

FAQs on COVID-19 Vaccines and Vaccination Program

A. GENERAL

1. Is vaccination for COVID-19 mandatory?

As per the operational guidelines issued by the GOI and disseminated to all States/ UTs the COVID-19 vaccination is totally voluntary; however, all individuals are encouraged to take vaccination for protecting themselves and their families from serious Covid-19 infection.

2. Which COVID-19 vaccines are used in the country at present for COVID-19 Vaccination?

The vaccines namely **Covishield** (AstraZeneca's vaccine manufactured by Serum Institute of India), **Covaxin** (manufactured by Bharat Biotech Limited), **Sputnik V** (Manufactured by Gamaleya Research Institute, Russia and imported by Dr Reddy's Lab), **CorBEvax** (manufactured by M/s Biological E) and **Covovax** (manufactured by M/s Serum Institute of India) are being used in the country. As on August 2022, Covishield and Covaxin have received market authorization with certain conditions, where as other vaccines are permitted for restricted use in emergency situation in the country by Central Drugs Standard Control Organization (CDSCO), the National Regulator.

3. What is Emergency Use Authorization (EUA)/ Permission for restricted use?

Emergency Use Authorization (EUA) is a regulatory mechanism to allow the use of vaccines and medicines to prevent and/or reduce the impact of life-threatening diseases or conditions as caused by COVID-19. However, before grant of the EUA, there are rigorous assessments of laboratory and clinical trial data, including data on quality, safety, production of protective antibodies and efficacy. Safety is particularly critical aspect of this scrutiny and a risk-versus-benefit evaluation is done in the context of a public health emergency. Full licensure is obtained when the manufacturer submits the complete data. EUA by Indian regulators is aligned with global guidelines.

4. Is the EUA a new process introduced for COVID-19 Vaccine?

Concept of EUA always existed to save the lives of people all over the world with vaccine and medicines for life threatening diseases while companies continue to obtain additional safety and effectiveness information to enable full licensure. Previously, EUAs have been granted to vaccines for outbreaks due to Anthrax, Ebola, Enterovirus, H7N9 influenza, and Middle East Respiratory Syndrome. WHO EUL COVID-19 vaccines and their status is available on WHO website (<https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjUnIHVm6L4AhWf7zgGHQ96BIIQFnoECAUQAQ&url=https%3A%2F%2F covid19.t rackvaccines.org%2Fagency%2Fwho%2F&usq=AOvVaw2df7h7IPYNceyKBqoAVvtv>)

5. Have the vaccines undergone the needed clinical trials before EUA?

All vaccines have conducted their phase I, II & III clinical trials before EUA and only after these clinical trials, they have been granted EUA by CDSCO.

6. What is Phase I, II and III of clinical trial for a vaccine?

The clinical trial phases include:

Phases of vaccine development/trial	Purpose
Pre-clinical	Vaccine development in laboratory animals
Phase I Clinical trial (small number of participants)	Assess vaccine safety, immune response and determine right dosage (short duration)
Phase II Clinical trial (few hundred participants)	Assess safety and the ability of the vaccine to generate an immune response (short duration)
Phase III Clinical trial (thousands of participants)	Determine vaccine effectiveness against the disease and safety in a larger group of people (duration 1-2 years)

7. Why vaccination is not provided to children who are usual target?

The general practice is to first evaluate any new vaccine in older population and then age reduction is done to assess the safety and effectiveness in paediatric population. Presently COVID-19 vaccines in India have received approval for Childrens of 12-17 years of age group among children. Therefore, COVID-19 vaccines are given to Childrens of 12-17 years age group under the National Covid-19 Vaccination Programme based on the recommendation of Domain knowledge experts.

8. What are the vaccines that have received approval for children in India?

ZyCoV D by M/s Cadila healthcare limited, Covaxin by M/s Bharat Biotech, CorBEvax by M/s Biological E Ltd. and Covovax by M/s Serum Institute of India Ltd. have received emergency used authorization by Central Drugs Standard Control Organization (CDSCO), by the National Regulator.

