

IFS recommendations for COVID-19 Vaccination COVID-19 before ART

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INTRODUCTION

The coronavirus pandemic has wreaked havoc on life and healthcare globally. According to WHO database as on 7th June 2021, there have been 173 million confirmed covid19 cases worldwide and 3.7 million deaths. The World Health Organization declared the outbreak a Public Health Emergency of International Concern on 30 January 2020, and a pandemic on 11 March 2020. SARS CoV 2 is a positive-sense single-stranded RNA virus that is contagious in humans. As described by the US National Institutes of Health, it is the successor to SARS-CoV-1, the virus that caused the 2002–2004 SARS outbreak

India is just recovering from the deadly second wave of the pandemic with more than 28 million confirmed cases and 3.49 lakh deaths.


In these trying times, as societies are gradually trying to return to a state of normalcy, it is also important to consider sexual and reproductive health of people.

Couples seeking conception are particularly distressed and need clear guidelines to help them make decisions about their treatment.

This document of the IFS has been prepared after taking inputs from all the chapter secretaries of the IFS and hence includes insights and common queries addressed by the healthcare providers across the country. It intends to provide both the providers and the patients an overview of covid vaccination in patients desiring fertility in order to help them make an informed choice regarding the vaccination.

THE VIRUS

COVID-19 disease is caused by the virus, SARS CoV2 (Severe acute respiratory syndrome coronavirus 2) which is a beta coronavirus. Coronaviruses infect humans, other mammals, and avian species, including livestock and companion animals. Human coronaviruses are capable of causing illnesses ranging from the common cold to more severe diseases such as Middle East respiratory syndrome

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(MERS, fatality rate ~34%). SARS-CoV-2 is the seventh known coronavirus to infect people, after 229E, NL63, OC43, HKU1, MERS-CoV, and the original SARS-CoV.

It bears 80% homology to SARS Cov and 50% to MERS.^[1]

Each SARS-CoV-2 virion is 50–200 nanometres in diameter.

It is an enveloped positive-sense single stranded RNA virus with four main structural proteins i.e. Spike (S) protein, Membrane (M) protein, Nucleocapsid (N) protein and envelope (E) protein.^[2] In SARS CoV 2, the spike protein, which has been imaged at the atomic level using cryogenic electron microscopy, is the protein responsible for allowing the virus to attach to and fuse with the membrane of a host cell; specifically, its S1 subunit catalyzes attachment, the S2 subunit fusion.

It binds to **angiotensin receptor conversion enzyme 2** (ACE2) on host cells for viral entry and with the help of **Transmembrane serine proteases 2** (TMPRSS2) is incorporated in host cell wall.^[3] Initial spike protein priming by transmembrane protease, serine 2 (TMPRSS2) is essential for entry of SARS-CoV-2.^[2] The host protein **neuropilin 1** (NRP1) may aid the virus in host cell entry using ACE2. After a SARS-CoV-2 virion attaches to a target cell, the cell's TMPRSS2 cuts open the spike protein of the virus, exposing a fusion peptide in the S2 subunit, and the host receptor ACE2. After fusion, an endosome forms around the virion, separating it from the rest of the host cell. The virion escapes when the pH of the endosome drops or when cathepsin, a host cysteine protease, cleaves it. The virion then releases RNA into the cell and forces the cell to produce and disseminate copies of the virus, which infect more cells.

SARS CoV 2 produces at least three virulence factors that promote shedding of new virions from host cells and inhibit immune response.

An understanding of the structure of the virus has helped in developing preventive and treatment strategies against it.

The need for vaccination

Impact on reproduction

COVID-19 may influence both male and female steroidogenesis, germ cells and reproductive health.^[4] The reproductive system in both sexes has abundant ACE2 receptors and are susceptible to SARS CoV 2 infection. Studies have suggested that downregulation of ACE 2 may cause alteration in

follicular development and oocyte maturation affecting their quality and subsequently affecting embryo development. Also increased oxidative stress may have detrimental pro inflammatory effect. Endometrial receptivity may also be altered leading to unfavourable outcomes.^[5]

Hajizadeh Malekiand Tartibian conducted a prospective, longitudinal cohort study of 84 men with laboratory-confirmed COVID-19 and 105 men without the disease in Iran. The researchers analyzed changes in angiotensin-converting enzyme 2 (ACE2) activity, markers of inflammation and oxidative stress, apoptotic variables and semen quality, all of which were evaluated at 10-day intervals for up to 60 days. They also had higher levels of reactive oxygen species and lower superoxide dismutase activity compared with healthy controls.

