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DELHI COMMISSION FOR PROTECTION OF CHILD RIGHTS
GOVT. OF NCT OF DELHI

DELHI - 110006

D.O.No.F6(1)/DCPCR/21-22/CPPB/1689-94

Dated: 12th May 2021

Dear Sir

I write this letter to bring to your kind attention the issue of Covid-19 vaccination of pregnant women and lactating mothers, which the current vaccination drive rolled out in India for people aged 18 years and above excludes.

India had rolled out its Covid-19 vaccination drive on January 16th, 2021. India has adopted a phased manner for vaccinating her population, where vaccinations rolled out from 16th January 2021 with priorities for frontline/healthcare workers, and elderlies. From 1st May 2021 vaccination for the age group 18 years and above had been made available.

Currently, Pregnant and lactating women through an advisory issued by the Ministry of Health and Family (vide letter No. T-22020/14/2020-IMM dated 14th January 2021), have not been recommended to take the vaccine. This is an understandable position due to lack of clinical trials data on the effect of the Covid-19 vaccine on pregnant and lactating mothers.

Each year, 2.6 crore (Vital Statistics of India based on the Civil Registration system 2018) women deliver a child, add to that another 2.6 crore lactating mother and we have close to 5.2 crore women who are left out of the current vaccination program. Clearly, this is a critical population both in numbers and their vulnerability priority.

Kindly allow me to draw your kind attention to the recommendation of the Federation of Obstetric and Gynaecological Societies of India (FOGSI position statement on covid vaccination for pregnant & breastfeeding women) has recommended that obstetricians and gynaecologists and women's health care providers should be allowed to administer the Covid vaccines in pregnant & breastfeeding women with preparations to manage adverse events. They have pointed out that the method of administering and monitoring the vaccine and the schedule of vaccination should be the same for pregnant and lactating women as for the general population and concluded that *"there is no obvious basis for excluding pregnant or lactating women from vaccination."*

However, it must be noted that FOGSI has recommended that pregnant women receive vaccination based on the studies conducted by the Centre for Disease

Control and Prevention in the U.S. Countries such as the USA and the U.K. have started the vaccination drive to include this group of women as Pregnant mothers are classified as high risk by the Centre for Disease Control, the regulatory authority in the United States as compared to non-pregnant women.

India, on the other hand, has not categorised them as high risk. The CDC classifies pregnant women as being “*At increased risk for severe illness from COVID-19 when compared to non-pregnant people*”. Increased risk of severe illness which includes illness that requires hospitalization, intensive care, or a ventilator, or may even result in death and they are also at risk of adverse pregnancies such as preterm birth. Pregnant women with Covid-19 might also be at increased risk of adverse pregnancy outcomes, such as preterm birth. Poor maternal outcomes are associated with poor perinatal outcomes.

Hence, the CDC has recommended that pregnant women can receive a COVID-19 vaccine. This is because getting a COVID-19 vaccine during pregnancy can protect them from severe illness from COVID-19. In the USA, around 90,000 pregnant women have been vaccinated mainly with Pfizer and Moderna vaccines and no safety concerns have been identified. The study is based on a registry of 100,000 pregnant and lactating women who have received the MRNA vaccination as of now provides corroborating evidence.

CDC data also provides evidence that immunisation of pregnant and lactating mothers has led to transfer of antibodies to the infant and hence extending protection of the vaccination to the infant. World over, especially in Brazil, maternal death due to Covid-19 has been acknowledged as being on the rise and requiring special attention.

In the United Kingdom, the Joint Committee on Vaccination and Immunisation (JCVI) has advised that pregnant women should be offered COVID-19 vaccines at the same time as people of the same age or risk group.

I now draw your attention to the WHO guidelines for immunization of pregnant women which state the following:

“At present (March 2021), the WHO Strategic Advisory Group of Experts on Immunization currently recommends that pregnant women may receive the vaccine if the benefits of vaccination outweigh the potential risks, such as occupational activities with unavoidable high risk of exposure, and pregnant women with co-morbidities which place them in a high-risk group for severe COVID-19 disease.”