SN	Age group	Vaccine	Covid Vaccination Centres (CVCs)
1	12-14 year	CorBEvax	Govt and Pvt CVCs
		Covovax	Only at Pvt CVCs
		ZyCoV-D	Only at Pvt CVCs
2	15-17 years	CorBEvax	Only Pvt CVCs
		Covaxin	Govt and Pvt CVCs
		Covovax	Only at Pvt CVCs
		ZyCoV-D	Only at Pvt CVCs

B. VACCINE ATTRIBUTES

1. What technology has been used in development of the currently available vaccines in India?

Covishield® vaccine, manufactured by the Serum Institute of India, is a Viral Vector-based Technology which is also used to manufacture Ebola vaccine.

Covaxin® vaccine, manufactured by the Bharat Biotech, is a whole-Virion Inactivated Corona Virus Vaccine which is also used to manufacture vaccines like Influenza, Rabies and Hepatitis-A.

Sputnik V is manufactured by Gamaleya research Institute in Russia and is imported by Dr Reddy's Laboratories for Gam-COVID-Vac Combined vector vaccine (Component I & II).

CorBEvax is developed by Biological E Ltd. is a protein subunit vaccine which has receptor binding domain of SARS-CoV-2 gene.

Covovax manufactured by Serum Institute of India is a SARS-CoV-2 rS Protein COVID-19 recombinant spike protein Nanoparticle Vaccine.

ZyCoV-D manufactured by Zydus Cadila is recombinant DNA Novel Corona Virus-2019-nCoV vaccine.

2. What are the compositions of the above vaccines?

Composition of Covishield® includes inactivated adenovirus with segments of Corona Virus, Aluminium Hydroxide Gel, L-Histidine, L-Histidine hydrochloride monohydrate, Magnesium chloride hexahydrate, Polysorbate 80, Ethanol, Sucrose, Sodium chloride, and Disodium edetate dihydrate (EDTA).

Composition of Covaxin® includes inactivated Corona Virus, Aluminium Hydroxide Gel, TLR 7/8 agonist, 2-Phenoxyethanol and Phosphate Buffered Saline

Composition of Sputnik V: Component I Active substance: replication incompetent recombinant adenovirus serotype 26 particles containing the SARS-CoV-2 protein S gene.

Component II Active substance: replication incompetent recombinant adenovirus serotype 5 particles containing SARS-CoV-2 protein S gene.

Excipients: Tris (hydroxymethyl) aminomethane, sodium chloride, sucrose, magnesium chloride hexahydrate, EDTA disodium salt dihydrate, polysorbate-80, ethanol 95%, and water for injection.

Composition of CorBEvax: The CorBEvax includes the following ingredients: Aluminium hydroxide gel as Al⁺⁺⁺, CpG 1018, Buffer(Tris and NaCl in WFI).

Composition of Covovax: The COVOVAX™ Vaccine includes the following ingredients: SARS-CoV-2 rS Protein, DS Adjuvant Matrix-M1 Disodium hydrogen phosphate heptahydrate, Sodium dihydrogen phosphate monohydrate, Sodium chloride Polysorbate 80.

3. All vaccines currently used in National Covid-19 vaccination program require cold chain temperature. How is the cold chain been maintained during storage and transportation of vaccine?

The vaccines (Covishield, Covaxin, CorBEvax, Covovax and ZyCoV-D) need to be stored and transported at +2^o to +8^o Celsius. The cold chain for the vaccines is maintained through active and passive cold chain equipment available at approximately 29,000 cold chain points across India.

Sputnik V requires storage temperature of -18^oC to -22^oC (minus eighteen degrees centigrade to minus twenty two degree centigrade) or below . This vaccine is being administered by private hospitals only.

4. Is COVISHIELD® same as the vaccine been given by other countries like in UK by Astra Zeneca?

Yes, Covishield® vaccine, manufactured by the Serum Institute of India, is based on the same patent technology as the AstraZeneca vaccine administered by other countries.

5. What is the dose schedule of the vaccines under the national Covid-19 vaccination program?

In the National Covid-19 vaccination programme following dose schedule is as followed:

- Covishield®: two doses, an interval of 12-16 weeks (84-112 days)
- Covaxin®: two doses at an interval of 4-6 weeks (28-42 days)
- CorBEvax: two doses at an interval of 4 weeks (28 days)
- Covovax: two doses at an interval of 3 weeks (21 Days)
- Sputnik V: two doses at an interval of 3 weeks (21 days)
- ZyCoV-D : two doses at an interval of 4 weeks (28 days)
- Precaution dose (with the same vaccine or with CorBEvax following primary vaccination of Covishield & Covaxin), at an interval of 6 months (26 weeks) from the date of administration of 2nd dose.