The markers of inflammation and oxidative stress in sperm cells of men with COVID-19 were increased by more than 100% compared with controls, according to the researchers. Sperm concentration was reduced by 516%, mobility by 209% and sperm cell shape was altered by 400%. Although these effects were reported to improve over time — representing “a transient state of male subfertility like those with oligoasthenoteratozoospermia” — the researchers wrote they remained “significantly and abnormally higher in the COVID-19 patients, and the magnitude of these changes were also related to disease severity.”

So couples should be advised to continue with efforts at conception, follow all preventive measures and meanwhile seek vaccination at the earliest.^[11] **Basigin (BSG)** is also one of the most crucial receptors for COVID-19 that mediates its entry to host cells. BSG is expressed not only in the uterus but also in the stroma and granulosa cells of the ovary. BSG may play a role during follicle development, corpus luteum formation and embryo implantation.

In men viral orchitis may develop and impair semen parameters albeit transiently. The long term effects still need to be evaluated.^[6]

COVID-19 infection in pregnant women is more severe than their nonpregnant counterparts with increased morbidity and mortality and adverse perinatal outcome in the form of preterm birth, growth restriction, still birth and increased caesarean delivery.^[7,8]

Also vertical transmission though not proven is still a possibility.^[9]

The psychological effects of stress due to fear of the disease, social restrictions and financial implications may also disturb the HPO axis.

Drugs used in the treatment of COVID-19 infection and sanitization agents in the environment may also result in changes at the molecular level and have a bearing on the fertility potential of a couple.^[4]

Most scientific societies have advocated that people of reproductive age whether planning conception or not should receive covid vaccine.^[10]

RECOMMENDATION Even though the evidence is scant, it is important to prevent this infection as well as augment immunity against this infection prior to commencing fertility treatment.

IFS therefore recommends vaccination before initiating fertility treatment. However, certain circumstances may warrant initiation of treatment before taking the vaccine, for instance,

- (a) scarcity or non-availability of vaccine in some states,
- (b) medical conditions like fertility preservation for cancer, advanced age, poor ovarian reserve etc.

In these circumstances, the patient may be advised to initiate treatment but the final decision may be left to the patient after explaining all pros and cons and an informed consent taken before starting treatment. The vaccine can be taken as and when it becomes available.

Prevention of infection

Though risk mitigation measures like wearing a mask, maintaining hand hygiene and social distancing remain the best preventive strategy, availability of vaccines have provided a new hope of curtailing the virus and averting further waves of COVID-19.

So, couples are advised to continue with efforts at conception, follow all preventive measures and meanwhile seek vaccination at the earliest.^[11]

Generally, any vaccine which is available can be taken by those seeking pregnancy with the exception of live attenuated one to avoid harm in case of accidental pregnancy.

For patients who have already been infected with COVID, IFS advises to take the vaccination in order to enhance their immunity and dampen the effect of a re infection if it occurs.

The various covid vaccines are being developed using different platforms like nucleic acid based, viral vector based, protein and peptide subunit based, killed whole virus, nanoparticle and virus like particle based vaccines.

The COVID-19 vaccines approved in our country and the ones in the pipeline are shown in Tables 1 and 2

Other international vaccines which may be available in near future in our country are

Table 1: Vaccines approved for use in India

Vaccine (Company name)	Dosage	Type of vaccine	Efficacy	Remarks
Covishield (Serum Institute of India)	2 doses im 12-16 weeks apart	Non replicating viral vector vaccine (using recombinant Chimpanzee adenovirus as vector, encoding SARS CoV2 Spike (S) glycoprotein	70-80%	Phase III completed
Covaxin (ICMR & Bharat biotech)	2 doses im 4-6 weeks apart	Whole virion killed virus vaccine	81%	Phase III completed Paediatric study trial ongoing
Sputnik V(Gamaleya Institute, Russia)	2 doses im 21 days apart	Non replicating double viral vector vaccine	91.6%	Phase III to be completed

