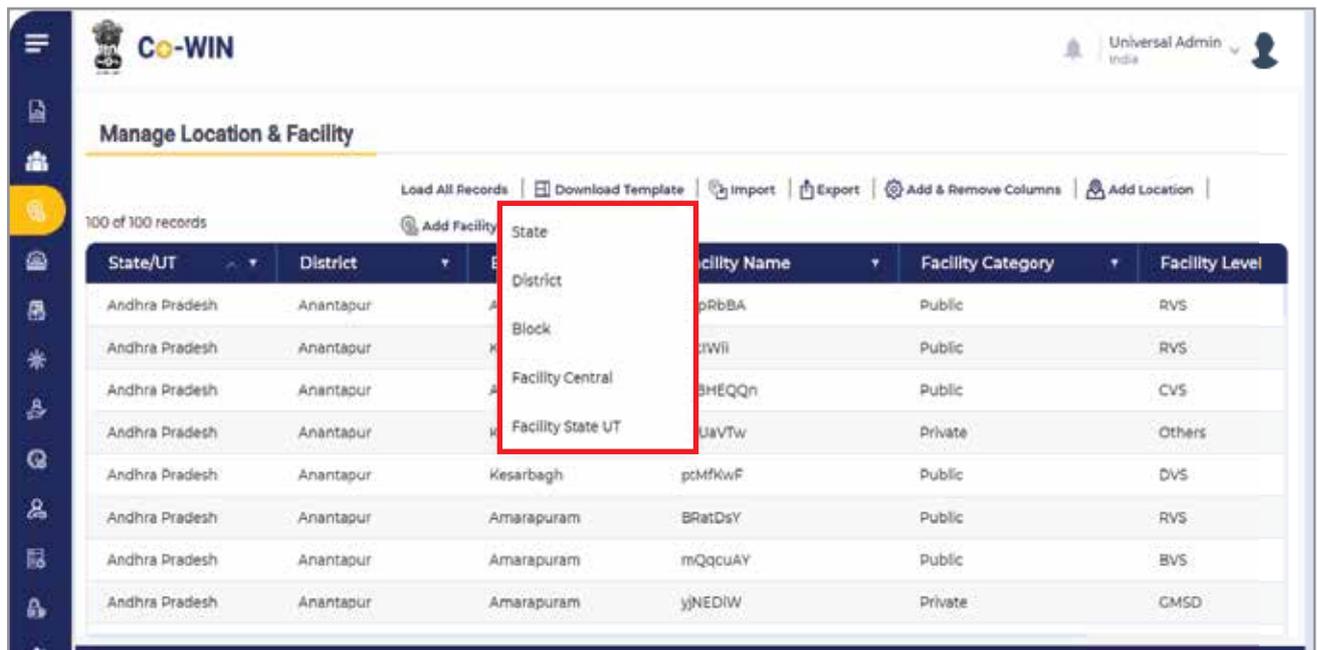


Figure 3b – Creation of Facilities/Planning Units using Bulk Upload

### 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:

- 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).
- 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:

- 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).
- 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

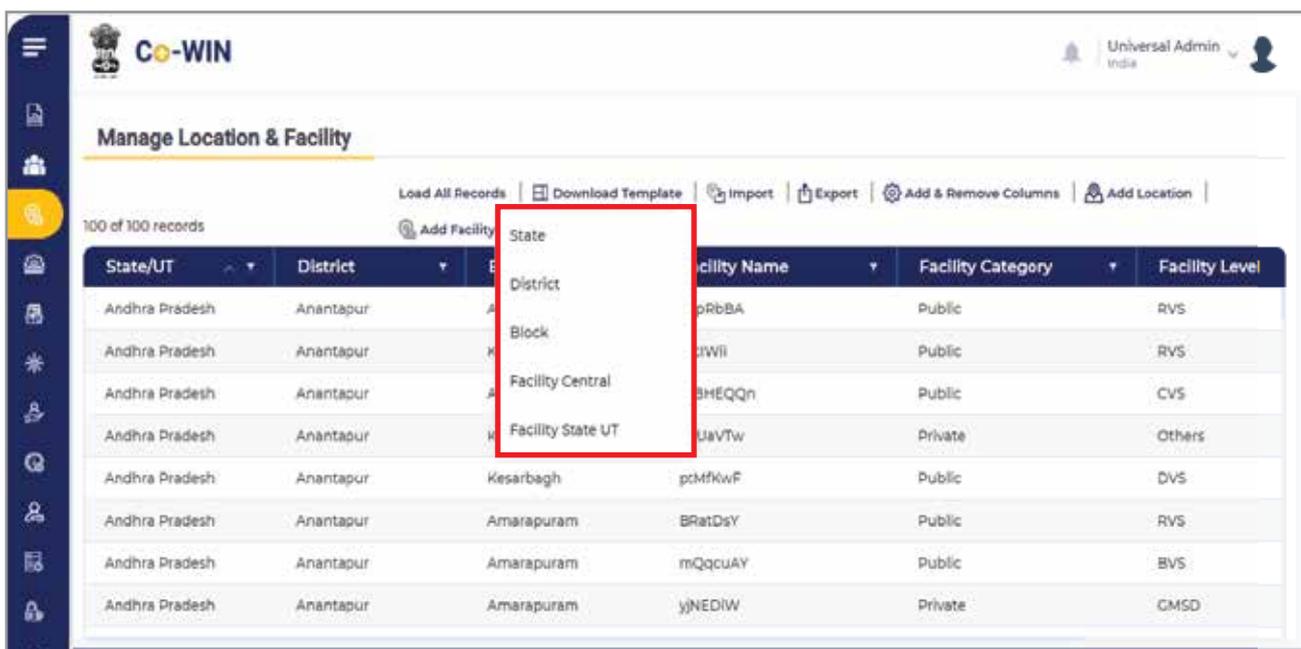


Figure 4b – Creation of Session Sites using bulk upload

## 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
- Manufacturer Details;
  - Batch Number;
  - Doses per vial; and
  - 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)

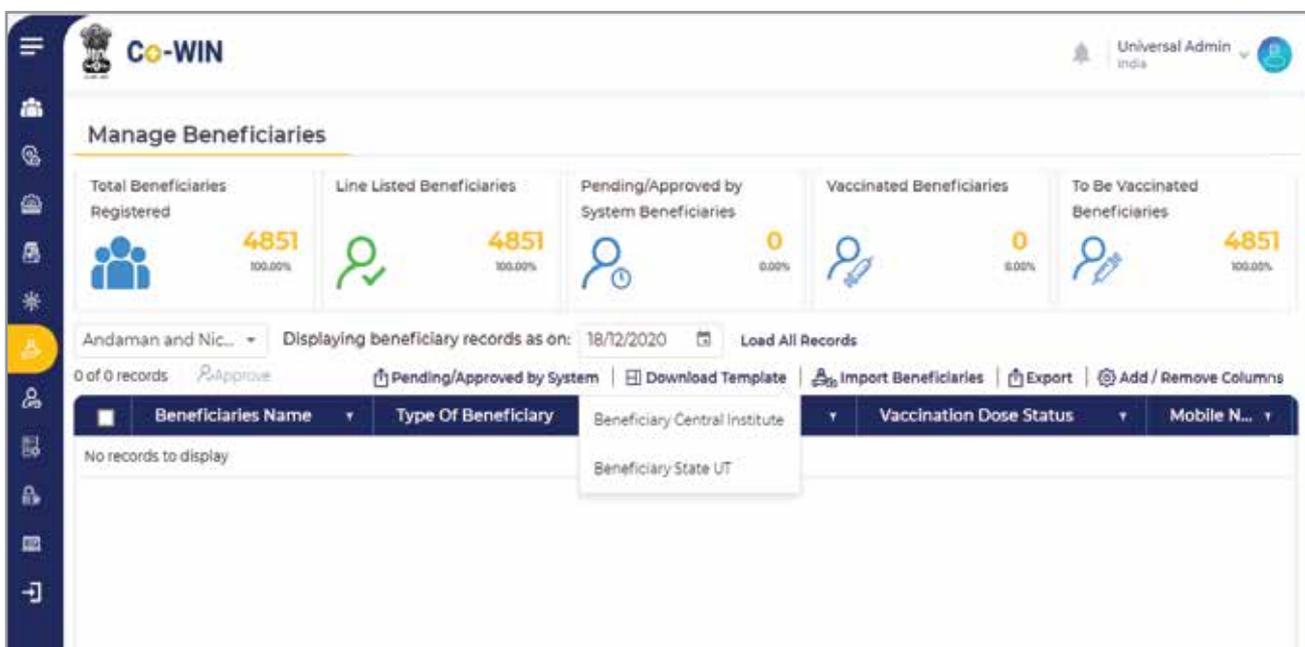


Figure 6a – Downloading template for bulk uploading of beneficiaries

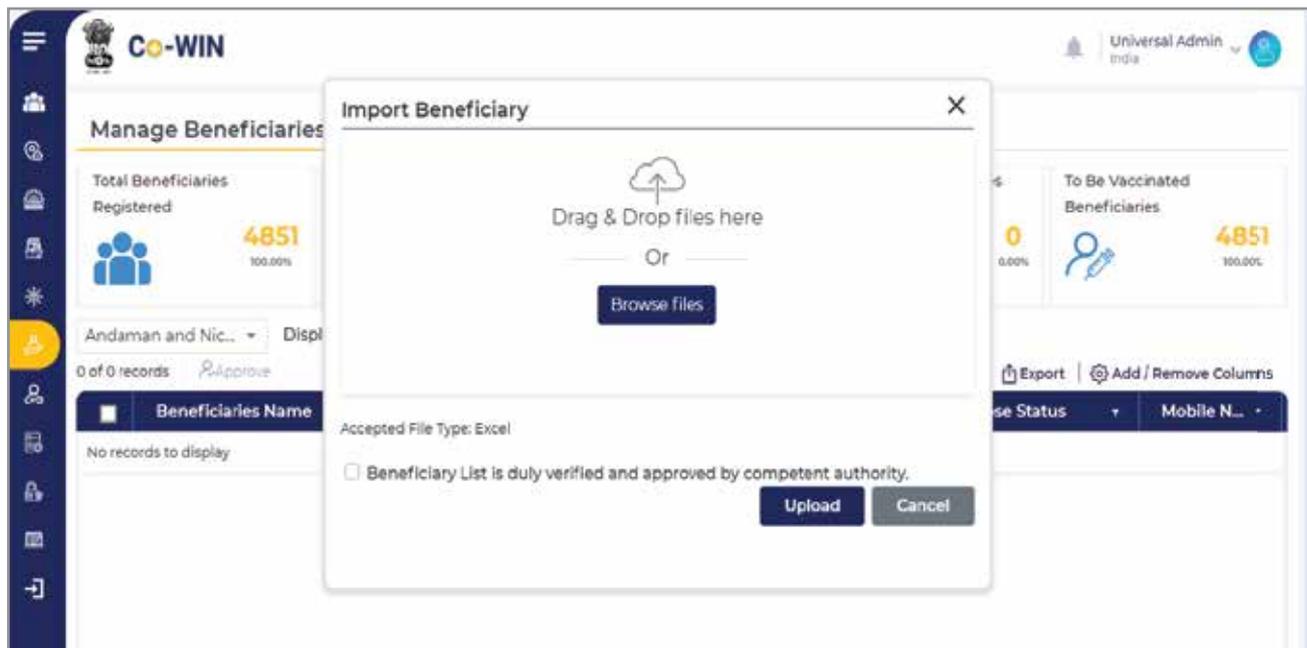


Figure 6b – Uploading of filled template

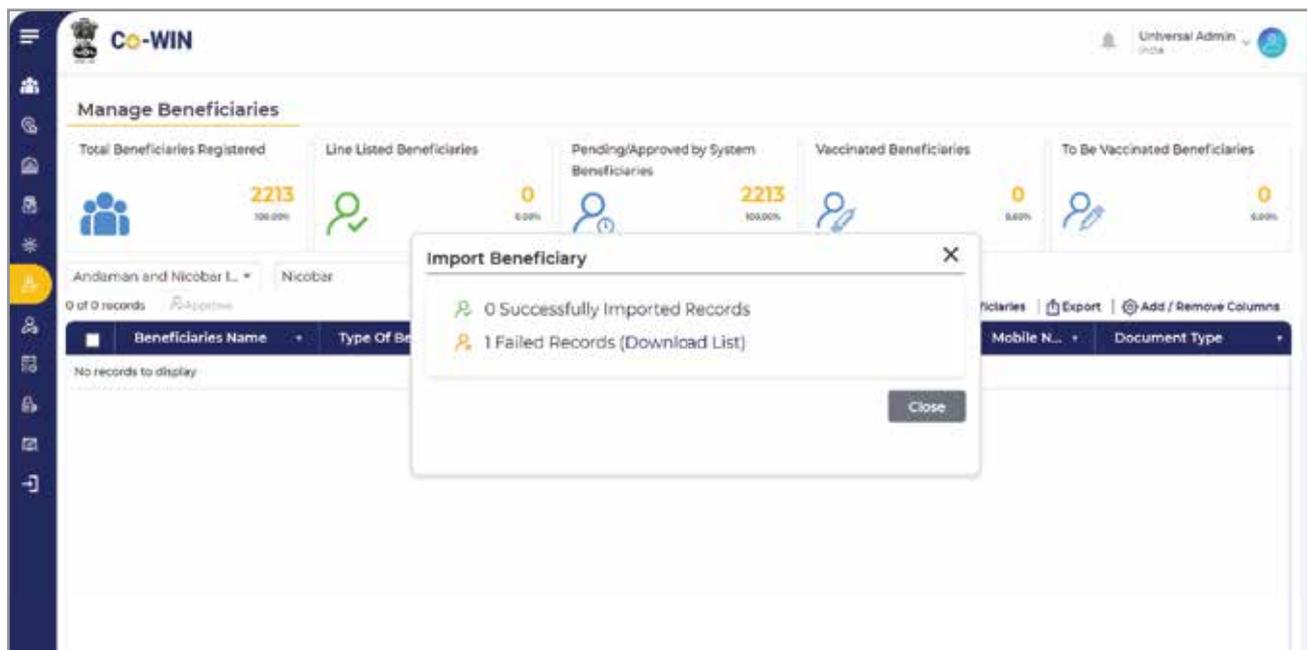


Figure 6c – Message regarding successful and failed records

## 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.

The screenshot displays the 'Register Beneficiary' interface on the Co-WIN platform. At the top, the Co-WIN logo and the time 13:58 are visible. The main heading is 'Register Beneficiary'. Below it, there's a 'Select ID Proof From:' section with a radio button for 'Application' selected. A red error message 'Select Photo ID Proof\*' is shown. The 'Basic Details' section includes fields for Name, Gender, Month Of Birth, and Date Of Birth. The 'Permanent Address' section has a Street field. A modal window is overlaid on the form, titled 'Select Photo ID Proof\*', with radio buttons for: Aadhaar Card, Driving License, Health Insurance Smart Car..., MNREGA Job Card, Official Identity cards issue..., and PAN Card. At the bottom of the modal are 'CANCEL' and 'OK' buttons.

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)

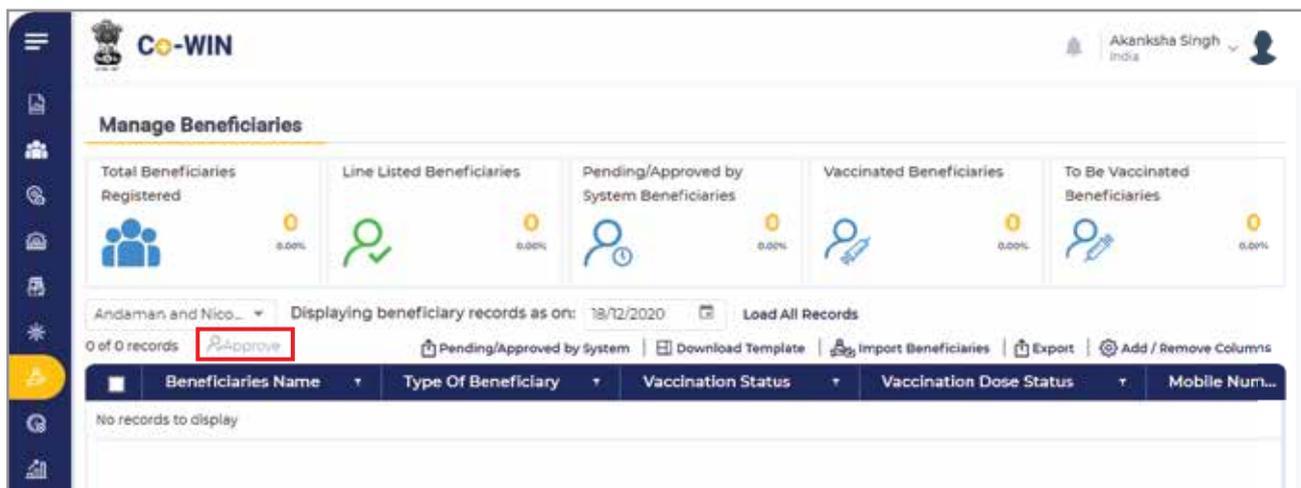


Figure 8a – Approving registered beneficiaries for line listing and session allocation

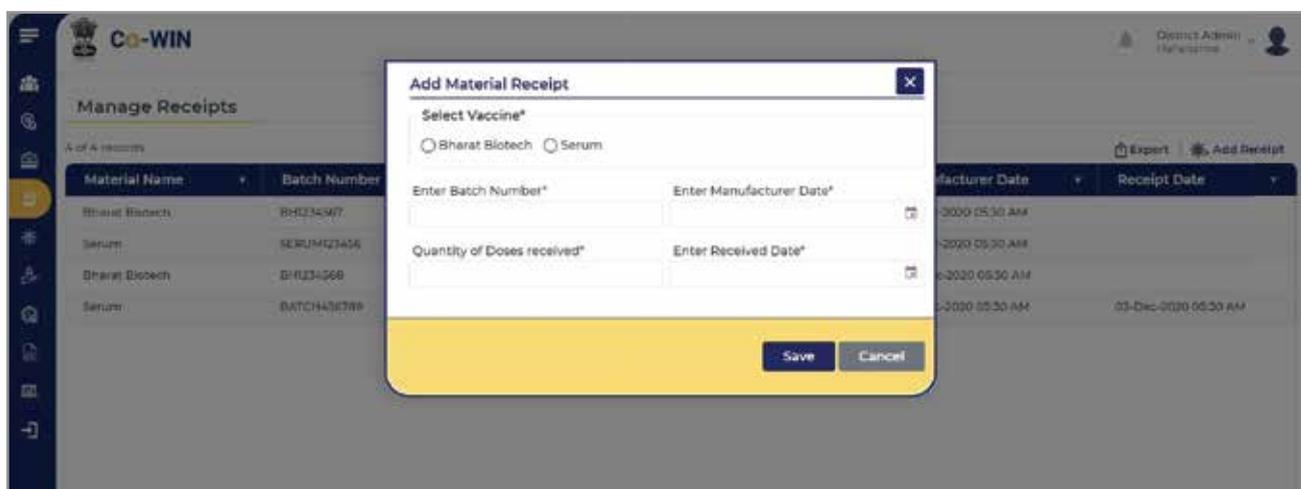


Figure 8b – Receipt of Vaccines by District Admin

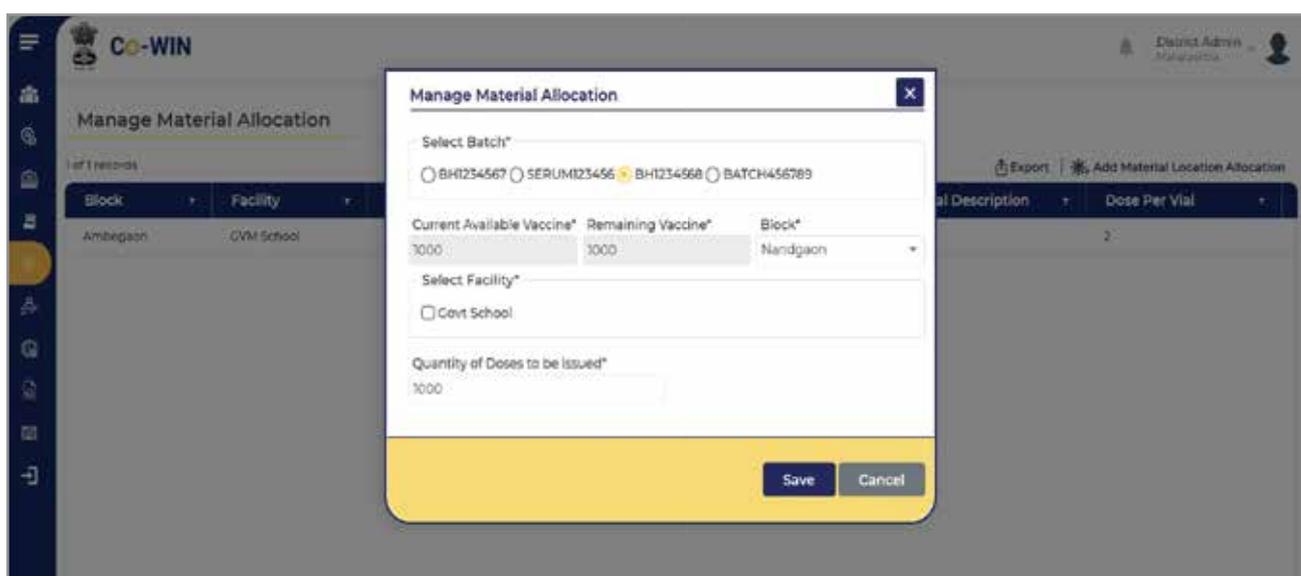


Figure 8c – Allocating vaccines to facilities

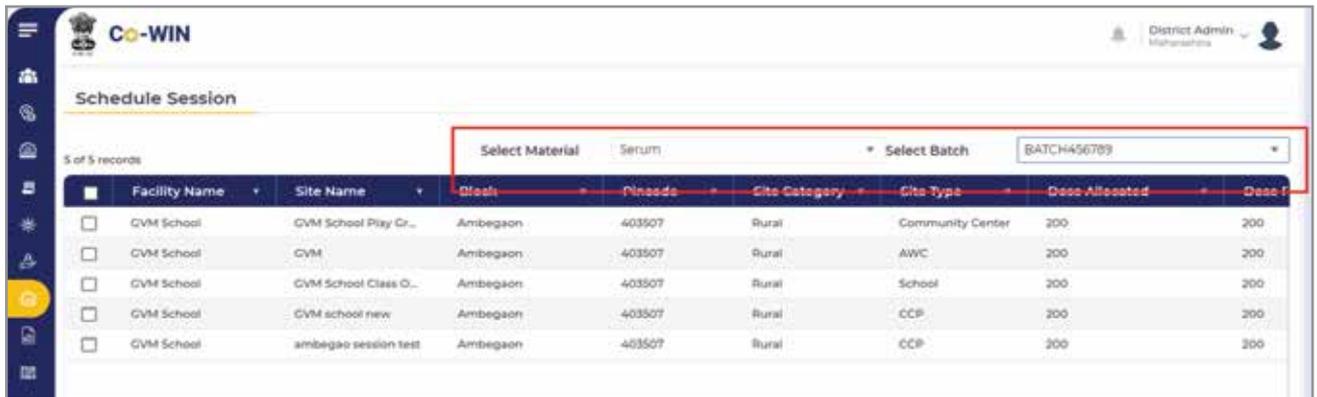


Figure 8d – Selecting session site for allocation based on vaccine type and batch number

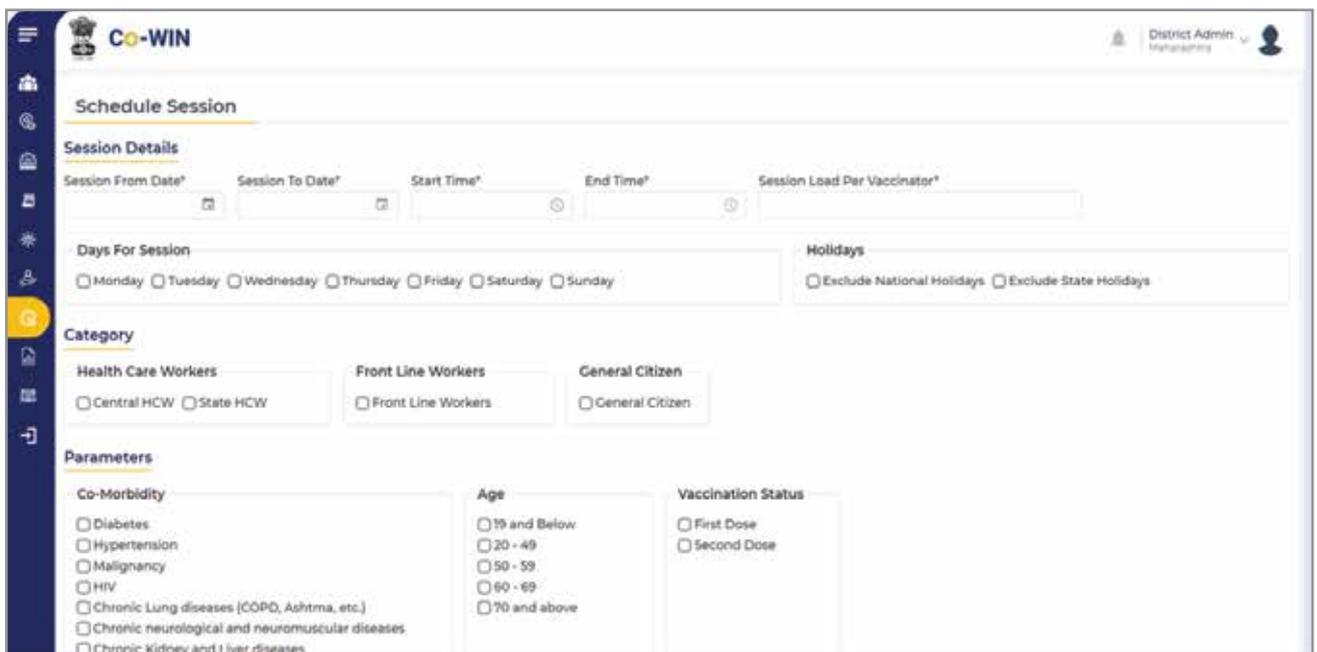


Figure 8e – Scheduling of Session

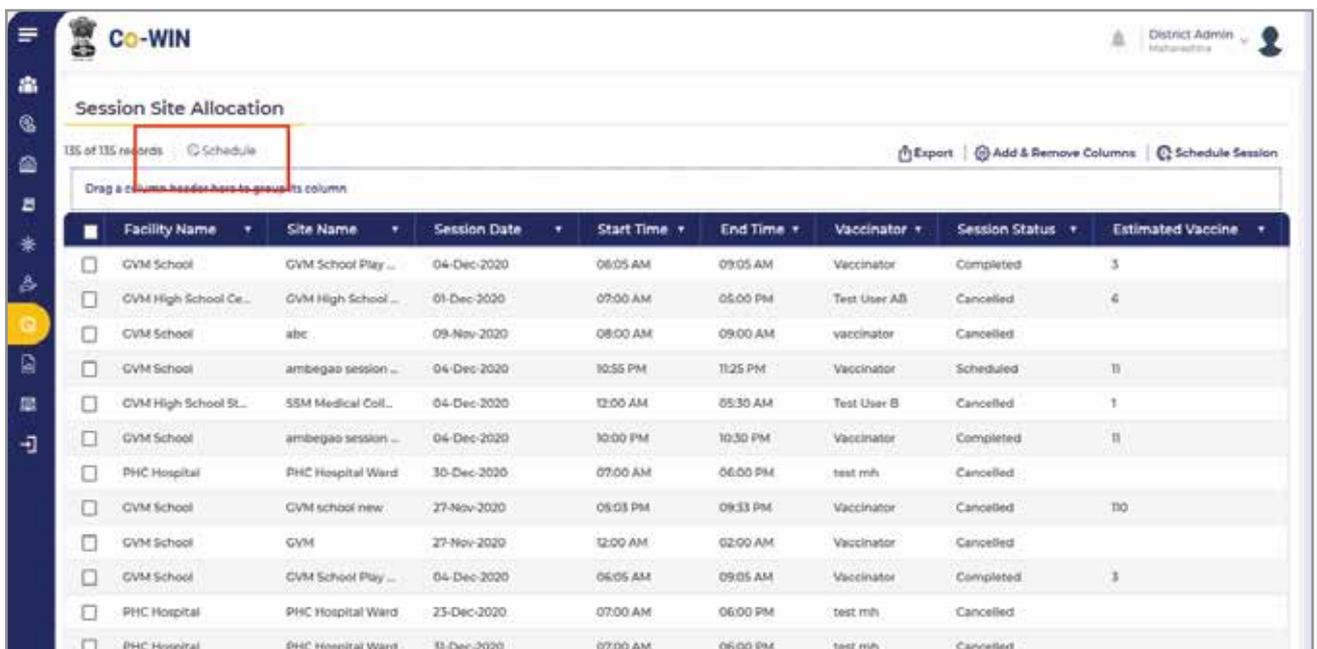


Figure 8f – Scheduling Draft sessions

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.

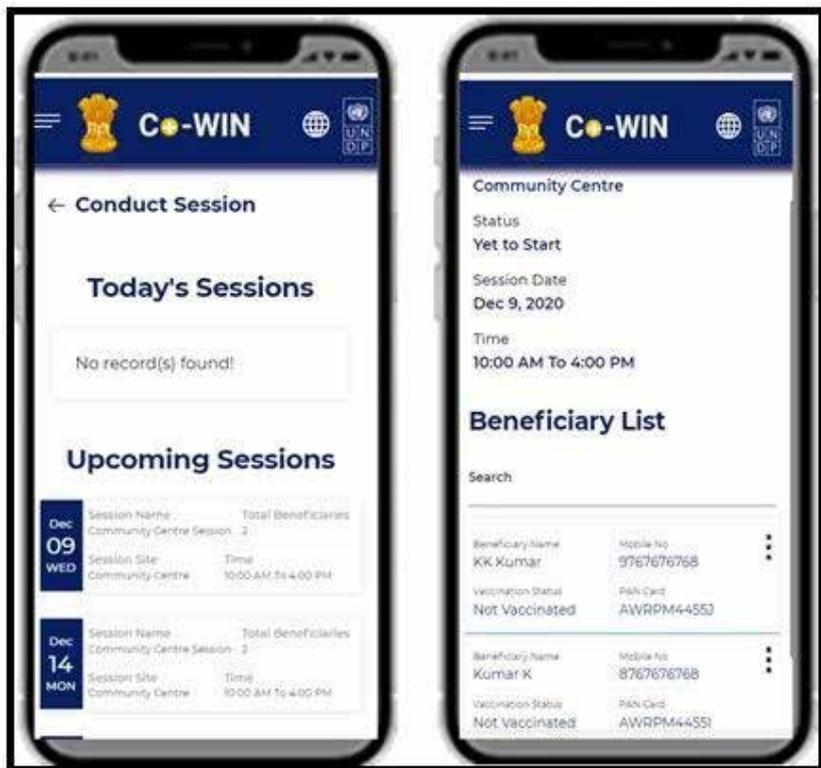


Figure 9a – Vaccination Officer's module – List of sessions and beneficiaries

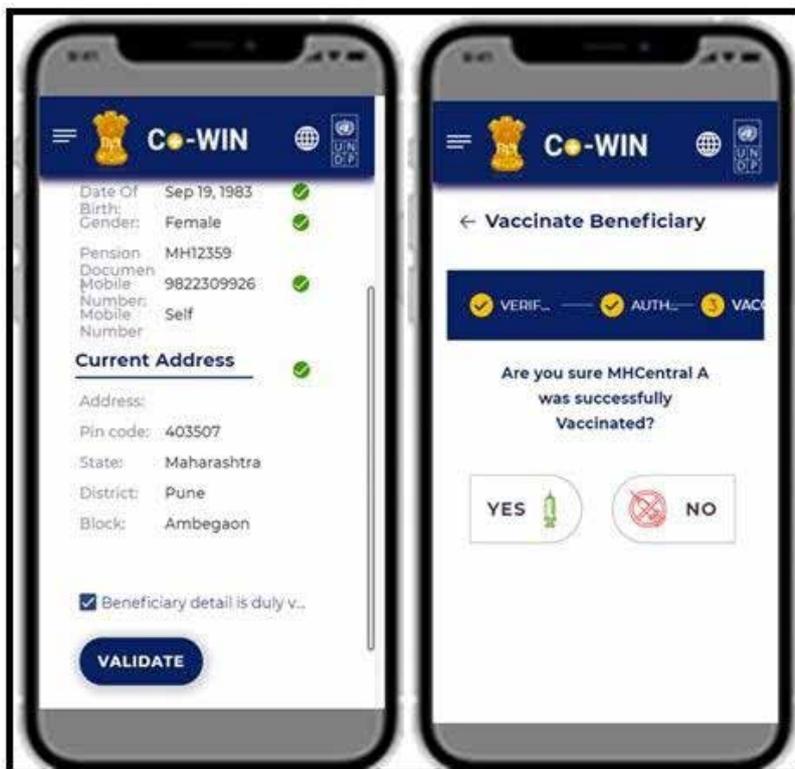


Figure 9b – Vaccination Officer's Module – Verifying and Confirmation of Vaccination



## 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. The overall effort will be guided by the National COVID-19 Vaccination Policy at annexure 9.

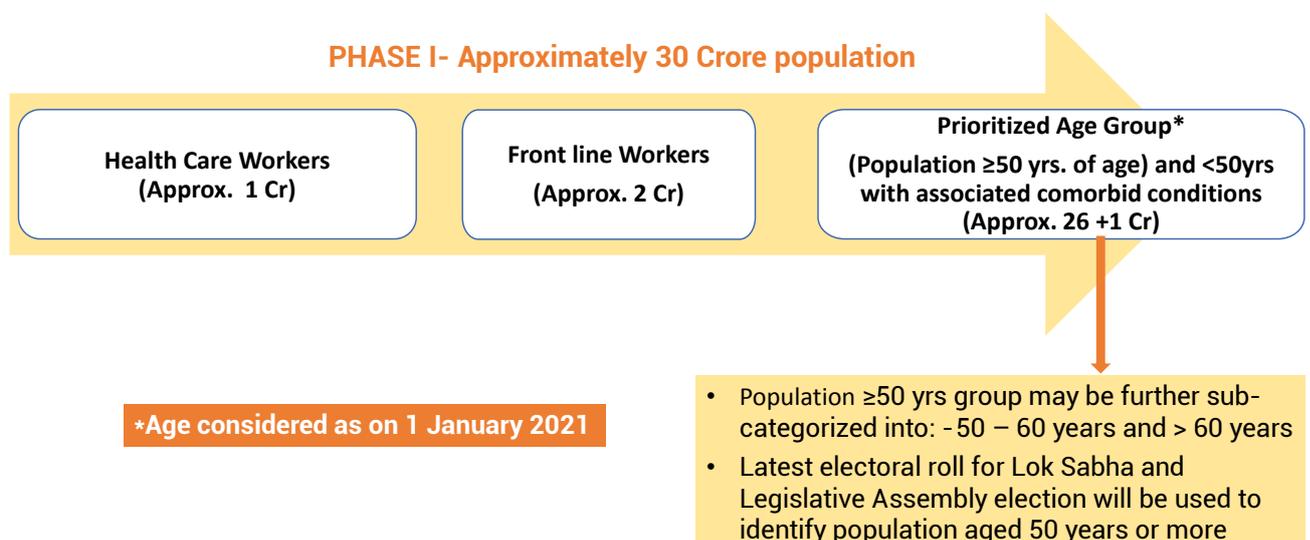
### 7.1 PRIORITIZATION OF BENEFICIARIES FOR COVID-19 VACCINE

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:

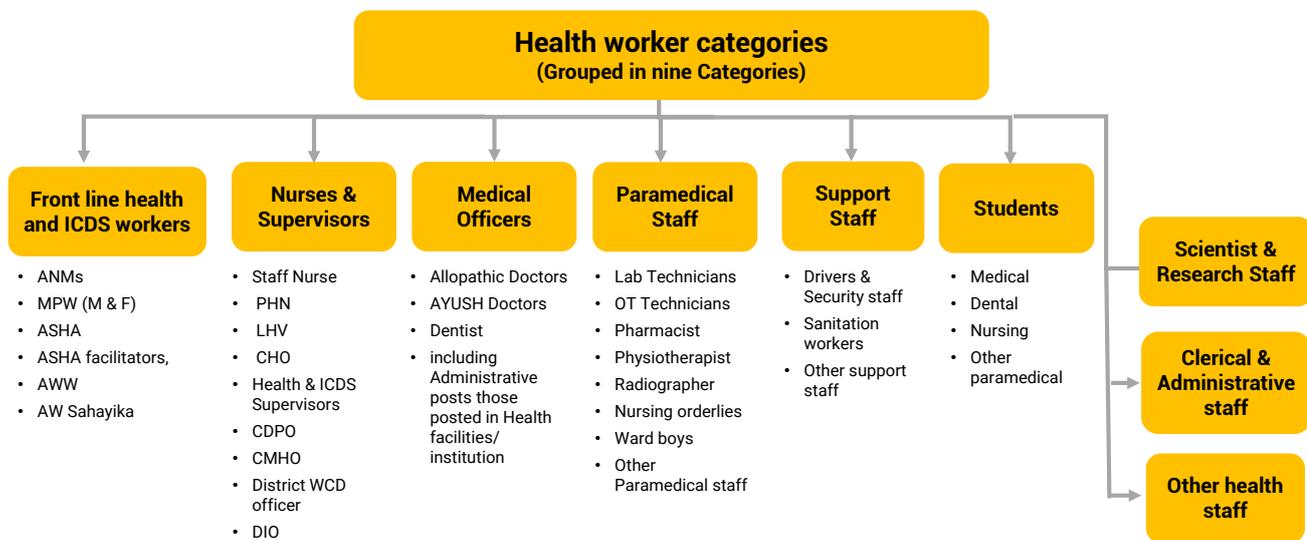


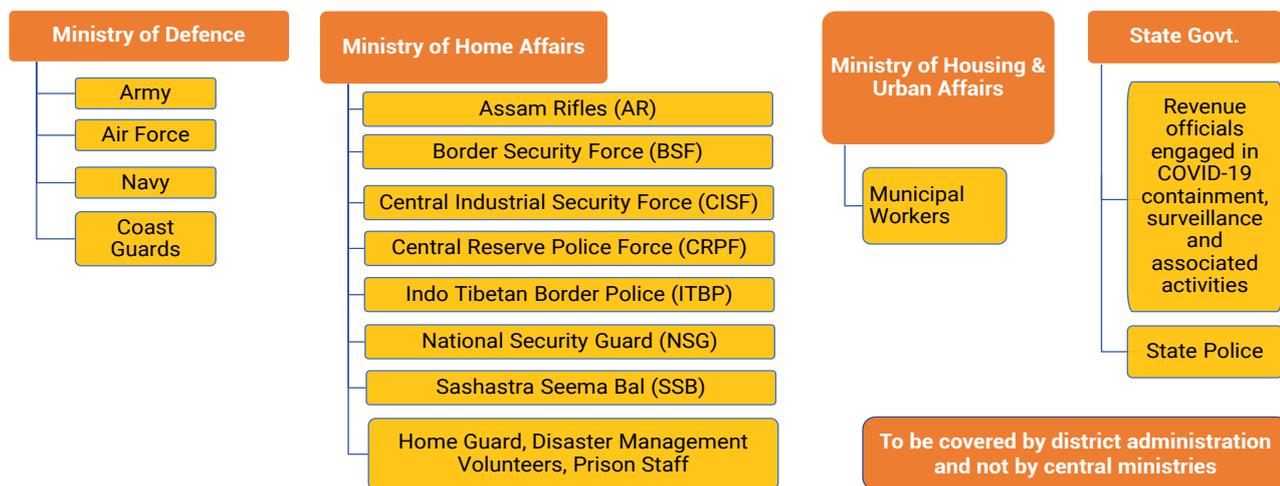
Figure 7.2: Health Care Worker categories for COVID-19 vaccination

## 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:

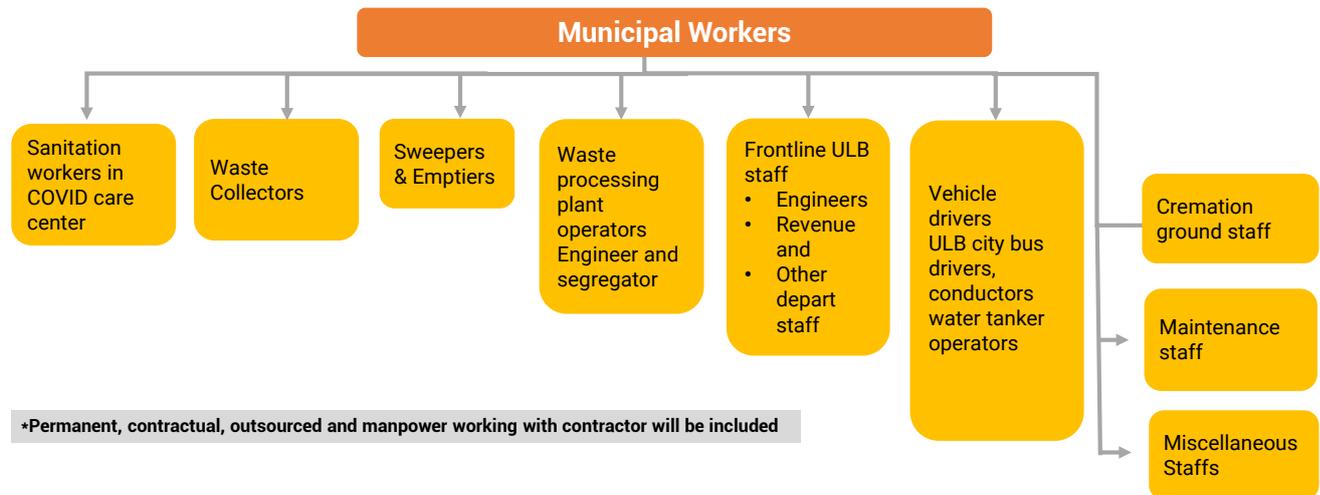
### FIGURE 7.3: FRONTLINE WORKERS CATEGORIES

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.

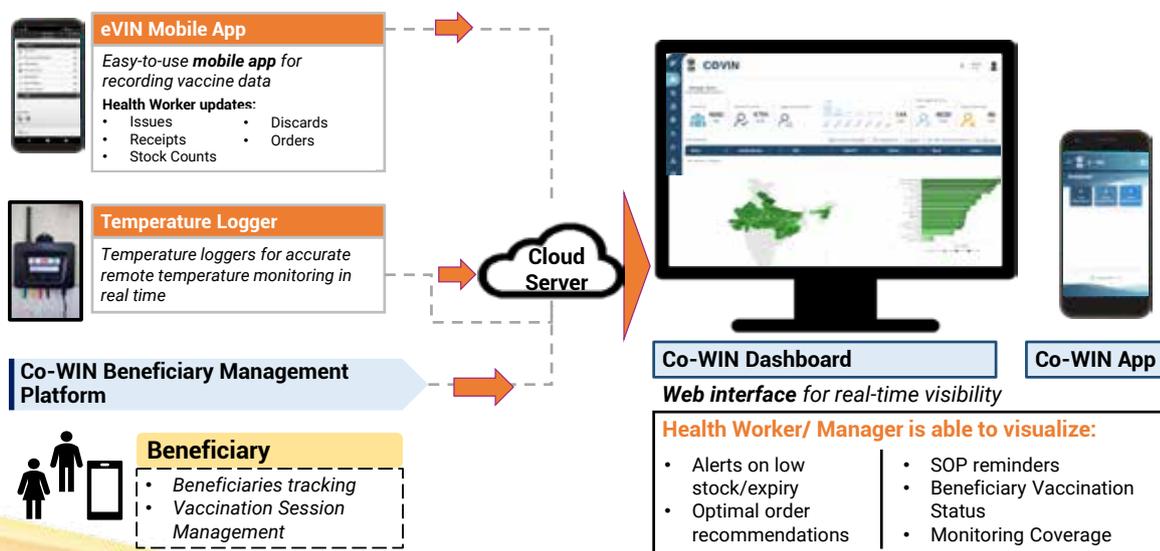
**4. Geographical Prioritization:** States/ UTs will also have the generic flexibility to do priority phasing of the roll-out for the identified priority groups (as decided by the NEGVC) in identified geographical areas where the COVID-19 infection prevalence is high.