6. Do I have a choice of the vaccine that I will receive?

Yes, Co-WIN portal displays the availability of the different vaccines across the COVID Vaccination Centres, both government and private as per the age appropriate criteria. The beneficiary can choose to get vaccinated with a particular vaccine at a particular CVC of his/her choice. For more details please visit CoWIN (www.cowin.gov.in)

7. What are the general indications for COVID-19 vaccination?:

- a. **Co-administration with non-COVID-19 vaccines:** If required, COVID-19 vaccine and other adult vaccines should be separated by an interval of at least 14 days. However, if a person seeks emergency care due to injury/accident and had received COVID-19 vaccine in less than 14 days, tetanus toxoid injection may be provided.
- b. **Interchangeability of COVID-19 vaccines:** Till now:
 - A. First & Second dose of Covid-19 vaccination should be of same vaccine and
 - B. Precaution dose

I) should also be of the same COVID-19 vaccine OR
II) Heterologous Precaution Dose with CorBEvax is allowed after vaccination with second dose of Covaxin or Covishield only.

8. Who are eligible for Precaution dose?

The following types of beneficiaries who are fully vaccinated (with 2 doses) and have completed 6 months (26 weeks) after the 2nd dose, as per the records available on Co-WIN, are eligible to take precaution dose.

- a. Health Care Workers (HCW)
- b. Frontline Workers (FLW)
- c. Citizens aged 60 years and more. It is availed at all Government CVCs free of cost and Private CVCs in all States/UTs

Under Covid Vaccination Amrit Mahostav, all Citizens aged 18 years and more are eligible **for Precaution dose** free of cost at Govt CVCs. and also eligible for precaution dose at private CVCs on a payment basis.

C. EFFICACY & PROTECTION

1. Developing a vaccine takes years. However, this time our scientists have developed a vaccine against the novel corona virus in such a short time. How was this possible?

Developing a vaccine generally involves years of research. First, we need a vaccine candidate that is evaluated in animals for its safety and efficacy. After a vaccine candidate passes a pre-clinical trial, it enters the clinical trial phase. While scientists have worked round the clock in the laboratory, even regulatory approvals that used to take several months have been fast-tracked as per standard guidelines. It helped eliminate all the time lapses between the pre-clinical and clinical trial stages. Earlier, the vaccine development involved a series of steps, but in the case of the coronavirus vaccine, the scientists and regulators worked in tandem, accelerating the whole process without compromises on any protocols and any steps.

2. What is the safety and efficacy of the vaccines used in the country?

To ensure that a vaccine is safe, we need to try it on a large number of people. The vaccine developers have not reduced the sample size at any stage of clinical trials rather it was bigger than what usually a vaccine is tested on.

When a vaccine is tested, most of the adverse events or unwanted effects, if any, occur in the first four to six weeks of its administration. Therefore, in order to ensure that it is safe, a close watch is kept on the people it has been given to for the first two-three months. This data helps to decide if a vaccine is safe. All concerned in the line of vaccine development, testing and evaluation have followed these procedures. The vaccines being used are considered safe on this yardstick.

As for the efficacy of the vaccine, we need time to tell how effective a vaccine is. All the global agencies have set the benchmark that only those vaccine candidates that show an efficacy of at least 50-60% will be considered. Most of the vaccines have shown an efficacy of 70-90% within the short period of two or three months of observation. Besides when a vaccine is given as emergency use authorization/permission for restricted use, as in the case of the COVID-19 vaccine, the trial follow-up continues for one to two years to assess the total duration of protection the vaccine will provide.

More than 100 crore people have received at least a single dose of Covid-19 vaccine and the proportion of side effects is very low.

3. Do I need to use mask/other COVID appropriate precautions after receiving the vaccine?

Yes, it is absolutely necessary that everyone who has received the COVID vaccine should continue to follow COVID appropriate behaviour i.e., mask, do gaj ki doori (physical distance of 6 feet) and hand sanitization; this is required to protect themselves and those around from spreading the infection.

4. How long I will remain protected after vaccination?

The longevity of the immune response in vaccinated individuals is yet to be determined. Hence, continuing the use of masks, handwashing, maintaining physical distance and other COVID-19 appropriate behaviours is strongly recommended.