Courtesy : Dr A K Pandey

Table 2: Vaccines under trial in India

Vaccine (Company name)	Dosage	Type of vaccine	Remarks
ZyCoV-D(Zydus Cadilla)	3 doses intradermal at 0,28,56 days	Indigenous recombinant DNA vaccine	Completing Phase III
BECOV2A/B/C/D(Biological E limited)	2 doses im 28 days apart	Recombinant protein vaccine	Reached Phase II trials
Ub612(Vaxxinity Inc)	2 doses im 28 days apart	Recombinant protein vaccine	To start Phase II & III
Arct-021(Arcturus)	Single im dose	mRNA vaccine	To start Phase II
BBV154(Bharat biotech)	Intranasal	Intranasal Adenoviral vector COVID-19 vaccine	Phase I
HGCO19(Gennova Biopharm. Ltd.)	2 doses im 28 days apart	first indigenously developed self-replicating mRNA vaccine	In Phase I & II
Covovax(ICMR & Serum Institute of India jointly)	-	recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) with Matrix-M1™ adjuvant	In Phase II & III

Courtesy: Dr A K Pandey,

- (1) mRNA based vaccines- BioNTech/ Pfizer and Moderna. These do not contain the COVID-19 virus and so theoretically cannot lead to infection. In addition, they do not interact with the host's DNA and so cannot cause genetic changes.
- (2) Viral vector vaccine – Janssen (Johnson & Johnson) single dose vaccine, Oxford- Astrazeneca
- (3) Inactivated Virus vaccine: Coronavac, Sinopharm
- (4) Protein based- Novavax

Most vaccines have either no or minimal minor side effects like immediate pain, sweating and nausea after receiving the vaccine. There could be fever, fatigue, myalgia, arthralgia, lymphadenopathy, local pain, swelling, redness, rash and diarrhea in the first week after the vaccine. Most of these adverse effects can be alleviated by simple medications.^[12] Rarely there may be severe anaphylactic reactions, thromboembolic phenomena resulting in cardiopulmonary or cerebrovascular events, severe gastrointestinal disturbances, facial palsy and local infections like cellulitis.

RECOMMENDATION

IFS strongly recommends all preventive measures including vaccination to mitigate the possibility of infection to all those planning a pregnancy or contemplating ART treatment. Any of the available vaccines in the country may be taken.

There are many queries in the minds of the patients which need to be addressed. However, because of limited knowledge about the disease and the daily emerging evidence, *it is recommended that the final decision to vaccinate should be left to the couple or the individual seeking advice.*

Similarly, the advice to the person seeking opinion would be that although covid vaccines have been developed in a short time frame, they seem to be safe and efficacious. The final decision to accept or decline the vaccine by couples desiring conception and those who are pregnant should be in consultation with a healthcare professional after understanding the benefits and presumed risks as more evidence continues to evolve.

The present guidance attempts to provide answers to most of the queries raised.

FREQUENTLY ASKED QUESTIONS

For which ART procedures should vaccinations be taken? • IFS recommends Vaccination to be taken ideally before all ART Procedures like: Protein based- Novavax Most vaccines have either no or minimal

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minor side effects like immediate pain, sweating and nausea after receiving the vaccine. There could be fever, fatigue, myalgia, arthralgia, lymphadenopathy, local pain, swelling, redness, rash and diarrhea in the first week after the vaccine.