## 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.

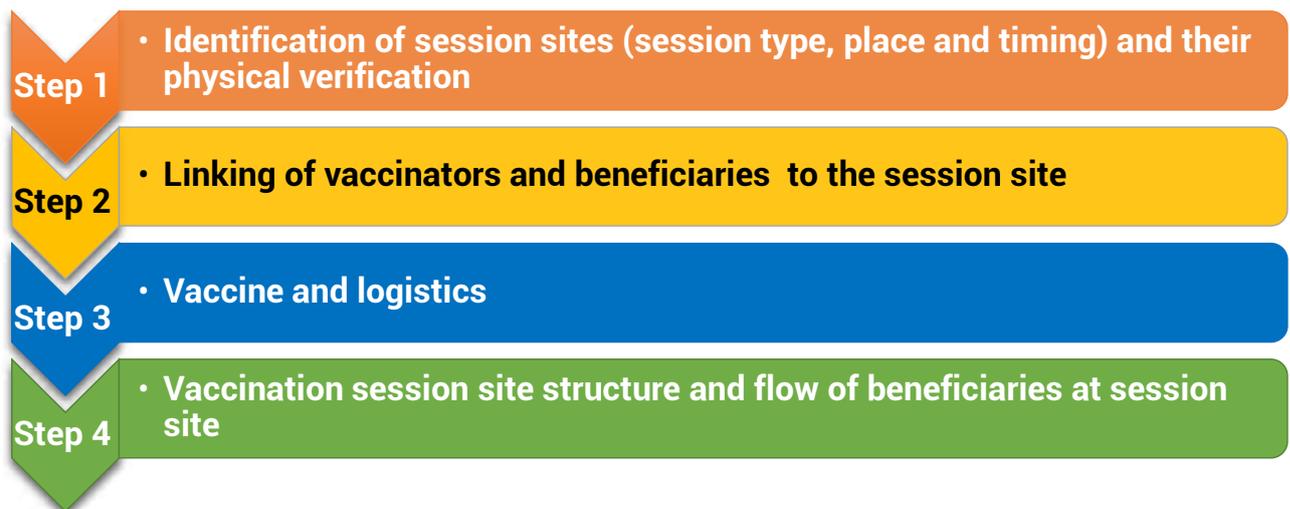
**Staggering beneficiaries will help to avoid over crowding at vaccination session site**

**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.



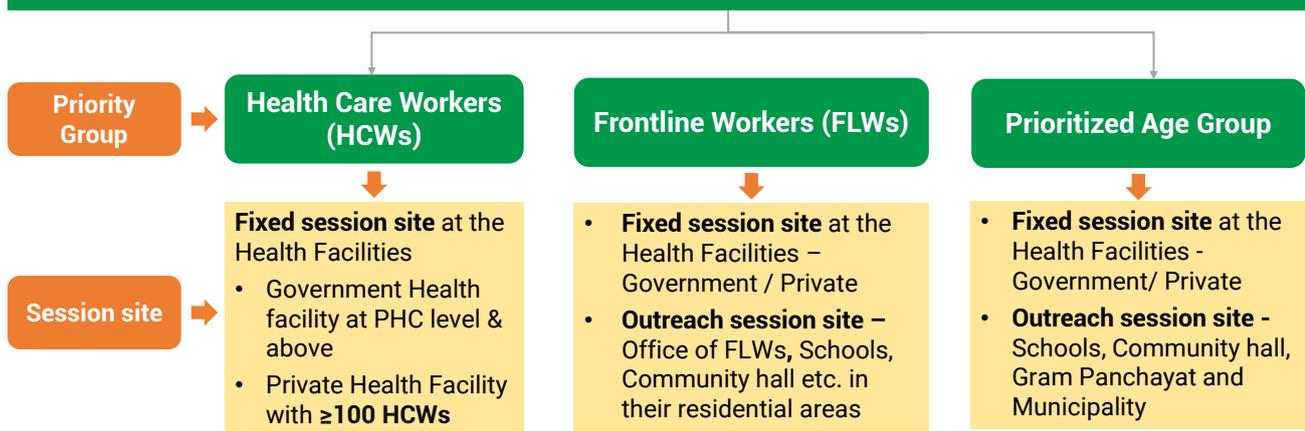
*Figure 7.6: Steps of session site planning and management*



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:

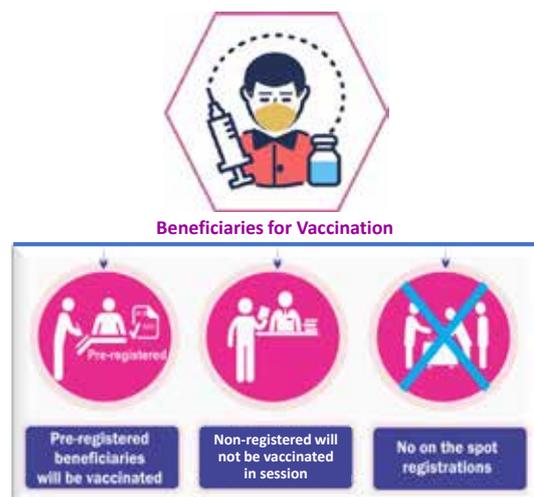




Figure.7.8: Key considerations for selection of session site

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.



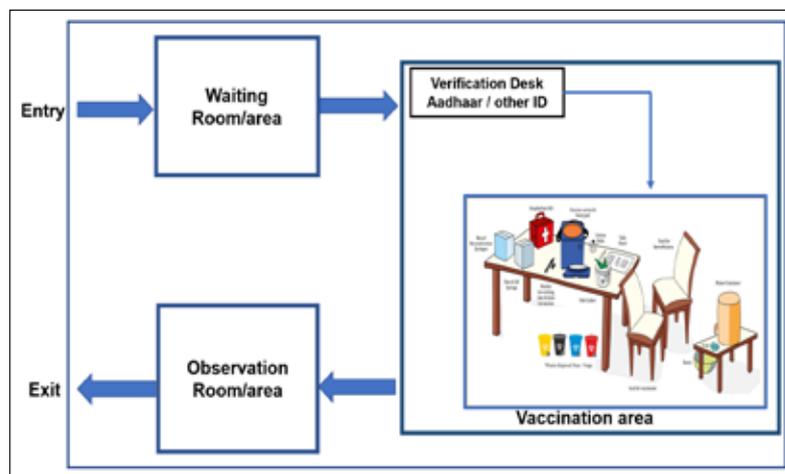
Figure.7.9: Physical distancing at session site

- 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**

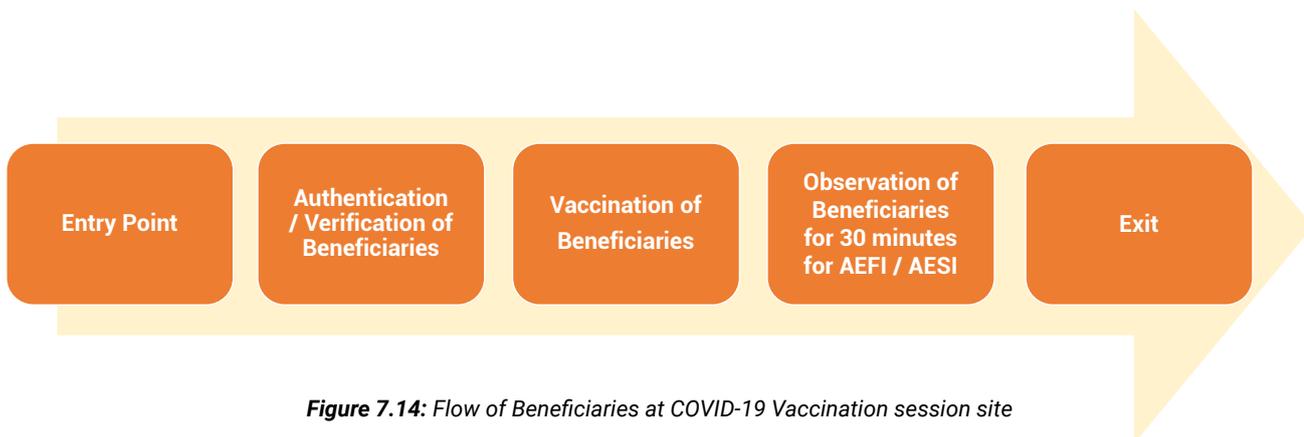
- Beneficiaries wait for 30 minutes post vaccination
- Seating arrangement ensuring physical distancing norms
- IEC materials on COVID appropriate behaviour may be displayed
- Drinking water should be available



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.

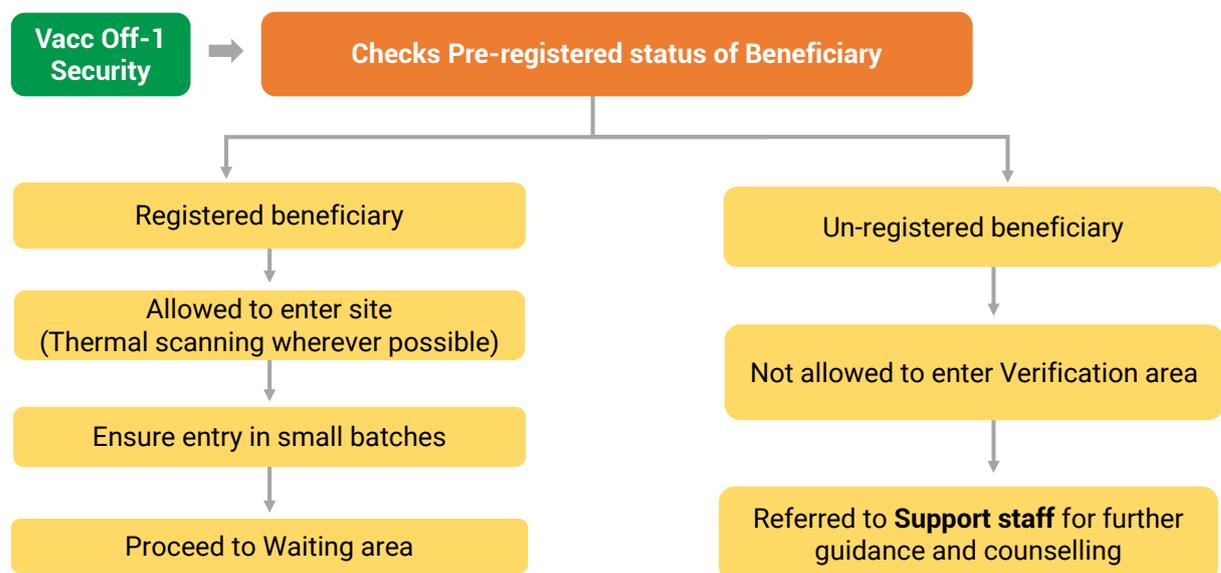
For three to five vaccination team a supervisor will be deployed for closed supervision at session site. Allocation of teams to supervisor will depend upon distancing of vaccination session and travel time. Supervisors working in hilly and difficult to reach areas may have less teams whereas those working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

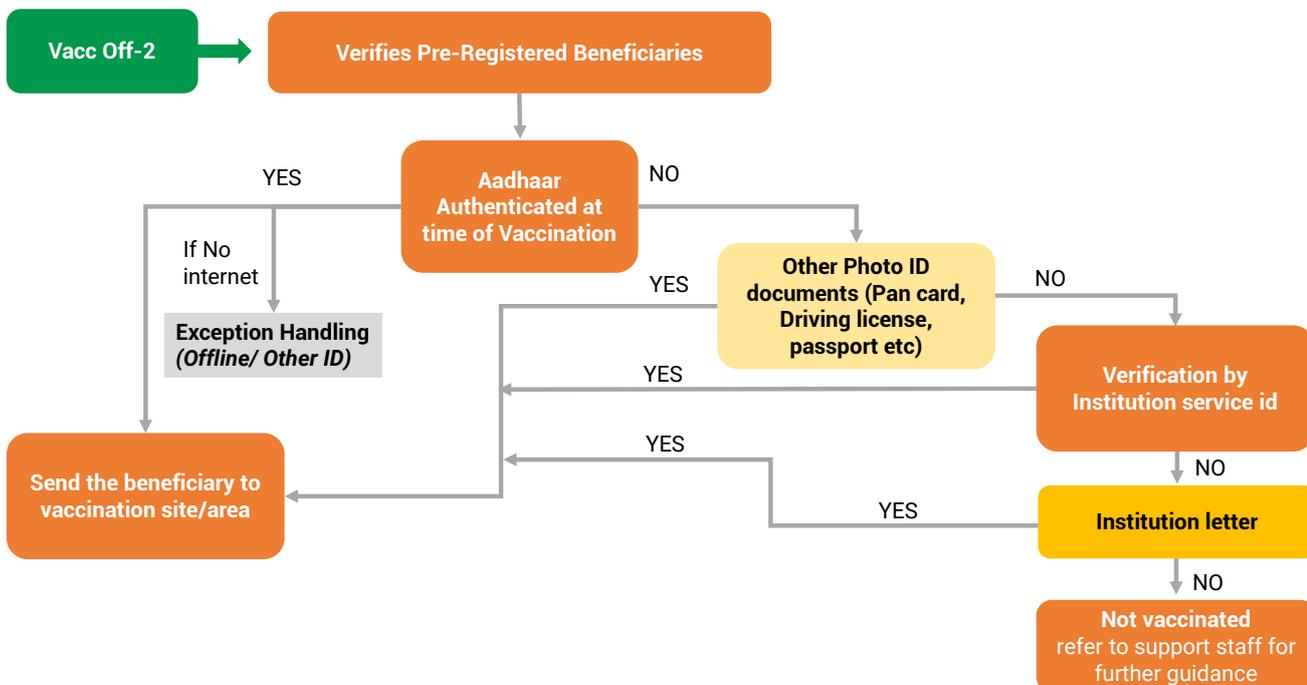
**FIGURE 7.15: ROLE OF VACCINATION OFFICER-1 AT ENTRY POINT OF SESSION SITE**



## 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.

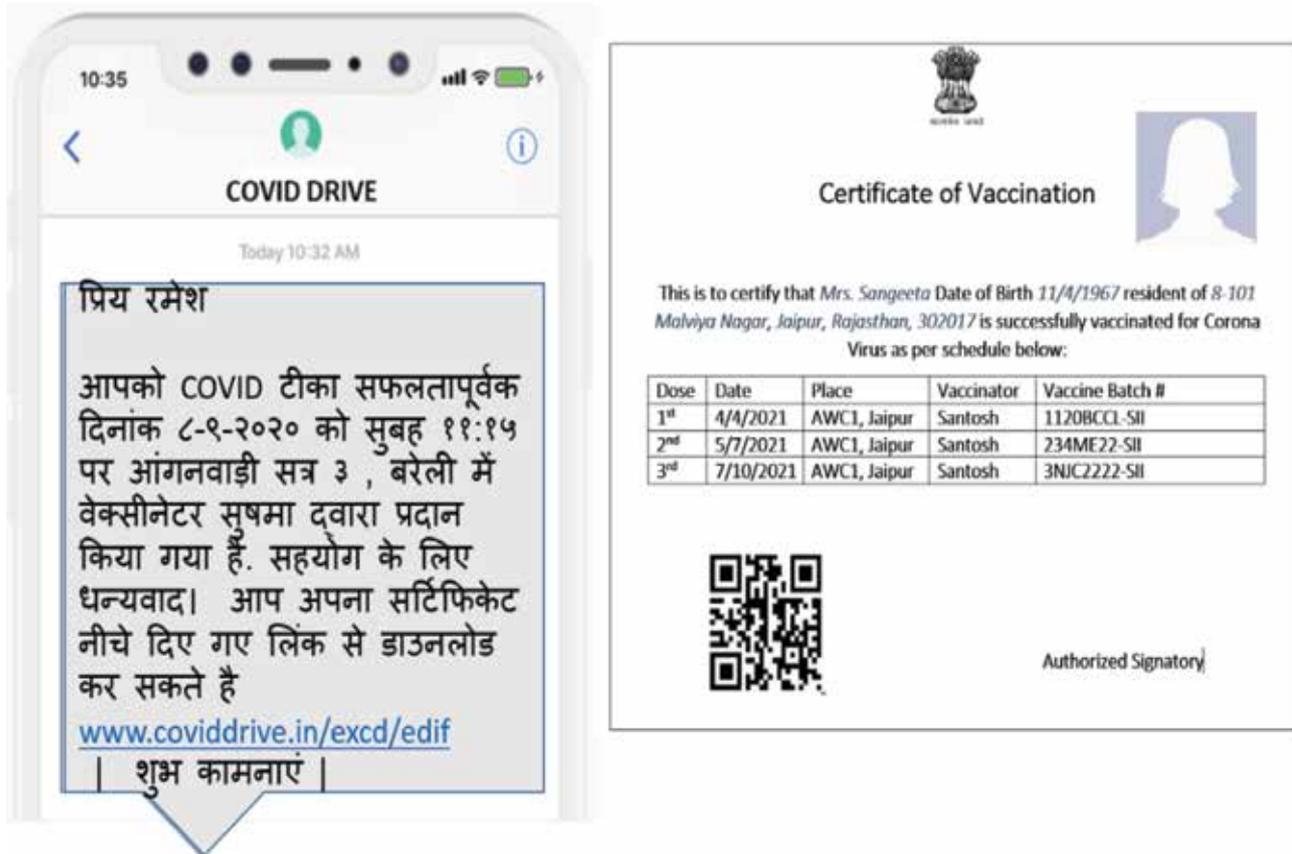


Figure 7.17: Vaccination completion SMS and certificate template

## 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, APHI: 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.



## 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. 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

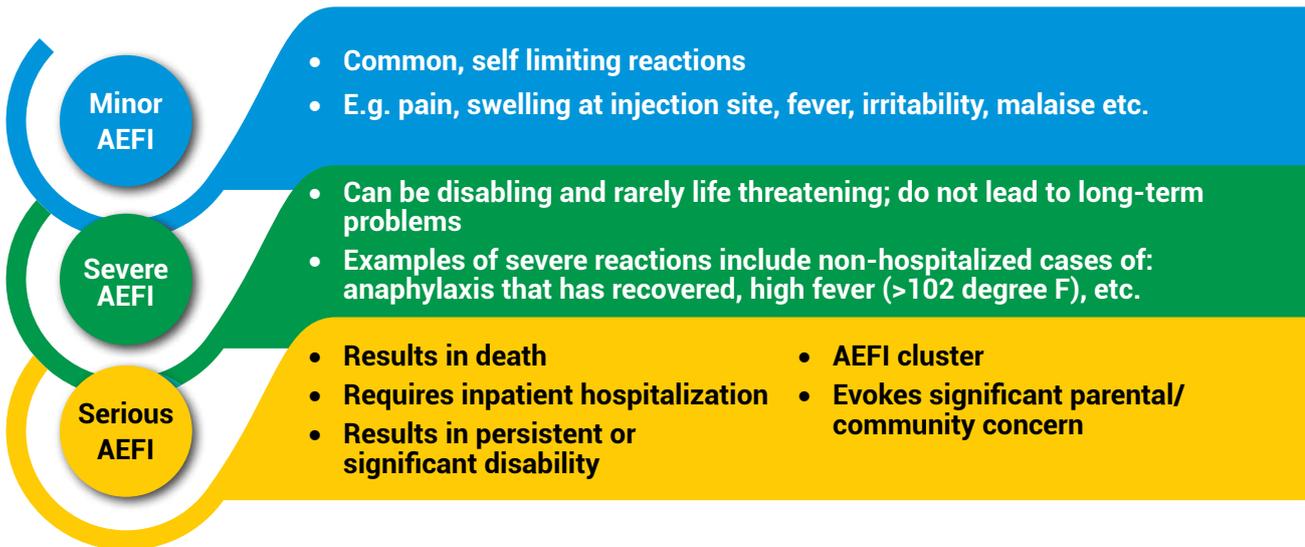
The overall goal of AEFI surveillance is to ensure that vaccines are administered safely to the recipients and the trust in vaccines is sustained. The specific objectives of AEFI surveillance are to:

- 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).

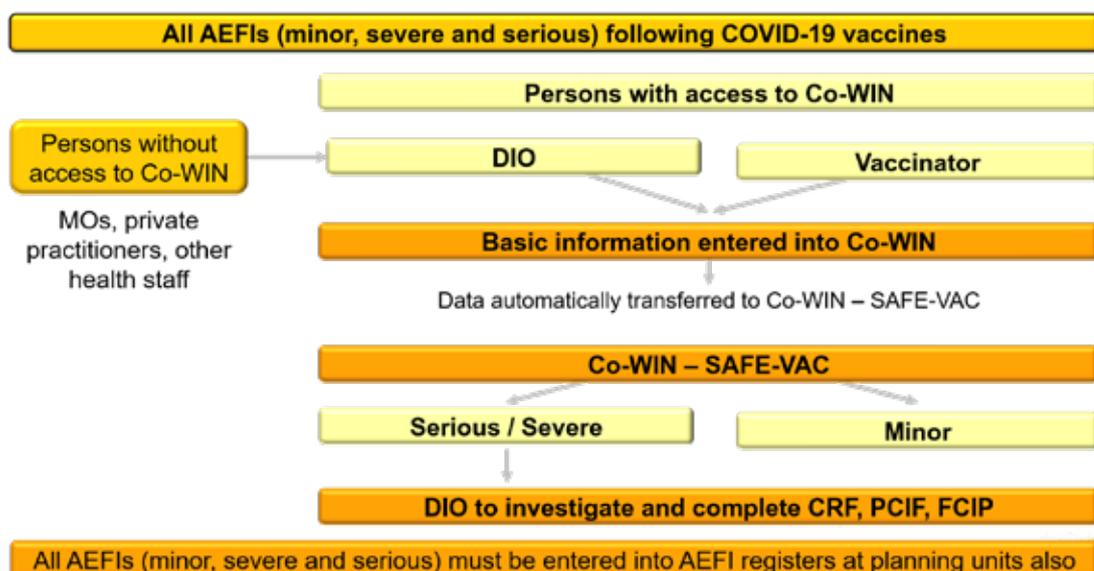
All serious and severe AEFIs should be treated as a medical emergency and priority should be given to its management followed by its reporting and investigation on the standardized AEFI formats. All serious and severe AEFIs should be documented on a CASE REPORTING FORM (CRF).

## 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.

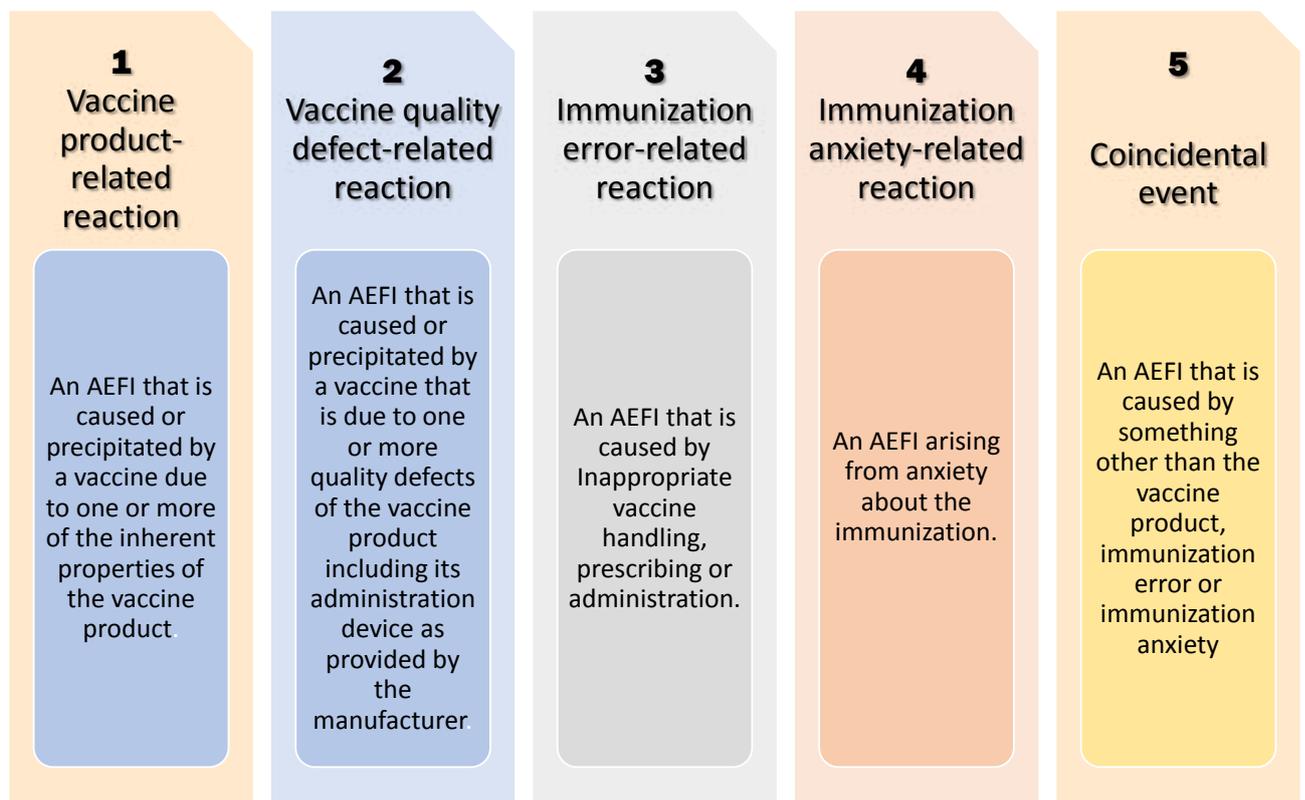
## 10.7 TESTING OF VACCINE SAMPLES

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

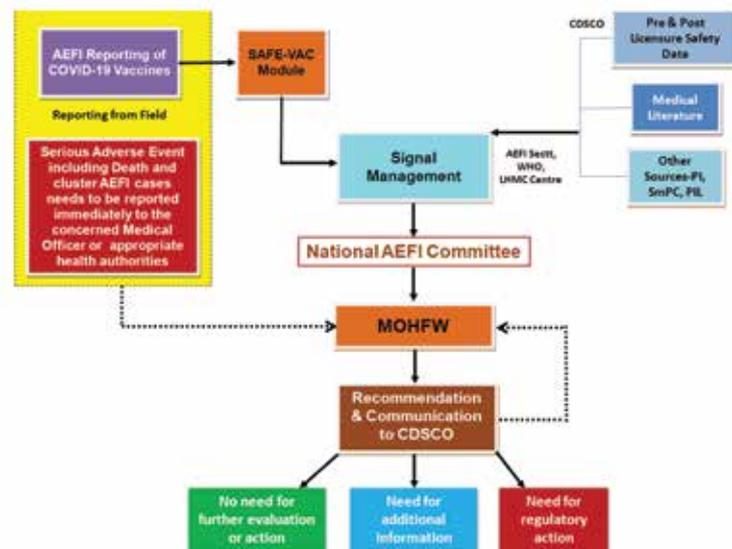
When a new vaccine is approved for use, there is a theoretical possibility of occurrence of some events based on available data for existing and new vaccines. Such Adverse Events of Special Interest (AESI) should be monitored

- 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 is 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 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 being followed. State and districts will deploy supervisors specially for high risk / poor performing districts and blocks.

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 (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:
<b>Time of visit →</b>			
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	M	F	T	M	F	T	M	F	T	M	F	T	M	F	T							
1								Target		1st																																
										2nd																																
2								Achievement		1st																																
										2nd																																
3								Target		1st																																
										2nd																																
4								Target		1st																																
										2nd																																
5								Target		1st																																
										2nd																																
Total								Target		1st		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		0	
								2nd		0	0	0	0		0		0		0		0		0		0		0		0		0		0		0		0		0		0	

Planning Unit Reporting Format: COVID-19 Vaccination Campaign 20__																					
COVID-19 Vaccination Campaign																					
Name of State: _____																					
Date: _____																					
Name of District: _____																					
Name of Block / Planning Unit: _____																					
S. No.	Name of Health Facility	Sessions Planned	Sessions Held	Target / Achievement	Dose	Beneficiaries															
						Health Care Providers						Front Line Workers			Elderly Population and comorbidity			Total Beneficiaries			
						Public			Private			Total			M	F	T	M	F	T	M
1				Target	1st	M	F	T	M	F	T	M	F	T	M	F	T				
				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
				Achievement	2nd	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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

S. No	Name of Block / PU	Sessions Planned	Sessions Held	Target / Achievement	Dose	Name of District:														Date:			No. of Vials Issued	No. of Vials utilized	No. of Vials balanced
						Beneficiaries														Total Beneficiaries					
						Health Care Providers						Front Line Workers				Elderly Population and comorbidity				Total Beneficiaries					
						Public		Private		Total		M		F		T		M		F		T			
1				Target	1st	M	F	T	M	F	T	M	F	T	M	F	T	M	F	T					
				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		
	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	
4	If Yes, Order in place for renting and availability of tent	Yes / No	
	Premises cleanliness	Yes / No	
5	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	Yes / No	
	Logistics availability at session site:		
	At least one table for vaccination room	Yes / No	
9	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>
	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	
10	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	



# ANNEXURE 7: READINESS ASSESSMENT CHECKLISTS

## 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
9	Y / N /Planned (mention date) / Yet to be planned	Sensitization of district level administrators completed?
10	Y / N /Planned (mention date) / Yet to be planned	State workshop for COVID-19 vaccine introduction completed?
11	Y / N /Planned (mention date) / Yet to be planned	State media workshop completed?
12	Y / N /Planned (mention date) / Yet to be planned	Orientation for Professional bodies (IMA, IAPSM, Med College) completed?
13	Y / N	State control room team tracking the Health Care Workers data upload/ FLW database reflection on Co-WIN software
14		Number of districts completed HCW database upload on CoWIN Software
15		Number of districts where FLW database is reflected in CoWIN Software
16	Y / N	Allocation of vaccine to districts initiated in CoWIN Software
17	Y / N	State control room team providing feedback to districts on HCWs database upload
18	Y / N	State HQ has sufficient cold chain space to store COVID-19 vaccine in addition to UIP vaccine stock
19	Y / N	STF reviewed logistics planning by districts?
19	Y / N	Logistics procurement finalised between state and district?

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	Y / N	If Yes, mention numbers:
	Y / N	"Vaccinators required (numbers): Vacc Officer-1 (Security person) required (numbers): Vacc Officer-2 (Verifiers) required (numbers): Officer 3 & 4 (Mobilisers) required (numbers):"
10	Y / N	Has the district team estimated the human resources needed to conduct the vaccination in the session sites and the required number of days
11	Y / N	District identified sufficient vaccinators for vaccination?
12	Y / N	District identified sufficient team members (VO 1-4) required
13	Y / N	District Workshop for COVID-19 vaccine introduction conducted
14	Y / N / Partial	Orientation of Vaccinators (as per Co-WIN) conducted % of Vaccinators oriented
15	Y / N / Partial	Orientation of other team members (vaccination officer 1-4) conducted % of team members (vaccination officer 1-4) oriented
16	Y / N / Partial	Orientation of cold chain handlers conducted
17		% of Cold Chain handlers oriented
18	Y / N / Partial	Orientation for members of Professional bodies (like IMA, IAPSM, Med College)
19	Y / N ? Planned	District Media Workshop conducted
20	Y / N / Partial	HCWs database upload completed
21	Y / N / Partial	FLWs database upload reflected
22	Y / N	Session allocation through Co-WIN started
23	started/ planned	Status of vaccine allocation for session using Co-WIN
24	Y / N	DTF reviewed microplans with details of team members by blocks (COVID-19 Vaccination Planning Template)?

Activities	Achieved (Y/N)	Actions suggested during the assessment
Logistics	Y / N	
	Y / N / Partial	Mention gaps
AEFI Surveillance	Y / N	
	Y / N	Date of Last AEFI meeting Check the list
Communication	Y / N	
	Y / N / Expected	If Expected, mention date
Block Progress Assessment		
Readiness assessment findings appraised to District Magistrate / District Collector		Date Assessment Findings shared
Preparedness assessment findings shared with state		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	If Yes, mention numbers:
7	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):"
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?
	14	Y / N / Partial	Micro plan (COVID-19 Vaccination Planning Template) shared with district?
Trainings	15	Y / N	Urban Workshop for COVID-19 vaccine introduction completed
	16	Y / N / Partial	Orientation of Vaccinators (as per Co-WIN) completed
	17		% of Vaccinators oriented
	18		% of Supervisors oriented
	19		% of Team members oriented
Session Site Preparations	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

Activities	Achieved (Y/N)	Actions suggested during the assessment	
AEFI	31	Vaccinator oriented on AEFI management	
	32	Anaphylaxis kit with adrenaline and syringe available for all sessions?	
	33	AEFI management centers identified	Check the list
	34	AEFI management centers equipped with AEFI kits	
	35	No of ambulances / vehicle identified for AEFI referrals	
Communication	36	Does the Urban have key communication and demand generation strategies in place on COVID-19 vaccination	Y / N
	37	Mention the communication challenges identified	
	38	Communication / IEC material for display at COVID-19 vaccination session site available at Urban? (Mention details)	Y / N/ Expected
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			

## ANNEXURE 9: NATIONAL COVID-19 VACCINATION POLICY

On 30 January 2020, WHO declared COVID-19 – a severe acute respiratory syndrome (SARS) caused by a novel coronavirus – a public health emergency of international concern (PHEIC). Since early 2020, there are global efforts on research and development of diagnostics, therapeutics, and vaccines to combat the global pandemic.

India's 'National Covid-19 Vaccination Policy' aims for timely introduction of COVID-19 vaccines and graded scale up in India so as to ensure vaccination of every eligible citizen in the shortest possible time as per availability of the Covid-19 Vaccines.

The overall framework and approach of COVID-19 vaccination policy & policy strategy approach is based on scientific and epidemiological evidence, global best practices and WHO guidelines.

Principles of Covid-19 vaccination are guided by expert opinion of National Expert Group on Vaccine Administration for COVID-19 (NEGVAC). The NEGVAC comprises of subject matter experts, secretaries of all pertinent Ministries of Government of India, eminent technical experts and State Governments representatives, for evidence based and collaborative decision making that is adaptive to local needs.

The policy is dynamic, flexible and would continue to update over time as per the evolving pandemic situation and available scientific evidence.

The Policy aims to protect health systems, people working in health systems, people who are on the frontline in the fight against the Covid -19 disease and most vulnerable groups who would be affected the most. It aims to minimize societal and economic impact by reducing COVID-19 mortality and spread.

Among the defined priority groups, Covid-19 vaccination would be expanded in a graded manner taking into account the vaccine production and availability in the country.

The entire vaccination effort will be a National effort and will be done in close collaboration with States/ UTs and Private Sector Health Facilities and Organizations.

It will utilize technology in an inclusive manner to make the process of vaccination simple, transparent and scalable. This will ensure that each beneficiary is administered all the required doses to provide complete protection.

The policy will be flexible involving all relevant stakeholders, citizen centric, accessible and affordable to all sections of the society.

All possible efforts would continue for regular engagement with vaccine manufacturers to augment the production of vaccines by working closely with pharmaceutical industry to boost vaccine research initiatives and development and production of vaccines through handholding, technical and financial support including technology transfer, to ultimately enable availability of a bouquet of COVID-19 vaccines to the citizens of the country.

COVID-19 vaccination is planned to be timely and a very large scale public health intervention. The vaccination activity will be reinforced in parallel by advocacy & communication efforts to address "vaccine eagerness" as well as "vaccine hesitancy" by bringing forward scientific facts and updates in a timely manner; it will communicate uniform, factual and evidence based messages in a transparent manner to tackle vaccine hesitancy, utilizing all media channels for dissemination.

Ensuring safety will remain one of the underlining components of the vaccination drive and the same will be implemented through use of vaccines that have received regulatory approval from the National Regulatory Authority. Safety will continue to be monitored during and post vaccination through the existing and strengthened Adverse Events Following Immunization (AEFI) surveillance program.

The policy would ensure every effort that COVID-19 vaccination drive should not adversely impact the essential health care services including primary care and routine immunization. Activities carried out for introduction of COVID-19 vaccination are expected to strengthen health systems through: microplanning; using an evidence-based decision-making process; strengthening human resource management; training for new vaccine introduction; technologies that are leveraged to ensure the integrity and efficiency of supply chains; use of digital tools for vaccine implementation in an inclusive manner; enhancing monitoring and reporting systems for integrated disease surveillance and adverse events following immunization (AEFI); and robust advocacy and communications activities.

The policy would encourage coordination and collaboration across programs and health service delivery platforms and health system etc. and different sectors, e.g. district administration, urban development, panchayati raj, women and child development, education, finance, education, transport, etc. It will provide opportunities to engage private health sector facilities, medical colleges, research institutes and professional bodies for advocacy, research, and deployment of COVID-19 vaccines.

It will ensure that the vaccination drive will diligently follow all protocols for prevention of COVID-19 and emphasize on COVID Appropriate Behaviour (CAB) by all citizens.





(As on 21/04/2021)

**Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy**

India's National Covid-19 Vaccination Strategy is based on scientific and epidemiological evidence and focuses on systematic end-to-end planning. This strategy derives guidance from Global Best Practices, SoPs of WHO as well as recommendations of India's foremost experts in the National Expert Group on Vaccine Administration for Covid-19 (NEGVAC). National Covid-19 Vaccination Strategy encourages domestic R&D, domestic manufacturing and efficient administration of vaccination to protect and strengthen country's Healthcare System as well as protect the most vulnerable.

2. The Union Govt., in close collaboration with State Governments/U.T administration, has been working over a period of time to ensure that maximum number of Indians are able to get the vaccine in the shortest possible time.

3. Phase-I of the National Covid-19 Vaccination Strategy was launched on 16<sup>th</sup> January 2021 and focussed on protecting Health Care Workers (HCWs) and Front Line Workers (FLWs). Phase-II was initiated from 1<sup>st</sup> March 2021 and 1<sup>st</sup> April 2021 and focussed on protecting the most vulnerable i.e. population more than 45 years of age that accounts for more than 80% Covid mortality in the country.

4. India has been following a dynamic mapping model based on availability of vaccines & coverage of vulnerable priority groups to take decisions of when to open up vaccination to other age groups. Significant coverage of vulnerable groups is expected by 30<sup>th</sup> April 2021.

5. Through out these phases, Government has coordinated and worked with research institutes, private companies and has leveraged the strength of India's vaccine manufacturing capability as well as brought about far-reaching governance changes in India's drug/vaccine regulatory system. This resulted in grant of "Restricted Use in Emergency Situation" (also referred to as "Emergency Use Authorisation-EUA) to two indigenously manufactured vaccines and one vaccine that is presently manufactured abroad but would eventually be manufactured in India. Govt. of India has been in regular touch with each vaccine manufacturer to facilitate public private collaborative research, trials and product development. Multiple Inter-Ministerial teams have been deputed by Govt. of India to various manufacturing sites to understand each one's requirements and to provide pro-active and customized support in the form of grants, advance payments, facilitating more sites for production etc. to significantly augment vaccine production capacities.

6. Govt. of India has ensured participation of the private sector in the vaccination drive right from the beginning. Now, as the vaccination capabilities and processes have stabilized, the public as well as private sector have the experience and confidence to rapidly scale up.

7. In its phase-III, the National Vaccine Strategy aims at liberalized vaccine pricing and scaling up of vaccine coverage. This would, on the one hand, incentivize vaccine manufacturers to rapidly scale up their production and on the other hand, it would also attract new vaccine manufacturers. It would make pricing, procurement and administration of vaccines more flexible and ensure augmented vaccine production as well as wider availability of vaccines in the country.

8. The main elements of the Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy that would come in effect from 1<sup>st</sup> May 2021, are as follows:-

- (i) Vaccine manufacturers would supply 50% of their monthly Central Drugs Laboratory (CDL) released doses to Govt. of India and would be free to supply remaining 50% doses to State Govts. and in the other than Govt. of India channel.
- (ii) Manufacturers would in a transparent manner make an advance declaration of the price for 50% supply that would be available to State Govts. & in the other than Govt. of India channel, before 1<sup>st</sup> May 2021. Based on this price, States, private hospitals, industrial establishments through their hospitals may procure vaccine doses from the manufacturers. Private Hospitals would have to procure their supplies of Covid-19 vaccine exclusively from the 50% supply earmarked for other than Govt. of India channel. The price charged for vaccination by private hospitals would be monitored.
- (iii) Consequently the present dispensation where private Covid vaccination centres receive doses from Govt. and can charge up to Rs.250 per dose will cease to exist.
- (iv) For Govt. of India vaccination centres, the eligible population would be the same which exists today i.e. Health Care Workers (HCWs), Front Line Workers (FLWs) and population above 45 years of age. For other than Govt. of India channel, the eligibility would be all adult citizens of the country i.e. everyone above the above of 18.

- (v) Covid-19 vaccination will continue to be free for eligible population groups in all those Government Covid Vaccination Centres which receive vaccine doses from Govt. of India.
- (vi) All vaccination (through Govt. of India vaccination centres and other than Govt. of India channel) would be part of the National Vaccination Programme, will follow all existing guidelines, will be captured on CoWIN platform alongwith the stocks and price per vaccination applicable in all vaccination centres, will comply with Adverse Event Following Immunization (AEFI) management and reporting, digital vaccination certificate & all other prescribed norms.
- (vii) The division of vaccine supply 50% to Govt. of India & 50% to other than Govt. of India channel would be applicable uniformly across for all vaccines manufactured in the country.
- (viii) However, the fully ready to use imported vaccine would be allowed to be utilized entirely in the other than Govt. of India channel.
- (ix) Govt. of India, from its share, will allocate vaccines to States/UTs based on the criteria of performance (speed of administration, average consumption), extent of infections (number of active Covid cases). Wastage of vaccine will also be considered in the criteria & will affect the allocation negatively. Based on the above criteria, State-wise quota would be decided and communicated to the States in advance.

- (x) Second dose of all existing priority groups i.e. HCWs, FLWs and population above 45 years, where ever it has become due, would be given priority, for which a specific and focused strategy would be communicated to all stakeholders.
  - (xi) The Co-Win digital platform would be refined to reflect the aforesaid main elements.
  - (xii) This policy would come into effect from 1<sup>st</sup> May 2021 and will be reviewed from time to time.
9. Govt. of India will make advance purchase offer for a maximum quantity that the manufacturers commit to supply by a pre-defined period. Such an advance purchase provision signals Government's willingness to pay upfront to the vaccine manufacturers to enable them to augment their production and supply capacities.

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## **Revised Guidelines for implementation of National COVID Vaccination Program**

India's National COVID Vaccination Program is built on scientific and epidemiological evidence, WHO guidelines and global best practices. Anchored in systematic end-to-end planning, it is implemented through effective and efficient participation of States/UTs and the people at large.

Government of India's commitment to the vaccination program has been unwavering and proactive from the beginning, from strengthening Research and Development capacity, to encouraging and enabling manufacturing and vaccinating each and every adult Indian safely, as fast as possible.

For the COVID vaccination program, Government of India initiated early and proactive steps as far back as April 2020:

- "Task Force for Focused Research on Corona Vaccine" (constituted in April 2020), to encourage domestic R&D of Drugs, Diagnostics and Vaccines, headed by Principal Scientific Advisor to the Government of India.
- "National Expert Group on Vaccine Administration for COVID-19" (NEGVAC), (constituted in August 2020), to formulate a comprehensive action plan for vaccine administration, co-chaired by Member (Health) NITI Aayog and Union Health Secretary.
- "Empowered Group on Vaccine Administration for COVID-19" (constituted in January 2021), to facilitate optimal utilization of technology to make COVID vaccination all inclusive, transparent, simple and scalable, headed by CEO, National Health Authority.

India's COVID vaccination program incorporates recommendations of the foremost experts in the field of immunization, public health, disease control and information technology. Based on scientific and epidemiological evidence, the programme gives priority to strengthening the country's healthcare system by protecting the professionals, health and frontline workers, manning it, as well as protecting the most vulnerable population groups.

COVID vaccination in the country commenced with vaccination to all Health Care Workers. The program was expanded with time to include vaccination of Front Line Workers, citizens more than 60 years of age, citizens more than 45 years of age and eventually citizens more than 18 years of age.

Under the National COVID Vaccination Program, from 16<sup>th</sup> January to 30<sup>th</sup> April 2021, 100% of vaccine doses were procured by Government of India and provided free of cost to State Governments. State Governments were in turn to administer vaccination free of cost to defined priority groups. To increase the pace of vaccination, participation of private hospitals was also enlisted where individuals could also chose to get vaccinated at a prescribed rate.

In response to the suggestions of many State Governments to be permitted the flexibility to procure vaccine directly and administer them as per their own prioritization based on local requirements, Government of India revised the Guidelines. Under the revised Guidelines effective from 1<sup>st</sup> May, 2021, Government of India was procuring 50% of the vaccine produced and was continuing to provide them to States free of cost for administering to priority groups. The State Government and private hospitals were now also empowered to directly procure from the remaining 50% vaccine pool.

Many States have however now communicated that they are facing difficulties in managing the funding, procurement and logistics of vaccines, impacting the pace of the National COVID Vaccination Program. It has also been noted that smaller and remoter private hospitals are also facing constraints.

Keeping in view the aforesaid aspects, the experiences gained from 1<sup>st</sup> May 2021 and the repeated requests received from States, the Guidelines for National COVID Vaccination Program have been reviewed and revised.

The main elements of the Revised Guidelines are as follows -

- Government of India will procure 75% of the vaccines being produced by the manufacturers in the country. The vaccines procured will continue to be provided free of cost to States/UTs as has been the case from the commencement of the National Vaccination Programme. These doses will be administered by the States/UTs free of cost to all citizens as per priority through Government Vaccination Centres.
- In respect of the vaccine doses provided free of cost by Government of India to the States, vaccination will be prioritized as the following:
  - Health Care Workers
  - Front Line Workers
  - Citizens more than 45 years of age
  - Citizens whose second dose has become due
  - Citizens 18 years & above

- Within the population group of citizens more than 18 years of age, States/UTs may decide their own prioritization factoring in the vaccine supply schedule.
- Vaccine doses provided free of cost by Government of India will be allocated to States/UTs based on criteria such as population, disease burden and the progress of vaccination. Wastage of vaccine will affect the allocation negatively.
- Government of India will provide States/UTs advance information of vaccine doses to be supplied to them. States/UTs should similarly, further allocate doses well in advance to districts and vaccination centers. They should also put in the public domain the information about the above availability at district and vaccination center level, and widely disseminate it among the local population, maximizing the visibility and convenience of citizens.
- In order to incentivize production by vaccine manufacturers and encourage new vaccines, domestic vaccine manufacturers are given the option to also provide vaccines directly to private hospitals. This would be restricted to 25% of their monthly production. States/UTs would aggregate the demand of private hospitals keeping in view equitable distribution between large and small private hospitals and regional balance. Based on this aggregated demand, Government of India will facilitate supply of these vaccines to the private hospitals and their payment through the National Health Authority's electronic platform. This would enable the smaller and remoter private hospitals to obtain timely supply of vaccines, and further equitable access and regional balance.
- The price of vaccine doses for private hospitals would be declared by each vaccine manufacturer, and any subsequent changes would be notified in advance. The private hospitals may charge up to a maximum of Rupees 150 per dose as service charges. State Governments may monitor the price being so charged.
- All citizens irrespective of their income status are entitled to free vaccination. Those who have the ability to pay are encouraged to use private hospital's vaccination centres.

- To promote the spirit of “Lok Kalyan”, use of non-transferable Electronic Vouchers which can be redeemed at private vaccination centers, will be encouraged. This would enable people to financially support vaccination of Economically Weaker Sections at private vaccination centres.
- The CoWIN platform provides every citizen the facility of conveniently and safely pre-booking vaccination appointments. All government and private vaccination centers would also provide onsite registration facility, available both for individuals as well as groups of individuals, for which detailed procedure is to be finalized and published by States/UTs, in order to minimize any inconvenience to citizens.
- States may also optimally utilize the Common Service Centres and Call Centres to facilitate prior booking by citizens.

The above revised program provides States/UTs with additional central government support across funding, procurement and logistics. It also facilitates scientific prioritization, wider access, harnessing of private sector capacity and flexibility at the state and local level.

The revised guidelines will come into effect from 21<sup>st</sup> June 2021 and will be reviewed from time to time.