5. Does vaccination protect me against newer strains / mutated virus of SARS-CoV2?

All vaccines are expected to provide reasonable amount of protection against the mutated virus also.

6. Which vaccine is better between Covishield®/Covaxin®/Sputnik V/CorBEvax/Covovax/ZyCoV-D?

There is no head-to-head comparison done between the vaccines being used in India, so one cannot choose one over another. All vaccines would work well in reducing the mortality and morbidity caused by COVID-19 disease.

7. In how many days will the vaccination create an adequate immune response and protection?

Adequate immune response develops approximately 2-3 weeks after completion of the Primary vaccination schedule i.e., after the second dose of Covid-19 vaccine in most of the beneficiaries.

8. Does this vaccine provide herd immunity?

When an increasing number of people get vaccinated in the community, indirect protection through herd immunity develops.

The percentage of people who need to be immune in order to achieve herd immunity varies with each disease. For example, its 95% for measles, however, the proportion of the population that must be vaccinated against COVID-19 to begin inducing herd immunity is not known.

D. SIDE-EFFECTS

1. What are expected immediate and delayed side effects of this vaccine?

Covishield®: Some mild symptoms may occur like injection site tenderness, injection site pain, headache, fatigue, myalgia, malaise, pyrexia, chills and arthralgia, nausea. Very rare events of demyelinating disorders, thrombosis with thrombocytopenia syndrome (TTS) have been reported following vaccination with this vaccine. **Any specific Information for vaccine beneficiaries in relation to Covishield® vaccine?**

A vaccine beneficiary vaccinated with any of the COVID-19 vaccines, particularly Covishield® and having one or more of the symptoms mentioned below should be suspected to have Thrombosis and Thrombocytopenia Syndrome (TTS). Persons taking Covishield should be vigilant for at least 30 days after taking vaccine for the following symptoms:

- Severe and persistent headaches with or without vomiting (in the absence of previous history of migraine or chronic headache)
- Shortness of breath
- Chest Pain
- Pain in limbs / pain on pressing the limbs or swelling in the limbs (arm or calf)
- Multiple, pinhead size red spots or bruising of skin in an area beyond the injection site
- Persistent abdominal pain with or without vomiting
- Seizures in the absence of previous history of seizures with or without vomiting
- Weakness/paralysis of limbs or any particular side or part of the body (includes cranial nerve involvements)
- Persistent vomiting without any obvious reason
- Blurred vision/ pain in eyes/Diplopia
- Mental status change / encephalopathy/ depressed level of consciousness
- Any other symptom or health condition which is of concern to the recipient or the family

Contraindications for the administration of COVISHIELD in the context of TTS:

Past history of major venous and arterial thrombosis occurring with thrombocytopenia.

Covaxin®: Some mild symptoms AEFIs may occur like injection site pain, headache, fatigue, fever, body ache, abdominal pain, nausea and vomiting, dizziness-giddiness, tremor, sweating, cold, cough and injection site swelling.

Sputnik V:

Short term general: Chills, fever, arthralgia, myalgia, asthenia, general discomfort, headache

- Local: injection site tenderness, hyperaemia, swelling
- Less common: nausea, dyspepsia, loss of appetite,
- Occasionally: enlarged regional lymph nodes

CorBEvax:

Systemic:

Common: Fever/Pyrexia, Headache, Fatigue, Body Pain, Myalgia, Nausea

Uncommon: Arthralgia, urticaria, Chills, Lethargy

Local:

Common: Injection Site Pain (Very common), Injection site erythema

Uncommon: Injection site swelling, Injection site rash, Injection site pruritis

Rare: Injection site irritation

Covovax:

Very Common: Injection site pain, Injection site tenderness, Feeling tired (fatigue) , Malaise ,Headache , Fever , Soreness of muscles , Joint pain , Nausea or vomiting

Common: Chills, Injection site redness , Injection site swelling , Injection site induration (hardness) , Pain in extremity (legs or arms) , Body ache

Uncommon: Asthenia (weakness or lack of energy), Injection site pruritus (itching) , Injection site rash , Rash , Skin redness , Itching , Hives , Enlarged lymph nodes , Back pain

Rare: Dizziness (feeling dizzy) , Sleepiness

ZyCoV-D :

Pain at injection site, redness, swelling and itching, headache, fever, muscle pain, and fatigue, Arthralgia, Back pain, Muscle spasms, Myalgia, Musculoskeletal pain, Neck pain, Vertigo, Diarrhoea, Gastritis, Gastroesophageal reflux disease, Nausea, Vomiting, Asthenia, Chills, Eye irritation, Abdominal distension, Abdominal pain, Fatigue, Pain, Pyrexia, Nasopharyngitis, Pain in extremity, Ageusia, Anosmia, Cerebral infarction, Dizziness, Headache, Cough, Dyspnoea, Nasal dryness, Oropharyngeal pain, Rhinorrhoea, Sneezing.