Most of these adverse effects can be alleviated by simple medications.^[12]

- IUI
- IVF
- OPU
- ET
- FET
- ICSI
- Fertility preservation
- Third party reproduction
- **Separate the date of vaccination by a week from some treatment procedures (for example, egg collection in IVF) preferably**, so that any symptoms, such as fever, are not wrongly attributed to the treatment and not the disease^[14] stand a higher risk of COVID-19 and hence, at a greater risk of pregnancy complications and women in whom likelihood of contracting SARS-CoV-2 (e.g. frontline workers), should be strongly advised to get themselves vaccinated prior to attempting conception.
- There is no scientific evidence proving an adverse effect of the vaccines on fertility. The COVID vaccine stimulates both antibody and a cell mediated immune response against the spike protein of the SARS-CoV-2 virus. Hence, they cannot possibly interfere with the functioning of the reproductive system.
- Couples are, therefore, advised to continue with efforts to conceive, follow covid appropriate behavior and get vaccinated as soon as it is available to them.
- Planning a pregnancy before getting fully vaccinated and vice versa is a personal choice. However, it is advisable to plan a pregnancy for those with a limited reproductive horizon like advanced maternal age, poor ovarian reserve, severe endometriosis and poor responders (POSEIDON group 3,4).
- **IFS recommends that men and women who choose not to be vaccinated or if vaccine is not available, should not be denied**

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<ul style="list-style-type: none"> When to restart fertility treatment post vaccination? 	<p>access to assisted reproduction treatments.</p> <ul style="list-style-type: none"> It is advisable to postpone the start of assisted reproduction treatments (sperm collection, ovarian stimulation, embryo transfer) for at least a one week after the completion of vaccination (i.e. after the first/second dose) to allow time for the immune response to settle. IFS recommends that vaccination may be considered during fertility treatment however, keeping in mind the minor side effects after vaccination which may be bothersome to some patients, it is recommended to separate the date of vaccination by 1–3weeks from some treatment procedures (for example, egg collection in IVF) preferably, so that any symptoms, such as fever, are not wrongly attributed to the treatment, and sero conversion is effective. However, Assisted reproduction treatments should preferably be delayed for a period extending from 2 weeks to 2 months in women who have had any significant side effects from COVID-19 vaccination like allergic reaction.
<p>How long will I be protected ?</p>	<ul style="list-style-type: none"> Studies done till now suggest that protection from COVID-19 vaccines lasts at least six months to even one year. Natural immunity (i.e. protection in people who have been infected with COVID-19) can last for up to eight months,
<p>Do I need a booster dose</p>	<ul style="list-style-type: none"> Scientists are currently exploring whether or not vaccines will require boosters or modifications to respond to emerging SARS-CoV-2 variants. A study comparing IVF-ET outcomes pre and post vaccination in the same couples did not find any difference in the ART cycle characteristics or outcome.^[13] It typically takes 2 weeks after vaccination for the body to build protection (immunity) against the virus. Hence, it is possible one could still get COVID-19 before or just after vaccination because the vaccine did not have enough time to provide protection. People are considered fully

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<p>Which vaccine is more safe ?</p>	<p>vaccinated 2 weeks after their second dose of Vaccine.</p> <ul style="list-style-type: none"> Covaxin, Covishield and Sputnik V, have more or less the same efficacy. IFS recommends taking any vaccination that is available so that the patient and her/his family are safe.
<p>Is antibody testing after vaccination recommended?</p>	<ul style="list-style-type: none"> Results from currently available SARS-CoV-2 antibody tests should not be used to interpret the level of immunity or protection from COVID-19, especially after the person has received a COVID-19 vaccination. Hence not recommended.
<p>Has anyone got COVID-19 after being fully vaccinated?</p>	<ul style="list-style-type: none"> Yes, it is possible. COVID-19 vaccines are not 100% effective in preventing COVID-19, so people have got COVID-19 even after being fully vaccinated. Vaccines are very good at preventing severe cases of COVID and hospitalizations. So while they can still get COVID-19, they are less likely to become very sick with it after vaccination.
<p>Is there any effect on fertility?</p>	<ul style="list-style-type: none"> It typically takes a fortnight after vaccination for the body to build protection (immunity) against the virus that causes COVID-19. That means it is possible a person could still get COVID-19 before or just after vaccination and then get sick because the vaccine did not have enough time to provide protection.
<p>Is Vaccination recommended in pregnancy?</p>	<ul style="list-style-type: none"> There is no scientific truth to this. Most professional bodies (ACOG 2021, ASRM 2020, SFMF 2020, RCOG 2020, WHO 2021, ESHRE 2021) have endorsed covid vaccination in pregnancy.^[16-20] WHO recommends the use of COVID-19 vaccine in pregnant women wherever the benefits outweigh the potential risks. FOGSI also recommends the same. WHO does not recommend to take a pregnancy test prior to covid vaccination.^[21] Also, it is not recommended delaying pregnancy or consider termination of pregnancy because of vaccination. Preliminary studies have shown the presence of SARS-CoV-2 IgG antibodies in both umbilical cord blood of babies and breast milk of mothers who received the

