FAQs on COVID-19 Vaccines and Vaccination Program

A. GENERAL

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

Three vaccines that have been granted authorization for restricted use in emergency situation by the Central Drugs Standard Control Organization (CDSCO) in India are Covishield® (AstraZeneca's vaccine manufactured by Serum Institute of India), Covaxin® (manufactured by Bharat Biotech Limited) and Sputnik V (developed by Gamaleya Research Institute, Russia), which is the third vaccine to get approval from the Drugs Controller General of India (DCGI).

2. 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.

3. 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. As of January 2021, nine COVID-19 vaccines were in emergency use in numerous countries around the globe.

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

Both the Indian COVID-19 vaccines and the Russian vaccine Sputnik V have conducted their phase I, II & III trials. Covishield® has completed its Phase III trials in UK and the bridging trial in India.

5. 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)

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

COVID-19 affects all age groups, however, the morbidity & mortality is several times higher in adults particularly in those above the age of 50 years. Children have either asymptomatic or mild infection.

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. The currently available vaccines in the country have not been evaluated in children so far. There are some clinical trials now underway to test the effectiveness and safety of the COVID 19 vaccines in children.

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 developed by Gamaleya Institute in Russia and is working closely with Dr Reddy's Laboratories for Gam-COVID-Vac Combined vector 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.

3. All three vaccines require cold chain temperature. How is the cold chain been maintained during storage and transportation of vaccine?

The two vaccines (Covishield & Covaxin) need to be stored and transported at $+2^0$ 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 -18^0C (minus eighteen degrees centigrade) or below. The deep freezers are available under Universal Immunization Programme across the country for storage of this vaccine.

4. Is COVISHIELD® same as the vaccine been given 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.

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

As per the permission granted by the Drugs Controller General (India), the dose schedule is as follows:

- Covishield®: two doses, an interval of 12-16 weeks
- Covaxin®: two doses at an interval of 4-6 weeks

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. The beneficiary can choose to get vaccinated with a particular vaccine at a particular CVC of his/her choice.

7. General Indications of COVID-19 vaccine:

a. **Authorized Age Group:** COVID-19 vaccination is indicated only for people aged 18 years and above.

b. **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 injection may be provided.

c. **Interchangeability of COVID-19 vaccines is not permitted**: As per the available global evidence till now, second dose should also be of the same COVID-19 vaccine which was administered as the first dose.

C. EFFICACY & PROTECTION

1. Developing a vaccine takes years. But 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 which used to take several months have been fast-tracked. 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 step.

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. So, 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 which 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.

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 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?

The body responds to vaccination by making more than one type of antibodies to virus parts including spike protein. Therefore, all vaccines are expected to provide reasonable amount of protection against the mutated virus also. Based on the available data, the mutations as reported are unlikely to make the vaccine ineffective.

6. Which vaccine is better between Covishield® / Covaxin®/Sputnik V

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 preventing the infection as well as prevent a person from going into severe state of the disease. As a long-term effect, it would be preventing death for elderly people or those who have co-morbidities.

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

Adequate immune response takes 2-3 weeks after completion of entire vaccination schedule i.e., after the second dose of COVISHIELD®, COVAXIN®, SPUTNIK V.

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 have been reported following vaccination with this vaccine but without the causal relationship establishment.

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. No other vaccine-related serious adverse effects have been reported.

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

2. 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.

iv. Persons with any serious general illness requiring hospitalization or ICU case should also wait for 4-8 weeks before getting COVID-19 vaccine.

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

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

In case of minor adverse effects such as injection site pain, tenderness, malaise, pyrexia, etc., paracetamol tablet may be used to alleviate the symptoms.

4. Should you avoid alcohol after receiving the COVID-19 vaccine?

As per experts, there is no evidence of alcohol impairing the effectiveness of the vaccine.

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 too for e.g. polio and measles. None of the available 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 use only after their safety and efficacy is assured.

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

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

7. Do I need to get myself tested before taking the vaccine?

No there is no requirement for screening of the vaccine recipient by Rapid Antigen Test (RAT) prior to COVID-19 vaccination.

E. PRECAUTIONS

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

COVID-19 vaccines are safe but in case of any discomfort or complaint, the beneficiary should 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. The maximum benefit of getting the COVID vaccine is for those who have such co-morbidities. However, if you are concerned for any specific reason, please consult your doctor.