Source: As per the data information provided by vaccine manufacturer

2. What do I do if I have fever, pain or any other side-effect after vaccination?

Post-vaccination, you must wait for at least half an hour at the center so that side-effects can be managed. If they occur afterwards, please contact the nearest health facility or the health care worker for guidance.

3. What are the contraindications to COVID-19 vaccines?

1. Persons with history of:

- Anaphylactic or allergic reaction to a previous dose of COVID-19 vaccine and its ingredients.
- A suspected or confirmed case of thromboembolic phenomenon following first dose of any of the COVID-19 vaccines
- Immediate or delayed-onset anaphylaxis or allergic reaction requiring hospitalization to vaccines or injectable therapies, pharmaceutical products, food-items and insect sting etc.

2. The vaccination may be deferred in the following scenario

- i. In case of individuals having lab test proven SARS-2 COVID-19 illness, COVID-19 vaccination to be deferred by 3 months after recovery.
- ii. In case of SARS-2 COVID-19 patients who have been given anti-SARS-2 monoclonal antibodies or convalescent plasma, COVID-19 vaccination is to be deferred by 3 months from discharge from the hospital.
- iii. In case of individuals who have received at least 1st dose and got COVID-19 infection before completion of the dose schedule, the 2nd dose should be deferred by 3 months from clinical recovery from COVID-19 illness.

3. An Individual can donate blood after 14 days of either receipt of COVID-19 vaccine or getting RT-PCR negative, if suffering from COVID-19 disease.

4. Which drug should be taken to minimize the adverse effects of this vaccine?

The minor adverse effects of Covid-19 vaccination such as injection site pain, tenderness, malaise, pyrexia, etc., are self-limiting. In case of no relief, Health Care Worker (HCWs) may be contacted to seek further advice.

5. Claims on social media suggested that COVID-19 vaccine could affect female fertility. Is it true?

Rumours or social media posts suggesting that COVID-19 vaccines could cause infertility are not true and totally baseless. Such rumours were floated in the past against other vaccines like e.g. polio and measles. None of the available Covid-19 vaccines affects fertility. All vaccines and their constituents are tested first on animals and later in humans to assess if they have any such side effects. Vaccines are authorized for Human use only after their safety and efficacy is assured and ascertained.

6. Should one avoid taking vaccine during and around menstruation?

The time period around menstruation is no contraindication for taking vaccines and like other vaccines, COVID-19 vaccine can be taken at any time of the monthly menstrual period.

7. Do I need to get myself tested for COVID-19 before taking the vaccine?

No, there is no requirement for screening of the vaccine recipient by Rapid Antigen Test (RAT) or RTPCR prior to COVID-19 vaccination. However, if you are symptomatic and suspected of suffering from COVID-19 infection, it is advisable to get tested yourself for Covid-19. In case of COVID-19 positive by lab test, COVID-19 vaccination can be deferred for 3 months (90 days)/12 weeks from the date of recovery of illness.

E. PRECAUTIONS

1. What precautions do I need to take after receiving the vaccine?

COVID-19 vaccines are safe but in case of any bodily discomfort or complaint, the beneficiary should contact Health Care Worker (HCWs) or visit the nearest health facility, District Immunization Officer or call at 1075.

2. If I suffer from HTN/DM/CKD/heart disease/lipid disorders etc., can I safely take this vaccine?

Overall, the vaccine is safe and efficacious in adults with co-morbidity. However, if you are concerned for any specific medical reason, please consult your Health Care Worker prior to Covid vaccination.

3. What medications should be avoided before taking COVID-19 vaccine and for how long?

A person receiving aspirin, clopidogrel (both of these are anti-platelet agents) or other anti-coagulants; the dose of that day should be taken after the vaccination. Patients on Vitamin K antagonist (VKA) should have an International Normalized Ratio (INR) less than 3 before administration of the vaccine. In all cases, application of firm pressure at the injection site for at least 5 minutes after the injection may be done to reduce the risk of haematoma formation. The beneficiary should also inform to vaccinator about the same, prior to Covid vaccination.