S. No.	Name of State / UT	Active Cases*		Cured/Discharged/Migrated*		Deaths**	
		Total	Change since yesterday	Cumulative	Change since yesterday	Cumulative	Change since yesterday
1	Andaman and Nicobar Islands	69	30	7245	31	127	
2	Andhra Pradesh	47790	1893	1811157	6313	12528	38
3	Arunachal Pradesh	2523	42	31792	305	165	3
4	Assam	29804	1210	462307	3977	4370	26
5	Bihar	2397	161	708951	365	9576	3
6	Chandigarh	241	6	60533	45	807	
7	Chhattisgarh	6889	425	972372	710	13423	8
8	Dadra and Nagar Haveli and Daman and Diu	52	7	10474	11	4	
9	Delhi	1680	87	1406958	198	24952	4
10	Goa	2667	60	159954	277	3027	5
11	Gujarat	4116	311	808849	431	10045	3
12	Haryana	1927	63	756864	185	9351	18
13	Himachal Pradesh	1956	167	195942	318	3465	2
14	Jammu and Kashmir	6157	380	303526	871	4291	7
15	Jharkhand	1184	40	338870	172	5107	1
16	Karnataka	107218	3328	2684997	6524	34539	114
17	Kerala	100680	372	2752492	11056	12699	118
18	Ladakh	293	21	19425	38	202	
19	Lakshadweep	313	9	9271	39	48	1
20	Madhya Pradesh	1110	170	779630	198	8871	22
21	Maharashtra	123866	1045	5772799	10138	120370	511
22	Manipur	5668	3506	59995	4083	1093	8
23	Meghalaya	4665	241	42001	354	814	7
24	Mizoram	4448	7	14554	238	89	1
25	Nagaland	1508	1	22770	129	481	2
26	Odisha	29565	772	860142	3644	3801	40
27	Puducherry	2970	107	111477	363	1739	5
28	Punjab	4832	442	573491	768	15956	12
29	Rajasthan	1873	146	941048	277	8905	
30	Sikkim	2255	27	17257	156	299	1
31	Tamil Nadu	47318	2527	2375963	8132	32051	150
32	Telangana	15524	506	599695	1556	3618	11
33	Tripura	3726	102	59768	390	665	3
34	Uttarakhand	2627	112	329663	231	7083	9
35	Uttar Pradesh	3423	129	1679416	320	22381	15
36	West Bengal	22231	77	1451437	1975	17551	35
<b>Total#</b>		<b>595565</b>	<b>17303</b>	<b>29193085</b>	<b>64818</b>	<b>394493</b>	<b>1183</b>
*(Including foreign Nationals)							
**( more than 70% cases due to comorbidities )							
#States wise distribution is subject to further verification and reconciliation							
#Our figures are being reconciled with ICMR							

**Cumulative Coverage Report of COVID-19 Vaccination**

(As on 26 Jun'21 at 7:00 AM)

	Beneficiaries vaccinated		
	1st Dose	2nd Dose	Total Doses
India	25,98,34,772	5,52,11,154	31,50,45,926
	(52,02,425 in last 24 Hours)	(9,16,744 in last 24 Hours)	(61,19,169 in last 24 Hours)

S. No.	State/UT	Beneficiaries vaccinated		
		1st Dose	2nd Dose	Total Doses
1	A & N Islands	1,38,286	15,846	1,54,132
2	Andhra Pradesh	1,16,81,705	28,44,212	1,45,25,917
3	Arunachal Pradesh	4,60,067	80,744	5,40,811
4	Assam	55,36,768	11,52,586	66,89,354
5	Bihar	1,33,60,096	21,56,756	1,55,16,852
6	Chandigarh	4,08,647	79,844	4,88,491
7	Chhattisgarh*	70,22,150	13,55,541	83,77,691
8	Dadra & Nagar Haveli	1,54,620	13,660	1,68,280
9	Daman & Diu	1,73,776	16,004	1,89,780
10	Delhi	54,56,734	16,64,891	71,21,625
11	Goa	7,28,178	1,05,658	8,33,836
12	Gujarat	1,90,53,658	52,17,941	2,42,71,599
13	Haryana	70,43,821	12,71,698	83,15,519
14	Himachal Pradesh	28,66,630	4,61,951	33,28,581
15	Jammu & Kashmir	36,03,415	6,29,715	42,33,130
16	Jharkhand	54,09,527	9,94,750	64,04,277
17	Karnataka	1,78,65,449	34,76,929	2,13,42,378
18	Kerala	1,04,03,348	29,01,942	1,33,05,290
19	Ladakh	1,68,168	43,402	2,11,570
20	Lakshadweep	46,057	7,376	53,433
21	Madhya Pradesh	1,65,43,406	22,57,638	1,88,01,044
22	Maharashtra	2,44,57,024	58,27,552	3,02,84,576
23	Manipur	5,23,661	72,808	5,96,469
24	Meghalaya	5,78,969	76,211	6,55,180
25	Mizoram	4,87,327	53,195	5,40,522
26	Nagaland	3,98,147	54,796	4,52,943
27	Odisha	93,29,423	19,67,738	1,12,97,161
28	Puducherry	4,08,403	61,352	4,69,755
29	Punjab*	58,68,652	9,35,925	68,04,577
30	Rajasthan	1,99,33,012	37,40,339	2,36,73,351
31	Sikkim	3,62,037	61,526	4,23,563
32	Tamil Nadu	1,20,60,839	24,22,366	1,44,83,205
33	Telangana	86,33,026	14,49,466	1,00,82,492
34	Tripura	18,62,233	5,66,572	24,28,805
35	Uttar Pradesh	2,56,07,271	42,58,859	2,98,66,130
36	Uttarakhand	33,66,413	7,58,285	41,24,698
37	West Bengal	1,61,00,088	46,41,195	2,07,41,283
38	Miscellaneous	17,33,741	15,13,885	32,47,626

**Market Price of COVID-19 Vaccines**

<b>Sr. No.</b>	<b>Vaccine</b>	<b>Lowest Price &amp; Region/Country</b>	<b>Highest Price &amp; Region/Country</b>
1	Astra Zeneca (with SII)	\$ 2.19 In European Commission	\$ 13.27 Bangladesh private market
2	Sinovac	\$ 9.5 Thailand	\$ 32.52 Thailand private market
3	Moderna	\$ 15 USA	\$ 34.50 HICs
4	Pfizer-BioNtech	\$ 6.75 African Union	\$19.50 USA
5	Sputnik V	\$ 3 Latin America	\$ 27.15 Pakistan Private Market
6	Janssen	\$ 8.5 European Commission	\$ 10 USA & African Union
7	Covaxin	\$ 5.45 in India	\$ 35 Nepal private market

Source: UNICEF COVID – 19 Vaccine Market Dashboard

**VACCINATION IN 1,62,881 RURAL AND URBAN VACCINATION CENTRES FROM 01.05.21 TO 23.06.21**

**(AS REPORTED BY STATES ON CO-WIN)**

State	Total number of CVCs	Total No. of Doses	Number of Rural CVC	Doses in Rural CVCs	Number of Urban CVC	Doses in urban CVCs	% of rural CVCs	% doses in rural CVCs
1 Andaman and Nicobar Islands	49	71973	25	52696	13	15177	51%	73%
2 Andhra Pradesh	4610	9065894	2479	5713471	944	2848381	54%	63%
3 Arunachal Pradesh	339	401561	280	202283	45	197231	83%	50%
4 Assam	6222	4395163	4072	2619976	836	1417715	65%	60%
5 Bihar	7317	7256208	4657	4670911	652	1401904	64%	64%
6 Chandigarh	134	349197	2	3116	99	325524	1%	1%
7 Chhattisgarh	5187	4170154	3840	2835902	1252	1310416	74%	68%
8 Dadra and Nagar Haveli	127	136067	57	71350	8	33479	45%	52%
9 Daman and Diu	67	142456	13	77464	7	31649	19%	54%
10 Delhi	2293	4336954	122	259590	1781	3639440	5%	6%
11 Goa	128	546610	64	357619	41	181124	50%	65%
12 Gujarat	13170	14901394	8383	7118643	2603	7156161	64%	48%
13 Haryana	4817	4964541	1945	2272950	1321	2219494	40%	46%

14	Himachal Pradesh	3131	2446407	2151	1883355	118	367417	69%	77%
15	Jammu and Kashmir	2439	2839380	1691	1813542	327	794667	69%	64%
16	Jharkhand	5136	3210992	3095	1883776	466	916670	60%	59%
17	Karnataka	13435	13318812	8526	6177767	2772	6289206	63%	46%
18	Kerala	3769	8304256	2273	6026326	639	1717982	60%	73%
19	Ladakh	175	142996	84	79538	9	38537	48%	56%
20	Lakshadweep	11	32102	11	32102	0	0	100%	100%
21	Madhya Pradesh	13070	11169788	7224	5000825	2606	4807571	55%	45%
22	Maharashtra	12592	19452752	6837	8489179	3359	9486555	54%	44%
23	Manipur	289	425767	153	244661	57	144236	53%	57%
24	Meghalaya	1304	485635	655	253832	268	197659	50%	52%
25	Mizoram	353	383766	124	130469	134	212901	35%	34%
26	Nagaland	487	299758	346	126170	75	160426	71%	42%
27	Odisha	3474	6773020	2102	3647104	905	2785439	61%	54%
28	Puducherry	85	303860	41	131390	34	169121	48%	43%
29	Punjab	4292	3532043	2581	1609260	602	1525878	60%	46%
30	Rajasthan	13532	12866285	6935	7391707	1593	4055688	51%	57%
31	Sikkim	236	298905	179	195408	28	87816	76%	65%
32	Tamil Nadu	5224	7179288	2196	3527290	1159	3132466	42%	49%
33	Telangana	2890	7271174	1065	2468354	1243	4314990	37%	34%
34	Tripura	1400	1393715	1071	906312	167	458449	77%	65%

<sup>35</sup>	Uttar Pradesh	19642	18885510	11812	10553429	3273	6635138	60%	56%
<sup>36</sup>	Uttarakhand	2284	2823334	1136	1271737	487	1160916	50%	45%
<sup>37</sup>	West Bengal	9171	12228489	4817	6085133	2002	4595950	53%	50%
	Total	162881	186806206	93044	96184637	31925	74833373	57%	51%



राजेश भूषण, आईएएस  
सचिव

**RAJESH BHUSHAN, IAS**  
SECRETARY

D.O. No. T-22011/01/2021- Imm  
27<sup>th</sup> May 2021

*Dear Colleague,*

The National COVID-19 Vaccination drive was initiated on 16<sup>th</sup> January 2021 as an important national initiative to curb the spread of the pandemic as well as to reduce the mortality due to COVID-19 disease. Based on WHO recommendations, global experience and scientific rationale, country's operational guidelines and advisories to the States/UTs are updated as per the evolving situation to provide the best possible solutions and guidance for implementation of the vaccination drive successfully for every strata of the society.

2. The vaccination drive was sequentially expanded for prioritized age groups and now covers all person aged 18 years and above. There has been a constant effort to make this drive people-centric, accessible to all and seamless.

3. The idea of taking the COVID vaccination centres closer to the homes had engaged this Ministry's attention for some time. A committee consisting of domain knowledge experts and doctors have examined this issue and multiple options available, based on scientific evidence. The Committee has suggested against door to door vaccination. However, they have recommended a more flexible and people centric approach to cater to special needs of elderly & differently abled persons. Accordingly, the strategy of Near to Home CVC for Elderly and Differently Abled Citizens has been formulated. This strategy was placed before the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) where it was discussed and deliberated by government & non-government experts and the same has been recommended to be adopted.

4. As per this strategy vaccination drive will be more accessible to elderly and differently abled citizens, who may not be able to travel to the existing Covid Vaccination Centres (CVCs), such beneficiaries can now be offered COVID-19 vaccination at Near to Home COVID Vaccination Centres (NHCVC). The NHCVC follows a community based approach where the sessions can be conducted nearer to home e.g. at Community Centre, Resident Welfare Association Centre, Group Housing Society Centre, Panchayat Building, school buildings etc. for the elderly and differently abled citizens. The NHCVC will be linked to an existing CVC for planning & execution. The guidance for Near to Home COVID Vaccination Centres for Elderly and Differently Abled Citizens has been developed keeping in mind the safety as well as convenience of the beneficiaries, and is enclosed herewith.

5. You are requested to advise the concerned officials to take the necessary measures towards the same and start planning and preparatory activities at the earliest. It is also advised to ensure that all other essential health services are maintained and, therefore, meticulous planning is required.

.....contd/-

: 2 :

6. I look forward to your support in successful implementation of this intervention and guidance to your Health team towards quality COVID-19 vaccination drive.

*Warm Regards .*

Yours sincerely,



**Encl** : as above

**(Rajesh Bhushan)**

**Additional Chief Secretary/Principal Secretary/Secretary (Health), All States/UTs**

## Near to Home COVID Vaccination Centres (NHCVC) for Elderly and Differently Abled Citizens

### Guidance Note

#### 1. Background

- As per the recommendation of National Expert Group on Vaccine Administration for COVID-19 (NEGVAC), besides Health Care Workers (HCWs) and Front Line Workers (FLWs), the prioritized group of beneficiaries for COVID-19 vaccination has been expanded to cover general population aged 45 years and above from 1 April 2021. The vaccination against Covid-19 is also made available for all citizens above 18 years of age from 1 May 2021, through State Government Channels and private hospitals
- The population aged above 60 years (senior citizens) are already included in prioritized age group for COVID-19 vaccination since 1 March 2021. The average national coverage with first dose for this age group is 42% as of 15 May 2021.
- Apprehensions have been expressed that many of the senior citizens and individuals with special needs may not be able to receive the doses of COVID-19 vaccine due to inability to travel to a Covid Vaccination Center.
- To ensure vaccination of senior citizens and differently abled population having limited mobility due to their physical condition, there is need to increase access by bringing vaccination services closer to the community and nearer to homes while maintaining all necessary precautions and safety measures, as per Operational Guidelines and Advisories issued from time to time.

#### 2. Rationale

- The elderly usually have high incidence of co-morbid conditions, making them more vulnerable to morbidity and mortality due to COVID-19 infection and its complications.
- There is a need to vaccinate the most vulnerable population (elderly & the differently abled) who may be left behind because of inability to travel to COVID-19 Vaccination Centers (CVC), thus ensuring equitable access to vaccines.

#### 3. Proposed Strategy for Near to Home COVID Vaccination Centres (NHCVC)

- It follows a community-based approach where sessions can be conducted in non-health facility based settings and are nearer to home, e.g. in a community centre, RWA centre/office, panchayat ghar, school buildings, old age homes etc.
- **Continuation of Community-based services:** Meticulous and need based planning for additional COVID-19 vaccination sessions in community needs to be undertaken to minimize its impact on routine immunization and other community based essential health services.
- **Human resource and Infrastructure:** Deployment of trained human resources to provide vaccination services in community settings in an overstretched health system needs to be planned meticulously along with identification of appropriate site for vaccination, that meets the criteria for quality vaccination as per the guidelines, which includes proper waiting area and observation room.

- Based on the learnings from Routine Immunization, listing of Elderly and Differently abled citizens will have to be prepared and Near to Home Vaccination Centres can be organized to provide COVID-19 vaccines to a defined population.
- These NHCVC will be organized specially for this target population only while vaccination for all other age groups will continue at the existing CVCs.
- Based on the cohort of this eligible population of elderly & differently abled, District Task Force (DTF) / Urban Task Force (UTF) will decide the location of NHCVC to maximize the reach of services to the target population, reduce vaccine wastage along with causing minimal impact on the existing health services.
- NHCVC will be linked to an existing CVC for vaccination purpose; the CVC in-charge will be responsible to provide vaccine, logistics and human resources required for vaccination.
- The site for NHCVC will be pre-identified in collaboration with community groups and RWAs. Such sites could be at Panchayat Bhawan, Sub-Health Centres and Health & Wellness Centres with availability of adequate space, Community Halls, RWA Premises, Polling Booths, Schools etc. and needs to have a Vaccination Room and a Waiting Area with appropriate access for the target group, for example ramp for wheel chair access and Observation Room to ensure waiting for 30 minutes post vaccination as per MoHFW Operational Guidelines available at the MoHFW website at <https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf>
- District Task Force (DTF) / Urban Task Force (UTF) will be responsible for planning and implementation of vaccination at the NHCVC, with full flexibility to adjust the proposed plan as per local circumstances and need.
- Once identified & verified for meeting CVC criteria, all such sites will be registered on the CoWIN portal as Near to Home Covid Vaccination Centres (NHCVC).
- Each team at NHCVC will comprise of five members – Team Leader (necessarily a Doctor), Vaccinator, Vaccination Officer 1 for Co-WIN registration and/or verification of beneficiary, and Vaccination Officer-2 and 3 for crowd control, assistance to vaccinator, ensuring 30 minutes observation of beneficiaries following vaccination for any AEFI and any other support.
- In a scenario where there is a group of target beneficiaries under one roof like Old Age Home etc., the NHCVC can be organized at that site as per the Operational Guidelines.
- Innovative strategies like the one adopted by Greater Chennai Corporation wherein each zone has been allotted 2 - 4 vehicles for two-way transportation of beneficiaries (differently abled) can be considered. The beneficiary can be linked to a helpline number to avail the support for pickup and drop to the NHCVC.

#### 4. Defining eligible population for COVID-19 vaccination at NHCVC:

- All individuals above 60 years age with no vaccination or first dose vaccination
- All individuals below 60 years with disability due to physical or medical conditions

#### 5. Registration & appointment through Co-WIN:

- The beneficiaries can either register themselves in advance, on-site or can be registered following Facilitated Cohort Registration process on Co-WIN.
- Verification will be done preferably using Aadhaar. Apart from Aadhaar, other IDs approved by the MoHFW are: 1. EPIC, 2. Passport, 3. Driving license, 4. PAN Card, 5. Smart

Card issued by RGI under NPR, 6. Pension Document with Photograph. The Guidance on vaccination of persons without the prescribed identity documents may also be referred to (available at MoHFW website at <https://www.mohfw.gov.in/pdf/SOPforCOVID19VaccinationofPersonswithoutPrescribedIdentityCards.pdf>)

- All Vaccination must be recorded in real time through the Co-WIN Vaccinator Module on the same day.
- Vaccination will follow standard procedure of registration, verification at session site and reporting in Co-WIN including AEFIs reporting and management (refer to operational guidelines) <https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf>

#### **6. Line listing of Beneficiaries**

- For differently abled citizens, line-listing available with health or other departments (for example, Department of Social Welfare at the State/District level) must be utilized.
- PRIs, Urban Local Bodies, Municipal Corporation will coordinate with relevant stakeholders such as Resident Welfare Associations (RWAs), Cantonment Board, Public/ Private Establishments to enlist target populations as defined above.
- Information could be collected through call centers regarding differently abled persons who may require transport or any other assistance for vaccination.
- DTF / UTF will ensure completeness of line listing and use these listings for adequate NHCVC planning.
- Line listing can be done by ASHAs in rural community, while in Urban areas multiple sources are to be utilized including Urban ASHAs, Mahila Arogya Samitis (MAS), Ward Committees, RWAs, Volunteers from Civil Defense etc.

#### **7. Identification of NHCVC Site and linkage with existing CVC**

- The District Task Force (DTF) / Urban Task Force (UTF) will finalize the NHCVC sites based on the eligible target population and availability of human resources.
- The DTF / UTF will identify and designate an existing Covid-19 vaccination center (CVC) to undertake vaccination at NHCVC.
- Nodal Officer In-charge of designated CVC will review the proposed NHCVC for essential criteria such as availability of 3 rooms / space for vaccination, feasibility of managing AEFIs (refer to Operational Guidelines) and availability of internet etc. and will coordinate to plan vaccination at site.
- Nodal Officer In-charge of designated CVC will ensure vaccination by deployment of vaccine, logistics and human resources on the day of vaccination.

#### **8. Microplanning:**

- Block / Urban Task Force will be responsible to prepare micro plan for vaccination session

- One team will be assigned to a minimum of 20-30 and a maximum of 100-120 beneficiaries for vaccination. In case more than 100-120 beneficiaries are to be vaccinated at a site on one day, another vaccination team may be deployed.
- District/ Urban Task Force will review plan and ensure availability of human resources, vaccine transport arrangements and other logistics
- Block / Urban Task Force will ensure sufficient awareness and visibility for vaccination.

#### 9. Organizing a Near to Home Covid Vaccination Centre (NHCVC)

- A five-member team 'Vaccination Team (VT)' would be deployed at each NHCVC.
- **Each VT will comprise of**
  - Team leader (necessarily a doctor)
  - One trained Vaccinator
  - Vaccination officer 1: For registration and/or verification of beneficiaries at session site
  - Vaccination officer 2 and 3: For observing vaccinated members for any adverse event, crowd management and to support the vaccinator in conducting the session.
- More than one VT can be deployed at each NHCVC based on due list and other factors.
- Each NHCVC will be backed up by an Advanced Life Support ambulance/Basic Life Support ambulance/transport vehicle.
- The District Administration will make adequate arrangements for maintaining law and order situation at every session and mitigate any chances of undue pressure on vaccination team to cover non-targeted beneficiaries.
- Panchayat, local Self-Help Groups (SHGs), Resident Welfare Associations, Urban Local Bodies etc. need to support the line listing process and organization of session, including steps to avoid overcrowding at session sites.
- Each NHCVC will be supervised by a Medical Officer for planning and implementation as under RI.
- **Registration of beneficiaries:**
  - Vaccination team will facilitate on-site registration of the targeted beneficiaries in the CoWIN portal, if they are not already registered.
  - After vaccination, the physical copy of Vaccination Certificate should be provided to each beneficiary.
- At a given session, only one type of vaccine will be provided. This is necessary to avoid mixing of vaccine types between 1st and 2nd dose of a beneficiary. In case there are target beneficiaries who have a requirement of a different vaccine as 2<sup>nd</sup> dose (possibility of some elderly having already received the 1<sup>st</sup> dose), then different sessions/days could be dedicated in such cases.
- An anaphylaxis kit for management of any kind of adverse event at the site, with contents as per operational guidelines of Govt of India will be available at each NHCVC.
- All vaccination sites will be linked to an AEFI Management Centre as referral for medical management post vaccination. An advanced/basic life support (BLS)

ambulance must be dedicated for vaccination activities being conducted at non-hospital/ health facility -based NHCVC as well as at outreach NHCVC at Sub Health Centre or Health & Wellness Centre and should be utilized for shifting beneficiaries to the linked AEFI management center, if required.

- The district authorities will ensure the availability of logistics including IT infrastructure for registration and data entry in CoWIN software.
- To optimize the use of all remaining vaccine doses in the last opened vial, the remaining doses may be provided to health care workers, front line workers and other eligible populations in order of priority.
- As a follow-up post vaccination, the local mobilisers (ASHA, ANM, AWW, volunteers- NYK, NSS, panchayat/Ward Committee members) will plan visit to beneficiaries a day after vaccination, specially to those who are living alone to know their wellbeing and note any adverse events and provide guidance.
- Operational guidelines and standard operating procedure for COVID-19 vaccination should be referred for detailed planning and operationalization. These are available at <https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf>

#### **10. Facilitate travel of elderly and persons with special needs to Session Site**

- To support elderly and differently abled citizens residing in areas around NHCVC both in urban and rural areas, transport arrangements may be made to facilitate their travel to the session site
- Involvement of Resident Welfare Associations in urban areas and the Panchayat in rural areas/Urban local Bodies/community leaders/volunteers/religious institution/philanthropic organization/corporates etc. in supporting the transport arrangements may be encouraged.

#### **11. Making the vaccination center friendly to elderly and persons with special needs**

- a. The session site should be chosen and arranged in a way so as to facilitate entry and exit of elderly and differently abled citizens including provision of wheelchair, seating arrangement, drinking water and toilet facilities.
- a. Differently abled beneficiaries may be allowed to be accompanied by a caregiver/ family member.
- b. Signages must be ensured in the facilities to guide beneficiaries to the vaccination site. Due assistance must be provided for hearing and visually impaired people.

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विकास शील  
अपर सचिव

VIKAS SHEEL  
Additional Secretary



भारत सरकार  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
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Ministry of Health & Family Welfare  
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E-mail : sheelv@nic.in

D.O No /2072903/2021/IMMUNIZATION  
Dated, 7<sup>th</sup> June 2021

*Dear Colleague,*

Please refer to the Guidance note for Co-WIN 2.0, dated 2<sup>nd</sup> March 2021, vide which the seven prescribed Photo ID Cards for verification of beneficiary prior to vaccination have been specified.

It has come to the notice of the Ministry that, the **Unique Disability Identification Card (UDID)**, issued to persons with disability by Department of Empowerment of Persons with Disabilities, Ministry of Social Justice & Empowerment, has all the necessary features such as the name, year of birth, gender and photograph of the person, for the said card to be used for COVID-19 vaccination.

Therefore, with a view to further facilitate access to vaccination for persons with disability, it has been decided to include the UDID in the list of prescribed Photo ID document for Covid-19 vaccination. A sample of the UDID is also enclosed for ready reference. The necessary provisions for same are being made and would be available in Co-WIN shortly.

It is requested that necessary instructions on same may please be issued to all concerned and the inclusion of UDID as one of the permissible photo ID cards for accessing covid vaccination, may be widely publicised.

Encl: As above.

*warm regards*

Yours Sincerely

*(Signature)*  
(Vikas Sheel) 3/6/21

To,

Addition Chief Secretary/Principal Secretary/Secretary, Health - All States/UTs

**UNIQUE DISABILITY ID**  
Government of India

 STATE ID:  
N/A

Aadhaar No. [REDACTED]

Address of the Card Issuing Authority State/District level  
[REDACTED]

 **UNIQUE DISABILITY ID**   
Government of India

नाम / Name [REDACTED]

UD ID [REDACTED]

Disability Type  
**Locomotor Disability**

Year of Birth [REDACTED] % of Disability  
**51% (Fifty One Percent)**

Date of Issue [REDACTED] Valid upto  
**Permanent**

   
Issuing Authority Sign



विकास शील  
अपर सचिव

**VIKAS SHEEL**  
Additional Secretary



भारत सरकार 246

स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
निर्माण भवन, नई दिल्ली - 110011

Government of India

Ministry of Health & Family Welfare  
Nirman Bhavan, New Delhi - 110011

Phones : 23061481, 23063506 (T/F)

E-mail : sheelv@nic.in

D.O. No. T-22014/12/2021-IMMUNIZATION-Part(1)

Dated:16<sup>th</sup> June 2021

*Dear Sir,*

This is in reference to your letter No MGC/F/4600 dated 3<sup>rd</sup> June 2021 to permit 2<sup>nd</sup> dose of Covishield to beneficiaries before 84 days on compelling & compassionate grounds.

In this regard, you may be aware that Govt of India has already issued guidelines on 6<sup>th</sup> May 2021, regarding Administration of Second Dose of Covishield Vaccine Prior to Prescribed Time Interval (after 28 days but before 84 days) to the persons intending to undertake international travel for education purpose, for joining employment in foreign countries and for India's contingent to Tokyo Olympics. As per Govt of India SOPs, there is no provision for relaxation for family members. The SOPs are available on MoHFW website on following link. <https://www.mohfw.gov.in/pdf/AdministrationofSecondDoseofCovishieldVaccinePriorToPrescribedTimeInterval.pdf>

The necessary provisions for same has been also incorporated in Co-WIN portal for facilitation of second dose of Covishield vaccine to above mentioned eligible beneficiaries.

*warm regards*

Yours sincerely,

(Vikas Sheel)

Shri I.L Chahal,  
Commissioner,  
Municipal Head Office,  
Mahapalika Marg,  
Mumbai-400001

**SOPs on  
Administration of Second Dose of Covishield Vaccine Prior to Prescribed Time Interval  
(after 28 days but before 84 days) to persons intending to undertake international travel  
for education purpose, for joining employment in foreign countries  
and for India's contingent to Tokyo Olympics.**

1. Presently, based on the recommendations by National Expert Group on Vaccine Administration for COVID-19 (NÉGVAC), the schedule of Covishield vaccine under National Covid-19 Vaccination Strategy is to administer the 2nd dose at 12-16 weeks interval (i.e. after 84 days), after administration of 1st dose.
2. The Union Ministry of Health & Family Welfare has received several representations for allowing administration of second dose of Covishield for such persons who have only taken first dose of Covishield and are seeking to undertake international travel for educational purposes or employment opportunities or for part of India's contingent for Tokyo Olympic games, but whose planned travel dates fall prior to completion of the currently mandated minimum interval of 84 days from the date of first dose.
3. The matter has been discussed in Empowered Group 5 (EG-5) and appropriate recommendations have been received. In this context, with a view to provide full coverage of vaccination and facilitating international travel for such genuine reasons, following procedure shall be followed for administration of second dose of Covishield vaccine for such beneficiaries –
  - a. This special dispensation will be available to –
    - (i) Students who have to undertake foreign travel for the purposes of education.
    - (ii) Persons who have to take up jobs in foreign countries.
    - (iii) Athletes, Sports persons and accompanying staff of Indian contingent attending International Olympic Games to be held in Tokyo.
  - b. States/UT governments shall designate a competent authority in each District for according permission for such administration of second dose of Covishield.
  - c. The competent authority shall check the following before according a permission for administration of second dose before the period of 84 days after the date of first dose –
    - (i) Whether a period of 28 days has elapsed after the date of first dose.
    - (ii) Genuineness of the purpose of travel based on documents related to –
      1. Admission offers or associated formal communications for the purpose of education.

2. Whether a person is already studying in a foreign educational institution and has to return to that institution for continuing his/her education.
  3. Interview calls for a job or offer letters for taking up employment
  4. Nomination to participate in the Tokyo Olympic games.
- d. It is advised that vaccination may be availed in such cases through Passport which is one of the permissible ID documents as per the current guidelines, so that the passport number is printed in the vaccination certificate. However, if Passport was not used at the time of administration of first dose, the details of the photo ID Card used for vaccination will be printed in the vaccination certificate and mention of the Passport in the vaccination certificate is not to be insisted upon. Wherever necessary, the competent authority may issue another certificate linking the vaccination certificate with the passport number of the beneficiary.
- e. This facility shall be available to those who need to undertake international travel for these specified purposes in the period up to 31st August, 2021.
- f. All technical protocols as prescribed in the Guidelines of the Ministry regarding COVID Vaccination Centres and AEFI management etc. shall have to be followed.
4. It is clarified that Covishield, produced by the Serum Institute of India and approved by the DCGI, is one of the vaccines recognised by the WHO for emergency use as on 3<sup>rd</sup> June 2021. The relevant entry is at S.No. 4 of the WHO EUL, available at <https://extranet.who.int/pqweb/sites/default/files/documents/Status%20of%20COVID-19%20Vaccines%20within%20WHO%20EUL-PQ%20evaluation%20process%20-%203%20June%202021.pdf>. Mention of vaccine type as “Covishield” is sufficient and no other qualifying entries are required in the vaccination certificates.
5. The Co-WIN system will soon provide the facility for administration of 2nd dose in such exceptional cases.
6. This is to clarify that these SoPs have been issued specifically only for Covishield because only the time interval between the 2 doses of Covishield has been increased from 6-8 weeks to 12-16 weeks. The period for COVAXIN has remained the same i.e. 4-6 weeks and hence there was no need for any special dispensation for 2nd dose of COVAXIN. It is also clarified that complete vaccination with COVAXIN is also sufficient for foreign travel.



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स्वास्थ्य एवं परिवार कल्याण विभाग  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
Government of India  
Department of Health and Family Welfare  
Ministry of Health and Family Welfare

राजेश भूषण, आईएएस  
सचिव

**RAJESH BHUSHAN, IAS**  
SECRETARY

D.O. No. 2146926/2021/Imm  
6<sup>th</sup> April 2021

*Dear Colleague,*

As you are aware, COVID-19 vaccination has been extended to all citizens aged 45 years or more from 1<sup>st</sup> April 2021. A substantial proportion of population aged 45 years and above are in the organized sector of the economy and is involved in formal occupation in offices (government and private) or manufacturing and services etc.

2. With support of the State Governments/UT administration, the efforts have been to consistently make the vaccination drive more pragmatic and also more acceptable and purposeful to the beneficiaries. On similar lines, in order to increase the access of vaccine to these populations, COVID-19 vaccination sessions may be organized at Work Places (both public & private) which are having about 100 eligible and willing beneficiaries by tagging these work places with an existing COVID Vaccination Center (CVC). In order to support the States in this initiative, guidelines have been prepared and the same are enclosed herewith. These guidelines will support the State and District Programme Managers with the requisite information and guide them on organizing vaccination sessions at such work places (both public & private).

3. Please initiate due consultations with Private/Public Sector employers & management to prepare for launch of Work Place Vaccination. Such Work Place Vaccination Centres may be launched across States/UTs from 11<sup>th</sup> April 2021.

6. As we make the vaccination drive more accessible, quality focused and citizen-centric, I look forward to your continued support in this national endeavour.

*Warm Regards,*

Yours sincerely,

(Rajesh Bhushan)

Encl : as above

**Additional Chief Secretary/Principal Secretary/Secretary (Health)**  
**All States/UTs**

**Guidance on COVID-19 Vaccination at Work Places (Government & Private)****1. Background:**

- a. As per the recommendation of National Expert Group on Vaccine Administration for COVID-19 (NEGVAC), the prioritized group of beneficiaries for COVID-19 vaccination has been expanded to cover general population aged 45 years and above from 1st April 2021.
- b. A substantial proportion of population aged between 45-59 years (in some cases up to 65 years) are in the organized sector of the economy. They are involved in formal occupation in offices (government and private), in manufacturing and services etc.
- c. COVID-19 vaccination sessions may be organized at Work Places which are having about 100 eligible and willing beneficiaries (to facilitate optimal utilization of vaccine dosage and reduce wastage) for COVID-19 vaccination. Organizing vaccination at Work Place will not only be convenient to the staff at Work Places but also help to avoid travel and hence reducing the risk of exposure to COVID-19 virus.

**2. Identification of Work Places for COVID-19 vaccination:**

- a. The District Task Force (DTF) chaired by District Magistrate and Urban Task Force (UTF) chaired by Municipal Commissioner will identify such government and private Work Places after due deliberations with relevant employers and / or Head of offices.
- b. Work Place management will designate one of their senior staff to work as “Nodal Officer” to coordinate with district health authorities/ private COVID Vaccination Centres (CVCs) and support vaccination activities.
- c. The Nodal Officer will oversee and facilitate all aspects of vaccination at Work Place CVC like registration of beneficiaries, availability of physical and IT infrastructure and oversight to vaccination etc.

**3. Identification of Eligible and Willing Beneficiaries at Work Places**

- a. Only employees of Work Place aged 45 years or more will be eligible for vaccination at Work Place, no outsiders including eligible family members will be allowed for vaccination at “CVC at Work Place”.
- b. Beneficiaries must be registered in Co-WIN portal prior to vaccination. CVC Nodal Officer will ensure registration of all targeted beneficiaries and facility of on-the spot registration will also be available but only to employees of the work place.

**4. Registration of Work Place as CVC in Co-WIN**

- a. Once identified, all such Work Place vaccination centres will be registered in the CoWIN portal as Government or Private COVID-19 Vaccination Centre (CVC) at Work Place.
- b. The name of Work Place CVC should be recorded in Co-WIN as full name and not as abbreviation to have clarity.
- c. DTF / UTF will ensure verification of availability of three rooms as waiting, vaccination and observation rooms at Work Place CVC (refer annexure 1). These rooms should be part of the permanent structure of the Work Place or proper and stable structure like hangars should be erected. Temporary shamiyana / tent like structure should not be used.
- d. Once verified, DIO will ensure registration of Work Place CVC in Co-WIN portal

**5. Linkage of Work Place CVC with Public and Private CVCs**

- a. Every CVC in government Work Place will be tagged to an existing and nearest CVC in the government medical facility.
- b. Every CVC in private Work Place will be tagged to an existing and nearest CVC in the private medical facility.
- c. The designated government and private CVC to whom the Work Place CVC has been tagged will be responsible for deployment of vaccination team at Work Place CVCs.
- d. The in charge of the designated government and private CVC to whom the Work Place CVC has been tagged will plan session at the Work Place CVC. For optimal utilization of resources, vaccination session will be planned at Work Place CVC once at least 50 beneficiaries get registered for vaccination.
- e. In charges of government or private CVCs with which the Work Place CVCs are tagged for COVID-19 vaccination will be responsible to provide vaccine and ensure reporting in Co-WIN from these Work Place CVCs
- f. The schedule of vaccination session can be made up to 15 days in advance and intimated to the Work Places so that maximum attendance is ensured on the day of vaccination. In most of the work places vaccination schedule may, however, be completed in less than 15 days.

**6. Linkage of Work Place CVC with cold chain points**

- a. All government and private CVCs are already linked to some cold chain point for receiving vaccine. These CVCs will continue to use same mechanism to receive vaccine needed for vaccination at tagged Work Place CVC.

**7. Engaging health infrastructure and health care workers of Work Place CVC**

- a. Some of the Work Places may have health infrastructure in form of hospitals, health clinics, nursing centers etc. This infrastructure may be utilized to set-up vaccination site in case sufficient space for waiting, vaccination and observation rooms are available (refer annexure 1).
- b. The health care workers of this health infrastructure of the Work Place CVCs (such as doctors, nurses and other staff) may be deployed for the COVID-19 vaccination activities at Work Places as vaccination team members.
- c. In-charges of government or private CVCs with which the Work Place CVCs are tagged for COVID-19 vaccination will be responsible to ensure training of these health care staff prior to deployment.
- d. The Work Place CVCs staff engaged in COVID-19 vaccination activities will follow the same SOPs for vaccination and reporting including management and reporting of AEFIs.

**8. Deployment of Vaccination team at Work Place CVC**

- a. District health authorities will normally deploy the vaccination team at government Work Places. Private CVC will deploy the vaccination team at private Work Places
- b. One fully trained vaccination team will be assigned to vaccinate 100 beneficiaries at Work Place CVC. Additional teams shall be deployed in case work load is more than 100 beneficiaries and if sufficient space for vaccination is available (refer annexure 1).
- c. The management of Work Place will be responsible for arranging adequate rooms / space for vaccination (waiting room, vaccination room and observation room)
- d. Each team will consist of:

- Team leader (necessarily a doctor),
- Vaccinator (authorized to give injections),
- Vaccination Officer-1 to work as verifier to work on CoWIN and
- Vaccination officers-2 & 3 for crowd management and AEFI observation

Role of individual team members are defined as refer annexure 2.

#### **9. AEFI management:**

- a. All Work Place CVC will have a medical officer as supervisor / team leader.
- b. All Work Place CVC will have anaphylaxis kit for management of any adverse event and will be linked to the nearest Health Facility (AEFI Management Centre) in case of referral for medical management post vaccination that may be required. The travel time from Work Place CVC to the AEFIs management center should be less than one hour.
- c. A basic life support (BLS) ambulance must mandatorily be deployed at the Work Place CVC and should be utilized for shifting beneficiaries to the linked AEFI management center if required.

#### **10. Vaccination at Work Place CVC:**

- a. One type of vaccine will be provided at such sessions that are conducted at the Work Places. This is necessary to avoid mixing of vaccine types in 1st and 2nd dose of a beneficiary.
- b. Beneficiaries at the Work Place who have already received one dose of a vaccine different from the one being administered at the Work Place CVC shall not be vaccinated at session in the Work Place CVC. They are expected to get the second dose of the same vaccine at an appropriate COVID vaccination centre. However, those who have received same vaccine as first dose may be provided second dose at the Work Place CVC.
- c. The full list of beneficiaries, as available in Co-WIN, will be visible to all verifiers and vaccinators, option of on-the-spot registration will also be available.
- d. Verification will be done by Verifier (Vaccination Officer-1) preferably using Aadhar.
- e. In case Aadhar authentication is not possible for any reason, the Verifier will verify the identity and eligibility of the beneficiary from the photo ID Card indicated by the beneficiary at the time of registration.
- f. Apart from Aadhar, other IDs approved by the MoHFW are: 1. EPIC, 2. Passport, 3. Driving license, 4. PAN Card, 5. Smart Card issued by RGI under NPR, 6. Pension Document with Photograph.
- g. If the identity and eligibility of a beneficiary is established upon verification, the beneficiary will be vaccinated and his/her vaccination status will be updated, else the beneficiary will not be vaccinated.
- h. All Vaccination must be recorded in real time through the Co-WIN Vaccinator Module on the same day.
- i. The digital vaccination certificate of the beneficiary will be generated through Co-WIN, Work Place CVC Nodal Person will be responsible for providing a printed copy of the vaccination certificate, both after 1<sup>st</sup> and 2<sup>nd</sup> doses, to the beneficiary, on site after vaccination.
- j. Operational guidelines and standard operating procedure for COVID-19 vaccination should be referred for detailed planning and operationalization. These are available at <https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf>  
<https://www.mohfw.gov.in/pdf/GuidancedocCOWIN2.pdf>

**11. Monitoring of vaccination at Work Place CVCs**

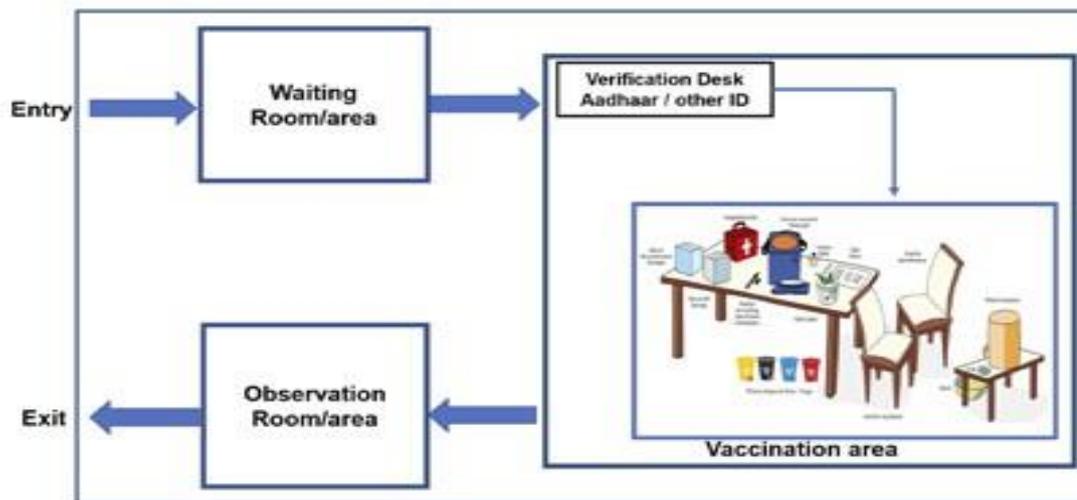
- a. In charges of government or private CVCs with which the Work Place CVCs are tagged for COVID-19 vaccination will review site preparedness and other preparatory activities prior to vaccination.
- b. District and Urban task forces will plan random monitoring at the Work Place CVCs to ensure:
  - Adherence to standard operating procedures for vaccination including verification of beneficiaries to ensure only eligible beneficiaries are vaccinated
  - Training status of human resources
  - AEFI management

**12. Financial Guidelines for Vaccination at Work Places:**

- a. COVID 19 vaccination at government Work Place organized by district health authorities will be free of cost.
- b. COVID 19 vaccination organized by private CVC would be on payment basis and will be at same rate as of vaccination at private health facility.
  - Service charge subject to a ceiling of INR 100 /- per person per dose,
  - Vaccine cost INR 150/- per person per dose.
  - Hence, the financial ceiling of the total amount recoverable by private health facility is INR 250/- per person per dose.
- c. The Private health facility that will be organizing vaccination at the private sector Work Place will deposit cost of vaccines upfront in the bank account designated by the National Health Authority. The hospitals will provide proof of payments to the DIO in-charge of the concerned district. The payment gateway on the NHA portal will be used by the private CVC for this purpose.

**Annexure – I – Details of norms for vaccination at Work Place**

1. The Work Place should make available three demarcated rooms/ areas:
  1. Waiting room
  2. Vaccination room
  3. Observation room
- 1.1. The rooms should preferably have 2 doors, one for entry and one for exit as depicted in the diagram. Adequate physical distance of at least 2 gaz should be maintained between chairs/ seats in the waiting and observation rooms. Crisscross movement of beneficiaries should be avoided by clearly marking the direction of movement from waiting room to vaccination room and then to observation room.
- 1.2. **The waiting room** should have facility for hand washing/ sanitization and display IEC materials on COVID appropriate behavior.



- 1.3. **The Vaccination Room** should have a 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. Only one beneficiary should enter the vaccination room at a time to ensure privacy. The following logistics will be made available by the district authority for vaccination in the room:

1. Adequate COVID-19 vaccine in appropriate cold chain
2. Adequate numbers of syringes
3. Hand sanitizer and masks;
4. Hub cutter/ Needle destroyer;
5. Screen for privacy (if room is not separate);
6. Anaphylaxis kit;
7. Separate color-coded bags for waste segregation as per guidelines;
8. Cotton wool;
9. IEC material;

- 1.4. **The observation room** should have sufficient space for 30-minute waiting and observation of adverse event following immunization. Appropriate IEC materials on COVID appropriate behavior may be displayed in observation areas.

## Annexure – 2 – Role of Vaccination Team Members

DIO will be responsible for overall planning, implementation, and grievance redressal for Work Place vaccination. S/He will also be responsible for maintaining stocks and accounts & safekeeping of vaccines supplied to the CVC at Work Place.

**Role of Work Place Nodal Officer:** The key roles and responsibilities of the Nodal Officer from the Work Place are as follows:

1. S/he will be responsible to identify staff and get them registered in the Co-WIN portal
2. S/he will ensure adequate logistic arrangements like adequate space & infrastructure, internet connectivity, enough computers/smart phones/tablets, printers, availability of drinking water.
3. S/he will ensure adequate mechanisms for queuing, verification, vaccination, observation.
4. S/he will also support in display of suitable signages for guiding the movement of the beneficiaries at the Work Place vaccination site.
5. Ensure that a printed copy of the vaccination certificate is provided to the beneficiaries on-site.

**Role of Team Leader (Medical Officer)-** Key role includes:

1. Ensure verifier follows standard process of verification of beneficiaries using Co-WIN application
2. Vaccinator follows standard process of vaccination and waste disposal
3. Complete AEFI kit is in place at session site and manage AEFIs
4. Ensure referral & transport of beneficiary to the linked AEFI management centre, in case such need arises.

**Vaccinator (Vaccinator Officer) –** A trained health care worker who will provide the vaccination services. Their roles and responsibilities are already detailed in the Operational Guidelines.

**Role of Verifier (Vaccination Officer-1)–** Verifier Officer will be the person responsible for verifying the identity of the beneficiaries at the time of vaccination before a vaccine dose is administered. Verifier will also be responsible for on-site registration and verification of any unregistered beneficiaries.

**Vaccination Officer – 2& 3** The vaccination officer 2& 3 will undertake the following activities:

1. Be stationed in the observation room
2. Ensure that the beneficiaries maintain physical distancing of 2 yards from each other
3. Ensure that each beneficiary is under observation for 30 minutes
4. Inform vaccinator in case any beneficiary has adverse event
5. Support vaccinator to manage the AEFI

### Annexure – 3 – Adequate arrangement for management of Adverse Events Following Immunization

An Adverse Event Following Immunization (AEFI) is any untoward medical occurrence that follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine.

#### 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 concern following vaccination.

All minor, severe and serious AEFIs need to be reported through the Co-WIN app by the vaccinator or the CVC manager. In addition, serious and severe AEFIs need to be reported immediately to the District Immunization Officer by telephone followed by written communication.