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.

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. For them, vaccines are absolutely safe.

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 vaccinator should have a record of one's 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.

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.

- Individuals who are yet to receive COVID vaccine
    - Persons having laboratory test proven SARS-CoV-2 illness should defer the COVID 19 vaccination till 12 weeks after recovery
- Individuals who have received at least the first dose and develop SARS-CoV-2 infection before completion of the dosing schedule
    - Such individuals should wait for 12 weeks after clinical recovery from the COVID illness

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

Chronic diseases and morbidities like the Cardiac, neurological, pulmonary, 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. Any other serious illness requiring hospitalization/ICU care should also wait for 4-8 weeks before getting the next COVID-19 vaccine.

F. FOLLOW-UP & BOOSTER

1. Is it important for me to receive the same vaccine during second dose?

As the vaccines available are not interchangeable, it is important to receive the second dose of same vaccine as the first one. The Co-WIN app is also going to help to ensure that everyone receives the same vaccine.

2. How long I will remain protected?

The duration of protection is yet to be established.

3. Will this require any repeated vaccination or booster dose after the 2nd dose in future?

The requirement of booster dose is yet to be determined.

4. Will I get any certificate that I am vaccinated?

Yes, a provisional certificate would be provided after the first dose of the vaccine. On completion of the second dose, the vaccine recipient will receive a message on completion of schedule which would include a link to download digital certificate of vaccination for your perusal. This certificate can then be saved in the digi-locker.

5. 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).

Symptoms occurring within 20 days after receiving any COVID 19 vaccines
(Recipient should report to the health facility where vaccine was administered)

- 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
- Severe and persistent headaches with or without vomiting (in the absence of previous history of migraine or chronic headache)
- 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.

G. 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.

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 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. Nearly 88% of all COVID deaths in the country have been reported in the age group of 45 years and above. Starting 1st May, 2021 the eligible age for vaccination was expanded to cover all adults above 18 years.

From 21st June 2021, Revised Guidelines for Implementation of National COVID Vaccination Program came into effect under which Government of India is procuring COVID-19 vaccines and providing it free of cost to States/UTs Government. The domestic vaccine manufacturers can provide upto 25% of their monthly vaccine production directly to private hospitals. 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.

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. Presently, they have started vaccination of younger population.

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 now COVID-19 vaccination is available to all adults. 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 CoWIN platform, the backbone of vaccine delivery which is a very citizen friendly platform, is being 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 C0VID 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. Will COVID vaccination be available for eligible citizens at Public as well as Private facilities?

Yes, vaccination can be availed at government or private COVID Vaccination Centre (CVC) as per convenience. The nearest CVC can be located on Co-WIN portal and appointment can be booked as per the choice of CVC.

8. Is there a difference in registration process at private and at public facilities?

There is no difference between registration process for vaccination at Public & Private CVCs. In both cases, beneficiaries need to register on Co-WIN. The various modes of registration include:

- Online registration and appointment
- On-site or walk-in registration and vaccination of either single individual or groups of individual (such as those who do not have access to internet or smart phones) at COVID-19 Vaccination Centre (CVC)
- Registration at Common Service Centres (CSCs)
- Assisted registration through National COVID-19 Helpline (1075)/State Integrated Helplines

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

COVID-19 vaccination is available free of cost to all citizens aged 18 years and above at government CVCs. Those who have the capacity to pay may approach COVID Vaccination Centres at private hospitals. The price of different vaccine products at private CVC may differ and will be dynamic as per vaccine pricing offered by the manufacturers, which will be declared by each vaccine manufacturer. The private hospitals may charge upto a maximum of Rs 150 per dose as service charge. The price of vaccination would also be displayed on CoWIN portal and would be visible to citizens at the time of seeking online appointment.

H. COVID-19 VACCINATION IN PREGNANT AND LACTATING WOMEN

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

The vaccines being used under the national vaccination program are found to be safe and effective. Based on how these vaccines work in the body, experts believe they are unlikely to pose a risk for people who are pregnant. The National Technical Advisory Group on Immunization (NTAGI) has recommended that "pregnant women may take any one of the two Covid-19 vaccines and lactating women are also eligible for jabs at 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's important that pregnant women make an informed choice.