WHO has recommended vaccination of pregnant women post designing & establishing the design of a surveillance mechanism to monitor the effects of vaccination

They not only belong to the high risk category but there are potential other negative impacts on pregnant and lactating women due to covid. For instance, at the country-level, the largest increase in the number of stillbirths is expected in India

(60,179, 10% increase). Similarly, the number of maternal deaths is also expected to increase in 2020 as a result of the COVID-19 pandemic response, with the highest number of deaths anticipated in India (7,750, 18% increase). Child mortality is estimated to increase in India by 15.4%. Neonatal mortality by 14.5%. This is based on the report '*Direct and Indirect Effects of COVID-19 Pandemic and Response in South Asia published by the UN*'. It studied the impact of Covid-19 on mortality, hospitalisations, and ICU admissions due to the disease and the impact of nation-wide lockdown on maternal and child mortality, educational attainment of children, and the region's economy.

Evidence on COVID-19 vaccines is being continuously reviewed by the World Health Organization and the regulatory bodies in the UK, USA, Canada and Europe.

I acknowledge that India administers a different set of vaccines other than the mRNA vaccines based for which the CDC data exists. Impact of the vaccines administered in India on pregnant women is still not known due to lack of clinical trials data for the same. Clinical trials for vaccinations happen in three phases and the third phase involves administration to the general public to see the efficacy of the vaccination. The third phase did not include pregnant and lactating women.

Although the current datasets exist only for mRNA vaccines, Gynaecologists associations such as FOGSI are of the opinion that the theoretical benefits of India's vaccines would outweigh the risk of the disease. Covaxin is a killed (inactivated) virus vaccine while Covishield is a Adenovirus vector-based vaccine. Both are non-replicating. While inactivated virus vaccines are considered safe during pregnancy, adenovirus vector-based Zika virus vaccine used in pregnant mice showed no safety concerns.

The Commission diligently studied the medical literature on the subject with the help of organisation Indus Action and consulted experts such as Dr. Gagandeep Kang, Dr Rajani Bhat, and Dr. Aparna Hegde amongst others.

Hence, in exercise of powers vested in the Commission under section 15 of the Commission For Protection of Child Rights Act, 2005 and based of the consultations with experts, and review of medical literature, Delhi Commission For Protection of Child Rights (DCPCR) formally advises the Government of India to :

1. Categorise Pregnant and Lactating mothers as belonging to the **high-risk category**.
2. **Setting up a task force for the following purpose:** A working committee should be set up to look into the matters at the earliest and this category should be included in the vaccination drive. The task force should include experts from not only the health sector but also other institutions that work in operationalising a standard procedure and can help materialise a mechanism to track and monitor Pregnant Women & Lactating Mothers post vaccination.

3. Based on recommendations from other countries and FOSGI, India should not only include Pregnant Women & Lactating Mothers in the vaccination program but also **categorize them as belonging to the high risk category such as in other countries.**
4. **Communication :** Education and Standard Operating Protocols must be developed to educate women on the side effects of vaccination, effects of vaccination on pregnant and lactating mothers and ensure that informed consent is taken before taking the vaccine. Anganwadi Centres with Anganwadi workers and ASHA workers could drive the communication and messaging.
5. **Post Vaccination:** Creating a registry to register pregnant women and lactating mothers being vaccinated so that a continuous monitoring mechanism can exist to see if the vaccine has an adverse effect on pregnant women. Continuous monitoring of all pregnant and lactating women receiving vaccination is necessary. Hence a separate registry such as the V-safe registry in the United States should be created to collect such data.
6. As pointed out there is no existing data in India on the impact of Covid-19 vaccination on pregnant women. The aim of the vaccination drive should not only be to vaccinate this category of the population but also to monitor the impact of the vaccination and gather data on it's safety. Excluding them from the drive entirely is not the answer given the evidence on the effect of Covid-19 on pregnant and lactating mothers.

I hope you give our recommendations a fair consideration. Wishing our country the earliest possible relief from Covid-19 pandemic.

Regards

Sincerely


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Chairperson, DCPCR

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Copy for kind information to:

1. Pr. Secretary to Hon'ble Lt. Governor, Delhi
2. Additional Secretary to Hon'ble Chief Minister, Delhi
3. Secretary to Hon'ble Deputy Chief Minister, Delhi
4. Secretary to Hon'ble Minister (Health), GNCTD
5. Secretary to Hon'ble Minister (Women & Child Development), GNCTD