**At Work Place CVC:** Team Lead (medical officer) will ensure management of anaphylaxis / AEFIs as Work Place CVCs and referral to AEFI center (if needed).

**A basic life support (BLS) ambulance** must mandatorily be deployed at the Work Place CVC and should be utilized for shifting beneficiaries to the linked AEFI management center if required.

**Anaphylaxis kit:** The Team Lead / Supervisor (medical officer) will ensure the availability of an anaphylaxis kit at the vaccination centre and ensure that all contents are within expiry date.

- 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 date of contents





भारत सरकार

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

निर्माण भवन, नई दिल्ली - 110011

Government of India

Ministry of Health &amp; Family Welfare

Nirman Bhavan, New Delhi - 110011

Phones : 23061481, 23063506 (T/F)

E-mail : sheelv@nic.in

विकास शील

अपर सचिव

VIKAS SHEEL

Additional Secretary

D O No. T-22014/12/2021-IMMUNIZATION

Dated: 19 May 2021

Dear Colleague,

This is in the continuation to earlier communication vide D.O.No.2146926/2021/Imm dated 6<sup>th</sup> April, 2021 regarding guidelines for organization of COVID-19 vaccination at work places (Public & Private). The said guidelines are available on MoHFW Website ([https://www.mohfw.gov.in/pdf/GuidelinesforCOVID19\\_VaccinationatWorkplace.pdf](https://www.mohfw.gov.in/pdf/GuidelinesforCOVID19_VaccinationatWorkplace.pdf))

2. As you are aware that from 1<sup>st</sup> May, 2021 the Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy has come into effect, with expansion of the eligibility for COVID-19 to all adult citizens of the country i.e. everyone above ~~the above of~~ 18 years of age.

3. In this context, several queries have been received by this Ministry on inclusion of the extended age group of 18 to 44 year age group under Work Place Vaccination. In this regard, it is hereby clarified that Covid-19 Vaccination at Workplace (Government & Private) may be extended to all employees of the workplace above 18 years. However, as is the case for people aged 45 years or more, no outsiders including eligible family members will be allowed for vaccination at workplace CVC. Para 3(a) of the Guidelines referred to above in para 1, stands amended to that extent. The remaining guiding principles for vaccination at workplace remain the same. The same information may be disseminated to all concerned.

warm regards

Yours Sincerely,

(Vikas Sheel)

To,

Additional Chief Secretary/Principal Secretary/Secretary, Health – All States/UTs

Copy to:-

Mission Director, National Health Mission – All States/UTs

(Vikas Sheel)



विकास शील  
अपर सचिव

**VIKAS SHEEL**  
Additional Secretary

ANNEXURE R-14

WWW.LIVELAW.IN



भारत सरकार

स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
निर्माण भवन, नई दिल्ली - 110011

Government of India  
Ministry of Health & Family Welfare  
Nirman Bhavan, New Delhi - 110011  
Phones : 23061481, 23063506 (T/F)

E-mail : sheelv@nic.in

D. O. No. T-22014/12/2021-Immunization

Dated: 21<sup>st</sup> May 2021

Dear Colleague,

The "Guidance on COVID-19 Vaccinations at Workplaces (Government and Private)" was issued by the Ministry on 6<sup>th</sup> April, 2021. Thereafter, on 21<sup>st</sup> April, 2021, "The Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy", was issued by the Ministry, where in para 8(ii) outlined that – "the States, Private Hospitals, Industrial Establishments, **through their hospitals**, may procure vaccine doses directly from the manufacturers".

In this context, please refer to the D.O. letter No. T-22014/12/2021-IMMUNIZATION, dated 19<sup>th</sup> May, 2021, vide it has been clarified that Covid-19 vaccination at Workplace (Government & Private) COVID Vaccination Centres (CVCs), may be extended to all employees of the workplace.

Several queries have been received in the Ministry regarding coverage of family members of workers, along with the workers at the Industrial CVCs and the Workplace CVCs. In view of the provisions of the Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy and with the objective of further accelerating the vaccination drive, following clarifications are issued –

1. The family members and dependants of the workers, as defined by the respective employers, can also be covered with COVID-19 vaccination at the Industrial CVCs and the Workplace CVCs.
2. For the Industrial CVCs and the Private Workplace CVCs, for covering the beneficiaries as mentioned in para 1 above, the vaccine doses will have to be procured by the private hospitals with whom the respective employer tie up for vaccination.
3. For the Government Workplace CVCs, beneficiaries aged 45 years or more may be covered through the free vaccine doses supplied by the Government of India to the States/UTs. The beneficiaries in the age group of 18 to 44 years may be covered through the vaccine doses directly procured by the respective State/UT Government from the vaccine manufacturers.

These clarifications may be brought to the notice of all concerned.

Warm regards

Yours Sincerely

  
(Vikas Sheel)

To,

Additional Chief Secretary/ Principal Secretary/ Secretary, Health – All States/UTs

टीवी हारेगा, देश जीतेगा - अधिक जानकारी के लिए संपर्क करें 1800-11-6666 (टोल फ्री)

TB Harega, Desh Jeetega - For more Information contact 1800-11-6666 (Toll Free)

www.mohfw.nic.in

D. O. No. T-22014/12/2021-Immunization  
Dated: 21<sup>st</sup> May 2021

Copy to:-

1. PPS to Secretary HFW, MoHFW
2. PPS to AS&MD, National Health Mission, MoHFW
3. PPS to AS(MA), MoHFW
4. Mission Director, National Health Mission – All States/UTs.
5. Advisor, RCH, MoHFW
6. ADC(I), MoHFW

  
(Vikas Sheel) 21/5/21

**Near to Home COVID Vaccination Centres (NHCVC) for Elderly and Differently Abled Citizens**

**Guidance Note**

**1. Background**

- As per the recommendation of National Expert Group on Vaccine Administration for COVID-19 (NEGVAC), besides Health Care Workers (HCWs) and Front Line Workers (FLWs), the prioritized group of beneficiaries for COVID-19 vaccination has been expanded to cover general population aged 45 years and above from 1 April 2021. The vaccination against Covid-19 is also made available for all citizens above 18 years of age from 1 May 2021, through State Government Channels and private hospitals
- The population aged above 60 years (senior citizens) are already included in prioritized age group for COVID-19 vaccination since 1 March 2021. The average national coverage with first dose for this age group is 42% as of 15 May 2021.
- Apprehensions have been expressed that many of the senior citizens and individuals with special needs may not be able to receive the doses of COVID-19 vaccine due to inability to travel to a Covid Vaccination Center.
- To ensure vaccination of senior citizens and differently abled population having limited mobility due to their physical condition, there is need to increase access by bringing vaccination services closer to the community and nearer to homes while maintaining all necessary precautions and safety measures, as per Operational Guidelines and Advisories issued from time to time.

**2. Rationale**

- The elderly usually have high incidence of co-morbid conditions, making them more vulnerable to morbidity and mortality due to COVID-19 infection and its complications.
- There is a need to vaccinate the most vulnerable population (elderly & the differently abled) who may be left behind because of inability to travel to COVID-19 Vaccination Centers (CVC), thus ensuring equitable access to vaccines.

**3. Proposed Strategy for Near to Home COVID Vaccination Centres (NHCVC)**

- It follows a community-based approach where sessions can be conducted in non-health facility based settings and are nearer to home, e.g. in a community centre, RWA centre/office, panchayat ghar, school buildings, old age homes etc.
- **Continuation of Community-based services:** Meticulous and need based planning for additional COVID-19 vaccination sessions in community needs to be undertaken to minimize its impact on routine immunization and other community based essential health services.
- **Human resource and Infrastructure:** Deployment of trained human resources to provide vaccination services in community settings in an overstretched health system needs to be planned meticulously along with identification of appropriate site for vaccination, that meets the criteria for quality vaccination as per the guidelines, which includes proper waiting area and observation room.

- Based on the learnings from Routine Immunization, listing of Elderly and Differently abled citizens will have to be prepared and Near to Home Vaccination Centres can be organized to provide COVID-19 vaccines to a defined population.
- These NHCVC will be organized specially for this target population only while vaccination for all other age groups will continue at the existing CVCs.
- Based on the cohort of this eligible population of elderly & differently abled, District Task Force (DTF) / Urban Task Force (UTF) will decide the location of NHCVC to maximize the reach of services to the target population, reduce vaccine wastage along with causing minimal impact on the existing health services.
- NHCVC will be linked to an existing CVC for vaccination purpose; the CVC in-charge will be responsible to provide vaccine, logistics and human resources required for vaccination.
- The site for NHCVC will be pre-identified in collaboration with community groups and RWAs. Such sites could be at Panchayat Bhawan, Sub-Health Centres and Health & Wellness Centres with availability of adequate space, Community Halls, RWA Premises, Polling Booths, Schools etc. and needs to have a Vaccination Room and a Waiting Area with appropriate access for the target group, for example ramp for wheel chair access and Observation Room to ensure waiting for 30 minutes post vaccination as per MoHFW Operational Guidelines available at the MoHFW website at <https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf>
- District Task Force (DTF) / Urban Task Force (UTF) will be responsible for planning and implementation of vaccination at the NHCVC, with full flexibility to adjust the proposed plan as per local circumstances and need.
- Once identified & verified for meeting CVC criteria, all such sites will be registered on the CoWIN portal as Near to Home Covid Vaccination Centres (NHCVC).
- Each team at NHCVC will comprise of five members – Team Leader (necessarily a Doctor), Vaccinator, Vaccination Officer 1 for Co-WIN registration and/or verification of beneficiary, and Vaccination Officer-2 and 3 for crowd control, assistance to vaccinator, ensuring 30 minutes observation of beneficiaries following vaccination for any AEFI and any other support.
- In a scenario where there is a group of target beneficiaries under one roof like Old Age Home etc., the NHCVC can be organized at that site as per the Operational Guidelines.
- Innovative strategies like the one adopted by Greater Chennai Corporation wherein each zone has been allotted 2 - 4 vehicles for two-way transportation of beneficiaries (differently abled) can be considered. The beneficiary can be linked to a helpline number to avail the support for pickup and drop to the NHCVC.

#### 4. Defining eligible population for COVID-19 vaccination at NHCVC:

- All individuals above 60 years age with no vaccination or first dose vaccination
- All individuals below 60 years with disability due to physical or medical conditions

#### 5. Registration & appointment through Co-WIN:

- The beneficiaries can either register themselves in advance, on-site or can be registered following Facilitated Cohort Registration process on Co-WIN.
- Verification will be done preferably using Aadhaar. Apart from Aadhaar, other IDs approved by the MoHFW are: 1. EPIC, 2. Passport, 3. Driving license, 4. PAN Card, 5. Smart

Card issued by RGI under NPR, 6. Pension Document with Photograph. The Guidance on vaccination of persons without the prescribed identity documents may also be referred to (available at MoHFW website at <https://www.mohfw.gov.in/pdf/SOPforCOVID19VaccinationofPersonswithoutPrescribedIdentityCards.pdf>)

- All Vaccination must be recorded in real time through the Co-WIN Vaccinator Module on the same day.
- Vaccination will follow standard procedure of registration, verification at session site and reporting in Co-WIN including AEFIs reporting and management (refer to operational guidelines) <https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf>

## 6. Line listing of Beneficiaries

- For differently abled citizens, line-listing available with health or other departments (for example, Department of Social Welfare at the State/District level) must be utilized.
- PRIs, Urban Local Bodies, Municipal Corporation will coordinate with relevant stakeholders such as Resident Welfare Associations (RWAs), Cantonment Board, Public/ Private Establishments to enlist target populations as defined above.
- Information could be collected through call centers regarding differently abled persons who may require transport or any other assistance for vaccination.
- DTF / UTF will ensure completeness of line listing and use these listings for adequate NHCVC planning.
- Line listing can be done by ASHAs in rural community, while in Urban areas multiple sources are to be utilized including Urban ASHAs, Mahila Arogya Samitis (MAS), Ward Committees, RWAs, Volunteers from Civil Defense etc.

## 7. Identification of NHCVC Site and linkage with existing CVC

- The District Task Force (DTF) / Urban Task Force (UTF) will finalize the NHCVC sites based on the eligible target population and availability of human resources.
- The DTF / UTF will identify and designate an existing Covid-19 vaccination center (CVC) to undertake vaccination at NHCVC.
- Nodal Officer In-charge of designated CVC will review the proposed NHCVC for essential criteria such as availability of 3 rooms / space for vaccination, feasibility of managing AEFIs (refer to Operational Guidelines) and availability of internet etc. and will coordinate to plan vaccination at site.
- Nodal Officer In-charge of designated CVC will ensure vaccination by deployment of vaccine, logistics and human resources on the day of vaccination.

## 8. Microplanning:

- Block / Urban Task Force will be responsible to prepare micro plan for vaccination session

- One team will be assigned to a minimum of 20-30 and a maximum of 100-120 beneficiaries for vaccination. In case more than 100-120 beneficiaries are to be vaccinated at a site on one day, another vaccination team may be deployed.
- District/ Urban Task Force will review plan and ensure availability of human resources, vaccine transport arrangements and other logistics
- Block / Urban Task Force will ensure sufficient awareness and visibility for vaccination.

### 9. Organizing a Near to Home Covid Vaccination Centre (NHCVC)

- A five-member team '**Vaccination Team (VT)**' would be deployed at each NHCVC.
- **Each VT will comprise of**
  - Team leader (necessarily a doctor)
  - One trained Vaccinator
  - Vaccination officer 1: For registration and/or verification of beneficiaries at session site
  - Vaccination officer 2 and 3: For observing vaccinated members for any adverse event, crowd management and to support the vaccinator in conducting the session.
- More than one VT can be deployed at each NHCVC based on due list and other factors.
- Each NHCVC will be backed up by an Advanced Life Support ambulance/Basic Life Support ambulance/transport vehicle.
- The District Administration will make adequate arrangements for maintaining law and order situation at every session and mitigate any chances of undue pressure on vaccination team to cover non-targeted beneficiaries.
- Panchayat, local Self-Help Groups (SHGs), Resident Welfare Associations, Urban Local Bodies etc. need to support the line listing process and organization of session, including steps to avoid overcrowding at session sites.
- Each NHCVC will be supervised by a Medical Officer for planning and implementation as under RI.
- **Registration of beneficiaries:**
  - Vaccination team will facilitate on-site registration of the targeted beneficiaries in the CoWIN portal, if they are not already registered.
  - After vaccination, the physical copy of Vaccination Certificate should be provided to each beneficiary.
- At a given session, only one type of vaccine will be provided. This is necessary to avoid mixing of vaccine types between 1st and 2nd dose of a beneficiary. In case there are target beneficiaries who have a requirement of a different vaccine as 2<sup>nd</sup> dose (possibility of some elderly having already received the 1<sup>st</sup> dose), then different sessions/days could be dedicated in such cases.
- An anaphylaxis kit for management of any kind of adverse event at the site, with contents as per operational guidelines of Govt of India will be available at each NHCVC.
- All vaccination sites will be linked to an AEFI Management Centre as referral for medical management post vaccination. An advanced/basic life support (BLS)

ambulance must be dedicated for vaccination activities being conducted at non-hospital/ health facility -based NHCVC as well as at outreach NHCVC at Sub Health Centre or Health & Wellness Centre and should be utilized for shifting beneficiaries to the linked AEFI management center, if required.

- The district authorities will ensure the availability of logistics including IT infrastructure for registration and data entry in CoWIN software.
- To optimize the use of all remaining vaccine doses in the last opened vial, the remaining doses may be provided to health care workers, front line workers and other eligible populations in order of priority.
- As a follow-up post vaccination, the local mobilisers (ASHA, ANM, AWW, volunteers- NYK, NSS, panchayat/Ward Committee members) will plan visit to beneficiaries a day after vaccination, specially to those who are living alone to know their wellbeing and note any adverse events and provide guidance.
- Operational guidelines and standard operating procedure for COVID-19 vaccination should be referred for detailed planning and operationalization. These are available at <https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf>

#### **10. Facilitate travel of elderly and persons with special needs to Session Site**

- To support elderly and differently abled citizens residing in areas around NHCVC both in urban and rural areas, transport arrangements may be made to facilitate their travel to the session site
- Involvement of Resident Welfare Associations in urban areas and the Panchayat in rural areas/Urban local Bodies/community leaders/volunteers/religious institution/philanthropic organization/corporates etc. in supporting the transport arrangements may be encouraged.

#### **11. Making the vaccination center friendly to elderly and persons with special needs**

- a. The session site should be chosen and arranged in a way so as to facilitate entry and exit of elderly and differently abled citizens including provision of wheelchair, seating arrangement, drinking water and toilet facilities.
- a. Differently abled beneficiaries may be allowed to be accompanied by a caregiver/ family member.
- b. Signages must be ensured in the facilities to guide beneficiaries to the vaccination site. Due assistance must be provided for hearing and visually impaired people.

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## ANNEXURE R-16



भारत सरकार  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
निर्माण भवन, नई दिल्ली - 110011

GOVERNMENT OF INDIA  
MINISTRY OF HEALTH & FAMILY WELFARE  
NIRMAN BHAVAN, NEW DELHI - 110011

D.O. No. 2088847/2021/Imm

Dated: 29<sup>th</sup> May 2021

डॉ. मनोहर अगनानी, भा.प्र.से.  
अपर सचिव

**DR. MANOHAR AGNANI, IAS**  
Additional Secretary

*Dear All,*

It has come to the notice of Union Health Ministry that some private hospitals are giving package for Covid Vaccination in collaboration with some hotels, which is against the guidelines issued for the National Covid Vaccination Program.

As per Covid Vaccination guidelines following four options are available for carrying out Covid Vaccination: -

1. Government Covid Vaccination Centre.
2. Private Covid Vaccination Centre run by a private hospital.
3. work place Covid Vaccination Centre at government offices to be run by government hospital and at private companies to be run by private hospitals.
4. Near to Home Covid Vaccination Centre for elderly and differently abled person to be organised at group housing societies, RWA offices, community centres, Panchayat Bhawans, Schools/Colleges, Old Age Homes etc. on a temporary basis.

Apart from this there is no other avenues to carry out vaccination under national Covid Vaccination Program, therefore vaccination carried out in star hotels is contrary to the guidelines and must be stopped immediately. Necessary Legal & Administrative actions should be initiated against such institutions.

Therefore, you are also requested to monitor and ensure that National Covid Vaccination drive is carried out as per prescribed guidelines.

*with kind regards,*

Yours Sincerely,

*29/05/2021*

(Dr. Manohar Agnani)

To,

ACS/Principal Secretary, HFW/Secretary Health, All States/UTs

Copy to,

Home Secretary, Government of India, for information



राजेश भूषण, आईएएस  
सचिव

**RAJESH BHUSHAN, IAS**

SECRETARY

*Dear Colleague,*

This is with regard to facilities to be provided to differently abled persons for COVID-19 treatment, management and vaccination. In order to ensure that differently abled persons get proper access to COVID-19 related services including testing & vaccination, the States/UTs have been provided with appropriate advice from time to time. States/UTs are again advised to facilitate the following steps:

- i. District level officer of Disability/Social Welfare Department can be considered to be designated as Nodal designated made Nodal Officer for the purpose of grievance redressal of differently abled persons in connection with obtaining treatment for COVID-19. The Nodal Officer should work in close co-ordination with the Chief Medical Officer of the district.
- ii. The 104 helpline personnel may be oriented to provide requisite information to differently abled persons to facilitate their proper care and vaccination.
- iii. States may also make special arrangements for their vaccination through Near to Home Covid Vaccination Centres (CVCs) as per guidelines already shared by this Ministry with the States/UTs.
- iv. All district level officers may be directed to provide assistance to differently abled persons in matters such as availability of ambulances. Ambulance transport may also be provided to persons with 40% or more disability for COVID-19 testing. State government can also explore sample collection system for COVID-19 testing from home for differently abled persons through PPP mode and payment to private partners on per case basis can be explored for the same.
- v. Provision of oxygen beds, hospital admissions, vaccination etc. can also be prioritized for differently abled persons. The District/City Control & Command Centres being used for COVID-19 management, can facilitate this process.
- vi. Directions may be issued that differently abled persons should be provided hospital beds on priority basis.

2. Union Ministry of Health & Family Welfare has recently issued directions to States/UTs to facilitate COVID-19 vaccination for differently abled persons & senior citizens, vide letter no. T-22011/01/2021-Imm dated 27<sup>th</sup> May 2021 (also enclosed herewith). The implementation of these guidelines must be ensured.

.....contd/-

: 2 :

3. I am confident of your continued support in this direction and look forward to receiving an action taken report from you in this regard.

*Warm Regards .*

Yours sincerely,



(Rajesh Bhushan)

Encl : as above

Chief Secretary / Administrator of all States/UTs

Copy to:

1. Additional Chief Secretary/Principal Secretary/Secretary (Health), All States/UTs
2. Mission Director (NHM), All States/UTs



राजेश भूषण, आईएएस  
सचिव

**RAJESH BHUSHAN, IAS**  
SECRETARY

D.O. No. T-22011/01/2021- Imm  
27<sup>th</sup> May 2021

*Dear Colleague,*

The National COVID-19 Vaccination drive was initiated on 16<sup>th</sup> January 2021 as an important national initiative to curb the spread of the pandemic as well as to reduce the mortality due to COVID-19 disease. Based on WHO recommendations, global experience and scientific rationale, country's operational guidelines and advisories to the States/UTs are updated as per the evolving situation to provide the best possible solutions and guidance for implementation of the vaccination drive successfully for every strata of the society.

2. The vaccination drive was sequentially expanded for prioritized age groups and now covers all person aged 18 years and above. There has been a constant effort to make this drive people-centric, accessible to all and seamless.

3. The idea of taking the COVID vaccination centres closer to the homes had engaged this Ministry's attention for some time. A committee consisting of domain knowledge experts and doctors have examined this issue and multiple options available, based on scientific evidence. The Committee has suggested against door to door vaccination. However, they have recommended a more flexible and people centric approach to cater to special needs of elderly & differently abled persons. Accordingly, the strategy of Near to Home CVC for Elderly and Differently Abled Citizens has been formulated. This strategy was placed before the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) where it was discussed and deliberated by government & non-government experts and the same has been recommended to be adopted.

4. As per this strategy vaccination drive will be more accessible to elderly and differently abled citizens, who may not be able to travel to the existing Covid Vaccination Centres (CVCs), such beneficiaries can now be offered COVID-19 vaccination at Near to Home COVID Vaccination Centres (NHCVC). The NHCVC follows a community based approach where the sessions can be conducted nearer to home e.g. at Community Centre, Resident Welfare Association Centre, Group Housing Society Centre, Panchayat Building, school buildings etc. for the elderly and differently abled citizens. The NHCVC will be linked to an existing CVC for planning & execution. The guidance for Near to Home COVID Vaccination Centres for Elderly and Differently Abled Citizens has been developed keeping in mind the safety as well as convenience of the beneficiaries, and is enclosed herewith.

5. You are requested to advise the concerned officials to take the necessary measures towards the same and start planning and preparatory activities at the earliest. It is also advised to ensure that all other essential health services are maintained and, therefore, meticulous planning is required.

.....contd/-

: 2 :

6. I look forward to your support in successful implementation of this intervention and guidance to your Health team towards quality COVID-19 vaccination drive.

*Warm Regards .*

Yours sincerely,



Encl : as above

(Rajesh Bhushan)

**Additional Chief Secretary/Principal Secretary/Secretary (Health), All States/UTs**

## Near to Home COVID Vaccination Centres (NHCVC) for Elderly and Differently Abled Citizens

### Guidance Note

#### 1. Background

- As per the recommendation of National Expert Group on Vaccine Administration for COVID-19 (NEGVAC), besides Health Care Workers (HCWs) and Front Line Workers (FLWs), the prioritized group of beneficiaries for COVID-19 vaccination has been expanded to cover general population aged 45 years and above from 1 April 2021. The vaccination against Covid-19 is also made available for all citizens above 18 years of age from 1 May 2021, through State Government Channels and private hospitals
- The population aged above 60 years (senior citizens) are already included in prioritized age group for COVID-19 vaccination since 1 March 2021. The average national coverage with first dose for this age group is 42% as of 15 May 2021.
- Apprehensions have been expressed that many of the senior citizens and individuals with special needs may not be able to receive the doses of COVID-19 vaccine due to inability to travel to a Covid Vaccination Center.
- To ensure vaccination of senior citizens and differently abled population having limited mobility due to their physical condition, there is need to increase access by bringing vaccination services closer to the community and nearer to homes while maintaining all necessary precautions and safety measures, as per Operational Guidelines and Advisories issued from time to time.

#### 2. Rationale

- The elderly usually have high incidence of co-morbid conditions, making them more vulnerable to morbidity and mortality due to COVID-19 infection and its complications.
- There is a need to vaccinate the most vulnerable population (elderly & the differently abled) who may be left behind because of inability to travel to COVID-19 Vaccination Centers (CVC), thus ensuring equitable access to vaccines.

#### 3. Proposed Strategy for Near to Home COVID Vaccination Centres (NHCVC)

- It follows a community-based approach where sessions can be conducted in non-health facility based settings and are nearer to home, e.g. in a community centre, RWA centre/office, panchayat ghar, school buildings, old age homes etc.
- **Continuation of Community-based services:** Meticulous and need based planning for additional COVID-19 vaccination sessions in community needs to be undertaken to minimize its impact on routine immunization and other community based essential health services.
- **Human resource and Infrastructure:** Deployment of trained human resources to provide vaccination services in community settings in an overstretched health system needs to be planned meticulously along with identification of appropriate site for vaccination, that meets the criteria for quality vaccination as per the guidelines, which includes proper waiting area and observation room.

- Based on the learnings from Routine Immunization, listing of Elderly and Differently abled citizens will have to be prepared and Near to Home Vaccination Centres can be organized to provide COVID-19 vaccines to a defined population.
- These NHCVC will be organized specially for this target population only while vaccination for all other age groups will continue at the existing CVCs.
- Based on the cohort of this eligible population of elderly & differently abled, District Task Force (DTF) / Urban Task Force (UTF) will decide the location of NHCVC to maximize the reach of services to the target population, reduce vaccine wastage along with causing minimal impact on the existing health services.
- NHCVC will be linked to an existing CVC for vaccination purpose; the CVC in-charge will be responsible to provide vaccine, logistics and human resources required for vaccination.
- The site for NHCVC will be pre-identified in collaboration with community groups and RWAs. Such sites could be at Panchayat Bhawan, Sub-Health Centres and Health & Wellness Centres with availability of adequate space, Community Halls, RWA Premises, Polling Booths, Schools etc. and needs to have a Vaccination Room and a Waiting Area with appropriate access for the target group, for example ramp for wheel chair access and Observation Room to ensure waiting for 30 minutes post vaccination as per MoHFW Operational Guidelines available at the MoHFW website at <https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf>
- District Task Force (DTF) / Urban Task Force (UTF) will be responsible for planning and implementation of vaccination at the NHCVC, with full flexibility to adjust the proposed plan as per local circumstances and need.
- Once identified & verified for meeting CVC criteria, all such sites will be registered on the CoWIN portal as Near to Home Covid Vaccination Centres (NHCVC).
- Each team at NHCVC will comprise of five members – Team Leader (necessarily a Doctor), Vaccinator, Vaccination Officer 1 for Co-WIN registration and/or verification of beneficiary, and Vaccination Officer-2 and 3 for crowd control, assistance to vaccinator, ensuring 30 minutes observation of beneficiaries following vaccination for any AEFI and any other support.
- In a scenario where there is a group of target beneficiaries under one roof like Old Age Home etc., the NHCVC can be organized at that site as per the Operational Guidelines.
- Innovative strategies like the one adopted by Greater Chennai Corporation wherein each zone has been allotted 2 - 4 vehicles for two-way transportation of beneficiaries (differently abled) can be considered. The beneficiary can be linked to a helpline number to avail the support for pickup and drop to the NHCVC.

#### 4. Defining eligible population for COVID-19 vaccination at NHCVC:

- All individuals above 60 years age with no vaccination or first dose vaccination
- All individuals below 60 years with disability due to physical or medical conditions

#### 5. Registration & appointment through Co-WIN:

- The beneficiaries can either register themselves in advance, on-site or can be registered following Facilitated Cohort Registration process on Co-WIN.
- Verification will be done preferably using Aadhaar. Apart from Aadhaar, other IDs approved by the MoHFW are: 1. EPIC, 2. Passport, 3. Driving license, 4. PAN Card, 5. Smart

Card issued by RGI under NPR, 6. Pension Document with Photograph. The Guidance on vaccination of persons without the prescribed identity documents may also be referred to (available at MoHFW website at <https://www.mohfw.gov.in/pdf/SOPforCOVID19VaccinationofPersonswithoutPrescribedIdentityCards.pdf>)

- All Vaccination must be recorded in real time through the Co-WIN Vaccinator Module on the same day.
- Vaccination will follow standard procedure of registration, verification at session site and reporting in Co-WIN including AEFIs reporting and management (refer to operational guidelines) <https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf>

#### 6. Line listing of Beneficiaries

- For differently abled citizens, line-listing available with health or other departments (for example, Department of Social Welfare at the State/District level) must be utilized.
- PRIs, Urban Local Bodies, Municipal Corporation will coordinate with relevant stakeholders such as Resident Welfare Associations (RWAs), Cantonment Board, Public/ Private Establishments to enlist target populations as defined above.
- Information could be collected through call centers regarding differently abled persons who may require transport or any other assistance for vaccination.
- DTF / UTF will ensure completeness of line listing and use these listings for adequate NHCVC planning.
- Line listing can be done by ASHAs in rural community, while in Urban areas multiple sources are to be utilized including Urban ASHAs, Mahila Arogya Samitis (MAS), Ward Committees, RWAs, Volunteers from Civil Defense etc.

#### 7. Identification of NHCVC Site and linkage with existing CVC

- The District Task Force (DTF) / Urban Task Force (UTF) will finalize the NHCVC sites based on the eligible target population and availability of human resources.
- The DTF / UTF will identify and designate an existing Covid-19 vaccination center (CVC) to undertake vaccination at NHCVC.
- Nodal Officer In-charge of designated CVC will review the proposed NHCVC for essential criteria such as availability of 3 rooms / space for vaccination, feasibility of managing AEFIs (refer to Operational Guidelines) and availability of internet etc. and will coordinate to plan vaccination at site.
- Nodal Officer In-charge of designated CVC will ensure vaccination by deployment of vaccine, logistics and human resources on the day of vaccination.

#### 8. Microplanning:

- Block / Urban Task Force will be responsible to prepare micro plan for vaccination session

- One team will be assigned to a minimum of 20-30 and a maximum of 100-120 beneficiaries for vaccination. In case more than 100-120 beneficiaries are to be vaccinated at a site on one day, another vaccination team may be deployed.
- District/ Urban Task Force will review plan and ensure availability of human resources, vaccine transport arrangements and other logistics
- Block / Urban Task Force will ensure sufficient awareness and visibility for vaccination.

#### 9. Organizing a Near to Home Covid Vaccination Centre (NHCVC)

- A five-member team 'Vaccination Team (VT)' would be deployed at each NHCVC.
- **Each VT will comprise of**
  - Team leader (necessarily a doctor)
  - One trained Vaccinator
  - Vaccination officer 1: For registration and/or verification of beneficiaries at session site
  - Vaccination officer 2 and 3: For observing vaccinated members for any adverse event, crowd management and to support the vaccinator in conducting the session.
- More than one VT can be deployed at each NHCVC based on due list and other factors.
- Each NHCVC will be backed up by an Advanced Life Support ambulance/Basic Life Support ambulance/transport vehicle.
- The District Administration will make adequate arrangements for maintaining law and order situation at every session and mitigate any chances of undue pressure on vaccination team to cover non-targeted beneficiaries.
- Panchayat, local Self-Help Groups (SHGs), Resident Welfare Associations, Urban Local Bodies etc. need to support the line listing process and organization of session, including steps to avoid overcrowding at session sites.
- Each NHCVC will be supervised by a Medical Officer for planning and implementation as under RI.
- **Registration of beneficiaries:**
  - Vaccination team will facilitate on-site registration of the targeted beneficiaries in the CoWIN portal, if they are not already registered.
  - After vaccination, the physical copy of Vaccination Certificate should be provided to each beneficiary.
- At a given session, only one type of vaccine will be provided. This is necessary to avoid mixing of vaccine types between 1st and 2nd dose of a beneficiary. In case there are target beneficiaries who have a requirement of a different vaccine as 2<sup>nd</sup> dose (possibility of some elderly having already received the 1<sup>st</sup> dose), then different sessions/days could be dedicated in such cases.
- An anaphylaxis kit for management of any kind of adverse event at the site, with contents as per operational guidelines of Govt of India will be available at each NHCVC.
- All vaccination sites will be linked to an AEFI Management Centre as referral for medical management post vaccination. An advanced/basic life support (BLS)

ambulance must be dedicated for vaccination activities being conducted at non-hospital/ health facility -based NHCVC as well as at outreach NHCVC at Sub Health Centre or Health & Wellness Centre and should be utilized for shifting beneficiaries to the linked AEFI management center, if required.

- The district authorities will ensure the availability of logistics including IT infrastructure for registration and data entry in CoWIN software.
- To optimize the use of all remaining vaccine doses in the last opened vial, the remaining doses may be provided to health care workers, front line workers and other eligible populations in order of priority.
- As a follow-up post vaccination, the local mobilisers (ASHA, ANM, AWW, volunteers- NYK, NSS, panchayat/Ward Committee members) will plan visit to beneficiaries a day after vaccination, specially to those who are living alone to know their wellbeing and note any adverse events and provide guidance.
- Operational guidelines and standard operating procedure for COVID-19 vaccination should be referred for detailed planning and operationalization. These are available at <https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf>

#### **10. Facilitate travel of elderly and persons with special needs to Session Site**

- To support elderly and differently abled citizens residing in areas around NHCVC both in urban and rural areas, transport arrangements may be made to facilitate their travel to the session site
- Involvement of Resident Welfare Associations in urban areas and the Panchayat in rural areas/Urban local Bodies/community leaders/volunteers/religious institution/philanthropic organization/corporates etc. in supporting the transport arrangements may be encouraged.

#### **11. Making the vaccination center friendly to elderly and persons with special needs**

- a. The session site should be chosen and arranged in a way so as to facilitate entry and exit of elderly and differently abled citizens including provision of wheelchair, seating arrangement, drinking water and toilet facilities.
- a. Differently abled beneficiaries may be allowed to be accompanied by a caregiver/ family member.
- b. Signages must be ensured in the facilities to guide beneficiaries to the vaccination site. Due assistance must be provided for hearing and visually impaired people.

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**STATUS OF FREE COVID-19 VACCINE SUPPLY FROM GOI TO STATES/UTS  
FROM JAN,21 TO MAY,21**

Sl.No.	State/UTs	Covishield	Covaxin	Total
1	Andaman and Nicobar	2,11,410	-	2,11,410
2	Andhra Pradesh	66,18,890	15,17,450	81,36,340
3	Arunachal Pradesh	4,36,960	-	4,36,960
4	Assam	32,21,580	7,54,520	39,76,100
5	Bihar	87,65,190	0,44,580	98,09,770
6	Chandigarh	3,85,340	-	3,85,340
7	Chhattisgarh	72,21,720	4,97,540	77,19,260
8	Dadra and Nagar Haveli	1,13,160	-	1,13,160
9	Daman and Diu	97,750	-	97,750
10	Delhi	32,88,240	5,15,690	48,03,930
11	Goa	7,14,370	-	7,14,370
12	Gujarat	,42,18,960	1,33,630	,63,52,590
13	Haryana	45,78,730	9,73,270	55,52,000
14	Himachal Pradesh	25,58,770	-	25,58,770
15	Jammu & Kashmir	31,29,480	-	31,29,480
16	Jharkhand	38,09,660	7,93,350	46,03,010
17	Karnataka	,09,54,300	5,86,420	,25,40,720
18	Kerala	82,75,650	8,25,450	91,01,100
19	Ladakh	2,41,290	-	2,41,290
20	Lakshadweep	77,000	-	77,000
21	Madhya Pradesh	98,02,310	5,14,250	,13,16,560
22	Maharashtra	,77,26,080	6,42,880	,03,68,960
23	Manipur	5,42,730	-	5,42,730
24	Meghalaya	5,18,370	-	5,18,370
25	Mizoram	5,24,340	-	5,24,340
26	Nagaland	3,71,210	-	3,71,210
27	Odisha	66,66,010	0,93,010	77,59,020
28	Puducherry	4,47,020	-	4,47,020
29	Punjab	43,51,530	5,48,060	48,99,590
30	Rajasthan	,57,18,650	4,02,010	,71,20,660
31	Sikkim	3,55,270	-	3,55,270
32	Tamil Nadu	68,85,810	3,65,540	82,51,350
33	Telangana	51,48,330	9,91,430	61,39,760
34	Tripura	17,55,430	32,860	17,88,290
35	Uttar Pradesh	,52,36,290	3,49,110	,75,85,400
36	Uttarakhand	26,64,010	1,79,350	28,43,360
37	West Bengal	,18,09,070	8,37,980	,36,47,050
<b>Total</b>		<b>17,94,40,910</b>	<b>2,55,98,380</b>	<b>20,50,39,290</b>

COVID Vaccines Received by State/Uts under Direct Procurement - May 2021				
State	Covishield	Atrazeneca (50)	Covaxin	Total
A&N Islands	9,070	-	-	9,070
Andhra Pradesh	9,91,700	3,50,000	3,43,930	16,85,630
Arunachal Pradesh	20,180	-	-	20,180
Assam	3,71,480	50,000	1,50,000	5,71,480
Bihar	11,89,250	3,50,000	1,12,450	16,51,700
Chandigarh	33,000	-	-	33,000
Chhattisgarh	2,97,110	3,50,000	1,50,000	7,97,110
Dadra and Nagar Haveli	7,480	-	-	7,480
Daman and Diu	6,050	-	-	6,050
Delhi	5,67,690	1,00,000	1,50,000	8,17,690
Goa	32,870	-	-	32,870
Gujarat	10,18,650	3,50,000	2,49,240	16,17,890
Haryana	3,19,370	3,50,000	1,10,760	7,80,130
Himachal Pradesh	1,07,620	-	-	1,07,620
Jammu and Kashmir	1,84,950	50,000	1,50,000	3,84,950
Jharkhand	3,87,560	1,00,000	1,34,400	6,21,960
Karnataka	10,04,050	3,50,000	1,94,170	15,48,220
Kerala	3,96,710	3,50,000	1,37,580	8,84,290
Ladakh	5,000	-	-	5,000
Lakshadweep	1,250	-	-	1,250
Madhya Pradesh	9,04,190	1,00,000	3,13,580	13,17,770
Maharashtra	16,81,580	3,50,000	4,79,150	25,10,730
Manipur	39,840	-	-	39,840
Meghalaya	42,630	-	-	42,630
Mizoram	16,340	-	-	16,340
Nagaland	36,580	-	-	36,580
Odisha	4,78,480	1,00,000	1,65,940	7,44,420
Puducherry	30,010	-	-	30,010
Punjab	3,29,280	1,00,000	1,14,190	5,43,470
Rajasthan	11,44,750	3,50,000	2,92,970	17,87,720
Sikkim	9,940	-	-	9,940
Tamil Nadu	7,68,530	3,50,000	1,91,740	13,10,270
Telangana	2,90,010	1,00,000	1,00,580	4,90,590
Tripura	43,670	-	15,150	58,820
Uttar Pradesh	25,53,340	3,50,000	8,85,500	37,88,840
Uttarakhand	1,22,180	1,00,000	42,370	2,64,550
West Bengal	10,57,610	3,50,000	3,66,790	17,74,400
<b>India</b>	<b>1,65,00,000</b>	<b>50,00,000</b>	<b>48,50,490</b>	<b>2,63,50,490</b>

COVID-19 VACCINE STATUS OF PRIVATE HOSPITAL				
Sr.No	State/UT	Covishield	Covaxin	Total
1	A&N Islands	-	-	-
2	Andhra Pradesh	38,000	98,860	1,36,860
3	Arunachal Pradesh	50,000	-	50,000
4	Assam	69,000	4,600	73,600
5	Bihar	-	-	-
6	Chandigarh	44,480	-	44,480
7	Chhattisgarh	18,000	700	18,700
8	Dadra and Nagar Haveli	-	-	-
9	Daman and Diu	-	-	-
10	Delhi	16,60,000	1,49,980	18,09,980
11	Goa	12,000	28,100	40,100
12	Gujarat	4,16,000	10,000	4,26,000
13	Haryana	8,12,420	81,100	8,93,520
14	Himachal Pradesh	3,000	5,000	8,000
15	J & K	4,200	1,500	5,700
16	Jharkhand	41,000	5,120	46,120
17	Karnataka	17,81,420	4,38,220	22,19,640
18	Kerala	3,76,200	23,740	3,99,940
19	Ladakh	-	-	-
20	Lakshadweep	-	-	-
21	Madhya Pradesh	39,000	1,000	40,000
22	Maharashtra	36,71,760	5,28,000	41,99,760
23	Manipur	-	-	-
24	Meghalaya	-	-	-
25	Mizoram	12,000	-	12,000
26	Nagaland	-	-	-
27	Odisha	33,000	2,500	35,500
28	Puducherry	-	-	-
29	Punjab	2,39,200	36,240	2,75,440
30	Rajasthan	1,15,100	33,120	1,48,220
31	Sikkim	24,000	-	24,000
32	Tamil Nadu	5,48,730	1,15,080	6,63,810
33	Telangana	5,15,000	10,26,020	15,41,020
34	Tripura	-	-	-
35	Uttar Pradesh	4,44,640	38,580	4,83,220
36	Uttarakhand	1,13,200	-	1,13,200
37	West Bengal	18,37,500	83,820	19,21,320
	<b>Total</b>	<b>1,29,18,850</b>	<b>27,11,280</b>	<b>1,56,30,130</b>



भारत सरकार  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
निर्माण भवन, नई दिल्ली - 110011

GOVERNMENT OF INDIA  
MINISTRY OF HEALTH & FAMILY WELFARE  
NIRMAN BHAVAN, NEW DELHI - 110011

डॉ. मनोहर अगनानी, भा.प्र.से.  
अपर सचिव

**DR. MANOHAR AGNANI, IAS**  
Additional Secretary

DO No. 2088847/2021/Imm

Dated: 19<sup>th</sup> June 2021

*Dear Amit,*

India is implementing world's largest COVID-19 vaccination drive from 16<sup>th</sup> January 2021. Till date more than 27 crore doses of COVID-19 have been administered.

As per the 'Revised guidelines for Implementation of National Covid Vaccination Programme' which shall come into effect from 21st June 2021, Government of India will procure 75% of total production of covid vaccines and provide them free of cost to States/UTs. Balance 25% will be earmarked for private hospitals.

MoHFW has been regularly providing visibility of quantity of Covid Vaccines to all States/UTs in advance. In this regard, the advance visibility of vaccine availability for your State/UT for the month of July 2021 is annexed alongwith. Quantity indicated includes 25% vaccine doses for private hospitals for which you are requested to aggregate the demand as was done for June. The delivery schedule of vaccines supplied from Government of India i.e. 75% of the indicated quantity will be shared subsequently.

You are kindly requested to direct the concerned officials to ensure rational and judicious utilization of allocated vaccine doses and minimize the vaccine wastage. I look forward to your continuous support for the successful vaccination drive.

Enclosure: As above

*with kind regards*

Yours sincerely,

*Manohar Agnani*

(Dr. Manohar Agnani)

To,  
Shri Amit Singh Negi  
Secretary (Medical, H&FW) Department of Health & Family Welfare  
Uttarakhand

State/UT-wise allocation for Covishield and Covaxin for Jul'21									
S. No.	State	Target population for 18+ age group	Allocation of vaccine on prorata basis based on availability	Proposed allocation for Covishield vaccine (in doses)			Proposed allocation for Covaxin vaccine (in doses)		
				FS	Pvt.	Total	FS	Pvt.	Total
1	Andaman & Nicobar Islands	4,33,809	55,100	41,330	13,780	55,110	-	-	-
2	Andhra Pradesh	5,57,87,608	70,86,320	44,10,440	14,70,150	58,80,590	9,04,300	3,01,430	12,05,730
3	Arunachal Pradesh	9,78,264	1,24,260	93,200	31,070	1,24,270	-	-	-
4	Assam	2,30,55,475	29,28,580	18,22,720	6,07,570	24,30,290	3,73,720	1,24,570	4,98,290
5	Bihar	7,22,85,445	91,81,930	57,14,730	19,04,910	76,19,640	11,71,720	3,90,570	15,62,290
6	Chandigarh	15,75,709	2,00,150	1,50,110	50,040	2,00,150	-	-	-
7	Chhattisgarh	1,89,08,191	24,01,780	14,94,840	4,98,280	19,93,120	3,06,500	1,02,170	4,08,670
8	Dadra & Nagar Haveli	3,57,480	45,410	34,060	11,350	45,410	-	-	-
9	Daman & Diu	2,89,154	36,730	27,550	9,180	36,730	-	-	-
10	Delhi	1,59,50,750	20,26,110	12,61,030	4,20,340	16,81,370	2,58,560	86,190	3,44,750
11	Goa	15,71,030	1,99,560	1,49,670	49,890	1,99,560	-	-	-
12	Gujarat	4,70,72,608	59,79,310	37,21,460	12,40,490	49,61,950	7,63,030	2,54,340	10,17,370
13	Haryana	2,00,23,616	25,43,460	15,83,020	5,27,670	21,10,690	3,24,580	1,08,190	4,32,770
14	Himachal Pradesh	54,79,377	6,96,010	5,22,010	1,74,000	6,96,010	-	-	-
15	Jammu & Kashmir	87,31,752	11,09,130	6,90,310	2,30,100	9,20,410	1,41,540	47,180	1,88,720
16	Jharkhand	2,60,86,098	33,13,540	20,62,310	6,87,440	27,49,750	4,22,840	1,40,950	5,63,790
17	Karnataka	4,72,23,245	59,98,450	37,33,370	12,44,460	49,77,830	7,65,470	2,55,160	10,20,630
18	Kerala	2,87,40,289	36,50,680	22,72,140	7,57,380	30,29,520	4,65,870	1,55,290	6,21,160
19	Ladakh	2,20,448	28,000	21,000	7,000	28,000	-	-	-
20	Lakshadweep	60,054	7,630	5,720	1,910	7,630	-	-	-
21	Madhya Pradesh	5,53,34,785	70,28,800	43,74,650	14,58,220	58,32,870	8,96,960	2,98,990	11,95,950
22	Maharashtra	9,07,32,824	1,15,25,170	71,73,140	23,91,050	95,64,190	14,70,740	4,90,250	19,60,990
23	Manipur	19,69,137	2,50,130	1,87,600	62,530	2,50,130	-	-	-
24	Meghalaya	20,82,796	2,64,560	1,98,420	66,140	2,64,560	-	-	-
25	Mizoram	7,87,409	1,00,020	75,020	25,010	1,00,030	-	-	-
26	Nagaland	16,32,268	2,07,340	1,55,510	51,840	2,07,350	-	-	-
27	Odisha	3,20,24,612	40,67,870	25,31,800	8,43,930	33,75,730	5,19,110	1,73,040	6,92,150
28	Puducherry	14,33,306	1,82,060	1,36,550	45,520	1,82,070	-	-	-
29	Punjab	2,21,69,872	28,16,090	17,52,710	5,84,240	23,36,950	3,59,360	1,19,790	4,79,150
30	Rajasthan	5,13,30,937	65,20,220	40,58,110	13,52,700	54,10,810	8,32,060	2,77,350	11,09,410
31	Sikkim	4,63,253	58,840	44,130	14,710	58,840	-	-	-
32	Tamil Nadu	5,59,05,707	71,01,320	44,19,780	14,73,260	58,93,040	9,06,210	3,02,070	12,08,280
33	Telangana	2,20,37,645	27,99,290	17,42,240	5,80,750	23,22,990	3,57,230	1,19,080	4,76,310
34	Tripura	27,59,205	3,50,480	2,18,140	72,710	2,90,850	44,720	14,910	59,630
35	Uttar Pradesh	15,04,98,822	1,91,16,830	1,18,98,010	39,65,990	1,58,64,000	24,39,510	8,13,150	32,52,660
36	Uttarakhand	77,63,594	9,86,160	6,13,780	2,04,590	8,18,370	1,25,840	41,950	1,67,790
37	West Bengal	7,09,53,023	90,12,680	56,09,390	18,69,800	74,79,190	11,50,130	3,83,380	15,33,510
	<b>India</b>	<b>94,47,09,596</b>	<b>12,00,00,000</b>	<b>7,50,00,000</b>	<b>2,50,00,000</b>	<b>10,00,00,000</b>	<b>1,50,00,000</b>	<b>50,00,000</b>	<b>2,00,00,000</b>

**Government of India**  
**Ministry of Health and Family Welfare**

**Protocol for Management of Covid - 19 in the Paediatric Age Group**

### 1. Background and Epidemiology:

WHO declared Covid – 19 caused by SARS CoV-2 as a public health emergency of international concern on 30<sup>th</sup> January 2020 and subsequently declared it to be a pandemic on 11<sup>th</sup> March 2020.