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	<p>COVID-19 vaccine in antenatal period, suggesting that vaccinating pregnant and lactating females can provide protection to the fetus and newborn.</p> <ul style="list-style-type: none"> ● Though recently the Government of India has allowed vaccination in lactating females but the same benefit has not been extended to pregnant women even though FOGSI has strongly recommended it in view of the rising number of severe cases in pregnancy in the second wave.
<p>When should the vaccine be taken in pregnancy</p>	<ul style="list-style-type: none"> ● According to CDC, the vaccine is a mechanism to protect your baby, and the sooner you get it, the better. ● As of now, there is limited data on the safety of use in pregnancy, of COVID vaccines available in India. However, animal studies do not show any adverse fetal or neonatal effects of the vaccine. Every individual needs protection from the surging COVID-19 infections. There is a need to prevent severe covid infection and vaccine appears to be the answer. ● IFS recommends that this protection should be extended to pregnant women. ● Since safety data is presently unavailable and COVID is also a known cause of first trimester miscarriage, IFS recommends deferring the vaccination in the first trimester and taking it in the second or third trimester ● COVID-19 is also more likely than the vaccine to cause a fever, which can be problematic in the first trimester of pregnancy
<p>Should the male partner take the vaccine if the couple is trying to conceive</p>	<ul style="list-style-type: none"> ● All major fertility organisations recommend that COVID-19 vaccine should be offered to also men desiring fertility. ● Should the couple wish to start treatment, it is recommended that the cycle may be planned in such a manner that potential effects of fever post vaccination does not affect the cycle
<p>Is it safe to take vaccination during menstruation?</p>	<ul style="list-style-type: none"> ● IFS recommends that vaccination may be taken any time during a menstrual cycle.
<p>Should donors and surrogates be vaccinated?</p>	<ul style="list-style-type: none"> ● Donors and surrogates should be encouraged to get complete vaccination. At least one week gap is recommended from most <p style="text-align: right;">(Continued)</p>

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	<p>recent vaccination prior to gamete donation. If at all the donor feels unwell after vaccination, donation should be deferred for at least a week after all symptoms have abated.</p> <ul style="list-style-type: none"> ● The patient, partner, donor or surrogate, all should undergo COVID RTPCR testing prior to starting treatment and before any ART procedure. ● Oocyte donors (i) Clinics should consider incorporating additional counselling and documentation regarding screening for SARS-CoV-2 during ovarian stimulation for oocyte donation (OD) (ii) Oocyte donors should be screened with ART triage questionnaire and RTPCR test done before starting the treatment (iii) Clinics should consider cancellation if the donor has a positive RTPCR test for SARS-CoV-2 or develops COVID-19 during ovarian stimulation Sperm donors Similar protocol must be followed for sperm donors. RTPCR should be done before donation and vaccination should be mandatory. Data regarding presence of SARS-CoV-2 in semen is conflicting. Quarantine of all anonymous donor sperm specimens for 6 months must be carried out as per ICMR requirement.
<p>Can a different vaccine be taken for second dose?</p>	<ul style="list-style-type: none"> ● The answer to this is still debatable. Results of mixed vaccinations are awaited.
<p>Can vaccine curb the pandemic ?</p>	<ul style="list-style-type: none"> ● In communities with high vaccination, non-immune people have a lower risk of disease Their reduced risk results from the immunity of people in the community (i.e. herd immunity) When vaccine coverage is very high, the risk of disease among those who are non-immune can become similar to those who are truly immune.
<p>People are having serious side effects of vaccine like clots, death. Why should it be taken?</p>	<ul style="list-style-type: none"> ● Risks of serious side effects by any vaccine are far less than getting the disease itself. For example, tetanus can cause extreme pain, muscle spasms (lockjaw) and blood clots, measles can cause encephalitis (an infection of the brain) and blindness. The risks of the current COVID vaccines are rare and the benefit of its converting the disease into mild is definitely <p style="text-align: right;">(Continued)</p>