4. The Health Ministry has advised caution in vaccinating persons with a history of bleeding or coagulation disorder. How does a person know if he/she has a coagulation disorder? What tests can be conducted?

There are a few bleeding disorders like 'haemophilia'. These persons should take the vaccine under the supervision of their treating physician. Patients who are admitted in hospital or ICU and have bleeding problems should delay the vaccination till they are discharged. However, several people with heart and brain disorders are on blood thinners like aspirin and anti-platelet drugs. They can continue with their medicines and have the vaccines. Vaccine should be administered with caution in persons with history of any bleeding or coagulation disorder (e.g., clotting factor deficiency, coagulopathy or platelet disorder). In such persons, there is a slightly increased risk of bleeding through the intra-muscular route of administration.

Individuals with these disorders are to be treated as those with any co-morbidity, they are an at-risk population and hence should be encouraged to get COVID-19 vaccines. COVID-19 vaccine should be administered with caution in individuals with Thalassemia and hemoglobinopathies, those who have a history of any bleeding or coagulation disorders (e.g., clotting factor deficiency, coagulopathy or platelet disorders). The vaccinator/health worker should ask these individuals and or their care providers if they have blue spots (ecchymosis), bleeding spots on the skin or prolonged oozing of blood after any injury.

In case of presence of these symptoms or any doubt about the presence of bleeding/clotting disorder, these individuals should be referred to their treating physicians for further clarification and approval for COVID-19 vaccination.

5. The health advisory also states that those with immunity issues should be cautious about taking the vaccine. What are the markers of 'Immunity issues'?

Immune issues are of two types: first, immunosuppression due to any disease such as AIDS, and people on immunosuppressant drugs such as anti-cancer drugs, steroids, etc. Second, immunodeficiency in people who suffers from some defect in the body's protective system such as congenital immunodeficiency.

Currently, available COVID vaccines do not have any live virus and therefore individuals with immune issues can have the vaccine safely. But the vaccine may not be as effective in them. One should inform the vaccinator about the medicines they consume and if they are suffering from any known immune issues. The vaccine recipient should have a record of their medical condition.

Immuno-deficiency, HIV, patients having immune-suppression due to any condition (persons on stable immunosuppression for 12 weeks or more) should be able to safely receive the vaccine although the response to the COVID-19 vaccines may be less in these individuals.

It is advised that such beneficiaries may seek Health Care Worker advice before taking vaccine. However, the prescription is not required for taking the vaccine.

6. I had COVID infection and was treated, why should I receive vaccine?

Development of immunity or duration of protection after COVID-19 exposure is not established therefore it is recommended to receive vaccine even after COVID-19 infection.

7. Is the vaccine contraindicated in person with chronic diseases?

Chronic diseases and morbidities like the Cardiac, neurological, pulmonary, , metabolic, renal and malignancies etc. are not contraindicated. In fact, the benefit of COVID vaccines to reduce the risk of severe COVID disease and death is for those who have these co-morbidities.

F. COVID-19 VACCINATION PROGRAM

1. How are the policy decisions on COVID-19 vaccination being taken in the country?

- A National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) was constituted by Cabinet Secretariat on 7th August 2020 under the Chairpersonship of Member (Health) NITI Aayog and Co-Chairpersonship of Secretary (H&FW).
- NEGVAC has representation of Secretaries from Ministry of External Affairs, Dept. of Biotechnology, Dept. of Health Research, Pharmaceuticals, MeitY, Finance and State governments and technical experts including Director General Health Services (DGHS), Directors of AIIMS, National AIDS Research Institute (NARI) and experts from National Technical Advisory Group on Immunization (NTAGI) and five state governments.
- The NEGVAC has guided on all aspects of 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 neighbouring countries, communication & media response etc.
- Domain knowledge experts have continuously guided the policy decision in National Covid-19 vaccination programme.