It is well documented that children are less commonly affected with this infection and majority of them are asymptomatic or mildly symptomatic. A small proportion (<10%- 20%) of symptomatic children may need hospitalization and 1% to 3% of symptomatic children may have severe illness requiring intensive care admission.

Direct person to person transmission occurs through close contact, mainly through respiratory droplets that are released when the infected person coughs, sneezes or talks. These droplets may also land on surfaces where the virus remains viable.

Median incubation period is 5.1 days (range 2 to 14 days). As per current evidence, the period of infectivity starts 2 days prior to onset of symptoms and lasts up-to 8 days.

### 2. Patho– physiology:

Most patients with Covid-19 predominantly have respiratory tract infection associated with SARS CoV 2 infection. Some of them may progress to severe and systematic disease characterized by Acute Respiratory Distress Syndrome (ARDS), sepsis and septic shock, multiorgan failure including acute kidney injury, acute cardiac injury.

Autopsy findings in adults in China, European countries showed endothelial damage of pulmonary vasculature, microvascular thrombosis and haemorrhage linked to extensive alveolar and interstitial inflammation that ultimately results in pulmonary intravascular coagulopathy, hypercoagulability impaired ventilation – perfusion, Acute Respiratory Distress Syndrome. Limited data are available for children.

### 3. Case definition ( As per WHO surveillance guidelines )

Suspect Case:

A. A patient with acute respiratory illness (fever and at least one sign/ symptom of respiratory disease, e.g. cough, shortness of breath), AND a history of travel to or residence in a location reporting community transmission of Covid – 19 disease during the 14 days prior to symptom onset.

OR

B. A patient with any acute respiratory illness AND having been in contact with a confirmed or probable Covid – 19 case in the last 14 days prior to symptom onset;

OR

C. A patient with severe acute respiratory illness (fever and at least one sign/ symptom of respiratory disease, e.g.; cough, shortness of breath; AND requiring hospitalization) AND in the absence of an alternative diagnosis that fully explains the clinical presentation.

Probable Case:

A. A suspect case for whom RT – PCR testing for Covid – 19 virus is inconclusive.

OR

B. A suspect case for whom RT – PCR test could not be performed for any reason.

Confirmed Case:

A person/ child with laboratory confirmation of Covid – 19 infection irrespective of clinical signs and symptoms.

### 4. Clinical Features:

Majority of children with covid infection may be asymptomatic or mildly symptomatic. Common symptoms include- fever, cough, breathlessness/ shortness of breath, fatigue, myalgia, rhinorrhea, sore throat, diarrhea, loss of smell, loss of taste etc. Few children may present with gastrointestinal symptoms and atypical symptoms. A new syndrome with name of multi system inflammatory syndrome has been described in children. Such cases are characterized by: unremitting fever > 38°C, epidemiological linkage with SARS CoV – 2 and clinical features suggestive of Multi System Inflammatory Syndrome.

### 5. Management of children with Covid – 19 disease:

Children with Covid 19 infection may be asymptomatic, mildly symptomatic, moderately sick or severe illness.

**Asymptomatic** children are usually identified while screening, if family members are identified. Such children do not require any treatment except monitoring for development of symptoms and subsequent treatment according to assessed severity.

**Mild disease:** Children with mild disease may present with sore throat, rhinorrhea, cough with no breathing difficulty. Few children may have gastrointestinal symptoms also.

Such children do not need any investigations

These children can be managed at home with home isolation and symptomatic treatment.

For home isolation it is important to assess whether home isolation is feasible by following steps:

- i. There is requisite facility for isolation at his/her residence and also for quarantining the family contacts
- ii. Parents or other care taker who can monitor and take care of child
- iii. If available, Arogya Setu App should be downloaded
- iv. The parents/care giver has agreed to monitor health of the child and regularly inform his/her health status to the Surveillance Officer/ doctor
- v. The parents/ care giver has filled an undertaking on self-isolation and shall follow home isolation/quarantine guidelines

Children with underlying comorbid condition including: congenital heart disease, chronic lung diseases, chronic organ dysfunction, Obesity (BMI > 2SD) may also be managed at home, if they have features of mild disease and there is easy access to health facility in case of any deterioration. In case there is lack of proper arrangement to manage these children at home/ access to health facility is difficult, such children may be admitted.

**Treatment of mild illness** in home isolation is symptomatic.

For Fever: Paracetamol 10-15 mg/kg/dose; may repeat every 4-6 hours

For Cough: Throat soothing agents like warm saline gargles- in older children and adolescents

Fluids & feeds: Ensure oral fluids to maintain hydration, and nutritious diet

Antibiotics: Not indicated

**There is No role of** Hydroxychloroquine, Favipiravir, Ivermectin, lopinavir/ritonavir, Remdesivir, Umifenovir, Immunomodulators including Tocilizumab, Interferon B 1 a, Convalescent plasma infusion or dexamethasone.

**Monitoring at home:** Explain parents/ care taker to maintain a monitoring chart including counting of respiratory rates 2-3 times a day when child is not crying, looking for chest indrawing, bluish discoloration of body, cold extremities, urine output, oxygen saturation monitoring (hand held pulse oximeter) if feasible, fluid intake, activity level, esp for young children.

There should be regular communication to doctor or health care worker. Parents/ caregiver should be explained whom to contact in case of emergency.

**Management of children with Moderate Covid – 19 disease:**

A child with Covid-19 will be categorized as having moderate disease if he/ she has the following:

Rapid respiration as follows

Age: less than 2 months: respiratory rate  $\geq 60$ / min, Age: 2 to 12 months: respiratory rate  $\geq 50$ /min, Age: 1 to 5 years: respiratory rate  $\geq 40$ /min, Age: more than 5 years: respiratory rate  $\geq 30$ /min. And oxygen saturations above 90%.

Children with moderate Covid – 19 disease may be suffering from pneumonia which may not be clinically apparent.

**Investigations:** No lab tests are required routinely unless indicated by associated co-morbid conditions.

**Treatment:** Children with moderate Covid-19 disease should be admitted in Dedicated Covid Health Centre or Secondary level Healthcare Facility and monitored for clinical progress. Maintain fluid and electrolyte balance. Encourage oral feeds (breast feeds in infants); if oral intake is poor, intravenous fluid therapy should be initiated.

Children with moderate Covid – 19 disease should be administered:

- i. For fever: Paracetamol 10-15 mg/kg/dose. May be repeated every 4-6 hourly. (temperature > 38°C, i.e. 100.4°F).
- ii. Amoxicillin to be administered, if there is evidence/ strong suspicion of bacterial infection.
- iii. For SpO<sub>2</sub> below 94%, oxygen supplementation is required.
- iv. Corticosteroids may be administered in rapidly progressive disease. It is not required in all children with moderate illness, specifically during first few days of illness.
- v. Supportive care for comorbid conditions, if any.

**6. Management of children with Severe Covid-19 disease:**

Children with SpO<sub>2</sub> level less than 90% are categorized as having severe degree of Covid-19 infection. Such children may be having severe pneumonia, Acute Respiratory Distress Syndrome, Septic Shock, Multi-organ dysfunction syndrome (MODS), or pneumonia with cyanosis. Clinically, such children may present with grunting, severe retraction of chest, lethargy, somnolence, seizure.

Such children should be admitted in Dedicated Covid Hospital/ Secondary/ Tertiary level healthcare facility. Few children may require care in HDU/ICU areas of these facilities. They should be assessed for: thrombosis, haemophagocytic lymphohistiocytosis (HLH), and organ failure.

Investigations: Complete blood counts, liver and renal function tests, Chest X-ray

Treatment

1. Intravenous fluid therapy

- i. Corticosteroids: Dexamethasone 0.15 mg/kg per dose (max 6 mg) twice a day is preferred. Equivalent dose of methylprednisolone may be used for 5 to 14 days depending on continuous clinical assessment.
- ii. Anti-viral agents: Remdesivir is antiviral agent. There is lack of sufficient safety and efficacy data in children below 19 years of age. Randomized controlled trials of this drug in patients above 18 years of age has not shown significant survival benefits. An emergency use authorization for children has been granted. Till more data are available, it should be used in restricted manner in children with severe illness within three days of onset of symptoms after ascertaining that child's renal and liver functions are normal and they are monitored for side effects of medicine. Suggested doses if body weight > 40 kg: 200 mg on 1<sup>st</sup> day then 100 mg once daily for 4 days. If body weight is between 3.5 kg to 4 kg: 5mg/kg on 1<sup>st</sup> day, 2.5 mg/kg once daily for 4 days. **There is No role of** Hydroxychloroquine, Favipiravir, Ivermectin, lopinavir/ritonavir, Umifenovir.
- iii. Children may need organ support in case of organ dysfunction; e.g. Renal Replacement Therapy.

iv. Management of Acute Respiratory Distress Syndrome (ARDS): The principles of treatment are similar to that of ARDS due to any other underlying illness.

- Mild ARDS: High Flow Nasal Oxygenation, Non-invasive ventilation may be given.
- Severe ARDS: Mechanical ventilation may be given with low tidal volume ( $\leq 6$  mL/kg and High Positive End Expiratory Pressure).
- If the child does not improve clinically even then, may consider (if available) High Frequency Oscillatory Ventilation, Extracorporeal Membrane Oxygenation (ECMO).
- Awake prone position may be considered in older hypoxemic children if they tolerate.

Management of Shock: If the child develops septic shock or myocardial dysfunction then he/ she may require:

- Crystalloid bolus administration: 10 to 20 ml/kg over 30 to 60 minutes; be cautious if cardiac dysfunction is there.
- Early inotrope support with monitoring of fluid overload like any other cause of shock.

## 7. Management of Multisystem inflammatory syndrome in children and adolescents temporally related to COVID-19 (MIS-C):

A new syndrome with name of multisystem inflammatory syndrome as been described in children. Such cases are characterized by: unremitting fever  $> 38^{\circ}$  C, epidemiological linkage with SARS CoV – 2 and clinical features suggestive of Multi System Inflammatory Syndrome.

Diagnostic criteria of MIS-C in Children (WHO criteria): a constellation of clinical and laboratory parameters has been suggested for diagnosis. These include:

- Children and adolescents 0–19 years of age with fever  $\geq 3$  days

**AND** two of these:

- Rash or bilateral non-purulent conjunctivitis or muco-cutaneous inflammation signs (oral, hands or feet).
- Hypotension or shock.
- Features of myocardial dysfunction, pericarditis, valvulitis, or coronary abnormalities (including ECHO findings or elevated Troponin/NT-proBNP),
- Evidence of coagulopathy (by PT, PTT, elevated d-Dimers).
- Acute gastrointestinal problems (diarrhoea, vomiting, or abdominal pain).

**AND**

- Elevated markers of inflammation such as ESR, C-reactive protein, or procalcitonin.

**AND**

- No other obvious microbial cause of inflammation, including bacterial sepsis, staphylococcal or streptococcal shock syndromes.

**AND**

- Evidence of COVID-19 (RT-PCR, antigen test or serology positive), or likely contact with patients with COVID-19.

**Investigations:** as listed above in criteria and investigations to rule out common differential diagnoses.

### Treatment of MIS-C

Drugs to be used in case of Multi System Inflammatory Syndrome in Children in case the child has cardiac dysfunction, shock, coronary involvement, multi organs dysfunction (for details, see algorithm):

- i. Steroids: Methylprednisolone 1 to 2 mg/kg per day.
- ii. Intravenous Immunoglobulin 2 g/kg over 24 to 48 hours.
- iii. Antimicrobials

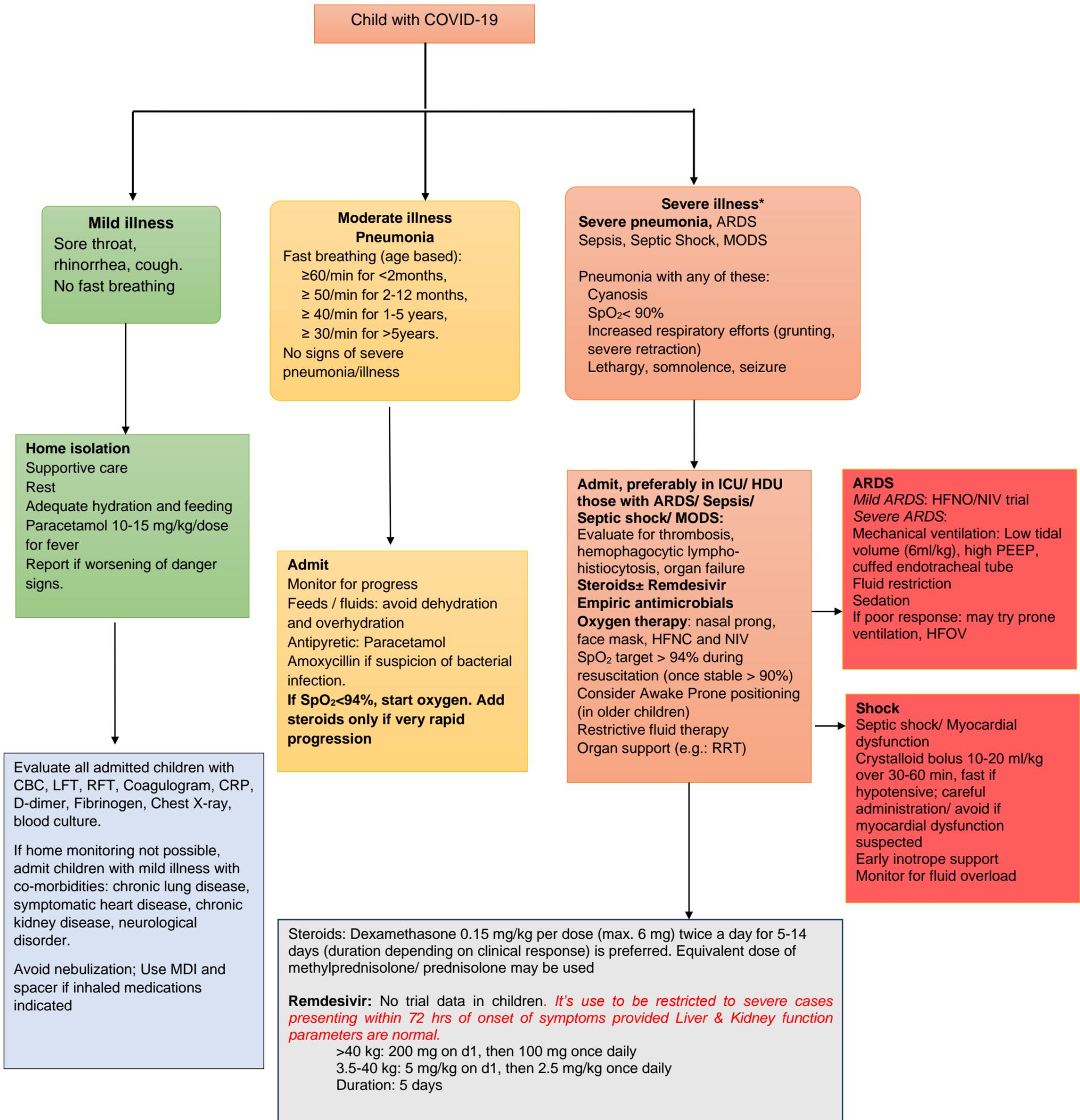
The child needs appropriate supportive care, preferably in ICU. In absence of cardiac dysfunction, shock, coronary involvement, multi organs dysfunction, one may use steroids or IVIG (for details, see algorithm)

If the child does not improve with the above treatment or deteriorates, options include:

- i. Repeat IVIg
- ii. High dose corticosteroid (Methylprednisolone 10 to 30 mg/kg/day for 3 to 5 days)
- iii. Aspirin: 3 mg/kg/day to 5 mg/kg/day max 81 mg/day (if thrombosis or Coronary Aneurysm Score is  $\geq 2.5$ )
- iv. Low Molecular Weight Heparin: Enoxaparin: 1 mg/kg twice daily subcutaneously. Clotting Factor Xa should be between 0.5 to 1 (if patient has thrombosis/ Coronary aneurysm score  $> 10$  or LVEF  $< 30\%$ )

Steroids have to be tapered over 2 to 3 weeks while monitoring inflammatory markers. For children with cardiac involvement, repeat ECG 48 hourly, repeat ECHO at 7 to 14 days and between 4 to 6 weeks and at 1 year if initial ECHO was abnormal.

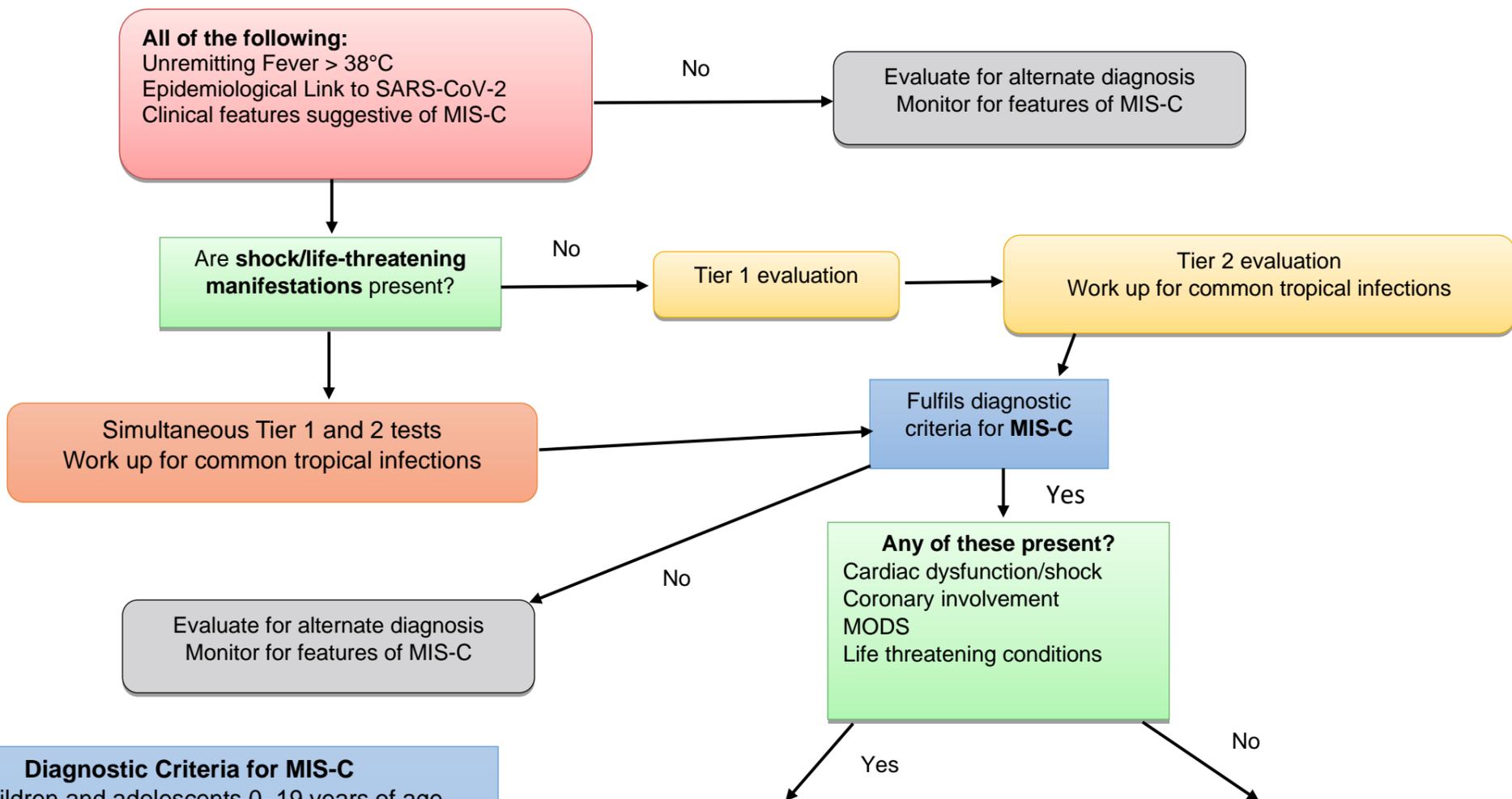
Management of COVID-19 in children (from 2 months to 18 years) (Interim Protocol)



\* Includes Critical illness defined by World Health Organization

For management of Multi System Inflammatory Syndrome in Children , refer to MIS-C protocol

**Management of Multisystem inflammatory syndrome in children and adolescents temporally related to COVID-19**  
(Interim Protocol)



#### Diagnostic Criteria for MIS-C

- Children and adolescents 0–19 years of age with fever  $\geq 3$  days
- AND two of these:**
  - Rash or bilateral non-purulent conjunctivitis or muco-cutaneous inflammation signs (oral, hands or feet).
  - Hypotension or shock.
  - Features of myocardial dysfunction, pericarditis, valvulitis, or coronary abnormalities (including ECHO findings or elevated Troponin/NT-pro BNP),
  - Evidence of coagulopathy (by PT, PTT, elevated d-Dimers).
  - Acute gastrointestinal problems (diarrhoea, vomiting, or abdominal pain).
- AND**
  - Elevated markers of inflammation such as ESR, C-reactive protein, or procalcitonin.
- AND**
  - No other obvious microbial cause of inflammation, including bacterial sepsis, staphylococcal or streptococcal shock syndromes.
- AND**
  - Evidence of COVID-19 (RT-PCR, antigen test or serology positive), or likely contact with patients with COVID-19.

**Steroid** (Methylprednisolone 1-2 mg/kg/d)  
**+ IVIg** (2 g/kg over 24-48 hr)  
**+ Antimicrobials**

May start treatment while completing evaluation for tropical infections (depending on acuity of condition)

Rule out tropical infections first  
**Steroid** (Methylprednisolone 1-2 mg/kg/d): first line,  
**OR**  
**IVIg** (2 g/kg over 24 hr to 48 hrs): alternative/first line, as per availability/feasibility

#### If no improvement or worsening of symptoms, options include

- Repeat IVIg and/ or High dose steroid (Methylprednisolone 10-30 mg/kg/d for 3-5 days)
- If unresponsive to above, may consider high dose Anakinra; 2-10 mg/kg/dose (max 100 mg/dose) SQ/IV q6-12h

**Aspirin** (indications: Thrombocytosis, or Coronary aneurysm Z-score  $\geq 2.5$ )  
➤ Dosage: 3 - 5 mg/kg/day; max 81 mg/day

**Enoxaparin** (indications: Coronary aneurysm (Z-score  $> 10$ ) or Thrombosis or LVEF  $< 35\%$ )  
➤ Dosage: 1 mg/kg twice daily SC  
➤ Preferably monitor with factor Xa level 0.5- 1

- Taper steroids over 2-3 weeks while monitoring inflammatory markers
- For Children with cardiac involvement
  - Repeat ECG 48 hourly, Repeat ECHO at 7-14 days and between 4 to 6 weeks (and after 1 year, if initial ECHO was abnormal)

**Tier 1 Investigations (may be done at Covid Care Centre, Dedicated Covid Health Centre):** CBC, Complete metabolic profile (LFT/RFT/blood gas/glucose), CRP and/or ESR, SARS-CoV-2 Serology and/or PCR, Blood Culture

**Positive Tier 1 screen (both of these should be present):** 1. CRP  $> 5$  mg/dL and/or ESR  $> 40$  mm per hour; 2. At least one of these: ALC  $< 1000/\mu\text{L}$ , Platelet  $< 150,000/\mu\text{L}$ , Na  $< 135$  mEq/L, Neutrophilia, Hypoalbuminemia.

**Tier 2 Investigations (may be done at Dedicated Covid Hospital):** Cardiac (ECG, Echocardiogram, BNP, Troponin T); Inflammatory markers (Procalcitonin, Ferritin, PT, PTT, D-dimer, Fibrinogen, LDH, Triglyceride, Cytokine panel); Blood Smear; SARS-CoV-2 serology.

**Common tropical infections** include: Malaria, Dengue, Enteric fever, Rickettsial illness (scrub typhus), etc.



Guidelines  
on  
**Operationalization of COVID Care Services  
for Children & Adolescents**



Government of India  
Ministry of Health and Family Welfare  
June, 2021

## Guidelines on Operationalization of COVID Care Services for Children & Adolescents

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**List of Abbreviations:**

AED	: Automated External Defibrillator	HFNC	: High Flow Nasal Cannula
AGP	: Aerosol Generating Procedure	HR	: Human Resources
ALS	: Advanced Life Support	HWC	: Health and Wellness Center
ANM	: Auxiliary nurse midwife	ICMR	: Indian Council of Medical Research
ASHA	: Accredited Social Health Activist	ICU	: Intensive Care Unit
AYUSH	: Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy	IEC	: Information Education and Communication
BiPAP	: Bilevel Positive Airway Pressure	iGOT	: Integrated Government Online Training
BLS	: Basic Life Support	IMA	: Indian Medical Association
BP	: Blood Pressure	IMNCI	: Integrated Management of Neonatal and Childhood Illness
BVM	: Bag Valve Mask	IPC	: Infection Prevention and Control
CBNAAT	: Cartridge based Nucleic Acid Amplification Test	IPHS	: Indian Public Health Standards
CBWTF	: Common Biomedical Waste Treatment and Disposal Facility	IV	: Intravenous
CCC	: COVID-19 Care Centre	LMA	: Laryngeal Mask Airway
CCTV	: Close Circuit Television	LMO	: Liquid Medical Oxygen
CHC	: Community Health Centre	LMWH	: Low Molecular Weight Heparin
CHO	: Community Health Officer	MDI	: Multi-dose inhaler
CMHO	: Chief Medical Health Officer	MIS-C	: Multisystem Inflammatory Syndrome in Children
COVID-19:	Coronavirus Disease 2019	MO	: Medical Officer
CPAP	: Continuous Positive Airway Pressure	MoHFW:	Ministry of Health and Family Welfare
CPCB	: Central Pollution Control Board	MPW	: Multi-purpose Worker
CPR	: Cardiopulmonary Resuscitation	MS	: Medical Superintendent
CRP	: C-reactive protein	NCDC	: National Centre for Disease Control
CRRT	: Continuous Renal Replacement Therapy	NGO	: Non-governmental organization
CSSD	: Central Sterile Services Department	NIBP	: Non-invasive blood pressure
CT	: Computed Tomography	NICU	: Neonatal intensive care Unit
DCH	: Dedicated COVID-19 Hospital	OPD	: Out Patient Department
DCHC	: Dedicated COVID-19 Health Centre	PCR	: Polymerase Chain Reaction
DH	: District Hospital	PD	: Peritoneal Dialysis
DNS	: Deputy Nursing Superintendent	PHC	: Primary Health Centre
ECG	: Electrocardiogram	PPE	: Personal Protective Equipment
ER	: Emergency Room	PSA	: Pressure Swing Adsorption
ETCO2	: End-tidal Carbon Dioxide	QoC	: Quality of Care
ETT	: Endotracheal Tube	RKS	: Rogi Kalyan Samiti
FRU	: First Referral Unit	RT PCR	: Reverse Transcriptase Polymerase Chain Reaction
GDMO	: General Duty Medical Office	SARS-CoV-2:	Severe Acute Respiratory Syndrome Coronavirus 2
HCW	: Health Care Worker	SNCU	: Special Newborn Care Unit
HD	: Hemodialysis	SOP	: Standard Operating Procedure
HDU	: High Dependency Unit	UHF	: Unfractionated Heparin
		USG	: Ultrasonography
		UT	: Union Territory

## **Guidelines on Operationalization of COVID Care Services for Children & Adolescents**

### **Executive Summary**

1. Based on sero-surveillance reports, COVID 19 infection in children above 10 years of age occurs in similar frequency to that of adults, even though, among the confirmed cases <12% are individuals < 20 yr age.
2. Children have less severe disease than adults. In the majority, infection is asymptomatic or mildly symptomatic. It is uncommon to have moderate to severe covid in healthy children. Children with co-morbid conditions have more severe manifestations and poorer outcomes; they should be a priority group for vaccination, once vaccines are approved for children.
3. It is anticipated that there may be intermittent surges in the number of cases. A combined effort from private & public sector is needed to handle any surge in future after the withdrawal of the lockdown, school re-opening or as third wave over next 3-4 months.
4. The basic principles of equity and dignity of care should be followed.
5. The estimates for additional bed capacity for pediatric care may be calculated based on the peak daily cases in different districts during the second wave. From this number, projections for pediatric cases and number of admissions required can be derived.
6. It is desirable to augment the existing covid care facilities to provide care to children with acute covid. This will need additional pediatric specific equipment, infrastructure, and pediatric formulations. Also, adequate number of trained manpower- both doctors and nurses should be provided. The health authorities should initiate capacity building programs for appropriate pediatric care. In standalone paediatric hospitals, separate arrangements for example - separate bed for paediatric COVID care need to be established.
7. It is desirable to designate specific areas in the COVID facilities for pediatric care. These facilities should allow parents to accompany the child.
8. For children with MIS-C, who test negative for acute COVID, care has to be provided by the existing pediatric facilities. These facilities also need augmentation esp. HDU and ICU services.
9. The document provides guidance about additional requirements for infrastructure, equipment and manpower.
10. The management protocols for children with acute COVID and MIS-C have been developed by the MoHFW\*. Most drugs used in adults such as Ivermectin/ HCQ/ Favipiravir/ Antibiotics such as Doxycycline or Azithromycin have not been tested in

children for prevention or treatment of COVID infection in children. Therefore, these are not recommended in children.

11. Majority of children have asymptomatic or mild illness and can be managed at home by parents. Treatment is symptomatic including paracetamol for fever, good monitoring for worsening by measuring respiratory rates, difficulty in respiration, oral intake and oxygen saturation. In a community setting, ASHA / MPW should be involved for management of children at home and also monitor to assess the need for referral/ admission.
12. National programs like IMNCI are in place in the country; COVID care should be embraced in the same with follow up for children. At the community level, it is important to train community health workers to pick red flag signs. Additionally, all stake holders including the community should be educated by IEC.
13. Medical officers should provide leadership to ensure service delivery locally by involvement of community health workers.
14. For improving the quality of care and for capacity building, hand-holding of district hospitals and other facilities should be taken up by the medical colleges. Few centers may be designated as the Regional Centres of Excellence for COVID care as well as research. These centers can provide leadership in clinical management and training. Telemedicine could be harnessed for reaching out to large number of facilities.
15. Data drives science, the importance cannot be over emphasised. Therefore, it is important to ensure data collection at all levels and transmission from community to higher centers. A national registry should be launched for pediatric COVID. There is need to encourage and facilitate research in area of pediatric COVID; this could cover various aspects of management. Similarly, issues of optimal treatment for MIS-C need to be addressed by clinical trials, e.g., comparison of low dose with high doses steroids; comparison of steroids with IVIG, etc.
16. Appropriate IEC campaign should be launched for communication of correct information and dealing with the mis-information campaigns on media and social media.

**\*Medical/clinical protocols are dynamic & continuously evolving and may change time to time.**

## Introduction

In the ongoing COVID-19 pandemic, morbidity and mortality has mainly been seen in adults. In India, < 12% of all confirmed cases are in individuals < 20 yr (1), while this population constitutes approx. 41% of the population (2). Similarly, of all deaths due to COVID-19, only <2% are contributed by < 20 yr age group (3). MIS-C has been reported to occur in children; typically, the surge in cases of MIS-C follows that of the surge in total COVID-19 cases after approx. 2-6 weeks.

In the second wave, there was a sharp increase in the numbers of cases of COVID-19, the peak crossing 4 lakh new cases a day. The proportion of individuals < 20 yr of all COVID-19 confirmed cases has remained unchanged (1). However, with increase in the number of cases, the numbers of children and adolescents with confirmed COVID-19 have also increased.

Among adults with confirmed COVID-19 infection, it is well documented that 80% experience mild illness, approximately 14-15% experience moderate- severe disease and 5% are critically ill. Earlier reports had suggested that illness severity was associated with age (>60 years old) and co-morbid disease. During the second wave, large numbers of younger individuals had moderate-severe disease.

Till date, children have relatively been spared of serious disease and poor outcomes. As per the available sero-survey data prior to launch of vaccination drive, children 10-17 years had seropositivity similar to that in adults, i.e., 25.3% (4). However, the proportion of <20 yr olds among confirmed COVID-19 cases is lower than expected. It means that children are as susceptible as adults to infection, but a large majority remains asymptomatic. Even among the symptomatics, vast majority have mild disease only. The clinical features of COVID in India are similar to that described elsewhere [5-7].

As has been seen in countries where a significant proportion of adults have received COVID-19 vaccines, the proportion of children among new cases increases gradually [in the US, the proportion has increase from 14% to 24% as in May 2<sup>nd</sup> week and changed to 19.8% in the third week (8)].

Various experts are predicting a third wave with a disproportionately high burden among the pediatric population. Re-opening of schools and colleges may contribute an increase in the infections in children. Therefore, there is a need to prepare for any future sudden surge of COVID cases in the pediatric age group. It is important to augment existing health facilities for children, particularly ICU and HDU facilities, while also strengthening community level care i.e., PHCs/ HWCs.

## Estimated burden of COVID-19 in children

National and international data indicated a maximum of 2-3% of such children requiring hospitalisation in wave 1/ 2. However, to meet the surge in India, we need to be ready for a little higher number and for an indicative projection, a figure of 5% of children with COVID have been estimated to be requiring hospitalisation. Box 1 provides estimates for requirement for beds for pediatric COVID care for various peak case numbers. It will be desirable to have estimates for the additional capacity at hospital level/ at level of administrative units to ensure adequate projections and preparedness; this is important because the incidence of COVID is likely to be variable in different areas and also the peak in number of cases will also be at different time points. The same framework could be used for estimating the bed requirements for different percentages of children needing hospitalization. Also, the focus has to be augmentation at all levels and not just of ICU beds. Investment in ICU beds alone or disproportionately will not be cost-effective.

### Box 1: Projections for beds for pediatric COVID care at different case loads

A	Peak cases per day →	100000	50000	20000	10000	5000	1000
B	Estimated number of confirmed cases in < 20 yr* at peak of the wave (@12% of A) [ref 1]	12000	6000	2400	1200	600	120
C	Percentage of children needing admission	5%	5%	5%	5%	5%	5%
D	Numbers of children needing admission daily at peak of wave (5% of B)	600	300	120	60	30	6
	1. Numbers needing ward admission	360	180	72	36	18	4 (3.6)
	2. Numbers needing HDU/ICU admission (2% of B)	240	120	48	24	12	2 (2.4)
E	Average length of stay of admitted child	10 days					
F	Total Beds required for pediatric care for managing at the peak of the surge (D X E)	6000	3000	1200	600	300	60
G	Total Ward Beds required for pediatric care for managing at the peak of the surge (D1 X E)	3600	1800	720	360	180	36
H	ICU/ HDU beds required for pediatric care for managing severe disease at the peak of the surge (D2 X E)	2400	1200	480	240	120	24

\* break-up for age groups available on NCDC dashboard at intervals of 10 yrs only.

Considering 40% of this will be managed by the private sector, 60% may remain dependent on public health facilities. With the COVID infections now being reported more in rural areas, the above-mentioned proportions for private and public sector may vary in different regions of the country.

For providing care to children with MIS-C, the existing pediatric facilities have to be strengthened. As per the IPHS norms, approx. 10% of beds in a district hospital should be earmarked for sick children. These facilities should be upgraded to have adequate emergency facility, and enough HDU beds. The guideline developed by the Child Health Division, MoHFW- “Strengthening Facility Based Paediatric Care: Operational Guidelines.” Provides detailed requirements

[[https://nhm.gov.in/images/pdf/programmes/childhealth/guidelines/Strenghtening\\_Facility\\_Based\\_Paediatric\\_Care-Operational\\_Guidelines.pdf](https://nhm.gov.in/images/pdf/programmes/childhealth/guidelines/Strenghtening_Facility_Based_Paediatric_Care-Operational_Guidelines.pdf)].

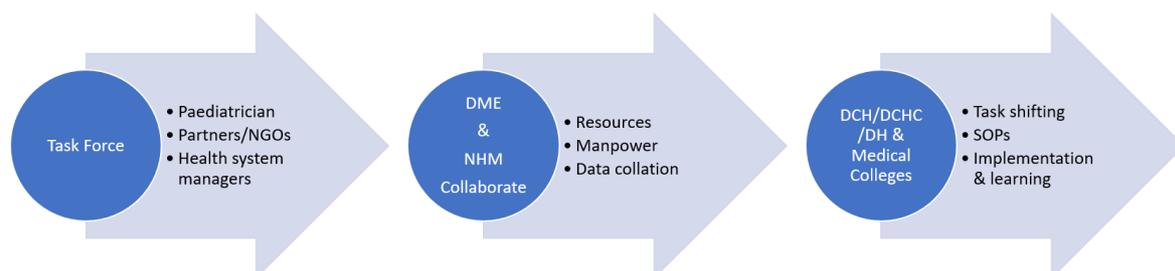
This document provides guidance for augmenting health facilities to be prepared for another surge, which may affect the children.

### **Development of Guidance to Prepare for Managing an increased number of Children and Adolescents with COVID-19**

An expert group was constituted under the chairmanship of Dr AK Deorari with representation from medical colleges and health facilities across the country and also experts from NHSRC. After an initial online meeting, the framework of the guidelines was decided and experts were allocated specific tasks. Thereafter, another online meeting was held to discuss the specific aspects of operationalization of pediatric COVID care. The technical documents prepared by the experts were summarized into the current document, and finalized after a review by all the committee members.

### **Proposed operationalization**

The document will provide the necessary guidance for augmentation of health facilities in various states. The following framework may be considered for the implementation:



The document presents an overall guidance. The implementation will require assessment of available facilities at the level of administrative units- a detailed mapping of beds (ward/HDU/ICU) for children at various facilities, equipment, trained staff has to be carried out. To prepare for a possible surge, it will be good to have a database of all medical and paramedical staff who could contribute in the roll-out of pediatric care during the surge. The estimates of beds/ manpower required during a possible surge should be reviewed considering the local

epidemiology of COVID. This will ensure an adequate response. Realtime “war rooms” (IT enabled) should be commissioned for managing the surge at local administrative unit level; these will also help in linking the community to DCHC/ DCH /district hospitals to Medical Colleges.

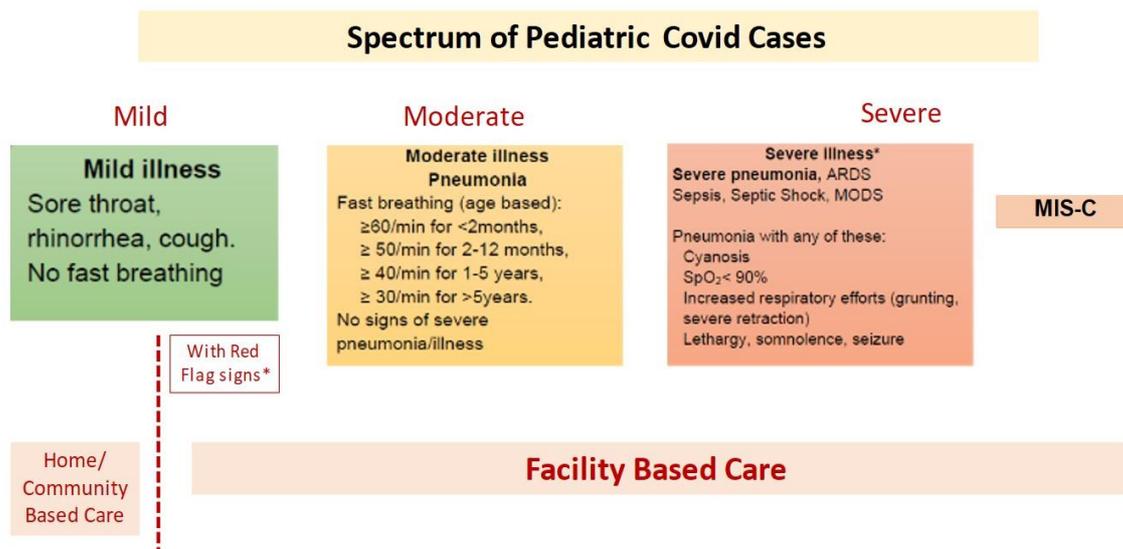
### Requirements for Pediatric COVID Care

Among the symptomatic children with COVID, fever and respiratory symptoms are the commonest symptoms. The children may have other symptoms also such as gastrointestinal symptoms (diarrhea, vomiting, etc.). The severity of symptomatic pediatric COVID illness ranges from mild to severe; additionally, MIS-C cases have to be considered

(<https://www.mohfw.gov.in/pdf/ProtocolforManagementofCovid19inthePaediatricAgeGroup.pdf>) (\*Medical/clinical protocols are dynamic & continuously evolving and may change time to time)

The following figure provides the classification of disease severity based on clinical criteria (Fig 1).

**Figure 1: Spectrum of Pediatric COVID Cases and scope of management**



Upper panel depicts the spectrum of pediatric COVID cases classified as mild, moderate and severe depending on clinical presentation of cases and lower panel depicts the type of care (Hospital/Community or Home) that needs to be provided

Given the spectrum of severity of illness in children and also the unique aspect of MIS-C (without active SARS CoV2 infection), the following framework is proposed (Box 2):

**Box 2: Framework for sites for screening/ testing and management of children with COVID-19/ MIS-C**

Screening	Confirmed COVID cases (PCR/ CBNAAT/ RAT positive)	MIS-C (PCR/ CBNAAT negative)
Existing screening facilities	Existing COVID facilities (CCC, DCHC, DCH, HDU, ICU)	In addition, also in existing Paediatric facilities- HDU/ ICU services.
Pediatrics ER		

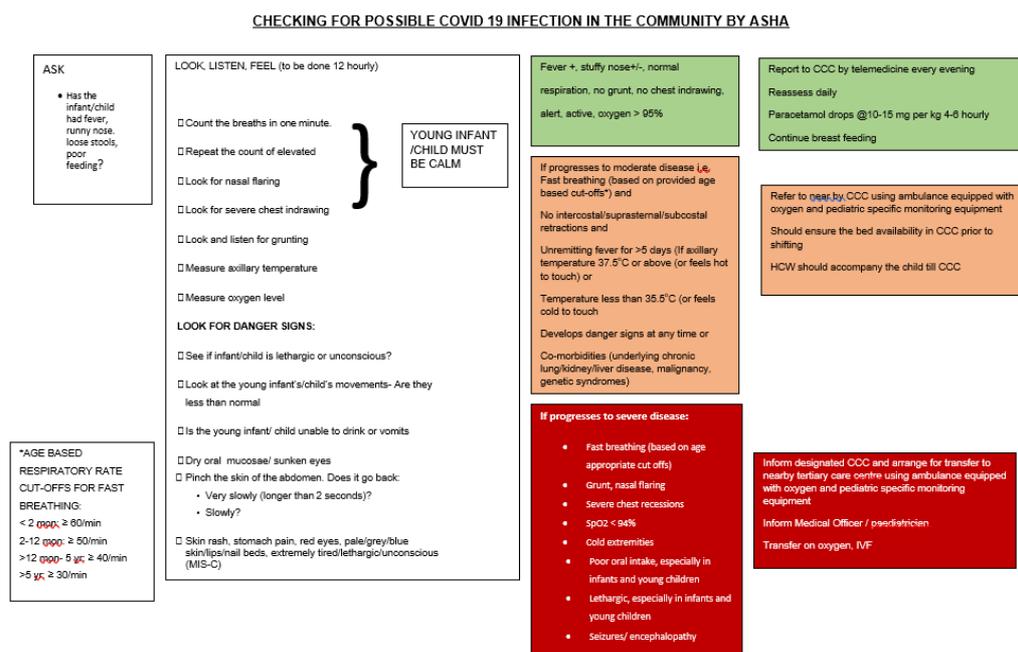
**Suspecting COVID-19 and testing in children**

The guidelines developed by the MoHFW for management of pediatric COVID-19 outlines the symptoms of COVID-19 (Fig 1). The indications for testing children for COVID-19 are the same as that proposed by the Ministry/ ICMR. Presence of a recent/ current confirmed case of COVID-19 in a family member or a close contact raises the index of suspicion.

At a community level, use of the IMNCI framework to manage children may suffice. The framework will be able to identify sick children needing referral. However, all children with fast breathing and confirmed COVID-19 will need referral for admission. Providing pulse oximeter to the MPW/ ASHA will improve the monitoring and care of children. Children with malnutrition, children with disability, and conditions such as HIV infection, underlying cardiac, liver, kidney ailments, children on cancer chemotherapy and immunodeficiencies would need special attention.

The following figure shows the IMNCI approach to COVID-19 in children (Figure 2).