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Can prophylactic pain killers be before vaccine ?	<p>beneficial. The benefits of vaccination greatly outweigh the risks, and many more illnesses and deaths would occur without vaccines.</p> <ul style="list-style-type: none"> ● It is recommended not to take painkillers before the vaccine shot as it may dampen body's immune response. A mild antipyretic like acetaminophen maybe taken for fever.
What about drinking alcohol?	<ul style="list-style-type: none"> ● Alcohol is not permitted during infertility treatment. It is also recommended that people avoid heavy drinking after vaccination because it can be dehydrating. Drinking could exacerbate the fatigue, achiness, or headache symptoms people might feel,"
Does taking the COVID-19 vaccine break the fast?	<ul style="list-style-type: none"> ● Contemporary Muslim scholars have deemed the injections non-nutritious, hence are inconsequential to the fast. Taking a vaccination would therefore not break the fast. This is the verdict (fatwa) of the International Islamic Fiqh Academy and various fatwa agencies in several Muslim countries. ● Taking the COVID-19 vaccines do not invalidate the fast, and it is permissible for the fasting person to take the vaccine.
Should vaccination be taken after a COVID infection ?	<ul style="list-style-type: none"> ● Yes, Even if you have already recovered from infection, it is possible that you could get a re-infection. You should wait 90 days before getting a COVID-19 vaccine. Re vaccination must be done according to the advice of the doctor who has treated the patient.
Is intercourse permitted after taking the vaccination?	<ul style="list-style-type: none"> ● Since this it is an integral part of fertility treatment, it can be practiced provided the couple/ patient is not discomforted by the side effects (like body aches and fever) of the vaccine
What works against new variants of SARS-CoV-2 virus?	<ul style="list-style-type: none"> ● The highly contagious strain which is responsible for the second apocalyptic wave in India was named the "Delta variant" by the World Health Organization. ● Chances of getting the Delta variant strain of COVID-19 are significantly lowered after complete vaccination. Both of India's vaccines, Covishield and Covaxin, have shown efficacy against the Delta Variant of coronavirus, also known as

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Should breast feeding be discontinued for a few days after the vaccine shot	<p>B.1.617 variant or "double mutant", While Covishield has an efficiency of 66% against the strain, Covaxin dampens it by nearly the same efficacy.Both prevent serious disease and death</p> <ul style="list-style-type: none"> ● There is no reason to halt or discontinue breastfeeding at all. It may be continued without any break.
Is any vaccine approved for pregnant women by WHO ?	<ul style="list-style-type: none"> ● The various stages of trials of all COVID-19 vaccines available in the world haven't been done on pregnant women. However, in circumstances where the risks outweigh the benefits, WHO permits use of vaccines eg for Health CareWorkers. The Pfizer and the Moderna Vaccines are presently recommended. ● Prominent organisations like the Federation of Obstetric and Gynaecological Societies of India (FOGSI) and The International Federation of Gynecology and Obstetrics (FIGO) recommend pregnant women and lactating mothers to go ahead with the vaccination in view of the rising number of severe cases in pregnancy during the second phase. This has been strongly recommended to the Indian Govt. and awaits approval. ● IFS also strongly recommends the same.

Vaccination during pregnancy

The MoHW has recently approved of the use of all vaccinations available in India for use during pregnancy.

A pregnant woman who opts for vaccination, could be vaccinated at any time of the pregnancy. To help pregnant women make an informed decision to be vaccinated, they should be provided with information about the risks of COVID-19 infection in pregnancy, the benefits of vaccination, along with the likely side effects of vaccination. The reader is referred to the MoHW site for detailed information on vaccination in pregnancy (22).

Recommendation

In view of the serious outcomes of COVID during pregnancy in some cases, IFS strongly endorses and recommends the use of vaccines during pregnancy. Patients may take the first dose before or during commencement of ART treatment and follow up the second dose during pregnancy. It is preferred that the

second dose be taken at the end of first trimester although it can be taken at any time, in any trimester.

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Conflicts of interest

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