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

No, the very real benefits of vaccinating pregnant and lactating women seem to far outweigh any theoretical and remote risks of vaccination. Lactating women are also considered for Covid vaccine as there are no known adverse effects on the neonate who is breastfeeding. In fact, there is a possibility of passage of protective antibodies to the child, which may have a beneficial effect.

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. What effect will COVID -19 have on my baby if I am diagnosed with the infection?

It has been seen that most (over 95%) of the newborns of COVID-19 mothers have been in good condition at birth. Current evidence suggests that if you have the virus it is unlikely to cause problems with your baby's development.

6. 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 in the market in India or globally. Historically, vaccines are being provided to pregnant women such as tetanus and diphtheria which are safe. Therefore, there is no 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. The COVID19 vaccination reduces the risk of serious disease in those with co-morbid conditions

7. 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.

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

COVID-19 vaccination is not mandatory, however, you can make an informed choice regarding receiving the vaccine. The Health Care Worker or doctor would brief you about COVID-19 vaccines and its benefits.

9. If I take COVID-19 vaccine during pregnancy, would it have any abnormal effect on the baby?

Currently, there is no evidence that shows COVID-19 vaccine administration affects the feotus/baby. The manufacturers of mRNA vaccines have done DART studies, which didn't show any safety issues, and the post marketing surveillance data did not show any safety signals in pregnancy.

10. Are there any additional risks with COVID-19 vaccination if taken during pregnancy or lactation?

No, based on reported risks from the general population, any additional risk during pregnancy or lactation is likely to be rare. As such, no such reports have emerged.

11. I have recently got COVID-19 vaccination. Can I plan for pregnancy?

Yes, you can plan for pregnancy as per your choice.

12. Does COVID-19 vaccine have any detrimental effect on pregnancy outcome?

Currently, there is no evidence that shows COVID-19 vaccine administration increases miscarriage rates or affects pregnancy outcome. It protects against serious COVID19 disease in pregnancy.

13. My pregnancy was confirmed recently and I want to take COVID-19 vaccine. What is the best time to get the Covid vaccine?

COVID-19 vaccine can be taken any time during pregnancy as per recommendation of the National Technical Advisory Group on Immunization (NTAGI).

14. 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.

15. I am convinced to take COVID-19 vaccine during my pregnancy, but how should I proceed?

You can register on the Co-WIN portal and schedule your vaccination appointment as per your convenience, through website-https://www.cowin.gov.in/home . There is also option of onsite registration in the Government and private covid vaccination centers. You could call at 1075 to assist you on the process.

16. Are the body immune responses following COVID-19 vaccination in a pregnant or lactating woman same as in non-pregnant person?

Yes, pregnant and lactating women elicit comparable vaccine induced humoral immune responses as in non-pregnant persons. Vaccine-generated antibodies are also present in umbilical cord blood and breast milk after maternal vaccination.

17. Will I experience any side effects after vaccination?

Yes and No**.** Side effects are variable after vaccination but there is no reason to think that the vaccine will have worse side-effects in pregnant women. These effects are usually similar to side effects in non-pregnant women, and usually are not serious and do not require any specific medical attention except symptomatic relief.

18. What are the common side effects after vaccination?

Commonly seen minor side-effects may be immediate in the form of pain at injection site, sweating and nausea. In the first seven days, the vaccine may even cause fever, fatigue, myalgia, arthralgia, local pain, swelling, redness, rash and diarrhea. Please consult your doctor immediately if fever or other symptoms persist.

19. Which vaccines should I take if I am pregnant?

National Technical Advisory Group on Immunization (NTAGI) recommends that pregnant women may take any one of the two Covid-19 vaccines (Covishield or Covaxin). You must consult your doctor about the choice of vaccine in particular case. Both COVISHIELD and COVAXIN can be used during pregnancy or lactation.

20. 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 district immunization officer for guidance.

21. Can women who are on contraception courses and women planning for pregnancy get vaccinated?

Yes, women on contraceptives can certainly get vaccinated. Pregnant women fall in the vulnerable group in terms of risk of serious disease in case of exposure. It might be safer for them to be fully immunized before she conceives.

22. 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.

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

Expectant woman may consider to discuss the following with their doctor/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.

*****