**Figure 2: IMNCI type approach for COVID-19 in children**



Children seeking care at various facilities should be screened for COVID if they have the clinical features of COVID (Fig 1). Children with indications for testing for COVID should be tested at the designated facilities; children seeking care in ER should be tested in the facility itself. It will be desirable to have RAT kits in ER for quicker confirmation of the diagnosis. RAT may help in early diagnosis in symptomatic children, however negative test should be followed by RTPCR. Children who need admission and need to undergo a RTPCR/ CBNAAT, should be transferred to a holding area while awaiting the reports. The holding area should have requisite facilities for oxygen therapy, HDU/ ICU support.

### **Management of COVID-19 cases at community level**

Children with mild COVID-19 can be managed in the community setting with home isolation under direct care of the parents and family. Parents should be explained about the danger signs for progression of disease (fast breathing, increased work of breathing, bluish discoloration, SpO<sub>2</sub> < 94%, not accepting feeds, lethargy, fever persisting beyond 5 days, or high grade fever for more than 3 days). Community health workers (MPW and ASHA) should visit the home at least once daily for providing basic medications as necessary, and monitoring for vitals and danger signs. Checklists for surveillance and monitoring by the MPW/ASHA have been developed (**Appendix 1**). If any worsening is suspected, community health workers should contact the designated physician (MO/CHO) for a teleconsultation (phone call, video call). Community health workers should inform the patient transfer ambulance/team for transfer of the patients to DCHC/DCH in case there are indications for admission. Overall services should be monitored in a COVID Control Room under supervision of MO. Appropriate infographics should be developed to support the care of child at home.

### **Community level preparations**

A comprehensive IEC campaign which includes messages about pediatric COVID. There has to a specific emphasis on vulnerable children. The orphanages, boarding schools, hostels would need special attention as these could be potential hotspots. Suggested components of the IEC campaign should include

- Reassurance about disease in children
- Symptoms and signs of COVID-19
- Need for early testing for COVID-19 in case of symptoms
- Principles of home isolation
- Avoidance of self-medication for COVID-19
- Whom to contact in case of emergency
- Awareness about MIS-C

- Not to neglect routine immunization of the child
- Following COVID-19 appropriate behaviour including use of mask, social distancing and hand hygiene. (Masks recommended in children aged 5 years or above)
- Those eligible to take COVID-19 vaccination
- Continue other medications for chronic illnesses

This community level intervention will include pamphlets in vernacular languages, posters and home isolation kit. We may bring in tools like number mothers made aware vs. number of mothers registered in RCH portal each district-wise for ensuring a wide reach-out.

Pulse oximeters can be loaned to a family with support of community platforms such as VHSNC/MAS if needed and then can be used later for another family once the previous family recovers. There are concerns about the reliability and ability to record accurate saturation with the finger pulse oximeters in the youngest children. So, adequate importance should be given to the symptoms and clinical findings to assess a child for seeking further medical advice.

Once COVID vaccines are approved for children, community level programs should focus on appropriate communication to facilitate a wide coverage.

### **Categorization of COVID Health Facilities**

On 7<sup>th</sup> April, 2020, the Ministry of Health and Family Welfare issued a guidance document on appropriate management of suspect/confirmed cases of COVID-19. Based on this guidance, every state and UT have augmented or created infrastructure for managing COVID cases which are largely catering to adult cases due to the small proportion of paediatric cases. This infrastructure developed for COVID care needs to be augmented for managing paediatric COVID-19 cases for future. This infrastructure will need additional resources to care for the increased number of child patients who often would need accompanying one family member. Children's area/wards should preferably be separate from adult wards for their mental comfort and to ensure parent is allowed to accompany the child, in contrast to the policies in adult area. In addition, to cope up with a **COVID-19 related condition unique to children- MIS-C**, there is also a need to strengthen the existing health facilities for providing assured quality critical care.

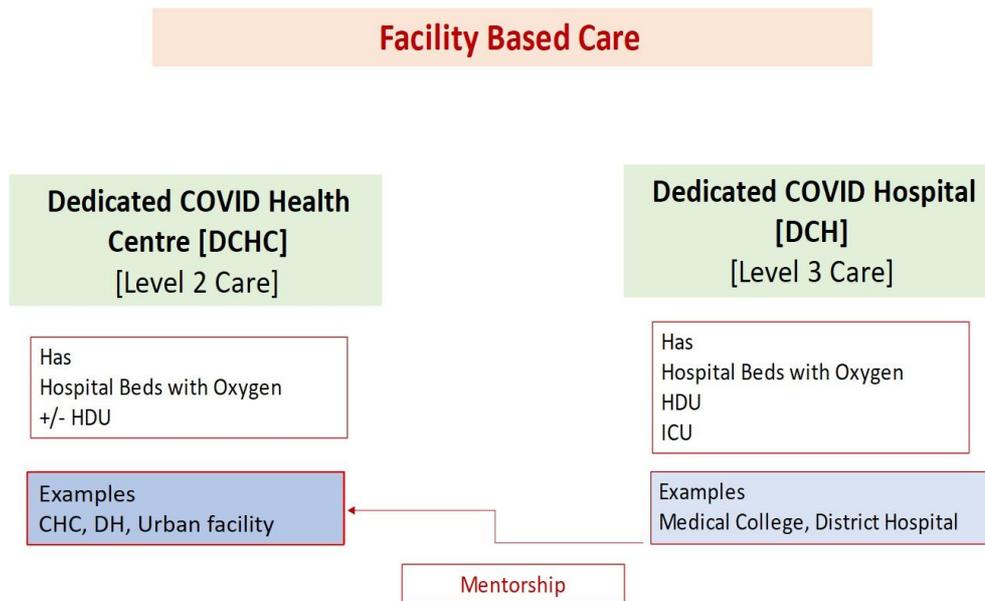
The emergency services need strengthening. There has to be appropriate triage systems in place. To keep patients suspected to have COVID-19, while awaiting reports, a holding area is required. The available holding area mainly for adult patients may be augmented to provide appropriate space for children. Such a facility should have facilities for oxygen therapy, HDU and preferably ICU support.

Currently, the COVID-19 hospitals are categorized into three types. As per the management algorithm for COVID-19 cases, infrastructure and other health system requirements

varies by symptoms (see Figure 1), wherein the severe cases are admitted in **dedicated COVID-19 hospitals (DCHs)**, cases with moderate symptoms, particularly those requiring oxygen support are admitted in **dedicated COVID-19 health centres (DCHCs)** and mild or asymptomatic cases are either home isolated or admitted in **COVID-19 care centres (CCCs)**.

Figure 3 provides the framework for facility-based treatment.

**Figure 3: Types of Facility based care**



Overview of types of facility based care for management of COVID Cases: Two types of facility based care models are available: DCHC and DCH. While the former has hospital beds with facilities to cater for Oxygen delivery with/ without High Dependency Units (HDU); the latter typically has all components of hospital care including Intensive Care Unit (ICU). DCHC are also referred to as Level 2 Care and DCH as Level 3 Care.

Examples where DCHC/Level 2 Care can be established are Primary Health Centres (PHC), Community Health Centres (CHCs), Smaller District Hospitals (DH) and Urban Health facilities. Most of these locations would need upgradation/augmentation of current infrastructure and mentoring by a higher centre.

Examples where DCH/ Level 3 Care can be established include the Medical colleges and large district hospitals. These often have infrastructure to meet the needs of higher care, but often need re-purposing of prevailing structure to cater for special needs of pediatric COVID cases.

**Triaging/ deciding the level of care of children with COVID-19**

Children seeking care at a facility should be triaged appropriately with assessment of severity of illness.

Triaging involves two stages - One at the entrance/ screening facility/ ER, and the other at the holding area before entering into the isolation ward/rooms. It consists of both screening plus detailed evaluation wherein patients can be monitored before being wheeled into specific hospital isolation wards.

**Depending upon the type and severity of cases the three types of health facilities presently functional for care of patients with active COVID-19 are:****COVID-19 Care Centre (CCC)**

The COVID Care Centres are for cases that have been clinically assigned as mild cases or mild COVID suspect cases, in the scenario where there is no facility to isolate at home. All Non FRU CHCs/ PHCs/ UPHCs can be considered under this category, in case the number of cases increases manifold.

In case there is an increase in cases, additional centres can also be created in makeshift facilities so the existing hostels, hotels, schools, stadiums, lodges etc., both public and private facilities can be used for the same. All such facilities should have separate areas for suspected and confirmed cases with separate entry and exit.

All these COVID care centres have to be mapped to one or more DCHC in case the patient requires referral. One BLS enabled ambulance is to be attached with each of these facilities with sufficient oxygen support on a 24x7 basis. The AYUSH doctors can be utilised in giving clinical care in these hospitals.

**Dedicated COVID-19 Health Centre (DCHC)**

The Dedicated COVID Health Centres are the hospitals that offer care for all cases whose severity has been clinically assigned as moderate. All FRU- CHC, SDH, DH, AH etc. can be considered under this category. They are either a full hospital or a separate block in a hospital with separate entry and exit and zoning area. These hospitals are to have assured Oxygen support and have an appropriate referral mechanism for referring to higher centre i.e., DCH, if the symptoms worsen. 10% of total beds at DCHC can be earmarked for paediatric cases; these should be equipped well to handle pediatric cases. There should be provision for augmentation by another 10%, if need arises.

**Dedicated COVID-19 Hospital (DCH)**

Dedicated COVID Hospitals offer comprehensive care primarily for those who have been clinically assigned as severe. Either a full hospital is dedicated as DCH or a separate block within a hospital with separate entry or exit gates is defined as DCH. All FRU- CHCs, DH, SDH, GH, AH, Medical Colleges, etc. can be considered under this category. Ten percent of total beds at DCH can be earmarked for paediatric cases and 10% more can be further augmented. All DCH with more than 300 beds should have a separate area designated for children.

Augmentation of additional beds/ ICUs will be done in the existing identified DCH facilities. These hospitals should be equipped with fully functional ICUs and Ventilatory beds with assured Oxygen Support. The Dedicated COVID Hospitals would also be referral centres for the Dedicated COVID Health Centres and the COVID Care Centres.

There should be ambulance facilities for smooth inter-facility transfers (Appendix 2).

**Augmentation of the above facilities for pediatric care**

Appropriate tools for monitoring should be available (e.g., pulse oximeters with pediatric and newborn size probes). Appropriate formulations of medications required for supportive care should be available. Adequately trained manpower (doctors and nurses) should be available for care of sick children (details below).

Common examples of anticipated care at different levels of care for Pediatric COVID patients are depicted in Table 1. These depend on the availability of specialist providers and the oxygen needs of the patient.

**Table 1: Examples of type of Care vis-à-vis type of facility**

Type of Care	Examples
<b>Level 2 Care</b>	<ul style="list-style-type: none"> <li>● Oxygen requirement up to 5 L/min to maintain oxygen saturation <math>\geq 95\%</math> with stable vital parameters</li> <li>● Oxygen by face mask or nasal prongs or oxy-hood</li> <li>● Monitoring by Medical doctor with a remote on-call Pediatrician / Internal medicine specialist</li> </ul>
<b>Level 3 Care</b>	<ul style="list-style-type: none"> <li>● Oxygen requirement <math>&gt;5</math> L/min and/or unstable vitals</li> <li>● Requisite backup (Lab, Radiology, Blood bank services etc) to maintain 24X7 ICU Care</li> <li>● High flow oxygen: Non rebreathing masks, High flow nasal cannula</li> <li>● Non invasive ventilation: Bubble CPAP, BiPAP</li> <li>● Mechanical Ventilation,</li> <li>● Monitoring under supervision of Pediatrician/ Intensivists</li> </ul>

Table 2 provides the summary of requirements for various levels of care

**Table 2: Summary of recommendations for type of facility-based care for pediatric COVID cases**

Type of Care	Recommended number of beds	Examples of Care	Recommended Oxygen source	Pediatric Ventilators	HR needs	Locations for set-up (examples)
<b>Level 3</b> [at DCH]	30 PICU and HDU beds  HDU beds: 3:1 PICU beds	Mechanical / Non-invasive ventilation Continuous monitoring of vital parameters  Delivery of COVID positive mothers and care of neonates	LMO, PSA Units	At least 1/3 <sup>rd</sup> of all HDU/ PICU beds. There should be provision to convert HDU to PICU beds with minimal inputs	Pediatrician/ Intensivist/ Obstetrician/ Anesthetist and corresponding required numbers of SR/JR in Med Colleges	Medical Colleges, Large District hospitals, Private health facilities
<b>Level 2</b> [at DCH and DCHC]	30-50 beds or depending on regional needs capable of providing oxygen therapy	Oxygen therapy needing a flow of 5L/minute	PSA Units/ Oxygen cylinders	Nil Can have equipment for NIV if expertise available	General Medical Doctor with on-call pediatrician	Smaller District Hospitals and Community Health Centres
<b>Level 1</b> [at CCC]	Depends on local needs, part of COVID Care Centres for adults	Children of adults who are admitted at COVID Care centres; children with co-morbidities not needing oxygen therapy and home isolation care is not feasible	Oxygen concentrators Oxygen Cylinders	Nil	Paediatrician / Medical Officer with teleconsultation from paediatrician (Public/ Private)	At Corona Care Centres
<ol style="list-style-type: none"> <li>1. All levels of care should be equipped with optimal transport facilities</li> <li>2. The actual needs will vary depending on regional requirement</li> <li>3. The above models can be either a hybrid model (with re-purposed beds meant for adult care under a given setting) or a standalone model specific for pediatric care. For immediate scale-up, it is recommended that hybrid model with re-purposing of existing adult beds for pediatric care be made available. Simultaneously, efforts should be undertaken to develop specific pediatric beds.</li> <li>4. Each pediatric bed should also cater for beds for corresponding care givers, alongside.</li> </ol>						
<p>DCH: Dedicated COVID Hospitals; DCHC: Dedicated COVID Health Centre; CCC: Corona Care Centre; LMO: Liquid Medical Oxygen; PSA: Pressure Swing Adsorption; NIV: Non-invasive ventilation</p>						

**Provisions to allow parent/ family member to stay with the child**

These facilities should have provision for the stay of a parent/ care-giver with the child. This could be an adult family member who also has mild COVID/ asymptomatic infection, or one who has previously recovered from COVID. In case the caregiver is COVID negative, he/she still may be allowed to be with the child, after due counselling, appropriate consent, and providing them with appropriate PPE (esp. a good fitting N95/ FFP2 mask).

**Augmentation of existing pediatric care facilities to provide care to children with MIS-C**

MIS-C is a severe post-COVID-19 inflammatory disorder in children which is frequently associated with complications such as cardiac dysfunction, coronary aneurysms, thrombosis, and multi-organ dysfunction etc. MIS-C cases tend to peak 2-6 weeks following the peak of COVID-19 cases in the community. MIS-C should be suspected in children with persistent fever beyond 3 days with clinical manifestations (Rash, bilateral non-purulent conjunctivitis, diarrhoea, vomiting, or abdominal pain, bleeding, respiratory distress, shock), especially if child had contact with COVID-19 patient in past 1-2 months or had acute covid infection. These features should be included in IMNCI fever algorithms for early suspicion of MIS-C in community and first referral. If MIS-C is clinically suspected, children should be referred to centres capable of providing intensive care support (mechanical ventilation, shock management, facilities for echocardiography, as needed). Management involves supportive care, organ support and immunomodulation (steroids-first line).

Clinical definition of MIS-C, evaluation and treatment protocols have been published (<https://www.mohfw.gov.in/pdf/ProtocolforManagementofCovid19inthePaediatricAgeGroup.pdf>). (\*Medical/clinical protocols are dynamic & continuously evolving and may change time to time).

Most children with MIS-C will be presenting to the emergency rooms. As the numbers are likely to increase after a surge in infections, there has to be adequate facilities for their management. The main aspects of care are adequate monitoring esp. of the cardiovascular status. Many of these children, who are PCR/ CBNAAT negative, will be cared for in the pediatric facilities. The HDU/ ICU facilities will need augmentation for the same. The mainstay of management of children with MIS-C are steroids (iv methylprednisolone) and IVIG.

For providing care to children with MIS-C, the existing pediatric facilities have to be strengthened. As per the IPHS norms, approx. 10% of beds in a district hospital should be earmarked for sick children. These facilities should be upgraded to have adequate emergency facility, and enough HDU beds. The guideline developed by the Child Health Division, MoHFW- "Strengthening Facility Based Paediatric Care: Operational Guidelines." Provides detailed requirements [[https://nhm.gov.in/images/pdf/programmes/childhealth/guidelines/Strenghtening\\_Facility\\_Based\\_Paediatric\\_Care-Operational\\_Guidelines.pdf](https://nhm.gov.in/images/pdf/programmes/childhealth/guidelines/Strenghtening_Facility_Based_Paediatric_Care-Operational_Guidelines.pdf)].

At a 300 bedded DH, the following can be recommended:

- 4 beds in Emergency
- 20 bedded Pediatric ward
- 8 bedded HDU
- 4 bedded ICU

The numbers will proportionately be higher in DH with higher bed strength. These beds do not include the beds for newborn care and SNCUs.

The administration should ensure that at least these minimum numbers of beds are assigned for Pediatrics and these are well equipped as well as well staffed. At the same time efforts should be made to increase the overall numbers of beds as well as beds for pediatric care in the public health system. Additional details of staffing and equipment requirements are discussed later in the document.

### **Augmenting bed capacity for pediatric care in urban, peri urban and rural area**

1. The existing covid facilities should be augmented; the numbers of beds available should be enhanced by at least 10%. These facilities should have provisions to allow the parents to be with the child; separate areas could be earmarked within the covid facilities for children and their parents.
2. These augmented facilities should have adequate provision for oxygen supplies, pediatric specific respiratory support devices, monitoring equipment for children, pediatric formulations. Adequate number of trained manpower for managing pediatric cases should be made available.
3. Standalone pediatric hospitals should create areas dedicated for pediatric covid care.
4. For managing MIS-C, the existing pediatric facilities within various hospitals need strengthening for HDU/ ICU care.
5. If the surge is excessive and the capacity of covid facilities is overwhelmed, then use of general beds/ wards/ ICUs in hospitals may be considered.
6. Pandemics like COVID-19 may affect us at any point of time. Thus, parallely we also need to strengthen our existing health facilities particularly DH and secondary care facilities for provision of assured non-COVID-19 critical care.
7. This is also to flag here that any strengthening in the facility will only be able to respond adequately if it is properly linked with community-based home care. Lesson from the present pandemic has clearly indicated reactions by the public, rushing to the facilities, seeking care for the cases which could have been well managed at home and this may have resulted in denial of certain services for those who actually needed the admission. It is therefore also proposed that every district should have a COVID control room under the guidance of paediatrician and physician so that focus on adequate IEC, reassurance for

community and home-based management particularly for mild cases is properly disseminated and assured to the people.

### **Admission criteria in different types of health facilities**

Suspected cases of paediatric COVID-19 need to be screened based on the symptoms using a standard flow chart (Figure 1) by a trained health worker at community level with proper PPE.

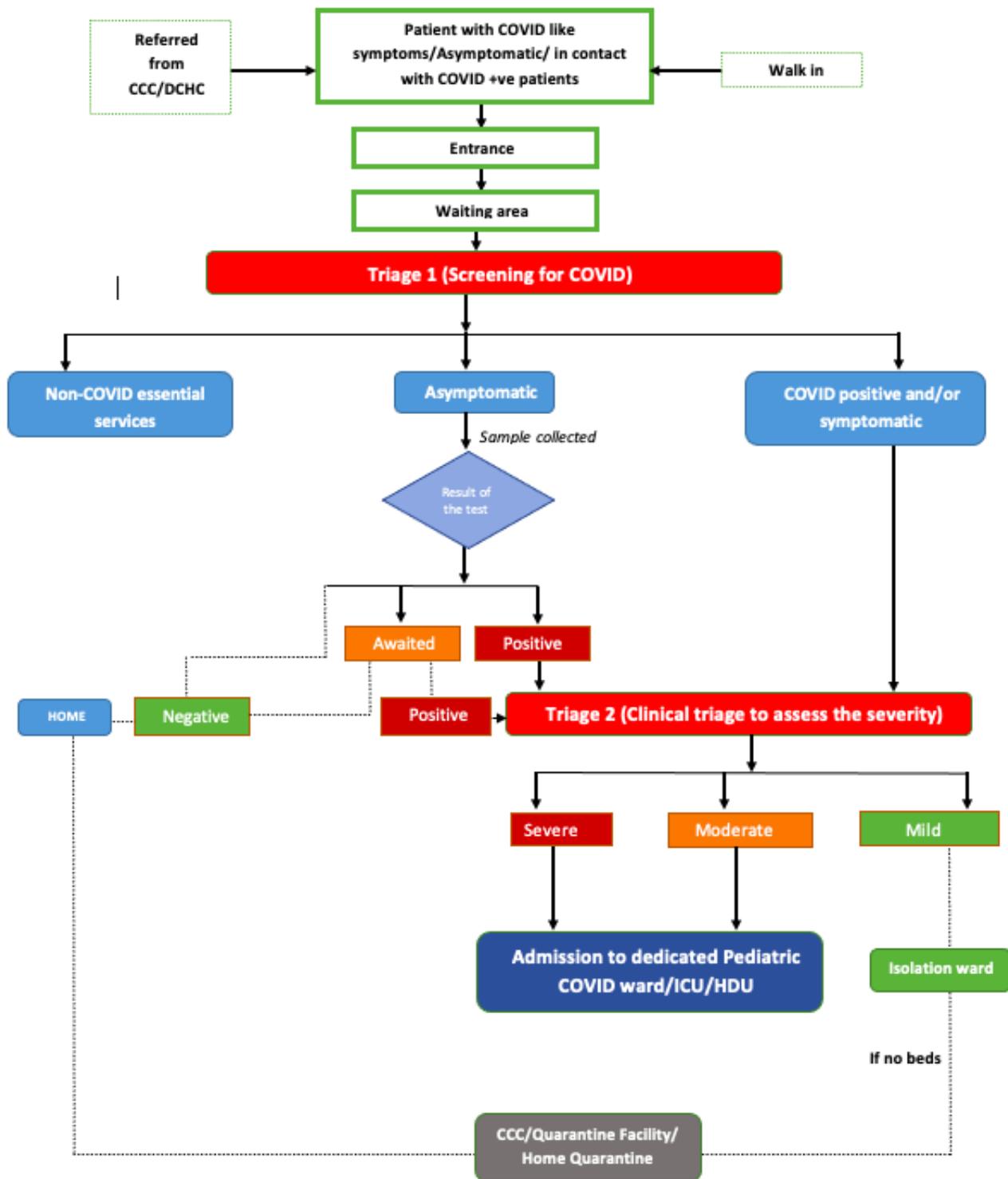
Based on these criteria, patients can be categorized as mild, moderate or severe. The mild cases are then referred to COVID Care Centre or home isolation. Paediatric cases screened with moderate and severe symptoms should be referred to higher facilities (DCHC or DCH). On the basis of above screening, once the patient reaches designated facility, following steps are undertaken:

### **Initial Screening and Triage 1 at the health facility**

- 1) Just at the entry gate, trained personnel with the recommended PPE to screen the patient by recording temperature, recording SpO<sub>2</sub>, take the history of the patient if they have come in contact with COVID-19 patient or if they have any symptom. Patients with low SpO<sub>2</sub> (<94%) should be immediately started on oxygen support in the triage area.
- 2) Attendants and patients beyond 5 years of age group, should wear mask and also follow hand hygiene. A distance of at least 1- meter to be maintained.

### **Triage 2**

- 1) The cohorting of patients may further be done by the attending doctor based on the clinical observations and will be placed accordingly for appropriate management.
- 2) The moderate cases are shifted to the yellow/ orange area where COVID-19 testing is done (if not tested earlier). If COVID-19 positive, whether moderate or severe symptoms, they will be admitted to DCH/ DCHC for advance care. If the child tests negative for COVID-19, they are provided with non- COVID-19 essential services. Children in whom there is a strong suspicion of COVID, particularly with family member having COVID, but the child tests negative for COVID, the child should be managed in the holding area and the RTPCR should be repeated.
- 3) For patients showing severe symptoms and requiring immediate lifesaving measures, emergency should be equipped with ventilator support, access to oxygen support and multipara monitors.
- 4) After stabilization in Emergency, they can be shifted to paediatric ICU.



## Hospital Infrastructure (DCHC/DCH)

### Area for Screening/ Triage / Emergency

- 1) The emergency area of a COVID facility should be comprehensively created keeping in mind easy accessibility and quick response.
- 2) The Emergency area should have a dedicated dual triage system with clinical management zones.
- 3) The triage area should have dedicated space with wall mounted multipara monitors and medical gas outlets. The multipara monitors should have probes/ accessories suitable for children.
- 4) Necessary accessories for providing oxygen therapy/ respiratory support to children of all age groups should be available; please see section below
- 5) Pediatric formulations of the commonly used medications should be available; please see section below.
- 6) Service provision as per the process flow explained above should be available through adequately trained human resource round-the-clock.
- 7) There should be easy approach and access for ambulances with adequate space for the free passage of vehicles and a covered area for alighting patients.
- 8) Space to ensure distancing, stretchers, wheelchairs and trolleys should be available at the entrance of the emergency at a designated area.

### Oxygen supported beds

- 1) **Oxygen supported beds**- All beds in DCHC will be oxygen supported whereas DCH will have both ICU and HDU beds. The distance between the beds should be at least 1 metre/ 3 feet.
- 2) A separate room/Anteroom at the entry of the ward to be made- where all the precautionary steps of PPE, hand sanitizing and hand wash facility can be practiced before entering the room (Donning area).
- 3) Paediatric wards, similar to other wards, need to have adequate cross ventilation.
- 4) An attendant / guardian can be allowed with every paediatric patient. They should be trained and oriented on infection prevention, hand hygiene, and providing supportive care to the patients.
- 5) A designated area should be earmarked in all such hospitals for keeping personal belongings of paediatric patients/ attendants, washroom, etc.
- 6) The beds in the Paediatric ward should be placed either on one side or both the sides of the nursing station ensuring good visibility. It should also be ensured that COVID patients

are not left unattended in the wards as this may have an impact on their mental health leading to isolation and depression.

- 7) Male and Female toilets should be conveniently located.

**Critical care beds: HDU and ICU**

- 1) Critically ill patients requiring highly skilled lifesaving medical aid and nursing care will be admitted here.
- 2) Generally, Paediatric HDU beds are for patients with single organ failure where a specialist can monitor and manage. Paediatric ICU beds are for patients with multiple organ failure and life is eminently at threat requiring ventilator support with backup for super and multispecialty care. So, a hybrid critical care area (HDU +ICU) with both ventilatory and non-ventilatory beds can be established.
- 3) **Intensive Care Unit with ventilatory beds** with access to oxygen and multipara monitors (with 3 meter distance from centre of each bed)
- 4) The unit will also need specialized services such as suction (central supply or through standalone machines), medical gas supply, oxygen (through central supply or cylinders with humidifiers and flowmeters), uninterrupted electric supply, heating, ventilation and air handling unit. Pediatric and newborn specific equipment and consumables should be made available.
- 5) Ceilings, flooring and walls should be constructed of materials with high sound adsorption capabilities.
- 6) There should be  $\geq 12$  air exchanges per hour and preferable, a negative air pressure maintained.

### Linkages with tertiary care hospital

*All secondary care hospitals should be linked with District hospital where assured critical care for COVID and related complications (such as MIS-C etc) can be managed.*

*The state must ensure linkages with Tertiary care centres. The medical colleges should be linked with district hospitals irrespective of the state boundaries. For the same and nodal person shall be appointed who would coordinate regarding bed availability and preparedness.*

*The medical college should regularly update the number of beds available in the public domain.*

### Augmenting the capacity of medical college

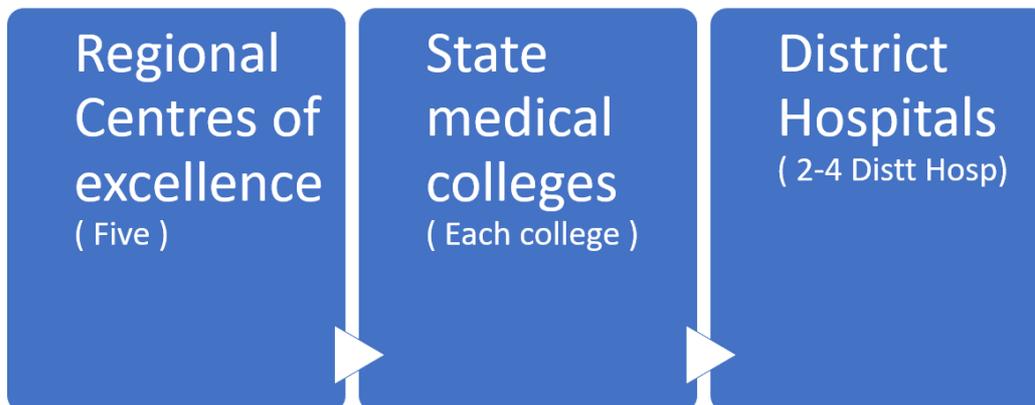
*All paediatric beds at Medical college must be supported by regular oxygen supply and basic equipments.*

*All medical college should have minimum 30 bedded paediatric hybrid HDU consisting of both ventilatory and non-ventilatory beds. The number for the same shall be decided by the medical college depending upon the case load.*

*The paediatric unit catering or being created to serve COVID cases should have preferably separate entry and exit. It should also have a facility to allow one attendant within a critical care ward to support the admitted cases. During non-COVID time, it can serve as a critical care unit.*

*Additional beds may also be added as paediatric COVID positive case increases.*

**The following framework may be considered for supportive supervision & mentoring:**



Telemedicine could be harnessed for supporting various pediatric COVID care facilities and also facilities managing MIS-C. The concept of e-ICU should be deployed for improving care of sick children in the periphery.

Please refer to Appendix 3 for the details of **common services for all types of health facilities**

For the **human resource requirements**, please refer to Appendix 4.

**Training**

Capacity building of HR on surveillance, infection prevention and control, clinical management and risk communication should be ensured. Training modules available on the website of MoHFW (<https://www.mohfw.gov.in/>) or iGOT Diksha portal (<https://diksha.gov.in/igot/>) for these activities shall be used. A combination of online training with virtual interactions, and supplemented by in-person training (Hybrid) may be developed for optimal capacity building. The regional centers should supervise the medical colleges and each of the medical colleges could support/ mentor 2-4 district hospitals; appropriate linkages for the same should be developed.

Both the doctors and nurses posted in emergency, HDU/ICU, paediatric wards should be trained in routine and critical paediatric care. Customised packages for training hospital attendants, security staff & parents will be needed.

**Equipment**

Medical equipment plays a significant role in patient care in COVID Hospitals. All the necessary equipment to provide clinical, support and other services should be ensured. Additional equipment, if required, can be procured to provide the full range of services being offered at the facility. Before initiating procurement of any equipment, facility wise gap analysis is a must. A systematic and robust programme for bio-medical equipment maintenance and monitoring should be in place with dedicated responsible people. For equipment requirements, please refer to **Appendix 5**.

For specification of equipment, please refer to the link <http://nhsrcindia.org/category-detail/technical-specifications/ODgz>

**Infection Prevention & Control**

Since COVID-19 infection is highly infectious, every hospital handling such patients is expected to put robust infection prevention control protocol in place. Such protocols would be based on latest guidelines, issued by the MoHFW, ICMR, NCDC and CPCB. Safe-guarding health of service providers, attendants and community is of paramount importance. The protocols for pediatric care areas are the same as those for the covid areas.

Following steps need to be undertaken immediately –

Constitution of Hospital Infection Control Committee, if not constituted earlier and weekly meetings

- 1) Reorientation training of all categories of hospital staff on infection control and prevention.
- 2) Adherence to infection prevention protocols including cleaning, segregation and transport.

- 3) Ensuring uninterrupted supply of Sodium Hypochlorite, Isopropyl Alcohol, Ethyl Alcohol, Hydrogen Peroxide, Alcohol based hand rub, Glutaraldehyde, Bins, Linens, etc.
- 4) Ensuring supply of water and availability of liquid soap, and paper to dry hands and dispenser at all patient care points
- 5) Facilitate access to full complement of PPE by all category of staff and ensuring its usage on 24x7 basis
- 6) Availability of Alcohol based hand rub at every possible point of use by the staff and attendants
- 7) Collection of segregated waste from COVID patients and its labelling throughout the chain of its movement till disposal.
- 8) Re-ensuring that Common Biomedical Waste Treatment and Disposal Facility (CBWTF) operator collects the waste at least once in a day
- 9) Reinforced IEC activities on hand hygiene, PPE, cough etiquette, etc.
- 10) Ventilation and air-exchanges in patient care and visitors' area.
- 11) Appropriate Bio-safety measures in the laboratories, as per guidelines

Inventory of consumables need to be maintained ensuring an uninterrupted supply chain of consumables. Nodal person should be assigned to oversee

### **Disposal of the deceased**

While the outcomes in pediatric covid are good, deaths may occur occasionally. Dead body disposal for children dying due to COVID-19 should be streamlined; the principles are same as that for adults. Availability of paediatric size body bags should be ensured. Cremation services should be equipped and sensitized to handle bodies of the children. For details please refer to MoHFW guidelines

([https://www.mohfw.gov.in/pdf/1584423700568\\_COVID19GuidelinesonDeadbodymanagement.pdf](https://www.mohfw.gov.in/pdf/1584423700568_COVID19GuidelinesonDeadbodymanagement.pdf)).

### **Discharge criteria**

For children admitted in a facility, the criteria for discharge are same as that for adults [<https://www.mohfw.gov.in/pdf/ReviseddischargePolicyforCOVID19.pdf>]

### **Post COVID-19 care**

Children who have suffered from severe COVID-19 infection especially those who have needed invasive ventilation will need enhanced care on follow up. Likely post discharge complications include infections (pneumonia, invasive fungal infections including mucormycosis), thromboembolism, progressive fibrosis and hypoxemia among others. Since children have good regenerative capacity the likelihood of persistent pulmonary dysfunction and

need for home oxygen therapy is likely to be less. The following are recommended for discharge and post discharge care of children who have suffered severe COVID-19

1. A pulse oximeter should be given to the patient at discharge with advice about how the saturation should be monitored
2. Advice about warning signs which include development of fever, persistent drop in oxygen saturation, increased cough or breathlessness, chest pain, headache/ jaw pain/ tooth pain/ nasal blockage.
3. Provision for home oxygen therapy in those that need it and emergency contact number in case of exhaustion of oxygen supply or malfunction of concentrator
4. Emergency contact number in case of warning signs
5. Influenza and pneumococcal vaccination may be considered

#### **Care of neonates born to COVID-19 positive mothers**

Up to 10% of neonates born to COVID-19 positive mothers may be RT-PCR positive for SARS-CoV-2 during birth hospitalization (9). Majority of these neonates remain asymptomatic. Occasionally, moderate to severe infections with oxygen requirement can occur. A significant proportion of neonates may however require special or intensive care due to prematurity and perinatal complications. Breastfeeding, rooming-in, kangaroo mother care (when required) should be encouraged in all cases. Therefore, the pediatric facility should have equipment and surgical consumables suitable for neonates including preterms. Routine immunization should be done for stable neonates. Management guidelines for perinatal-neonatal COVID-19 have been published (6).

#### **Neonates with Late-onset Covid-19 disease**

During the second wave, an increasing number of neonates with moderate to severe Covid-19 pneumonia and gastrointestinal symptoms have been seen. These neonates typically acquire the infection at home from other family members. Occasional cases of MIS related to COVID antibodies transmitted from the mother have also been seen. The pediatric HDU/ ICU should have suitable equipment and surgical items for care of these neonates e.g.,servo-controlled open care systems, air-oxygen blending systems, CPAP, ventilators capable of supporting preterms and appropriate sized nasal interfaces and endotracheal tubes.

The following types of clinical areas are required for the care of neonates (Table 3):

**Table 3:** Requirements for various scenarios for new born care

S No.	Type of facility	Type of care	Location	Remarks
1.	Newborn Care Corners	Resuscitation facilities	Next to or within each delivery area for suspect and confirmed Covid-19 pregnant women	Special attention required for ensuring thermoregulation and availability of blended air-oxygen
2.	Special Care Newborn Unit/Neonatal intensive care Unit for care of 'suspect' neonates	Special or intensive care for prematurity or other perinatal illnesses.	Ideally should be located close to the delivery area. Can be part of pediatric suspect ward, or as a standalone unit, or carved out of existing SNCU/NICU with separate entry/exit and donning/doffing facilities.	Special attention required for ensuring thermoregulation and appropriate equipment. As majority of neonates born to Covid-19 mothers will turn out to be negative and will need to stay in the area for 5-6 days before they can be confidently declared negative for SARS-Cov-2, this area will need the largest proportion of neonatal beds, staff and equipment
3.	Special Care Newborn unit /Neonatal intensive care unit for care of 'confirmed' neonates	Special or intensive care for prematurity or other perinatal illnesses or early onset Covid-19 disease	Part of pediatric COVID confirmed area	As the number of such cases is going to be small, it will be more efficient to locate them within the pediatric COVID facility.
4.	Postnatal COVID ward /rooms for mother-baby dyads	Rooming-in of stable babies with suspect or confirmed Covid-19 mothers	Part of obstetric postnatal wards/rooms for 'suspect' or 'confirmed' Covid-19 mothers.	Equipment and staff for monitoring and essential neonatal care will be required. (thermoregulation, lactation and KMC support, monitoring for blood glucose, jaundice and phototherapy

5.	Well-baby COVID area	Rooming-in of stable neonates with family caregivers in case of non-availability of mother.	An area under pediatrics will have to be marked for this. If such a facility cannot be created, these babies may be accommodated in the SNCU for 'suspect' cases (item no.2) until fit for discharge	Family members may also be positive or not available for baby care. In such cases, the babies can be accommodated in the SNCU for 'suspect' cases.
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It will be more efficient and beneficial for patients as well as care providers, if the obstetric and delivery areas for suspect and Covid-19 pregnant women are located along with neonatal and pediatric areas.

For the **Governance structure for Pediatric COVID Care**, please refer to Appendix 6

**Equity and dignity of care** is critical in all health care services, including the covid facilities. Please refer to Appendix 7 for the framework to provide and monitor appropriate services, roles and responsibilities of the nodal officers to ensure high-quality care.

### **Research and Registry**

To understand disease burden, profile, pattern and outcomes, including any changes over time, efforts should be made to establish a national registry to collect data from pediatric cases, including severe COVID & MIS-C. In a phased manner, the registry may be operationalized at the level of medical colleges and major private institutions, and then expanded to district hospitals. It will also be important to include data for the more vulnerable children; e.g., malnourished children, children with disabilities, children with chronic medical conditions, and children living with HIV. At the same time, important research areas should be identified and projects undertaken to address various aspects of management of COVID in children. Operational research is also a need of the hour.

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**Appendix 1:** Checklists for surveillance and monitoring by ANM/ASHA**Physical Triage Checklist – Surveillance in Children**

(To be used by ASHA/MPW-M or F/Community Health Worker/Community Volunteer)

**1. Demographics**

- a. Name: .....
- b. Age: ..... 0-2 months  2- 12 months  1-5 years  >5-9 years  
 10-14 years  15-18 years
- c. Sex: .....

RT-PCR/RAT status with date \_\_\_\_\_

**2. Symptoms (Please consult CHO/MO if any one of the following symptoms is present):**

Symptom	No. of Days since onset of symptom	Symptom	No. of Days since onset of symptom
Fever <input type="checkbox"/>		Fatigue <input type="checkbox"/>	
Cough <input type="checkbox"/>		Body ache <input type="checkbox"/>	
Shortness of breath <input type="checkbox"/>		Loss of smell <input type="checkbox"/>	
Loss of taste <input type="checkbox"/>		Headache <input type="checkbox"/>	
Runny/blocked nose <input type="checkbox"/>		Vomiting <input type="checkbox"/>	
Sore throat <input type="checkbox"/>		Rash <input type="checkbox"/>	
Blood in sputum <input type="checkbox"/>		Confused status <input type="checkbox"/>	
Redness of eye, lips <input type="checkbox"/>		Loose stools <input type="checkbox"/>	
Abdominal pain <input type="checkbox"/>		Chest pain <input type="checkbox"/>	

**3. Co-morbidities (if already known):**

Diabetes Mellitus Type 1 <input type="checkbox"/>	Chronic Liver disease <input type="checkbox"/>
Hypertension <input type="checkbox"/>	Congenital Heart Disease <input type="checkbox"/>
Cardiac disease <input type="checkbox"/>	Cancer <input type="checkbox"/>
Respiratory illness <input type="checkbox"/>	On steroid/chemotherapy <input type="checkbox"/>
Chronic kidney disease <input type="checkbox"/>	Regular dialysis? <input type="checkbox"/>
Psychiatric illness <input type="checkbox"/>	Obesity <input type="checkbox"/>
Chronic arthritis <input type="checkbox"/>	Severe malnutrition <input type="checkbox"/>
Neurological disorders <input type="checkbox"/>	

**4. List of current medications:**

- a. \_\_\_\_\_  
 b. \_\_\_\_\_  
 c. \_\_\_\_\_

**5. Examination (Please consult CHO/MO if any one of the following signs is present):**

S. No.	Parameter	Response	Action required- Consult CHO/MO in case of the following finding
1	Mental status	Conscious, oriented <input type="checkbox"/> Altered sensorium <input type="checkbox"/>	Altered sensorium
2	Respiratory rate (RR) (count/min)	...../min	If more than $\geq 60$ /min for 0-2 months $\geq 50$ /min for 2-12 months, $\geq 40$ /min for 1-5 years $\geq 30$ /min for >5years
3	Oxygen saturation	.....%	below 94%

**1. Eligibility criteria for home isolation (Please tick the response)**

A.	Is respiratory rate < age specific cutoff	Yes	No
B.	Is room air SpO <sub>2</sub> $\geq$ 94%	Yes	No
C.	Absence of <b>ALL</b> of the following high-risk features <ul style="list-style-type: none"> <li>● Cardiovascular disease including hypertension</li> <li>● Diabetes</li> <li>● Immunocompromised states</li> <li>● Chronic lung disease</li> <li>● Chronic kidney disease</li> <li>● Chronic liver disease</li> <li>● Cancer</li> <li>● Transfusion dependent thalassemia/hemophilia</li> <li>● Cerebrovascular disease</li> <li>● Obesity (BMI &gt; 2SD)</li> <li>● Severe malnutrition</li> </ul>	Yes	No

**2. Social eligibility criteria for home isolation (Please tick the response)**

A	The patient has a requisite facility for isolation at his/her residence and also for quarantining the family contacts	Yes	No
B	Caregiver is available to provide care on a 24X7 basis	Yes	No

C	The parents/caregiver has agreed to monitor health of the child and regularly inform his/her health status to the Surveillance Officer/ doctor	Yes	No
D	The parents/ caregiver have filled an undertaking on self-isolation and shall follow home isolation/quarantine guidelines	Yes	No

**Red flag signs:**

S. No.	Parameters	When to refer (Danger Signs)
1	Fever	>100.4 F for more than 3days
2	SpO2	below 94 %
3	Bluish discolouration of body	Refer if Yes
4	Respiratory rate	If more than ≥60/min for 0-2 months ≥ 50/min for 2-12 months, ≥ 40/min for 1-5 years ≥ 30/min for >5years
5	Chest indrawing	Refer if Yes
6	Skin rashes	Refer if Yes
7	Redness or swelling of lips and tongue	Refer if Yes
8	Redness and swelling of hands and feet	Refer if Yes
9	Oral Intake	Refer if reduced
10	Lethargic	Refer if Yes
11	Urine output (at least 6 times/day for newborn)	Refer if Reduced
12	Cold extremities (check in newborn)	Refer if Yes

**Physical Triage Checklist- Home Isolation Daily checklist  
(To be filled for 14 days)**

Date: .....

**Number of Days of home isolation: .....**

1. Demographics

a. Name: .....

b. Age: ..... 0-2 months  >2- 12 months  1-4 years  5 to 9 years   
10-14 years  15-18 years

c. Sex: .....

**General Examination**

S. No.	Parameters	Observation	When to refer (Danger Signs)
1	Fever		>100.4 F for more than 4 days
2	SpO <sub>2</sub>		below 94 %
3	Cold extremities	Yes No	Refer if Yes
4	Respiratory rate		If more than ≥60/min for 0-2 months ≥ 50/min for 2-12 months, ≥ 40/min for 1-5 years ≥ 30/min for >5years
5	Chest in-drawing	Yes No	Refer if Yes
6	Skin rashes	Yes No	Refer if Yes
7	Redness or swelling of lips and tongue	Yes No	Refer if Yes
8	Redness and swelling of hands and feet	Yes No	Refer if Yes
9	Oral Intake	Adequate Reduced	Refer if reduced
10	Lethargic	Yes No	Refer if Yes
11	Urine output (at least 6 times/day for newborn)	Adequate Reduced (less than 6 times a day)	Refer if Reduced
12	Cold extremities (check in newborn)	Yes No	Refer if Yes

**Other observations:**

<b>S. No.</b>	<b>Parameters</b>	<b>Observation</b>	<b>Action required</b>
1	Daily monitoring chart updated	Yes No	Ensure adherence to home isolation protocol
2	Drugs available and administered on a timely basis	Yes No	
3	Warm saline gargles (for children more than 5 years age and adolescents)	Yes No	
5	Oral fluids taken regularly	Adequate Reduced	
6	Timely Intake of nutritious diet	Yes No	
7	Child wearing mask (>5 years of age)	Yes No	

## **Appendix 2**

### **Specific requirements for Inter- Facility transport – transfer to a higher facility**

#### **Background:**

A referral pathway and emergency transport need to be in place for the transfer of patients with history of contact, suspected or positive for COVID-19 with severe illness, to the designated higher facility. The guidelines for this inter facility transport-transfer will ensure their safe clinical care as well as make sure that the clinical team as well as the transport team are sufficiently protected from SARS-COV-2. Given the highly contagious nature of SARS-COV-2, we need to pay special attention to infection control and monitoring during transport of critically ill children.

#### **Transport of patients**

##### **AMBULANCES**

Ideally, separate ambulances and personnel should be earmarked for transporting COVID-19 suspect / proven cases.

There are 2 types of ambulances: ALS i.e., those with ventilators & BLS those without ventilators. There are also ambulances for neonatal transfer that have equipment meant for management of sick newborn.

If dedicated ambulances for COVID are not feasible then other ambulances having basic facilities like that of BLS can be used but strict adherence to cleaning & decontamination protocols must be followed before it is used for non-COVID purposes.

Each facility should make a list of all the ambulances available in the locality and empanel them to be used whenever required.

