

Ministry of Health & Family Welfare Government of India

COVID-19 VACCINES OPERATIONAL GUIDELINES

(Updated as on 28 December 2020)



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ABBREVIATIONS

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

JSI	John Snow Inc
JS	Joint Secretary
LHV	Lady Health Visitor
MAS	Mahila Aarogya Samiti
MD-NHM	Mission Director National Health Mission
MERS	Middle East Respiratory Syndrome
МО	Medical Officers
MOHFW	Ministry of Health and Family Welfare
MR	Measles-Rubella
NARI	National AIDS Research Institute
NCC	National Cadet Corps
NCCVMRC	National Cold Chain & Vaccine Management Resource Centre
NCDC	National Centre for Disease Control
nCoV	novel Coronavirus
NEGVAC	National Expert Group on Vaccine Administration for COVID-19
NHM	National Health Mission
NIHFW	National Institute of Health and Family Welfare
NIMHANS	National Institute of Mental Health and Neuro Sciences
NIV	National Institute of Virology
NPSP	National Public Health Surveillance Project
NTAGI	National Technical Advisory Group on Immunization
NYKS	Nehru Yuva Kendra Sangathan
PHC	Primary Health Center
PRIs	Panchayati Raj Institutions
PS	Principal Secretary
RCH	Reproductive and Child Health
RMNCH+A	Reproductive, Maternal, Newborn, Child and Adolescent Health
RNA	Ribo Nucliec Acid
RWA	Resident Welfare Association
SARS	Severe Acute Respiratory Syndrome
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SDM	Sub District Magistrate
SEPIO	State Expanded Programme on Immunization Officer
SIO	State Immunization Officer
SNID	Sub National Immunization Days
SOPs	Standard Operational Procedures
SPMU	State Programme Management Unit
SSC	State Steering Committee
STFI	State Task Force for Immunization
ToTs	Training of Trainers
UNDP	United Nations Development Project
UNICEF	United Nations Children's Fund
UTF	Urban Task Forces
WCD	Women and Child Development
WHO	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 2020.¹ 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 2020.² 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.³



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

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

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

² https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/ 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.





2.1 ABOUT COVID-19

Coronavirus disease (COVID-19) is an infectious disease that has spreads 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 WHO⁴

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.⁵

The most common signs of infection with COVID-19 include fever, dry cough, shortness of breath or difficulty in breathing, and tiredness or fatigue.⁶ Most people (~80%) experience mild disease and recover without requiring hospitalization. However, globally, around 20% of people who contract COVID-19 become more seriously



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

ill and have trouble in breathing.⁷ In more severe cases, the infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even lead to death.

In India, 1,01,46,845 confirmed COVID-19 cases and over 1,47,092 deaths have been reported as of 25th 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' 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.⁸

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.

⁸ 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

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

2.2.3 HAND HYGIENE

The WHO guidelines on hand hygiene in healthcare (2009) suggest that⁹ 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.





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 parts10 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.¹⁰

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).¹⁰

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.¹⁰

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.¹⁰

10 https://www.bing.com/search?q=5.+The+race+for+coronavirus+vaccines%3A+a+graphical+guide & 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.¹¹

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).¹²

Types of COVI	pes of COVID-19 vaccines		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					
Total		215	25	17	5	1	10	1

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

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 WHO¹³ 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/ 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.14
- 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.¹⁵
- The Moderna/NIAID vaccine remains stable at -20°C for up to six months and remains stable at +2° to 8°C for 30 days¹⁶ and the Gamaleya institute, Sputnik-V vaccine can be stored at +2° to 8°C.¹⁶

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.

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)

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

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-vaccineexpression-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

16 About Vaccine | Official website vaccine against COVID-19 Sputnik V. (sputnikvaccine.com)