2. What are the principles followed for selecting the priority groups for vaccination?

The prioritization of beneficiaries for COVID-19 vaccination in India has been done based on the review of available scientific evidence, guidelines issued by the World Health Organization (WHO), global examples and practices followed in other countries with the primary objective to:

- Protect the healthcare and the pandemic response system
- Prevent deaths due to COVID-19 and protect individuals at highest risk and vulnerability of mortality due to Covid-19 disease

The current prioritization is the most preferred approach as it follows WHO guidelines and is based on the principle of equity wherein the most vulnerable to complications and mortality from COVID-19 disease are prioritized for vaccination.

3. Whether the Central or State Governments propose to undertake targeted vaccination drives for persons who are at the forefront of the war against COVID-19 and those that are providing on-ground assistance during the pandemic?

Those who are at the frontline of the fight against COVID-19 include the healthcare workers in the public and the private health care facilities involved in direct care of the COVID-19 patients and are most at risk of exposure were the first to receive the vaccination. This was followed by those who are exposing themselves to risk of exposure while carrying out the surveillance and containment measures and were included as frontline workers and were the second to be vaccinated.

4. How has the COVID-19 vaccination been introduced and scaled up in the country?

Based on the recommendations of NEGVAC and approval of GoI, COVID-19 vaccination programme started with the Health Care Workers (HCWs) who were directly involved in care of the COVID-19 patients w.e.f 16th January 2021 followed by Front Line Workers (FLWs) who were involved in containment and enforcement activities from 2nd February 2021.

Subsequently, the individuals above 60 years and those between 45 years and 60 years with the identified 20 comorbidities were included for COVID-19 vaccination from 1st March 2021. Since 1st April 2021, prioritized age group was expanded to cover all persons aged 45 years and above for COVID-19 vaccination.. Starting 1st May, 2021 the eligible age for vaccination was expanded to cover all adults above 18 years.

- The program has further expanded to include adolescents aged 15 to 18 years from 3rd January 2022, and administration of precaution dose to Health Care Workers, Front Line Workers and persons aged ≥ 60 years with co-morbidities from 10th January 2022.
- On 14th March 2022, it was announced to expand National COVID-19 vaccination program to age group of 12-14 years of age along with precaution dose to all beneficiaries above 60 years of age effective from 16th March 2022.
- From 10th April 2022, precaution dose of Covid-19 vaccines are made available to the 18+ population at Private COVID-19 Vaccination Centers (PCVCs) on completion of nine months i.e. 39 weeks/273 days from date of administration of second dose.
- From 13th May 2022, early administration of precaution dose of Covid-19 vaccine to Persons who need to undertake international travel for educational Purpose, employment opportunities, participation in sports tournaments in foreign countries, participation in bilateral, multilateral meetings as part of India's official delegation, for attending business commitments in foreign countries, etc has been approved , as required by the destination country, subject to a minimum period of 90 days between 2nd dose and the precaution dose.
- From 6th July 2022, the time interval between second dose & precaution dose was reduced to 6 months i.e. 26 weeks for all 18 years & above beneficiaries.
- From 15th July 2022 to 30th September 2022, under Azadi ka Amrut Mahotsav precaution dose of Covid-19 vaccines are made available free of cost to the 18+ population at Govt. COVID-19 Vaccination Centers on completion of six months i.e. 26 weeks from date of administration of second dose.

5. How have the other countries phased out their COVID-19 vaccination?

Prioritization criteria from WHO and other countries shows that a step-wise layered approach is advisable. For instance, the UK followed a step-wise approach for vaccination by first prioritizing those who are 80 years of age or above, followed by those above 75 years of age, next covering those over 70 years, and so on. Likewise, France first covered those above 75 years of age, followed by those between 65 – 74 years. Similarly, USA started with vaccination of Health Care Workers and higher age groups and COVID-19 vaccination is available as per the prescribed age group. A staggered approach has been taken by other countries starting with those in the higher age group.

6. How has the citizen interest been kept in mind with the vaccination strategy?

The vaccination program has been strategized to maximize the reach of vaccines to the citizens, keeping in mind their vulnerability, and allowing the states to use their strengths in service delivery. The Co-WIN platform, the backbone of National Covid-19 vaccination programme which is a very citizen friendly platform, was continuously upgraded to respond to the States /UTs and citizens based on the feedback received.

The vaccination can be availed at both government and private CVCs, with government CVCs providing it free of cost. Those who can afford, may approach private hospitals where vaccination would be done at a price. Vaccination through private sector would facilitate improved access and will reduce the operational stress on the government vaccination facilities thus reducing the crowd.