The ambulance should have the following **basic equipment and drugs** in anticipation of any medical emergency en route:

1. Stretcher trolley (foldable) with IV stands
2. Vital sign monitor.  
NIBP, with cuffs of all sizes  
SPO<sub>2</sub>  
ECG
3. Transport Ventilator with O<sub>2</sub> source and inbuilt compressor
4. Syringe infusion pump
5. Ventimask with O<sub>2</sub> flow meter
6. Ambu bag, 250ml, 500ml, 1000ml with face masks 0,1,2 and reservoir
7. Laryngoscope with blades: 0,1,2 straight and curved
8. ETT No: 2.5, 3, 3.5, 4, 4.5, 5, 5.5
9. LMA 0, 1, 2
10. Oropharyngeal airway
11. Suction apparatus with suction and Catheter
12. Emergency drug tray: Adrenaline, Lorazepam, Phenytoin, Phenobarbitone, Atropine, Dextrose (25% & 10%), Furosemide, Midazolam, Hydrocortisone, Salbutamol respiratory solution
13. IV fluids: Normal saline, Ringer lactate, 10% dextrose
14. Nebulizer
15. Glucometer
16. IV Cannulae

17. Hood Box
18. Tapes to fix the tubes
19. Triple layered masks
20. Hand sanitizers.

Ambulances should have only the essential equipment and material for immediate use to avoid contamination

### **Protection of Personnel**

- For HCW providing clinical care during transport: Full PPE: Protective gown, N95 masks, double gloves, goggles, head cover, shoe covers.
- For drivers, technicians not directly involved in care of the patient: Gown, surgical masks, gloves
- For patients not requiring respiratory support: Surgical mask whenever feasible ( older than 5 years)
- For accompanying care giver: surgical mask
- Public health measures e.g. hand hygiene, respiratory etiquettes need to be adhered to.

### **Procedure**

The staff of the referring hospital has to first get in touch with the higher level referral hospital, ensure the availability of beds and inform about the condition of the child.

Prior to shifting of the patient, HCW from the ambulance will perform the following:

- Wear the appropriate PPE
- Assess the condition of the child
- Ensure that the child is stabilized
- Contact the identified facility for facility preparedness & readiness.

Only one caregiver, usually the mother, should be allowed to accompany the child.

### **Management on board**

- Measure vitals of patient and ensure the patient is stable
- Measure SPO2
- If required, give supplemental O2 therapy with oxygen hood instead of low flow O2 via nasal cannula, to maintain SPO2 >90%.
- If a Bag Valve Mask (BVM) is required in the event of worsening hypoxia during transport, provide only gentle bagging to reduce aerosolisation.
- Avoid unnecessary breathing circuit disconnection during transport
- In general, all Aerosol Generating Procedures (AGP) should be avoided during transport unless absolutely necessary for patient care.
- If a child is being transported on a ventilator to the higher center follow ventilator management protocols provided the HCW is either trained or is assisted by a doctor well versed in ventilator management.
- In the event of cardiac arrest in an intubated and mechanically ventilated patient: Do not disconnect the ventilator when starting CPR, increase FiO2 to 100%, give chest compression, check the ventilator tubing to ensure that, that was not the cause for the cardiac arrest as, early detection and proper treatment of potentially reversible causes during CPR, is very important.

**Handing over the patient**

- On reaching the receiving hospital, the HCW will hand over the child and give details of any intervention done during transport.
- HCW will then doff as per protocol, followed by hand washing. Use alcohol rub/ soap and water for hand hygiene.
- Transport staff should put on new PPE prior to the return journey in the same ambulance and doff after reaching back
- The Biomedical waste (including the PPE) to be disposed off in a bio- hazard bag (yellow bag). Inside would be sprayed with sodium hypochlorite (1 %) and after tying the exterior should also be sprayed with the same. It will be disposed off at their destination hospital. This is again followed by hand washing.
- The equipment used during transport should be cleaned and sterilized as per facility protocol.

**Disinfection of ambulance**

- All surfaces that may have come in contact with patient, attendant or materials contaminated during patient care (e.g.: stretcher, rails, control panels, floor, walls, work surface) should be thoroughly cleaned & disinfected using 1% sodium hypochlorite solution.
- Clean and disinfect reusable patient care equipment before use on another patient with alcohol-based rub.
- Cleaning of all surfaces & equipment in the ambulance should be done morning, evening, & after every use with soap / detergent & water.
- Cleaning staff should be in PPE

**Training of the ambulance staff**

- All the staff of the ambulances e.g., the driver, the technicians should undergo training in:
  - Some basic knowledge of what COVID-19 infection is
  - General principles of infection control
  - Donning and doffing of PPE

### **Appendix 3**

Common services for all type of health facilities

#### ***Waiting area***

1. To be set up along with the triage area where an attendant of the child can wait and can be sent back from a separate exit. A physical distance of at least one metre between two people should be maintained.
2. Only one attendant will be allowed with each patient. Mask and hand washing facility will be made available for all attendants.

#### ***Diagnostic Services***

In addition to Diagnostics tests required for confirmation of COVID 19 (details given in following section), tests for management of critical patients in ICUs, including Complete Blood Count, Serum Electrolytes, Kidney and liver function tests, CRP, Arterial Blood gas, Troponin are required. For ICUs, Point-of-care testing devices can also be used.

#### ***Support services***

Provision for medical gas pipeline system/ oxygen supply (details placed at Annexure 2), laundry (on or off site), Sanitation, housekeeping services, Kitchen service, CSSD services (can be linked with main services). Services like Bio Medical Equipment Management, CSSD, Mechanized Laundry, Dietary Services should be linked with the existing health facility. Personnel to manage these services should also be ensured.

#### ***Disaster Preparedness and Management***

Compliance as per state and centre government guidelines for disaster management should be ensured.

#### ***Fire Safety***

Access of fire tender and rescue teams, availability of open spaces on each floor, clearly visible fire exits with proper illumination and lighting (even during interruption in electric supply) are some of the important considerations for creating fire safe infrastructure. As a principle, none of the fire exit doors should be kept locked. These doors should be fire resistant and can be opened towards the outside with a push bar system on the doors. Fire detectors, extinguishers, sprinklers, and water connections should be functional and easily accessible.

#### ***Electrical Load***

1. Distribution of electric load along with load balancing to various equipment and installations in a facility is very important since overloading at any point can result in mis happening like electric fire hazard or can damage the equipment.
2. Similarly, fluctuation in voltage also adversely affects the equipment and hence automatic voltage regulators which regulate fluctuating input power voltage and maintain constant output voltage should be provided. So, electrical installation is a specialized job and must be given due importance to ensure proper care with reduced risks to the patient.

***Oxygen Support***

1. Provision of continuous supply of oxygen for oxygen therapy will be critical in Emergency Department, Intensive Care Units (ICUs), oxygen supported beds, isolation wards/rooms, etc. Oxygen generator based system to generate oxygen in-house is recommended as a preferred source of supply of oxygen, as this will ensure an uninterrupted supply.
2. This is to flag here, if the Oxygen Generation Plant is being installed, then it should cater to the needs of the entire hospital in both COVID and non-COVID cases.

***Administration area, storage room with adequate supplies.******Staff room/Rest room***

For health care workers to be made available separately. It should have provision for a changing room and a pantry for staff. A small locker for the staff to keep extra uniforms can also be provisioned for.

***Security arrangements***

Should be adequate and appropriate, for example, female security guards for female wards. CCTV cameras can be installed to ensure monitoring and surveillance. Security services should be properly planned and staff should be trained accordingly. Restricting unnecessary movements and visits to ensure patient safety and breaking possible chain of transmission is also the responsibility of security staff.

**Appendix 4****Human Resource**

- 1) HR at various facilities should be as per IPHS, however if any additional beds are added to fulfil additional service requirement for COVID cases, additional Human Resource will be required while addressing the following principles:
- 2) Ideally, staff to operationalize and manage the facility, should be utilized from the existing pool of staff/from the nearest non-functional or partially functional health facilities.
- 3) Services of Specialist such as Medicine, Anaesthesiologists, Paediatrics, Microbiologist (for diagnostic support and IPC), Psychiatrists, Psychologists, Psychiatric Social Worker and General Duty Medical Officers (GDMO), are required for care of the patients admitted in the facility.
- 4) For HR other than specialists, following ratio of staff can be adhered to:

Service Area	Type of Staff	Ratio (per shift )
<b>Emergency</b>	Nurses	Red + Yellow + Green + Triage + Isolation Beds (At least 2 nurses in each shift)
	Medical Officer	1:10
<b>Oxygen Supported Bed</b>	Nurses	1:6
	Medical Officer	1:10
<b>ICU</b>	Nurses	1:1
	Medical Officer	1:10
<b>SNCU</b>	Nurses	1:3
	Medical Officer	1:10
<b>HDU</b>	Nurses	1:2
	Medical Officer	1:10
<b>Wards</b>	Nurses	1:6
	Medical Officer	1:15

- 5) Arranging HR shall be the responsibility of the CMO/CMHO/Head of the district health department, etc.
- 6) They can also be hired on an hourly/temporary basis. Trusts, NGOs, mission hospitals, Professional organizations like IMA can also be contacted.
- 7) For specialists, doctors and nurses particularly working in DCH, there should be a defined roster. Administration should provide accommodation for them so that, if they wish, they may prefer to stay in the accommodation provided during quarantine and to keep their families safe.

**Appendix 5****Equipment/ Medications required at various levels of health care****Level 1: COVID Care Centres**

The list of key equipment and consumables for CCC are depicted in Table 1.

**Table 1: Proposed standard of Pediatric COVID Care at CCC (Level 1) facility/CHC**

<b>Essential Equipment (per 25 beds)</b>	<b>Consumables</b>	<b>Drugs / Medications</b>
<ul style="list-style-type: none"> <li>● Resuscitation Couch/ Bed (1-2)</li> <li>● Self-inflating bags newborn (250 ml), infant (500ml) &amp; pediatric (750 ml) (1-2 of each size)</li> <li>● Masks newborn, Infant, child (00,0,1,2)</li> <li>● O2 cylinders / Oxygen concentrators (2 Jumbo)</li> <li>● Laryngoscope handle and blades (curved &amp; straight) of all sizes (1-2)</li> <li>● Pulse oximeter (1-2)</li> <li>● Electrical / foot-operated suction machine (1-2)</li> <li>● Glucometer &amp; strips (1-2)</li> <li>● Thermometer (1 per bed)</li> <li>● ECG machine -1</li> <li>● Radiant warmer (1)</li> <li>● Emergency trolley (1)</li> <li>● Measuring tape (1-2)</li> <li>● Weighing scales for infants and children (1 each)</li> <li>● NIBP with all cuff sizes (1-2)</li> <li>● Torch (1-2)</li> <li>● Stethoscope (1-2)</li> <li>● Algorithms/flow charts</li> <li>● Printed drug dosages for children</li> <li>● AED (desirable)</li> <li>● X-ray view box (1)</li> <li>● Table and chairs for staff (2)</li> <li>● Almirah (2)</li> </ul>	<ul style="list-style-type: none"> <li>● Oxygen delivery devices: Nasal prongs, simple face masks, non-rebreathing masks, oxygen hood</li> <li>● Pediatric NRBM masks, Simple face masks and nasal cannula of all sizes</li> <li>● Oral / nasopharyngeal airways (different Ped. sizes)</li> <li>● Endotracheal tubes (2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 cuffed and uncuffed )</li> <li>● Intra-osseous needle</li> <li>● IV infusion sets/dosiflow</li> <li>● IV cannulae (size 20,22 or 24,26G), three way</li> <li>● Adhesive tape, 2 sizes</li> <li>● Syringes 1 ml, 2 ml, 5 ml, 10 ml</li> <li>● Disposable needles 22,23,26 G</li> <li>● Nasogastric tubes (sizes 6,8,10,16 fr)</li> <li>● Suction catheters: size 6, 8,10,12 Fr</li> <li>● RL / NS</li> <li>● 0.45% Saline with 5% Dextrose</li> <li>● Dextrose 10% ,25%, 50%</li> <li>● Povidone-iodine for local application, Spirit swabs</li> <li>● Spacers and Masks</li> <li>● Hand Rub</li> <li>● Gloves</li> <li>● Medical Waste Segregation Buckets</li> </ul>	<ul style="list-style-type: none"> <li>● Oral Rehydration Solution</li> <li>● Paracetamol (oral Syp. And Tabs, per rectal, IV)</li> <li>● Inj. Atropine</li> <li>● Inj. Adrenaline</li> <li>● Inj. Sodium bicarbonate</li> <li>● Inj. Calcium gluconate</li> <li>● Inj. Magnesium Sulphate (50%)</li> <li>● Inj. Phenobarbitone, Inj. Phenytoin</li> <li>● Inj. Diazepam,</li> <li>● Nasal/ buccal/ rectal diazepam or midazolam (desirable)</li> <li>● Salbutamol (MDI)</li> <li>● Inj. Hydrocortisone, dexamethasone), Tab. Prednisolone</li> <li>● Inj. Furosemide</li> <li>● Inj. oral Ampicillin, Amoxicillin, cloxacillin</li> <li>● 3<sup>rd</sup> generation cephalosporin</li> <li>● Inj. gentamicin/amikacin</li> <li>● Inj. Ranitidine/pantoprazole</li> <li>● Inj/Oral Anti-histaminics (Avil)</li> <li>● Inj. Potassium chloride</li> <li>● Inj. LMWH/UFH</li> <li>● Syp Zinc</li> <li>● Syp. Multivitamin</li> </ul>

<ul style="list-style-type: none"> <li>• IV stands (2)</li> <li>• Needle cutters (1)</li> <li>• Patient Stretcher and Wheelchair (1-2)</li> <li>• Water Cooler – 1 for each facility</li> <li>• Refrigerator – 1 for each facility</li> <li>• BLS Ambulance with 24X7 oxygen support – mandatory 24X 7</li> </ul>	<ul style="list-style-type: none"> <li>• Bandages, adhesives</li> <li>• Pediatric drip set</li> </ul>	
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## Level 2: Dedicated COVID Health Centres

**Table 2: Proposed standard of Pediatric COVID Care at DCHC (Level 2) facility**

Essential Equipment	Consumables	Drugs/Medications
<p><b>In addition to Level 1,</b></p> <ul style="list-style-type: none"> <li>• High flow nasal cannula (HFNC)</li> <li>• Bubble CPAP</li> <li>• BiPAP machine with appropriate pediatric NIV mask</li> <li>• Venturi masks</li> <li>• Syringe pumps</li> <li>• Otoscope</li> <li>• Ophthalmoscope</li> <li>• Defibrillator</li> <li>• Patient Transport trolley/ventilator</li> <li>• Multi para monitors</li> <li>• 12 lead ECG machine</li> <li>• Ventilators (invasive &amp; non-invasive) if skilled manpower is available</li> <li>• Indigenous CPAP/ Bubble</li> </ul>	<p><b>In addition to Level 1,</b></p> <ul style="list-style-type: none"> <li>• Blood transfusion sets</li> <li>• LP needles, ICD tubes (8,10,12 Fr), bags</li> <li>• Tracheostomy Kits</li> <li>• Ventilator tubing's</li> <li>• NIV masks(pediatric size)</li> <li>• Central venous lines (optional)</li> <li>• Umbilical catheters</li> <li>• Closed Suction Catheters(6,8,10,12Fr)</li> <li>• Urine Catheters and bags</li> <li>• Foley's catheters 6, 8, 10, 12, 14Fr</li> <li>• Urometers</li> </ul>	<p><b>In addition to Level 1,</b></p> <ul style="list-style-type: none"> <li>• Inj. Ketamine</li> <li>• Injections Dopamine, dobutamine, adrenaline, nor epinephrine,</li> <li>• Inj. Adenosine, Amiodarone, lidocaine</li> <li>• Inj. Fentanyl, Inj. morphine</li> <li>• Inj. Trenaxemic acid</li> <li>• Inj. Valproate, Inj. Leviteracetam</li> <li>• Inj Methylprednisolone</li> <li>• Inj IVIG</li> </ul>

**Level 3: Dedicated COVID Hospital (Medical colleges, teaching hospitals)****Table 3: Proposed standard of Pediatric COVID Care at Level 3 (DCH)**

<b>Essential Equipment</b>	<b>Consumables</b>	<b>Drugs/Medications</b>
<p>In addition to Level 2,</p> <ul style="list-style-type: none"> <li>● ICU ventilators capable of ventilating all pediatric age group including preterm neonates</li> <li>● Pediatric and neonatal reusable ventilator circuits with appropriate heating wire, humidification chamber, temperature sensor probes for humidification</li> <li>● Endotracheal cuff manometer</li> <li>● Portable USG with pediatric appropriate probes</li> <li>● Renal replacement therapy (in referral centers)</li> <li>● Transport Ventilator</li> <li>● Air Mattresses</li> <li>● Blood storage services</li> </ul>	<p>In addition to Level 2,</p> <p>Central venous access (3, 3.5, 4, 4.5, 5Fr catheters)</p> <p>Arterial line transducers</p> <p>Peritoneal dialysis catheters</p> <p>PD Dialysis Fluid</p> <p>Closed suction catheters</p> <p>Suction catheters sizes: 6,8,10,12,14,16Fr with gradation over (not plain)</p> <p>Pediatric and Neonatal HMEs</p> <ul style="list-style-type: none"> <li>● Neonatal and pediatric disposable ventilator circuits</li> <li>● Endotracheal tubes both cuffed and uncuffed (3,3.5,4,4.5,5,5.5,6,6.5)</li> <li>● Tracheostomy tubes (3, 3.5, 4, 4.5)</li> </ul>	<p>In addition to Level 2,</p> <p>Inj. Milrinone, Inj. Vasopressin</p> <p>Inj. Albumin</p> <p>Antibiotics: Piperacillin-Tazobactam, Meropenam, Colistin, Septran, Levofloxacin</p> <p>Inj. AMB, fluconazole</p>

1. Beds: Includes standard electrical fittings per type of bed as per standard hospital parameters.
2. Oxygen source could be from central pipeline, cylinders or concentrators. But all ICU beds must have central pipeline oxygen source.
3. Compressed air source: Are mandatory for ICU Ventilators. If the ventilators are turbine driven, then air compressors not needed.
4. Suction source could be central suction or stand-alone suction machine.

## **Appendix 6**

### **Governance**

- A. Effective governance of the public health system includes the establishment of institutional arrangements (existing facility and stand-alone COVID hospital) and policies along with their continuous monitoring to ensure proper implementation. Apart from ensuring good leadership, it also includes specific interventions such as:
- B. Existing hospitals have RKS in place, in-case a new hospital or temporary building is converted into COVID hospital, then, the RKS of the nearest hospital or as decided by the District Health Administration will work as the RKS/Hospital Management Committee.
- C. During pandemic, epidemic, disasters, or such crises, state and district administration support in procurement/supplies/hiring of HR and in establishing various need-based services for the hospital.
- D. Every district taskforce/RKS should include paediatrician as a member.
- E. Daily/ Weekly meeting on case reviews, follow up details of home isolated COVID positive cases, surge in active cases, home-based rehabilitation and death reviews should be ensured, as needed.

### **In addition to above, the RKS is empowered for taking decisions on:**

- 1) Procurement of equipment and consumables to fulfil operational requirement
- 2) Flexibility to hire human resource based on demand and needs
- 3) Capability to enhance functional capacity in terms of a greater number of beds
- 4) Building accountability into the system (monitoring) and ensuring patient safety and infection control mechanisms.
- 5) Patient centric services being delivered round the clock and assuring emergency services;
- 6) Addressing grievances through a robust and efficient system
- 7) Compliance with statutory norms (Acts and regulations) and ensuring robust clinical governance (adherence with SOPs and standard treatment guidelines, adverse incident reporting, near miss reporting, clinical audits)
- 8) Proactively seek out participation from charitable and religious organizations, community groups and corporates for providing volunteers for clinical and allied health services
- 9) Confirm that all patients do not incur any cost for their treatment, transport, diet and stay.
- 10) Ensure stress free environment for service providers.
- 11) Provision of non-clinical services (e.g. safe drinking water, diet, litter free premises, clean toilets and linen, security)
- 12) Ensuring adherence to Infection Prevention and Security Protocols.

- 13) Any other support required to hospital for its smooth functioning.

**Monitoring**

Monitoring, continuous support and encouragement by supervisors and administration will strengthen quality of service delivery. RKS should regular review the reporting on adverse events, infection control measures, safe clinical practices etc. Mechanisms for monitoring will include proper record keeping and maintenance, supportive supervision and a regular system of audits (clinical audit, death audit, disaster preparedness audit) as part of clinical governance.

**Roles and Responsibilities (SNO/DNO)**

1. The prime responsibility of a nodal officer would be to do a quick situational analysis with the help of public health team, identify priority action points to close the gaps.
2. Activate/ utilise the war rooms in terms of its ability to respond to dynamic emergent scenarios at field level.
3. Take a stock of the supply chain management (with a focus on oxygen and paediatric consumables) and ensure availability of essential medicines and consumables in the identified institutions.
4. State should ensure that capacity building of the staff at these SHC &PHC Health and wellness Centres and CHCs are completed at the earliest.
5. Officer in charge of CCCs/ PHCs / CHCs should provide a real time data on patient inflow and resources available with the institutions, district nodal officer/war room, immediate replenishments/ provide other support.
6. States may ensure the tele-consultation facility with a dedicated doctors for these facilities.

**Roles of MPW/ ASHA**

1. MPW/ ASHA should be able to identify children with symptoms suggestive of COVID using IMNCI based algorithm.
2. MPW/ ASHA workers should be trained for monitoring a child in home isolation and early recognition of indications for referral and facilitate the transport.
3. Calling BLS/ALS ambulance as soon the respiratory rate in a child is observed at the levels indicated
4. Follow the national protocols for home management of a child with COVID
5. To assist in the vaccination drive for children once COVID vaccines are approved for children.

## **Appendix 7**

### **Equity and Dignity of Care**

1. Well maintained Infrastructure, adequate & skilled human resource, functional equipment & instruments and sufficient drugs & consumables ensure the fulfilment of the 'Structural' requirements for a well-functional COVID care facility. However, for attaining enhanced satisfaction with improved clinical outcomes, it becomes equally pertinent to ensure 'Quality' in the 'Processes' of the care.
2. As a healthcare provider, while it is important to ensure provision of safe and evidence based clinical care, it is equally fundamental to provide the care that makes patients' and visitors' experiences rewarding. Ensuring 'Quality of Care' as a key component would require undertaking conscious and concerted efforts to identify the 'Gaps' by measuring the Quality of Care (QoC) as per the *National Quality Assurance Standards*.
3. Out of pocket expenditure should be taken care off by GOI /State
4. A well-built institutional framework under the guidance of SNO will oversee the functions of COVID care facilities for seamless implementation of the quality standards.
5. Key functional areas like laboratories, diagnostics, supply chain etc., should be monitored through an internal and external quality assurance systems.
6. Quality in services needs not only to be delivered but also to be perceived by the patient and the attendants coming to health facility. So, besides ensuring technical protocols, it is pertinent that care is delivered with respect and dignity in an environment which is client friendly.
7. Implementing a robust feedback system like "*Mera Aspataal*" and even exist interviews after OPD and indoor services are some of the important processes for understanding the patient perspective towards the care being provided by the health facilities.
8. Measures should be taken to decrease out of pocket expense of the patient.

### **Daily Rounds (MS/Deputy MS/HM/DNS/Matron/Nurse In-charge/SI)**

- A. Daily round by the health officers/ managers would have the advantage of picking up gaps in delivery of quality services, cleanliness, adherence to infection prevention protocols, provision of respectful care to all patients particularly to patient without attendants.
- B. They should ensure technical protocols are adhered in all service delivery areas, unnecessary stores and junk are removed, room-wise protocols are displayed in each department, cleaning schedule, adequate medicines, equipment, consumables for that particular day. They should also monitor whether equipment are in a functional state or not.

- C. Monitoring and recording the critical indicators of hospital like – bed occupancy, death rate, mid-night head count etc., handing-over and taking-over protocols, sharp management protocols, biomedical waste disposal practices are being followed as per protocols are also essential activities to be done during the daily rounds. Removal of unnecessary items, non-functional equipment etc. undertaking of pest control measures inside hospital building & all over the campus should also be done.

**Records, Registers & Death Audits**

Health intelligence in terms of standard formats to capture data on key performance indicators will facilitate a system for robust internal monitoring. This should be regularly reviewed by senior administrative and clinical personnel to enable gap analysis. An action plan with corrective measures, the person/department responsible and time lines should be prepared and reviewed at the next meeting. Every week death audits, not for blame, but to understand fixable root causes should be done in a non-threatening environment. Computer with Internet connections to be provided for entering facility MIS information.

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**Government of India**  
**Ministry of Health & Family Welfare**

**SOP on COVID-19 Containment & Management in Peri-urban, Rural & Tribal areas**

### 1. Background

COVID-19 outbreak in the country is still predominantly an urban phenomenon. However, besides urban areas reporting a large number of cases, a gradual ingress is now being seen in peri-urban, rural and tribal areas as well. In view of this there is a need to enable communities, strengthen primary level healthcare infrastructure at all levels to intensify COVID-19 response in peri-urban, rural & tribal areas, while continuing to provide other essential health services.

### 2. Scope

With larger spread of COVID-19 cases in peri-urban, rural and tribal areas, it is important to ensure that community-based services and primary level health infrastructure in these areas are equipped and oriented to manage COVID-19 cases. Primary healthcare facilities and health facilities in the private sector in these areas play a significant role in delivering health services to population. This document outlines the containment & clinical management practices to be put in place in these areas with respect to COVID-19 management.

### 3. Surveillance, screening, isolation and referral

- In every village, active surveillance should be done for influenza-like illness/ severe acute respiratory infections (ILI/SARI) periodically by ASHA with help of Village Health Sanitation and Nutrition Committee (VHSNC). Symptomatic cases can be triaged at village level by teleconsultation with Community Health Officer (CHO), and cases with comorbidity/low oxygen saturation should be sent to higher centres. Every subcentre should run an ILI/SARI OPD for a dedicated time slots/days.
- Identified suspected COVID cases should link for testing to the health facilities either through COVID-19 rapid antigen testing or by referral of samples to nearest COVID-19 testing laboratory, in accordance with ICMR guidelines for the same (available at: [https://www.icmr.gov.in/pdf/covid/strategy/Advisory\\_COVID\\_Testing\\_in\\_Second\\_Wave\\_04\\_052021.pdf](https://www.icmr.gov.in/pdf/covid/strategy/Advisory_COVID_Testing_in_Second_Wave_04_052021.pdf))
- CHOs and ANMs should be trained in performing Rapid Antigen Testing. Provision of Rapid Antigen Test (RAT) kits should be made at all public health facilities including Sub-centres (SCs)/ Health and Wellness Centres (HWCs) and Primary Health Centres (PHCs). These patients should also be counselled to isolate themselves till test results are available.
- Those asymptomatic but having history of high-risk exposure to COVID patients (exposure of more than 15 mins without a mask within 6 feet distance) should be advised quarantine and tested as per ICMR protocol.
- Depending upon the intensity of surge and number of cases, as far as feasible, contact tracing should be done as per Integrated Disease Surveillance Programme's (IDSP's) guidelines for

contact tracing of COVID-19 cases in community settings; (available at: <https://www.ncdc.gov.in/showfile.php?lid=570>).

#### 4. Home and community-based isolation:

- Nearly 80-85% COVID-19 cases are asymptomatic/ mildly symptomatic. These patients do not require hospitalization and may be managed at home or in Covid care isolation facilities. Home isolation shall be allowed as per the guidelines available at: <https://www.mohfw.gov.in/pdf/RevisedHomeIsolationGuidelines.pdf>
- The family members shall undertake quarantine as per the guidelines available at: <https://www.mohfw.gov.in/pdf/Guidelinesforhomequarantine.pdf>.

##### 4.1. Monitoring of active case in home- isolation:

- Monitoring of oxygen saturation is important for monitoring of COVID patients. For this it is desirable for each village to have adequate number of pulse oximeters and thermometers. The VHSNC through local PRI and administration should mobilize resources to make provisions for these equipments. A system of providing the pulse oximeters and thermometers on loan to families with a confirmed case of COVID should be developed through ASHA/ Anganwadi workers and village-level volunteers. The pulse oximeters and thermometers should be sanitized after each use with cotton/cloth soaked in alcohol-based sanitizer. Follow-ups for patients undergoing isolation/ quarantine could be done through household visits by a frontline worker/ volunteers/ teacher duly following required infection prevention practices including use of medical mask and other appropriate precautions.
- A Home Isolation kit shall be provided to all such cases which should include required medicines such as Paracetamol 500 mg, Tab. Ivermectin, cough syrup, multivitamins (as prescribed by the treating doctor) besides a detailed pamphlet indicating the precautions to be taken, medication details, monitoring proforma for patient condition during the home isolation, contact details in case of any major symptoms or deterioration of health condition and the discharge criteria.
- Patient / Caregiver will keep monitoring their health. Immediate medical attention should be sought if serious signs or symptoms develop. These could include-
  - Difficulty in breathing,
  - Dip in oxygen saturation (SpO<sub>2</sub> < 94% on room air)
  - Persistent pain/pressure in the chest,
  - Mental confusion or inability to arouse,
- If SpO<sub>2</sub> goes below 94%, the patient should be referred to a facility with an oxygen bed (DCHC or DCH depending on the SpO<sub>2</sub> level).

Patients under home isolation will stand discharged and end isolation after at least 10 days have passed from onset of symptoms (or from date of sampling for asymptomatic cases) and no fever for 3 days. There is no need for testing after the home isolation period is over.

## 5. Planning for Health infrastructure for managing COVID at rural level

Earlier, a 3-tier structure was devised for management of COVID-19 cases. These are:

- (i) **COVID Care Centre (CCC)** to manage mild / asymptomatic cases
- (ii) **Dedicated COVID Health Centre (DCHC)** to manage moderate cases
- (iii) **Dedicated COVID Hospital (DCH)** to manage severe cases.

The health infrastructure so planned for peri-urban, rural and tribal areas shall be aligned to the above mentioned 3-tier structure

### 5.1. COVID Care Centre (CCC)

#### 5.1.1. Infrastructure

Peri-urban and rural areas may plan a minimum of 30-bedded CCC. The COVID Care Centres shall offer care for asymptomatic cases with comorbidities or **mild cases** (Upper Respiratory Tract symptoms, without breathlessness, with oxygen saturation of more than 94%) where home isolation is not feasible. It could admit a COVID suspect or confirmed case. CCC should have separate areas for suspected and confirmed cases with preferably separate entry and exit for each. Suspect and confirmed cases should not be allowed to mix under any circumstances.

The CCCs are makeshift facilities under the supervision of nearest PHC/CHC. These may be set up in schools, community halls, marriage halls, panchayat buildings in close proximity of hospitals/healthcare facilities, or tentage facilities in Panchayat land, school ground, etc. The isolation beds should be placed at a minimum distance of one metre from each other to maintain physical distancing. Adequate natural room ventilation shall be ensured. Putting up exhaust fans to vent out air from the facility to an open area is desirable. The CCCs must have provisions for drinking water and toilets.

These CCCs should be mapped to one or more Dedicated COVID Health Centres (DCHC) and at least one Dedicated COVID Hospital (DCH) for referral purposes.

Such COVID Care Centres should also have a Basic Life Support Ambulance (BLSA) networked among such CCCs equipped with sufficient oxygen support on 24x7 basis, for ensuring safe transport of patients to dedicated higher facilities if the symptoms progress from mild to moderate or severe. In addition, the districts may consider providing additional ambulances for networking among nearby CCCs for referral services.

#### 5.1.2. Human Resource

**The Community Health Officer or the ANMs/Multipurpose Health Worker (Male) should be the nodal person for the CCC from the Health sector and ASHA/ Anganwadi Worker will be supporting them. Gram Panchayats supported by Village Health, Nutrition and Sanitation Committee (VHNSC) in rural areas and MAS in urban areas will be responsible for the implementation and upkeep of such facilities. The facility will work under the overall guidance of the Medical Officer of the local PHC-Health and Wellness Centre, supported by CHO of the SHC-HWC. Panchayats may have to hire additional staff for sanitation.**

The human resource to man these Care Centre facilities may also be drawn from Volunteers selected by the VHNSCs/**GPs in rural areas/MAS in urban areas**.

Qualified AYUSH doctors/ Final year AYUSH students/ Final year BSc nurses may be considered by VHNSC to run the CCC.

### 5.1.3. Training

The nodal officers will be trained in performing Rapid Antigen Detection Kit. The Volunteers selected by VHNSC (School Teacher, Staff, Village Officer etc) will be trained in basics of COVID, infection prevention control, use of Personal protective equipment, medical waste management, monitoring of temperature using infrared thermo-meter, recording respiratory rate, use of Pulse Oximetry and identification of early warning signs and referral. Training modules available on the website of MoHFW (<https://www.mohfw.gov.in/>) or iGOT Diksha portal (<https://diksha.gov.in/igot/>) for these activities shall be used.

### 5.1.4. Logistics

The equipment and consumables required for the rural CCC is placed at **Annexure-1**.

### 5.1.5. Risk Communication

Risk Communication materials available on infection prevention and COVID appropriate behaviour will be displayed at strategic locations in the village and in the CCC.

### 5.1.6. Clinical Management at CCC

- A. Patients at CCC should be provided symptomatic management for fever, running nose and cough, as warranted.
- B. Patients should perform warm water gargles or take steam inhalation twice a day.
- C. If fever is not controlled with a maximum dose of Tab. Paracetamol 650mg four times a day, PHC doctor may be consulted who may consider advising other drugs like non-steroidal anti-inflammatory drug (NSAID) (ex: Tab. Naproxen 250 mg twice a day).
- D. Consider Tab Ivermectin (200 mcg/kg once a day, to be taken empty stomach) for 3 days.
- E. Inhalational Budesonide (given via inhalers with spacer at a dose of 800 mcg twice daily for 5 to 7 days) to be given if symptoms (fever and/or cough) are persistent beyond 5 days of disease onset.
- F. Systemic **oral steroids** not indicated in mild disease. If symptoms persist beyond 7 days (persistent fever, worsening cough etc.) then only consult the PHC doctor for treatment with low dose oral steroids.

- G. In case of low oxygen saturation (<94%) or shortness of breath, the patient should be put on oxygen immediately before arranging referral transport. 2 oxygen cylinder/ concentrator may be dedicated at each CCC for this purpose

## 5.2. Planning for Dedicated COVID Health Centre (DCHC)

**The Primary Health Centre/ Community Health Centre/ Sub District Hospital in these areas shall be the Dedicated COVID Health Centre for management of COVID-19.** The facility may plan a minimum of 30 bedded DCHC. District should be prepared to increase DCHC beds as per the case trajectory & expected surge of cases.

These centres shall offer care for all cases that have been **clinically assigned as moderate** (Patient breathless; Respiratory Rate more than 24 per minute; Saturation between 90 to <94% on room air). The infrastructure shall be redesigned to function as DCHC, while retaining non-COVID essential services. Preferably, a separate block of PHC/CHC shall be designated as DCHC with separate entry, exit and zoning. Private hospitals may also be designated as COVID Dedicated Health Centres. Dedicated COVID Health Centre shall be re-designed for admitting both the confirmed and suspect cases clinically assigned as moderate while avoiding mixing of the two.

DCHC would have beds with assured Oxygen support. Every Dedicated COVID Health Centre should be mapped to one or more Dedicated COVID Hospitals. Care should be taken to locate these DCHCs in a manner that ensures availability of Oxygen supported beds in relative close vicinity to the patients.

### 5.2.1. Infrastructure Planning

#### (a) Outpatient Department (OPD)

With the intention to minimize the potential interaction between COVID and non-COVID patients visiting such facilities, it is necessary to redesign available infrastructure (or if feasible make suitable temporary arrangements) to carve out following areas:

- 1) Separate entry and exit point/s with provision for hand washing/hand sanitization stations at entry point/s.
- 2) Screening area: It should be a large area (preferably in open) enough to accommodate inflow of patients while maintaining a physical distancing of 6 feet. If required, specific markings may be made with sufficient distance to manage the queue and ensure physical distancing in the premises.
- 3) Screening area can have one or more screening desks where incoming patients may be screened into Acute Respiratory Illness (ARI) and non-ARI cases. These stations should have provisions for temperature recording as well as pulse oximetry.
- 4) The ARI and non-ARI patients shall be segregated into separate waiting areas.
- 5) The waiting area shall have adequately spaced sitting arrangement.

- 6) There shall be a separate consultation room with examination areas for ARI. These room/s should be well ventilated, preferably with an exhaust fan.
- 7) Ensure separate sampling area for ARI cases.
- 8) It shall have a separate pharmacy counter for ARI cases stocked with routinely prescribed drugs like paracetamol, antihistamines, cough syrups, multivitamin, Ivermectin, hydroxy-chloroquine, etc.
- 9) Dedicated areas for blood sampling and dedicated time slots for radiological investigations should be available.

### **(b) Inpatient Department (IPD)**

A minimum of 30 bed Isolation ward with oxygen supported beds (with separate areas for suspect and confirmed cases) in existing facility or as annexe through tentage/ temporary structure shall be planned and equipped to admit mild/ moderate cases and shall be made functional on 24x7 basis.

- 1) No intermixing of suspect and confirmed cases shall be allowed. Confirmed cases can be kept in isolation ward earmarked for confirmed cases.
- 2) The beds shall be placed with spatial separation of at least 1 meter (3 feet) from one another.
- 3) Adequate natural room ventilation shall be ensured. Putting up exhaust fans to vent out air from the facility (to open area) is desirable.
- 4) The facility should have a separate toilet for suspect and confirmed cases with proper cleaning and supplies.
- 5) Signages may be put up in the perimeter and on the entry indicating that the space is a COVID-19 isolation area.
- 6) Separate donning/ doffing room (changing room) would be created with partitions for wearing and taking off Personal Protective Equipment (PPE) for the staff.

A suggestive scheme for patient movement at a PHC/CHC is at **Annexure 2**

### **5.2.2. Human Resource**

Adequate number of dedicated trained staff shall be deployed at (i) Entry point/s, (ii) Screening desks and (iii) ARI consultation rooms, (iv) ARI sampling stations and (v) ARI pharmacy counter, (vi) Isolation ward. The number of persons shall be in accordance with the type of facility and patient load. If required, district administration may depute trained COVID warriors to man these facilities (Available at covidwarriors.gov.in).

A normative guidance on HR required is as detailed below:

S. No.	Station	Type of healthcare personnel	Number per shift

1	Entry point	Multi-skilled Group D worker/ Trained community volunteer	One per entry point
2	Screening desk	Health Worker (Male/Female)/ Trained community volunteer	One per desk
3	ARI consultation room	Medical officer (MBBS/AYUSH) Staff Nurse/ Trained community volunteer	One per room One per room
4	ARI sampling station	Staff Nurse Trained community volunteer	One per station One per station
5	ARI pharmacy counter	Pharmacist (allopathic/AYUSH)	One per counter
6	Isolation ward	Medical officer (MBBS/AYUSH) Staff nurse/ / Trained community volunteer (separate for suspect and confirmed sections)	Depending on number of beds

### 5.2.3. Training

The designated healthcare personnel assigned different tasks as brought out in the table above, shall be trained by Medical Officer in-charge of PHC/CHC on COVID basics, Infection Prevention and Control (IPC) protocol, sample collection, packaging and transportation, rapid antigen testing, clinical assessment & management and bio-medical waste management. The medical officers, other healthcare workers and volunteers can make use of training resources made available on the website of MoHFW (<https://www.mohfw.gov.in/>) or iGOT Diksha portal (<https://diksha.gov.in/igot/>) for all of these activities.

The medical officers shall network with Centre of Excellence in their States and attend regular webinars on various aspect of COVID-19 case management. Medical officers can also make use of “COVID-19 National Teleconsultation Centre” (CoNTeC) by AIIMS-Delhi by calling +91-9115444155 or any similar state-level initiative being undertaken. Wherever feasible, use of tele-medicine services may be made by treating doctors (detailed Telemedicine Practice Guidelines have been made available at: <https://www.mohfw.gov.in/pdf/Telemedicine.pdf>). To that extent the e-Sanjeevani telemedicine application launched by Union Health Ministry may also be utilised.

The above trainings shall be coordinated by the district administration preferably in local language by duly preparing a detailed plan of action in that direction.

#### 5.2.4. Infection Prevention and Control Practices

PHC/CHC medical officer in-charge should familiarise himself/herself with MoHFW's guidelines for infection prevention and control in healthcare facilities (available at: <https://www.mohfw.gov.in/pdf//National%20Guidelines%20for%20IPC%20in%20HCF%20-%20final%281%29.pdf>)

All personnel being deployed at (i) entry points, (ii) screening desks, (iii) consultation rooms, (iv) sampling area and (v) pharmacy counter and (vi) isolation ward should be provided with requisite PPEs and hand sanitizers. Choice of PPE shall be in accordance with MoHFW guidelines on rational use of personal protective equipment (available at: <https://www.mohfw.gov.in/pdf/GuidelinesonrationaluseofPersonalProtectiveEquipment.pdf>)

In addition to ARI screening and treatment areas, personnel working in other parts of the facilities should be provided with suitable PPEs. This shall be in accordance with the MoHFW's Additional guidelines on rational use of Personal Protective Equipment (setting approach for Health functionaries working in non-COVID areas) (available at: <https://www.mohfw.gov.in/pdf/UpdatedAdditionalguidelinesonrationaluseofPersonalProtectiveEquipmentsettingapproachforHealthfunctionariesworkinginnonCOVID19areas.pdf>)

In addition, proper provision of covered bio-hazard bins for disposal of used PPEs should be made available at these locations. Used PPEs, masks etc. should necessarily be disposed of in accordance with the guidelines issued by Central Pollution Control Board (available at: [https://cpcb.nic.in/uploads/Projects/Bio-Medical-Waste/BMW-GUIDELINES-COVID\\_1.pdf](https://cpcb.nic.in/uploads/Projects/Bio-Medical-Waste/BMW-GUIDELINES-COVID_1.pdf))

#### 5.2.5. Logistics

PHCs/ CHCs identified for COVID management needs to have 24x7 assured oxygen supply (oxygen cylinders, Oxygen concentrators or other means), and necessary equipment for oxygen administration (nasal prongs, bag and mask, non-re-breathable bag and mask).

The equipment and material requirements for PHC/CHC functional for managing COVID cases are as given at **Annexure-3**. The CMO In-charge of PHC/CHC will ensure that these equipment/devices/consumables are available in requisite quantities. If not, a requisition should be made with district administration.

Necessary logistics arrangements for such facilities shall be coordinated by the district administration on a regular basis.

#### 5.2.6. Risk communication

Suitable provisions for posters, standees and (if feasible) AV media may be made available throughout the facilities to create awareness among general public on (i) simple preventive health measures like use of mask/face cover, hand and respiratory hygiene, physical distancing, (ii) common signs and symptoms of COVID, (iii) need for early reporting of cases, (iv) National/State/district helpline numbers etc.

In addition, adequate signage and information notices (in local language) should be displayed prominently at all entrances, corridors, designated areas, wards etc. to prevent inter-mixing of patients and stream ARI patients away from regular clinical areas.

### 5.2.7. Cleaning and disinfection

Suitable provisions for disinfection of floors and surfaces should be done at least twice a day by cleaning with 1% sodium hypochlorite solution. This includes entrance area, screening area, waiting area, consultation area, designated area for suspected COVID-19 cases, laboratory, pharmacy, etc. All frequently touched surfaces shall be cleaned frequently (at least twice a day) with 1% sodium hypochlorite solution. Washrooms and hand washing stations shall be deep cleaned at least four times a day.

In addition, disinfection of ambulances transporting suspected/confirmed COVID-19 cases must be done after every visit.

### 5.2.8. Clinical management

Clinical management of cases admitted in these facilities shall be in accordance with the Clinical Management Protocol Algorithm for COVID-19 (available at:

<https://www.mohfw.gov.in/pdf/COVID19ManagementAlgorithm22042021v1.pdf>.

Paediatric cases may be managed as per the protocol available at:

<https://www.mohfw.gov.in/pdf/ProtocolforManagementofCOVID19inthePaediatricAgeGroup.pdf>

#### 5.2.8.1. Management of COVID cases in facilities not having specialist services (PHC/ Health Posts etc.)

- Mild cases of COVID-19 (with SpO<sub>2</sub> ≥ 94%) that cannot be managed at home (those who do not qualify for home isolation and treatment) or mild cases with co-morbidities and can be managed at this level.
- Moderate cases with or without controlled co-morbid conditions (on currently prescribed medication) can be managed at these centres provided patient is stable with administration of up to 10 litre/ minute Oxygen therapy through non-rebreathing face mask to target SpO<sub>2</sub> of 92-96%.
- Awake proning encouraged in all patients requiring supplemental oxygen therapy [Detailed procedure is available at:
  - <https://www.mohfw.gov.in/pdf/COVID19ProningforSelfcare3.pdf>]
- Cases should be managed based on symptoms (hydration, antipyretics, antitussive, multivitamins). If fever is not controlled with a maximum dose of Tab. Paracetamol 650mg four times a day, may consider advising other drugs like non-steroidal anti-inflammatory drug (NSAID) (ex: Tab. Naproxen 250 mg or ibuprofen 400 mg as required). In mild cases, if symptoms persist beyond 7 days (persistent high-grade fever/ worsening cough) low dose oral steroids (dexamethasone 6 mg once daily/ Methylprednisolone 32mg once daily) may be considered.

- Specific therapies based on the assessment of treating doctor that can be administered in these facilities are:
  - Tab Ivermectin (200 mcg/kg once a day for 3-5 days) (Avoid in pregnant and lactating women).

Or

  - Tab HCQ (400 mg BD for 1-day f/b 400 mg OD for 4 days) unless contraindicated.
  - Inhalational Budesonide (given via Metered dose inhaler/ Dry powder inhaler) at a dose of 800 mcg BD for 5 days) to be given if symptoms (fever and/or cough) are persistent beyond 5 days of disease onset.
  - Moderate cases as mentioned above may be given Inj. Methylprednisolone 0.5 to 1 mg/kg in 2 divided doses (or an equivalent dose of dexamethasone) usually for a duration of 5 to 10 days. Patients may be initiated or switched to oral route if stable and/or improving.
- Monitoring of temperature and oxygen saturation (by applying a SpO2 probe to fingers) four-hourly shall be undertaken for the patients. Maintain charting as per proforma given below:

Day of symptoms and time (every 4 hourly)	Temperature	Respiratory Rate	Blood Pressure	SpO2 %	Heart rate	Remarks

- In mild and stable moderate cases admitted to these facilities, if saturation dips below 90% even with the above prescribed oxygen therapy, the patients will be referred to higher centre in the referral framework.
- There could be a possibility of a severe case in respiratory distress reporting to these facilities. Till such time an ambulance (with oxygen support) is arranged, the patient should not be refused and stabilized in the health facility on oxygen with flow rate that would maintain a saturation of  $\geq 90\%$  in those without chronic respiratory co-morbidities (in patients with Chronic Obstructive Pulmonary Disease SpO2 of 88-92% may be targeted).
- Every facility identified for COVID management should also have a dedicated Basic Life Support Ambulance (BLSA) (equipped with sufficient oxygen support) on 24x7basis with established linkages with nearest Dedicated COVID Health Centre and Dedicated COVID Hospital.
- Discharge of mild cases shall be as per discharge policy of MoHFW (available at: <https://www.mohfw.gov.in/pdf/ReviseddischargePolicyforCOVID19.pdf>)

### 5.2.8.2. Management of COVID cases at facilities with specialist services (CHC/private hospitals etc.)

- Identified facilities will manage mild cases requiring facility care as well as moderate cases.
- Management of mild cases requiring facility care and moderate cases with stable co-morbidities will be as per protocol delineated in para 5.1.
- Oxygen Therapy for moderate cases should target saturation of 92-96% (88-92% in patients with Chronic obstructive pulmonary disease (COPD). Non-rebreathing face mask will be the preferred devices for oxygenation. Awake proning shall be encouraged in all patients requiring supplemental oxygen therapy.
- All moderate cases shall be given Inj. Methylprednisolone 0.5 to 1 mg/kg in 2 divided doses (or an equivalent dose of dexamethasone) usually for a duration of 5 to 10 days. If a patient is stable or improving, steroids may be initiated or switched to oral route.
- Anticoagulation shall be provided by giving conventional dose prophylactic unfractionated heparin or Low Molecular Weight Heparin (weight based e.g., enoxaparin 0.5mg/kg per day SC once daily). There should be no contraindication or high risk of bleeding.
- Monitoring
  - o Clinical Monitoring: Work of breathing, hemodynamic instability, change in oxygen requirement.
  - o Serial CXR to be done only if there is indication of pneumonitis.
  - o Lab monitoring: Inflammatory markers, such as CRP and D-dimer (48 to 72 hourly); CBC, KFT, LFT (24 to 48 hourly) to be done on the recommendation of the treating medical officer.
- Antibiotics should not be prescribed routinely unless there is clinical suspicion of a bacterial infection. However, Antibiotics (as per local antibiograms) should be available at these facilities for treatment of secondary bacterial infections.,
- Management of co-morbidities, if any, should also be addressed.
- Patients should be monitored for signs and symptoms of complications that should prompt urgent referral.
- Patients with risk factors for severe illness should be monitored closely, given the possible risk of deterioration. If they develop any worsening symptoms (such as mental confusion, difficulty breathing, persistent pain or pressure in the chest, bluish coloration of face/lips, dehydration, decreased urine output etc.), they should immediately be referred to a Dedicated COVID Hospital.
- Every such facility must also have a dedicated Advance Life Support Ambulance (ALS) on 24x7basis with established linkages with nearest Dedicated COVID Hospital.
- Discharge of mild to moderate cases shall be as per discharge policy of MoHFW (available at: <https://www.mohfw.gov.in/pdf/ReviseddischargePolicyforCOVID19.pdf>)

### 5.3. Dedicated COVID Hospital (DCH)

District Hospital or other identified private hospitals or a block of these hospitals shall be converted as the dedicated COVID Hospitals. In addition, Sub-district/ Block level hospitals fulfilling the requirements may also be designated as the Dedicated COVID Hospital for the identified CCC and DHCC in their catchment area. The upgradation in health facilities shall be undertaken based on case trajectory or the surge in cases.

## 6. Post COVID management

Medical officers in these facilities will also follow with recovered patients for post-COVID complications. Post COVID management protocol available at <https://www.mohfw.gov.in/pdf/PostCOVID13092020.pdf> shall be followed.

On discharge, patients should be counselled for post-COVID management at home and leaflets regarding danger signs (e.g. breathlessness, chest pain, recurrence of fever, low oxygen saturation, etc.), precautions and various respiratory exercises.

Patients with other comorbidities should also be followed up and primary assessment of other comorbidity (e.g. measuring blood pressure, blood glucose level) should be arranged and any modification treatment if necessary should be decided by a PHC medical officer. Telemedicine services may also be utilized for providing post-covid follow-up care.

## 7. Community mobilization and behaviour change communication

- A multi-pronged approach, led by Gram Panchayat (GP) and engaging health sector, ICDS, School teachers, Self-help group (SHG) of women and other community-based organizations, should be utilized for mobilizing the community in the fight against COVID-19 pandemic. Gram Panchayats will play the prime responsibility of coordinating community action and awareness creation at village level and the Block Development Officer (BDO) at Taluka level.
- The efforts in the medical care side will be coordinated by VHSNC along with the PHC/Sub Centre.
- VHSNC will be primarily responsible for the preparedness at village level for timely action for prevention of COVID-19. Major tasks will include preventive measures for the control of pandemic, help in surveillance activities, support quarantine and isolation facilities, availability of items of daily needs including food items, ensure continued provision of essential health services including referral transport. as well as to support needy families. The committees will also help in promoting COVID-appropriate behaviour and for limiting community rumours/fake news at village level.



Fig. 1. Key stakeholders within the village community that could be mobilized for COVID-19 management

- A checklist for community preparedness for COVID-19 response should be utilised after local adaptation based on the need (**Annexure 4**).
- Standard Behaviour Change Communication (BCC) materials developed in local language and approved by the health department should be circulated through all available platforms.
- Village Health Nutrition Sanitation Committee (VHNSC) will act as a centre of local level community health action for decentralized health planning. Preventive strategies like physical distancing and containment can be implemented in a better way if planned and organized strategically at village level by local stakeholders. Surveillance and its compliance will also be better. Members of women Self-help groups (SHGs) may be engaged actively in many activities like ensuring the supply of essential services in the community, providing food and other essentials to the needy families, supporting preventive measures, making masks, running kitchens for quarantine/ isolation facilities, etc. Religious leaders are trusted by the community. They may help to facilitate the COVID appropriate behaviour.
- The Block Development Officer (BDO) /Village Development Officer (VDO) will identify mentors from health, Integrated Child Development Scheme (ICDS) and other related departments to mentor the team at Gram Panchayat level. Each such mentor will have 5-10 villages to supervise. Village level resource mapping exercises should be conducted at each Gram Panchayat level. The mentors assigned by the BDO/VDO will ensure that village-wise resource mapping exercise, regular filling of the checklist and community dialogue for COVID-19 response happens regularly. A fortnightly review of community preparedness and progress should be undertaken at block and district level.
- A successful decentralized model of care for managing the COVID-19 would include:
  - i) Involvement of Gram panchayat (GP) at the forefront of pandemic management with financial allocation and administrative empowerment;
  - ii) Mobilization and involvement of SHGs for creating awareness for COVID-appropriate behaviours and for providing essential services, especially if there is a mass movement restriction;

- iii) Protect the high-risk vulnerable group and limit the spread of virus by advance payment of pension benefits to older adults, disabled and widows under national and state pension schemes;
- iv) Opening up Temporary Medical Centres (TMCs) at GP levels and COVID Care Centres; and
- v) Strengthening community-based management engaging frontline workers (i.e. Auxiliary Nurse Midwife (ANMs), Accredited Social Health Activist (ASHAs) and Anganwadi Workers) and support of other village/ Gram Panchayat level functionaries.

## 8. Mental health support at community level

Besides fear of contracting the disease, the fear of quarantine, isolation, lockdown, loneliness, loss of livelihoods and challenges with education of kids can cause widespread mental health problems during the COVID pandemic. Increased risk of depression, suicides and other mental health problems are reported frequently from different parts of the country. Provision of psychological support to enable people to remain mentally healthy during the difficult time should be one of the important elements of COVID response.

## 9. Adequate provision of support services and intersectoral coordination

- Community should ensure that basic needs of all the families including migrants are fulfilled. Attempts should be made for alternative employment opportunities including MGNREGA (Mahatma Gandhi National Rural Employment Guarantee Act).
- The dead bodies should be managed duly following the guidelines available at [https://www.mohfw.gov.in/pdf/1584423700568\\_COVID19GuidelinesonDeadbodymanagement.pdf](https://www.mohfw.gov.in/pdf/1584423700568_COVID19GuidelinesonDeadbodymanagement.pdf)

## 10. Undertaking of public health functions by PHC/ CHC in COVID containment operations

A PHC/CHC lying within or close to a containment/buffer zone shall be actively involved in COVID containment operations. The medical officer/nodal officer of the said health facility will also be in charge of COVID-19 surveillance activities in the allotted area. He shall:

- Familiarize with COVID-19 cluster containment plan (available at: <https://www.mohfw.gov.in/pdf/Containmentplan16052020.pdf>) and containment plan for large outbreaks (available at: <https://www.mohfw.gov.in/pdf/UpdatedContainmentPlanforLargeOutbreaksofCOVID19Version3.0.pdf>)
- Familiarize with the containment and surveillance manual for supervisors (available at: <https://www.mohfw.gov.in/pdf/ContainmentandSurveillanceManualforSupervisorsincontainmentzones.pdf>) and manual for surveillance teams functionaries (available at: <https://www.mohfw.gov.in/pdf/ManualforSurveillanceTeamsforcontainmentzones.pdf>)
- Train and retrain all PHC/CHC and field level (including ASHAs, ANMs, MPWs etc.) staff engaged in COVID management.

- Estimate the requirement of logistics for field operations including Personal Protective Equipment kits, N-95 mask, triple layer medical mask, gloves, sanitizers, pulse oximeters, thermometers, disinfectants etc. and arrange for the same for field-based teams.
- Divide the area under jurisdiction (in containment zone) into sectors [in coordination with district Rapid Response Team (RRT)] and allot supervisors and surveillance teams for each of the sectors.
- Collect lists of homes for each of the sector from district RRT and distribute among supervisors for house to house surveillance and follow up of cases and contacts
- Provide field-based teams with appropriate risk communication materials for effective awareness creation.
- Facilitate contact tracing of confirmed COVID cases along with supervisors and surveillance teams as per IDSP's guidelines for contact tracing of COVID-19 cases in community settings (available at: <https://www.ncdc.gov.in/showfile.php?lid=570>)
- Supervise the activities of surveillance teams and their supervisors.
- Certify appropriateness of residential facility for allowing Home Quarantine as per MoHFW's guidelines for home quarantine (available at: <https://www.mohfw.gov.in/pdf/Guidelinesforhomequarantine.pdf>)
- Certify residential facility appropriateness and clinically examine the cases to allow for home isolation as per MoHFW's guidelines for Home Isolation of very mild/pre-symptomatic/asymptomatic COVID-19 cases (available at: <https://www.mohfw.gov.in/pdf/RevisedHomeIsolationGuidelines.pdf>)
- Collect data from field units and submit to district RRT/Control room daily.
- Liaison with field units, district RRT/Control room, COVID testing laboratory, nearest CHC/Dedicated COVID Health Centre/Dedicated COVID hospital, ambulance service provider etc.
- Identify suspect COVID cases, ensure testing of all ILI/SARI cases reporting to the health facilities either through COVID-19 rapid antigen testing or by referral of samples to nearest COVID-19 testing laboratory, in accordance with ICMR guidelines for the same (available at: [https://www.icmr.gov.in/pdf/COVID/strategy/Testing\\_Strategy\\_v6\\_04092020.pdf](https://www.icmr.gov.in/pdf/COVID/strategy/Testing_Strategy_v6_04092020.pdf))

### **11. Preparedness for rapid coverage with COVID vaccination**

Ensuring high coverage with vaccination is a pivotal strategy for preventing future surge in COVID cases. Appropriate strategies for achieving high coverage with COVID vaccination in rural areas need to be devised. Frontline Line Workers along with community leaders will mobilize the beneficiaries for vaccination in compliance with the guidelines by the Government of India. Proper IEC efforts should be made using various channels for this purpose and to address vaccine hesitancy.

### **12. Non-COVID essential healthcare delivery services**

While focusing on COVID 19 related activities is crucial, ensuring continuity of other (non-COVID) essential health services is equally vital. Essential health services such as reproductive, maternal, newborn and child health, prevention and management of communicable diseases, treatment of prevalent

non-communicable diseases and addressing emergencies also need to be continued and use of telemedicine etc. shall be promoted for the same.

In this regard, MoHFW's guidance note on enabling delivery of essential health services during the COVID 19 outbreak may be referred to (available at: <https://www.mohfw.gov.in/pdf/EssentialservicesduringCOVID19updated0411201.pdf>)

### **13. Establishment of COVID-specific call centres at district level and utilization of telehealth facilities**

- Setup a central District level portal for information and help desk to provide information regarding availability of health facilities, available beds, ambulance, vaccination centers, home isolation guidelines and other relevant guidelines related to COVID-19 management.
- Utilize telemedicine/ e-Sanjeevani OPD services for both COVID and non-COVID essential services

### **14. Tribal COVID-19 care and response strategies for tribal area**

Besides the proposed health care strategies as above, tribal areas pose additional challenges and hence additional focus. Tribal communities are geographically and socioeconomically relatively segregated and may have poor access to health care. Strengthening community-based management through Gram Sabha should be taken and they should be involved at every stage of planning and executing COVID-care activities.

**Integration of COVID-care with Mobile Medical Units (MMUs) under NHM in tribal areas:** Mobile Medical Unit (MMU) under NHM to facilitate access to public health care in tribal areas. MMUs have an existing medical team (medical officers, pharmacist, staff nurse and lab technician). This team may be utilised to create awareness regarding COVID-appropriate behaviour, carry out Rapid Antigen Testing (RAT), take samples for RT-PCR, provide treatment for mild illness, and help establish referral linkage with DCHC and DCH.

Telemedicine/Teleconsultation should be utilized to bridge the geographical inaccessibility in tribal areas as per feasibility.

Non-governmental organizations (NGOs) working in these areas can play a crucial role in provisioning of public health services in tribal/remote areas due to their community rapport and local existence.

## Annexure-1-A

## List of Equipment for Covid Care Centre

Sr. No	Equipment COVID Care Centre (CCC)	
1	Beds	Standard Hospital Beds
2	Pulse oximeter	1 Per 10 beds
3	Crash cart	1
4	Self-Inflating resuscitation bag	1
5	Glucometer	2
6	BLS ambulance	1
7	Stethoscope	2
8	Digital B.P Apparatus	1 per 15 beds
9	Digital Thermometer	6
10	Mattress	1 per bed
11	Refrigerators 165 Litres	1
12	LED Torch Light	1
13	Blankets/mattress/bed sheet	As per requirements of the beds
14	Automated External Defibrillator (AED) (if not already included in crash cart)	1
15	Mobile bed screens	2
16	Sputum can, bed pan, urine pot	One per 10 beds
17	Wheelchair/ patient transfer trolley with side rail	One each
18	5 litre oxygen concentrator or oxygen cylinder	2

## Annexure-1 B

## List of Consumables for Covid Care Centre

Sr. No	Consumables for COVID Care Centre (for 1 month's consumption)	
1	Complete PPE kit	200
2	N-95 masks	200
3	Medical triple layer masks	3000
4	Non sterile Gloves, examination	200
5	Gloves, heavy duty	60
6	Face shield	200
7	Bio-hazardous bags	150
8	Glucometer strips (1000 strips with each glucometer in packets of 50 and lancets)	1
9	Oxygen Cylinders B Type with trolley, regulator, flow meter humidifier	2
10	Ortho Toludine Solution for refill (1 litre Bottle)	1
11	Soap/ handwash	10 (as per requirement)
12	IV stands	2
13	Oxygen face mask, nasal prongs, Non-rebreather mask	5 each
14	Commode chair	1

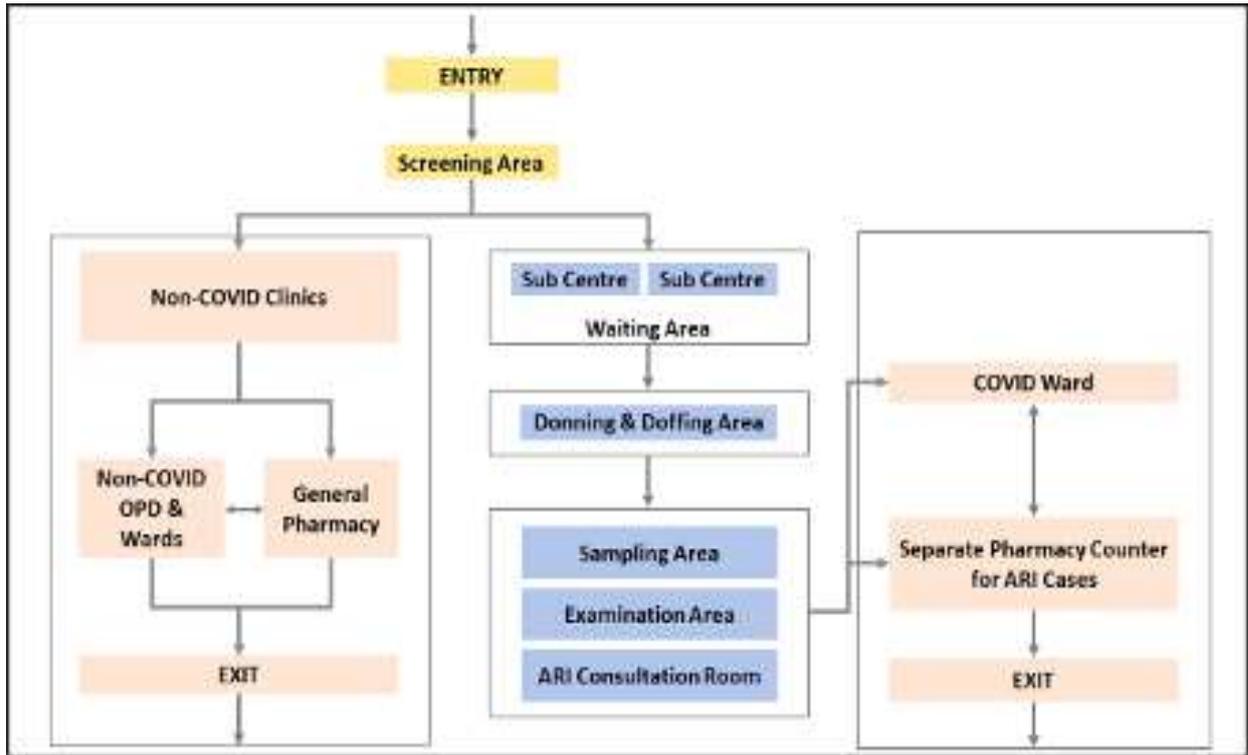
## Annexure 1 C

## Drugs, testing kits and other consumables

Sr. No	Drugs, testing kits and other consumables for COVID Care Centre (for 1 month's consumption)	
1	Paracetamol (650 mg)	5000
2	Hydroxychloroquine (400 mg)	500
3	Ivermectin (12 mg)	200
4	Antihistamines / Anti-tussives / multivitamins/ IV fluids	As per requirement
5	MDI / DPI Budesonide / respules	50
6	Drugs for management of non-communicable diseases	As per requirement
7	Rapid antigen testing kits	1000
8	Alcohol-based hand sanitizer (250 ml)	50
9	1% Sodium Hypochlorite solution (1 litre)	30
10	Standard IEC materials on COVID-19	1 set per center
11	Drugs for GI symptoms (drugs for gastric acidity e.g. PPIs, anti-emetics, anti-diarrheals, ORS)	As per requirement
12	Analgesic antipyretic (Ibuprofen 400 mg, naproxen 250 mg)	As per requirement

Annexure-2

Suggestive scheme for patient movement at a PHC/CHC



**Annexure-3 A**  
**List of Equipment for Dedicated COVID Health Centre (30 beds)**

Sr. No	Equipment for Dedicated COVID Health Centre (DCHC)	
1	Beds	Standard Hospital Beds
2	Oxygen Source (Cylinder/ piped medical oxygen supply/ Oxygen concentrator)	1 Per bed
3	Suction source	3
4	Transport Ventilator	1
5	Pulse oximeters	30
6	AED (if not already included in crash cart)	1
7	ECG (5 channel machine)	1
8	Crash cart	1
9	Self-Inflating resuscitation bag	5
10	X-ray unit	1
11	Facility for haematology and Biochemistry tests	Mandatory
12	Glucometer	2
13	ALS ambulance	1
14	Stethoscope	5
15	Digital B.P Apparatus	5
16	Digital Thermometer	4
17	IV Stand	30
18	Mattress and linen, and blanket	As per requirements of the beds
19	Refrigerators 165 Litres	1

Sr. No	Equipment for Dedicated COVID Health Centre (DCHC)	
20	LED Torch Light	1
21	Laryngoscope set	1
22	Table top NIBP and SpO2 monitor	10% of beds
23	Oxygen delivery devices (Nasal cannula, oxygen face mask, Venturi, NRBM)	✓
24	Patient transfer trolley with side rail	two per 50 patients
25	Portable suction pump	One per 25 patients
26	Bain circuits	one per 50 patients
27	10 liter oxygen concentrator/ oxygen cylinder	✓
28	Nebuliser machine, MDI spacer	✓
29	Syringe pump	2 per 50 patients
30	Multipara monitor	1 per 50 patients
31	Wheel chair	One per 50 patients
32	Commode chair	One per 25 beds

Sr. No	Equipment for Dedicated COVID Health Centre (DCHC)	
33	Sputum can, bed pan, urine pot	One per 5 beds
34	Computer with internet and printer	1
35	Portable non-invasive ventilator (BIPAP) with 0-30 oxygen bleed flow with high flow meter	2
36	Biomedical waste bins	2 of each colour

## Annexure- 3 B

## List of Consumables for Dedicated COVID Health Centre

Sr. No	Consumables for Dedicated COVID Health Centre	
1	Oxygen mask with reservoir	100
2	Nasal prongs (all sizes)	100
3	Endotracheal tubes cuffed (all sizes)	3 sets
4	Endotracheal tubes non-cuffed (all sizes)	3 sets
5	LMA (laryngeal mask airway) of different sizes	1 each
6	Oropharyngeal Airways (all sizes)	3 sets
7	Complete Personal protection kits	500
8	N-95 masks	500
9	Medical masks	3000
10	Gloves, examination	5000
11	Gloves, heavy duty	100
12	Face shield	500
13	Oxygen tubings	100
14	IV Catheters (all sizes)	100
15	Stopcock, 3-way, for infusion giving set, with connection line, sterile, single use	100

Sr. No	Consumables for Dedicated COVID Health Centre	
16	Syringes, Luer (all sizes)	500
17	Needles, hypodermic (all sizes)	500
18	IV Drip set	100
19	Bio-hazardous bags	150
20	Urinary Catheters with urobag	50
21	Glucometer strips (1000 strips with each glucometer in packets of 50 and lancets)	1
22	Nebulizer Mask Disposable Kit Adult	10
23	Nebulizer Mask Disposable Kit Pediatrics	10
24	Oxygen Cylinders B Type with trolley, regulator, flow meter humidifier	40
25	Oxygen face mask adult	100
26	Oxygen face mask Pediatrics	100
27	Ortho Toluidine Solution for refill (1 litre Bottle)	1
28	Suction Catheter	200
29	Nasogastric Tube	100
30	Yankauer suction set	10
31	HME filter	20

## Annexure-3 C

## Drugs, testing kits and other consumables for Dedicated COVID Health Centre

Sr. No	Drugs, testing kits and other consumables for Dedicated COVID Health Centre (for 1 month's consumption)	
1	Paracetamol (650 mg)	5,000
2	Hydroxychloroquine (400 mg)	1,000
3	Ivermectin (12 mg)	500
4	Dexamethasone – Injectable	200
5	Dexamethasone – Tablets 6/ 4/ 2 mg	2,000
6	Methylprednisolone – Injectable	200
7	Prednisolone – Tablets 40/20/10 mg	2,000
8	Antihistamines / Anti-tussives / multivitamins IV fluids	As per requirement
9	MDI / DPI Budesonide / respules	100
10	Resuscitative drugs (adrenaline, sodium bicarbonate, frusemide, deriphyllin, dopamine, dobutamine, etc.)	10 Ampules each
11	Low Molecular Weight Heparin (LMWH) / Ultra-fractionated heparin (UFH)	200
12	Drugs for management of non-communicable diseases (including Ischemic heart disease, hypertension, COPD, asthma, diabetes mellitus)	As per requirement
13	Rapid antigen testing kits	2,000

Sr. No	Drugs, testing kits and other consumables for Dedicated COVID Health Centre (for 1 month's consumption)	
14	Alcohol-based hand sanitizer (250 ml)	100
15	1% Sodium Hypochlorite solution (1 litre)	60
16	Standard IEC materials on COVID-19	2 set per center
17	Antibiotics	As per local antibiogram
18	Newer oral anticoagulants (dabigatran 110 mg or rivaroxaban 10 mg or apixaban 2.5 mg)	As per requirement
19	Inj Enoxaparin 40 mg and 60 mg	As per requirement
20	Analgesic antipyretic (Ibuprofen 400 mg,, naproxen 250 mg)	As per requirement
21	Drugs for GI symptoms (drugs for gastric acidity e.g. PPIs, anti-emetics, anti-diarrheals, ORS)	As per requirement
22	Sedation agents (Inj midazolam,)	As per requirement
23	Paralytic agents (scoline, atracurium,)	As per requirement
24	Other: Inj KCL, Calcium gluconate, Magnesium sulphate, sodium bicarbonate	As per requirement

## Annexure 4

## Checklist for community preparedness for COVID-19 response

**COMMUNITY PREPAREDNESS CHECKLIST****FOR ACTION AGAINST COVID-19 PANDEMIC**

This modified checklist has been developed for use by Gram Panchayat/ Village Health and Sanitation Committee to assess the preparedness at Gram Panchayat level. This filled in checklist will help the gram panchayat for timely action for prevention of COVID 19.

The checklist should be filled by the nodal person identified by the Gram Panchayat in consultation with the members of the Gram Panchayat fortnightly and the information so collected should be used for strengthening community action against the pandemic. It will be the responsibility of the Gram Panchayat Secretary to see that the checklist is filled regularly and to share the information with Extension Officer (Health) at Block Development Office. The Block Development Officer will take appropriate action and share the information at Zilla Parishad or District Panchayat Officer and the District Collector

Name of the Gram Panchayat:

Block:

District:

Date of filling checklist:

N o.	Assessment item	Status	Remarks
<b>I. Preventive measures for control of Coronavirus pandemic</b>			
1	Is the Village Health and Sanitation Committee constituted in your Gram Panchayat?	Yes/ No	
2	Did the committee identify a nodal person among members?		
3	Did the committee motivate and enrol volunteers to participate in COVID-19 activities?	Yes/ No	
4	Did the committee ensure participation of Self-help groups and other community-based organisations in COVID-19 activities?	Yes/ No	
5	Do the committee members and volunteers have knowledge regarding the following:		

	<ul style="list-style-type: none"> <li>• Modes of transmission/spread of COVID-19?</li> <li>• Importance of using mask/ cotton cloth?</li> <li>• Maintaining physical distance</li> <li>• Thoroughly washing hands with soap and water</li> <li>• Cough etiquettes</li> <li>• Home quarantine</li> <li>• Cleaning and disinfection of frequently used surfaces</li> <li>• Cleaning and disinfection of public places</li> <li>• Local and State level corona helpline numbers (1075, 011-23978046, 020-26127394)</li> </ul>	<p>Yes/ No</p>	
6	Did the Committee impart information about preventive and control measures against COVID-19 to the villagers?	Yes/ No	
7	Have the committee identified and used locally relevant modes of mass communication (e.g. Dawandi/ Announcement accompanied by beating drums)?	Yes/ No	
8	<p>How good is compliance of villagers with the following?</p> <ul style="list-style-type: none"> <li>· Physical distancing</li> <li>· Use of mask/handkerchief/ cotton cloth</li> <li>· Washing hands with soap and water</li> </ul>	<p>Very good/ Good/ Poor/ Very poor</p> <p>Very good/ Good/ Poor/ Very poor</p> <p>Very good/ Good/ Poor/ Very poor</p>	

9	Is there a system to check the compliance with the above?	Yes/ No	
10	Did the committee identify places or events when the village gathers e.g., weekly market, festival etc.	Yes/ No	
11	Have measures been taken to control the such gatherings? If yes, specify measures taken?	Yes/ No	
12	Have you enlisted the elderly and person with comorbidities in your village?	Yes/ No	
13	Do the committee have plan to ensure adequate care of elderly and persons with comorbidities	Yes/ No	
<b>II. Solidarity at community level and address any stigma associated with the disease</b>			
14	Does the committee have adequate representation of all sections of the society (including minority groups)?	Yes/ No	
15	Did the committee make adequate efforts to reach out and address concerns of all sections of the society (including minority groups)	Yes/ No	
16	Do the committee members/ villagers understand the importance of supporting individuals and their families, in case they get the disease?	Yes/ No	
17	Does the committee take any steps to address stigma associated with the disease?	Yes/ No	
<b>III. Help in surveillance activities related to Coronavirus pandemic</b>			
18	Did the committee prepare a list of following?		
	· Elderly above 60 years of age	Yes/ No	

	<ul style="list-style-type: none"> <li>· People with hypertension &amp; diabetes</li> <li>· Pregnant women</li> </ul>	Yes/ No	
19	Does the committee have a plan to ensure adequate care of the above groups of people?	Yes/ No	
20	Does the committee have a plan to keep a watch on the people suffering from cough, cold or fever?	Yes/ No	
21	Do the committee members help the ASHA/ AWW in conducting survey for cough, cold or fever?	Yes/ No	
22	Does the committee keep vigilance on arrival of any outsider in the village and take measures for prevention of COVID-19 transmission?	Yes/ No	
<b>IV. Support quarantine/ isolation</b>			
23	Do the committee members keep a watch on the people who have been quarantined in home?	Yes/ No	
24	Do the committee members advice and support the families having home quarantined person/s to take necessary precautions?	Yes/ No	
25	Has the committee make provision for doorstep delivery of essential items and services to the families with home quarantined person/s?	Yes/ No	
26	Has any arrangement been made for village level quarantine facility wherever and whenever home quarantine is not possible?	Yes/ No	
<b>V. Ensure continued provision of essential health services at village level</b>			

27	Are routine health care services at village level (including Village Health and Nutrition Days) being conducted regularly?	Yes/ No	
28	Are ASHA/ Anganwadi workers in regular contact with pregnant and lactating women to ensure continuity of care?	Yes/ No	
29	Are ASHA/ Anganwadi workers in regular contact with all high-risk cases of communicable and non-communicable diseases to ensure continuity of care?	Yes/ No	
30	Does the village committee ensure adequate stock of medicines for all individuals with hypertension and diabetes at village level?	Yes/ No	
31	Is transport facility available in village for referral in case of emergency?	Yes/ No	
32	Are the committee aware about the government ambulance services i.e. 108 for COVID-19 patients and 102 and other ambulances for other essential health services as the case may be?	Yes/ No	
33	Is the committee aware about the following COVID 19 related Services? <ul style="list-style-type: none"> <li>· Referral facility for suspected COVID 19 Patients</li> <li>· Helpline Number/ Nodal persons for availability of beds for COVID 19 Patients?</li> <li>· COVID 19 Testing Centres facility.</li> </ul> Ambulance services for Covid 19 Patients	Yes/ No  Yes/ No  Yes/ No	
<b>VI. Prompt response, in case Coronavirus positive case/s are detected</b> (This section needs to be filled, only if containment or micro-containment zones are declared OR there are large number of cases in the village)			
34	Is there single entry/ exit for the containment zone?	Yes/ No	
35	If Yes, are adequate IEC materials displayed at the entry?	Yes/ No	

36	Did the team ensure villagers are getting right information regarding risk?	Yes/ No	
37	Are traditional cremation ground/ burial attendants trained and equipped for safety precautions during all deaths during this period?	Yes/ No	
38	Does the village have a plan to ensure the safety and well-being of everyone during the process of last rite?	Yes/ No	
39	Has the committee ensured effective communication with the community for eliciting their support in ensuring required protocol management during containment?	Yes/ No	
40	Has the committee ensured that required house to house active case search is conducted by the special teams formed for the purpose?	Yes/ No	
41	Has the committee helped the surveillance efforts through providing required volunteers from the community?	Yes/ No	
<b>VII. Ensure Hygiene and sanitation in the Gram Panchayat</b>			
42	Is there adequate facility for washing hands with water and soap in primary school/ upper primary schools/ educational institutions/ market places, and Other public places?	Yes/ No	
43	Is regular fumigation of the village also being undertaken by the Gram Panchayat to prevent breeding of mosquitoes? If yes, indicate periodicity and chemical used? If not, why not?	Yes/ No	
44	Is the Gram Panchayat taking steps to ensure collection and disposal of solid waste? If yes, specify system put in place?	Yes/ No	

45	Are the drains cleaned regularly in the village?	Yes/ No	
46	Has the Gram Panchayat taken steps to ensure that there are no stagnant pools of water in the village? If yes, specify measures taken?	Yes/ No	
47	Has the community undertaken voluntary service to keep the village and its environment clean? If yes, please provide details.	Yes/ No	
<b>VIII. COVID 19 Vaccination</b>			
48	Have the committee identified and used locally relevant modes of mass communication for creating awareness regarding vaccination (e.g. Dawandi/ Announcement accompanied by beating drums)?	Yes/ No	
49	Does the committee prepare line list of eligible individuals from the community?	Yes/No	
50	Did the committee members try to motivate individuals who are eligible for vaccination and have not taken it till now for vaccination?	Yes/ No	
51	Did you make special arrangement for the needy person to take him to vaccination site?	Yes/No	
52	Did the committee seek support from influential person in society/religious leaders or groups for supporting the vaccination drive?	Yes/No	
<b>IX. If the lockdown has been implemented in district/ state</b>			
53	Has the committee ensured effective communication with the community for eliciting their support in ensuring required protocol management during lockdown?	Yes/ No	

54	Has the committee ensured that the relief measures provided by government are reaching to the most needy in the community?	Yes/ No	
55	Does the Committee have plans to deliver essential commodities to the needy people?	Yes/ No	
56	If yes, do you have identified resources to execute that plan?	Yes/ No	
57	Has the committee made any arrangement for accommodation and other essential services for migrants?	Yes/ No	
58	Has the committee made any plan to give work to the laborers under the schemes like MGNREGA?	Yes/ No	
59	In case of any migrant workers returning to the village, having any notifiable disease like TB etc., or any other comorbid conditions, has committee provided required support to them in consultation with Health officials?	Yes/ No	



राजेश भूषण, आईएएस  
सचिव

**RAJESH BHUSHAN, IAS**  
SECRETARY

भारत सरकार 369

स्वास्थ्य एवं परिवार कल्याण विभाग  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय

Government of India

Department of Health and Family Welfare  
Ministry of Health and Family Welfare

D.O.No.Secy.(HFW)/AS(VS)/2021

25<sup>th</sup> June, 2021

*Dear Colleague,*

I wish to draw your attention to some recent news items regarding allegedly "Fake" Covid vaccination sessions in some States.

As you are aware, any outreach Covid-19 vaccination sessions, either in workplaces (both public & private) or in housing societies, slums etc., can only be organized by the COVID Vaccination Centers (CVCs) registered on Co-WIN. It is also mandated under the Guidelines for COVID-19 Vaccination that, all vaccinations sessions, including the outreach sessions have to be created on Co-WIN and all vaccine doses administered in such outreach sessions, also are to be mandatorily recorded on Co-WIN.

In the above context, it is requested that State/UTs may issue suitable instructions to concerned field officers to monitor vaccination sessions being organized for workplaces or near-to-home, especially by the Private CVCs, to ensure that all such sessions are planned and created on Co-WIN and also all the vaccine doses administered therein are recorded in Co-WIN.

It is also requested that, wherever any instances of alleged irregularities are noticed, these must be promptly investigated and suitable action must also be taken, wherever necessary.

*Warm Regards.*

Yours sincerely,

  
(Rajesh Bhushan)

**Additional Chief Secretary/Principal Secretary/Secretary, Health-All States/UTs**

F.No. 35022/43/2021-Policy  
Government of India  
Ministry of Chemicals and Fertilizers  
Department of Pharmaceuticals

Shastri Bhawan, New Delhi  
Dated the 10<sup>th</sup> June, 2021

**OFFICE MEMORANDUM**

**Subject: Advisory to ensure efficient and rational distribution of drugs allocated by the Central Government to States/UTs - reg.**

Please take reference to various allocation letters issued from time to time by the Department of Pharmaceuticals and the Department of Health and Family Welfare (DoHFW) to ensure fair and equitable distribution of drugs across the States/UTs. Such allocations have been made for Remdesivir, Tocilizumab and Amphotericin-B so far.

02. The States and UTs were requested through these allocation letters to judiciously use the drug and strictly go by the treatment protocol contained in the clinical guidance issued by the DoHFW from time to time. It is again reiterated that the said drugs may be distributed efficiently and rationally within the State/UT to Government as well as Private Hospitals and their judicious use may be ensured strictly as per latest clinical guidance documents for managing patients of COVID-19 and Mucormycosis issued by DoHFW.

03. This issues with the approval of Secretary, Pharmaceuticals.

  
(Dr Sumit Garg) 10/6  
Deputy Secretary

To,  
Principal Secretary/Secretary Health- All States/UTs

Copy for information to-  
Secretary, Department of Health and Family Welfare

File No. 12-36/2021-DC (Pt-Misc-SND)  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
FDA Bhawan, New Delhi – 110002 (India)  
(Subsequent New Drugs Division)

Dated: 17 MAY 2021

CIRCULAR

To,

All State/UT Drugs Controllers

Sub: Applications for approval of New drugs used for Covid treatment.

Sir,

It is to state that applications for manufacture / import of 'new drugs' for Covid treatment are required to be made in appropriate format under the New Drugs and Clinical Trial Rules, 2019 and the same is required to be submitted on the SUGAM online portal along with necessary documents and requisite fees as per the said Rules.

It is requested to ensure that the aforesaid position is brought to the attention of the various stakeholders so that all those interested may apply accordingly. The CDSCO will process all such applications expeditiously keeping in mind the emergent need of such drugs during the pandemic.

You are requested to do the needful immediately.

Yours faithfully,



(Dr. V. G. Somani)  
Drugs Controller General (India)

Copy To:

All Zonal/Sub-Zonal Office of CDSCO.



ANNEXURE R-26

WWW.LIVELAW.IN



भारत सरकार 372

स्वास्थ्य एवं परिवार कल्याण विभाग  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय

Government of India

Department of Health and Family Welfare  
Ministry of Health and Family Welfare

राजेश भूषण, आईएएस  
सचिव

RAJESH BHUSHAN, IAS  
SECRETARY

D.O. No. Z.28015/126/2021-DMCell  
7<sup>th</sup> June, 2021

This is with reference to D.O. No. COVID-19/NTF Meeting/2020/ECD-1, dated 3<sup>rd</sup> June 2021, of Secretary Department of Health Research, vide which the Advisory of the Joint National Task Force on treatment and management of COVID-related Mucormycosis (CAM) has been communicated. The Joint Task Force is an expert body headed by Dr. Vinod Pal, Member, Niti Aayog and Prof. Balram Bhargava, Director General, Indian Council of Medical Research, which has deliberated on treatment options for management of CAM cases. A copy of the said Advisory, detailing various treatment options, is enclosed herewith for ready reference.

2. It may be noted that, the Joint Task Force has recommended that Amphotericin B, both in the Amphotericin B lipid complex/liposomal and the Amphotericin B Deoxycholate forms, is equally efficacious for treatment of CAM cases. The Joint Task Force has also recommended that injection Posaconazole can be used in cases of non-availability of Amphotericin B or in those patients having severe intolerance to Amphotericin B.

3. It is requested that the said Advisory may be brought to the attention of all medical institutions, both public & private, in the State/UT and may be widely disseminated among the medical professionals for following the Advisory for treatment/ management of CAM cases. Please also let us know any training needs on this matter so that the same can be facilitated.

Yours sincerely

Encl: As above

(Rajesh Bhushan)

**Additional Chief Secretary/Principal Secretary/Secretary (Health) – All States/UTs**

✓ Copy to:-

1. Ms. S. Aparna, Secretary, Department of Pharmaceuticals, Government of India – with the request to also consider allocation of Amphotericin B Deoxycholate to States/UTs, in light of the Advisory of the Joint Task Force.
2. Shri Harsh Vardhan Shringla, Foreign Secretary, Ministry of External Affairs, Government of India – for information please.

(Rajesh Bhushan)

Prof (Dr) Vinod K Paul  
Member  
NITI Aayog



Prof.(Dr.) Balram Bhargava  
Secretary  
Department of Health Research &  
Director General ICMR  
Ministry of Health & Family Welfare

D.O.No. Covid-19/NTF Meeting/2020/ECD-I  
03 June 2021

Subject: Advisory on Treatment & Management of COVID-19 Associated Mucormycosis (CAM) and Important Considerations

*Dear Sri Rajesh Bhargava,*

Greetings to you from ICMR

The National Task Force on COVID-19 reviewed the treatment of COVID-19 Associated Mucormycosis (CAM). The scarcity of medicines used in CAM was highlighted by the Co-chairs. Experts' recommendations on the various treatment options are recorded in the Advisory that is attached in this communication.

A summary of the Advisory is given below for your kind information.

- Amphotericin B is available in the following formulations: Lipid complex/ liposomal Amphotericin B & Amphotericin B Deoxycholate. They are similar in efficacy, but Amphotericin B Deoxycholate is more toxic to the kidneys
- **Measures to reduce nephrotoxicity** include slow infusion, 500 mL normal saline along with amphotericin B and premedication to avoid infusion reaction
- Amphotericin B Deoxycholate therapy should therefore be administered along with **monitoring of kidney functions** and electrolyte imbalance
- Liposomal Amphotericin B is to be preferred in patients who have **mucormycosis of the brain or in patients who are intolerant to Amphotericin B Deoxycholate**
- Injection posaconazole can be used in case of **non-availability of Amphotericin B or in those patients having severe intolerance to Amphotericin B**
- CAM is not associated with the **use of oxygen humidifiers or wearing of masks.**

The chairpersons would like to request to kindly consider these recommendations

With regards,

Yours sincerely

(Dr. V. K. Paul)  
Co-Chair, NTF

(Dr. Balram Bhargava)  
Co-Chair, NTF

Encl. as above

## Indian Council of Medical Research

### **The National Task Force on COVID-19** **Advisory on Treatment & Management of COVID-19 associated Mucormycosis (CAM)** **and Important Considerations**

#### ASSOCIATED FACTORS

- COVID-19 associated Mucormycosis (CAM) has become an issue of public health concern in India.
- CAM has not been found to be predisposed by the following:
  - Use of oxygen humidifier or oxygen concentrators or industrial oxygen
  - Wearing of masks
- Use of clean masks even in home environment at least one month beyond Covid hospital discharge, appropriate dose and duration of steroids use, proper sugar control in patients with COVID-19 can reduce the incidence of CAM.

#### MANAGEMENT GUIDANCE

- Early diagnosis and appropriate management by multidisciplinary team of physicians can improve the outcomes.
- Patients with COVID-19 should be made aware of early warning symptoms of CAM. The post COVID-19 health checkup may require consultation with an ophthalmologist, Ear Nose Throat specialist, neurosurgeon and a dentist.
- Patients with CAM should be managed in a healthcare facility where management of drug related adverse events could be managed.
- Management of mucormycosis should start with surgical debridement leaving clean margins, control of blood sugar levels and review followed by modification of immunomodulatory therapy as therapeutically appropriate.
- The drug of choice for primary therapy of CAM is Amphotericin-B (AMB). The two types of formulations- liposomal lipid complex AMB and AMB deoxycholate are similar in efficacy, but the latter needs to be monitored for nephrotoxicity and electrolyte imbalance. Second choice of drug is injectable Posaconazole (to be used in case of compromise of renal function, uncontrollable infusion reaction, electrolyte imbalance or in non-availability of AMB).
- Criteria for prioritizing patients for giving AMB:
  - Young patients
  - Patients in whom surgical debridement is not possible or incomplete

#### DO NOTS

- Do not use antifungals for prophylaxis for CAM.
- Do not escalate dose (slow escalation) with AMB rather start treatment with full dose (calculated as per body weight).
- Do not use combination of antifungal therapy for CAM.

### Indian Council of Medical Research

- Do not use voriconazole, fluconazole, echinocandins and 5flucytosine, since they are not effective in CAM

#### DOSING SCHEDULE AND MONITORING DURING THERAPY

- Primary therapy:
  - Amphotericin B deoxy cholate (1-1.5mg/kg/day, for 3-6 weeks)-creatinine value and electrolytes to be checked regularly during therapy for monitoring renal function
  - Liposomal or lipid formulations (5mg/kg/day, for 3-6 weeks) can be considered in case of intolerance to AMB deoxycholate and in case of cerebral mucormycosis (10mg/kg/day, for 3-6 weeks).
  - Intravenous (IV) posaconazole (300mg BD day1, followed by 300mg OD for 3-6 weeks) in case of non-availability of AMB or as salvage therapy in patients with renal compromise or intolerable infusion reaction.
  - Oral Posaconazole (tablet [300mg BD day1, followed by 300mg OD for 3-6 weeks]) to be considered only if IV formulation not available. Tablets are preferred over syrup due to faster steady state concentration, lesser food interaction, and better bioavailability.
  - If there is progressive disease while on amphotericin B therapy, the dose of liposomal amphotericin B may be escalated to 10mg/kg/day or shift to posaconazole therapy.
  - If there is progressive disease while on posaconazole, try to shift the patient to amphotericin B therapy.
- Consolidation phase of therapy
  - After 3-6 weeks of primary therapy with AMB IV posaconazole, if the patient is responding to treatment, continue with tablet Posaconazole (300mg BD day1, followed by 300mg OD for 3-6 months).
  - After 3-6 weeks of treatment with AMB, if the patient is NOT responding to treatment, increase dose of AMB (to 10mg/kg/day), or change to tablet Posaconazole (300mg BD day1, followed by 300mg OD for 3-6 months)
- Monitoring during therapy:
  - When using AMB
    - Monitor Kidney Function (eGFR and S. Creatinine are reliable markers to assess nephrotoxicity)
    - Monitor electrolytes (Serum Potassium, Sodium and Magnesium)
  - When using Posaconazole
    - Monitor for Drug-Drug interactions and Therapeutic Drug Monitoring (TDM) is advisable when available.
- Measures to reduce nephrotoxicity with use of AMB Deoxycholate
  - Slow infusion of drug over 6-8 hours or can go over 24 hour
  - 500 ml, normal saline infused before, during or after AMB therapy
  - Premedication to avoid infusion reaction
  - Close monitoring of renal function and electrolyte imbalance
  - Refer to facility with adequate infrastructure for monitoring and management of toxicity

Dr. Sanjay Chaulhan  
Member Secretary

Dr. Samiran Panda  
Head (ECDC), ICMR

Prof. Balam Bhargava  
Co-Chair

Prof. Vinod Paul  
Chair