To promote the spirit of “Lok Kalyan”, use of non-transferable Electronic Vouchers which can be redeemed at private vaccination centers, are being encouraged to enable people to financially support vaccination of Economically Weaker Sections at private vaccination centres.

Hon’ble Prime Minister has inaugurated the use of e-RUPI voucher for payment of Covid-19 vaccination at Private Covid Vaccination Centre. Efforts are being made to ensure that the e-RUPI Vaccination Vouchers are sponsored in the State/UT in sufficient numbers to facilitate better access for people to vaccination even in the private COVID Vaccination centres. The Public sector undertaking, Industry and the Corporates are being encouraged to issue these vouchers to their employees, dependants and other beneficiaries.

7. What will be the cost of vaccination for eligible citizens?

Currently, vaccination is free at Government hospitals. In private facilities, vaccination is available for a price. For more details on pricing, it is advised to visit <https://www.cowin.gov.in/faq>.

G. COVID-19 VACCINATION IN PREGNANT AND LACTATING WOMEN

1. Is it safe to get COVID vaccine during pregnancy?

The National Technical Advisory Group on Immunization (NTAGI) has recommended that “pregnant women may take any one of the two (Covishield and Covaxin) Covid-19 vaccines and lactating women are also eligible for vaccination any time before and after delivery.” This recommendation is based on the emerging evidence which shows that benefits of COVID-19 vaccination during pregnancy far outweigh the risk associated with contracting COVID infection during pregnancy (like increased risk for severe illness, preterm birth). However, it is important that pregnant women make an informed choice and opt voluntarily for vaccination.

2. Are risks of Covid vaccination more than benefits for a pregnant /lactating woman?

The benefits of vaccinating pregnant and lactating women seem to far outweigh the risks. Lactating women are also eligible for Covid vaccine.

3. I am a pregnant / lactating Health worker engaged with Covid patient care. Should I take Covid vaccine?

Yes. Since you are at higher risk of getting infected, you should consider getting yourself vaccinated.

4. A lady was provided Covid vaccination and now suspected of being pregnant. Should she terminate the pregnancy if found pregnant? What should she do?

It is not advised to delay or terminate pregnancy because of vaccination. As per the available evidence, the vaccines do not have any ill effects on the fetus or the outcome of pregnancy. Also, it is not necessary to conduct pregnancy testing prior to vaccination.

5. I was advised by my obstetrician not to take any vaccine as some vaccines are contraindicated during pregnancy. Should I take Covid vaccine?

In pregnancy, there could be concerns with live attenuated vaccines. There are no live attenuated COVID-19 vaccines presently in the National COVID-19 vaccination program. Historically, vaccines are being provided to pregnant women such as tetanus and diphtheria which are safe. Therefore, presently there is no evidence of risk with COVID-19 vaccines as such. In case you are on treatment for any other pre-existing conditions then you may seek advice of your treating physician.

6. During my lactation period, I got Covid infection, what should I do now? Should I discontinue breast feeding and stay isolated from my newborn baby?

Please continue with breast feeding, which is very important for the wellbeing of the newborn. A COVID positive lactating mother is unlikely to transmit SARS CoV 2 virus through breast milk. Consequently, WHO recommends that mothers continue to breastfeed their infants. At the same time, it is important to wear mask properly, wash

your hand frequently and take all precautions while taking care of baby and while breastfeeding.

7. I am a pregnant / lactating mother. Is it mandatory to take COVID-19 vaccine?

As per the Operational Guidelines document and guidance note for vaccination of pregnant women, COVID-19 vaccination is voluntary; however, it is encouraged that all eligible individuals take vaccination for public health good.

8. While in my pregnancy, I was recently diagnosed as COVID-19 positive. Should I immediately go for COVID-19 vaccination?

No, you should defer COVID-19 vaccination for 12 weeks/3 months after recovery.

9. Does getting the vaccine affect my future fertility and the chances of getting pregnant?

No, there is no evidence or no indications so far that the COVID vaccines impact fertility.

10. What should pregnant woman consider before getting the vaccine?

Expectant woman may consider to discuss the following with their /health care provider to guide them to make their decision:

- Likelihood of exposure to COVID-19, risks of COVID-19 to them and potential risks to her and fetus
- Benefits of getting vaccinated
- Information about the type of vaccine and known side effects of the vaccine.
