


# BMJ Open Protocol for a prospective, hospital-based registry of pregnant women with SARS-CoV-2 infection in India: PregCovid Registry study

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## ABSTRACT

**Introduction** Pregnant women are at increased risk of contracting COVID-19 due to several factors and therefore require special attention. However, the consequences of the COVID-19 pandemic on pregnant women and their newborns remain uncharted. The PregCovid registry aims to document the impact of SARS-CoV-2 infection on pregnant, postpartum women and their newborns. The aim of the registry is also to determine mother-to-child transmission of SARS-CoV-2 infection in India.

**Methods and analysis** PregCovid is a hospital-based registry for capturing information of pregnant, postpartum women with COVID-19 and their newborns in India. Medical case records of pregnant and postpartum women with a laboratory-confirmed diagnosis of COVID-19 will be captured in real-time using an online electronic patient record software. The data analysis will be carried out for symptoms, the severity of COVID-19, pregnancy complications, maternal morbidity and mortality, neonatal complications, mother-to-child transmission, etc. Data analysis will be carried out for different waves of the COVID-19 pandemic for rapid response and developing strategies well in advance to manage pregnant women infected with SARS-CoV-2. The evidence generated from the registry will be regularly shared with the appropriate authorities for policy decisions. Thus, the registry data may be useful for planning the strategies for better management of pregnant women with COVID-19.

**Ethics and dissemination** The study has been approved by the Institutional Ethics Committees of all the participating study sites under the Medical Education and Drugs Department, Government of Maharashtra, Topiwala National Medical College & BYL Nair Charitable Hospital, Mumbai and ICMR-National Institute for Research in Reproductive and Child Health, Mumbai, India. The results from this study will be disseminated with local, state, and national health authorities, collaborators and the general population on the study website (<https://pregcovid.com>) as well as dissemination through scientific meetings and publications.

**Trial registration number** CTRI/2020/05/025423.

## INTRODUCTION

COVID-19 has emerged as a public health emergency with more than 103 million

## Strengths and limitations of this study

- The PregCovid is the first registry on pregnant and post-partum women with COVID-19 in India.
- PregCovid registry will capture data on epidemiology, clinical characteristics, maternal and neonatal outcomes, response to treatment and mother-to-child transmission of SARS-CoV-2 infection.
- With the availability of hospital-based, harmonised data collected from the PregCovid registry network, a huge amount of data of pregnant and postpartum women with COVID-19 will be studied to improve the understanding of various aspects of COVID-19 disease.
- The continuous process evaluation and interim data analysis will be carried out for rapid response and developing strategies well in advance to manage pregnant women infected with SARS-CoV-2.
- The follow-up of mother and newborns is only till the discharge from the hospital which is a limitation of this registry.

confirmed cases of COVID-19, including 2.3 million deaths, worldwide as of 4 February 2021.<sup>1</sup> Several variants of SARS-CoV-2 are now emerging,<sup>2</sup> however, it is still unknown whether they have any clinical impact on pregnant women. Several International and National agencies are actively engaged to address the impact of the COVID-19 pandemic. Previously, members of the coronavirus family such as SARS-CoV and Middle East respiratory syndrome were reported to be associated with severe complications during pregnancy like miscarriage, fetal growth restriction, preterm birth and maternal deaths.<sup>3</sup> In general, pregnant women are a vulnerable population and need special attention. Pregnant women are particularly susceptible to respiratory pathogens and severe pneumonia, due to various factors such as physiologic changes in the immune

and cardiopulmonary systems (eg, diaphragm elevation, increased oxygen consumption and oedema of respiratory tract mucosa) which make them at risk of hypoxia.<sup>4</sup> Since the initial period of reporting case reports or case series on pregnant women with COVID-19 from China, now there are a number of studies published from different geographical regions. Initial studies mainly from China reported that clinical presentation of pregnant women with COVID-19 was comparable to non-pregnant cases and there was no risk of mother to child transmission of SARS-CoV-2 infection.<sup>5</sup> However, subsequently, studies were demonstrating the adverse impact of COVID-19 on both maternal and newborn health.<sup>4,6–9</sup> Evidence suggests that there might be population biases in the susceptibility of COVID-19. Analysis of 427 pregnant women of the UK registry revealed that there might be racial differences in the severity of presentation and outcomes.<sup>7</sup> Also, a higher incidence of maternal death due to COVID-19 is reported in some countries as compared with China or Europe.<sup>10</sup> Similarly, in the USA, ethnic disparities in incidence and outcomes are also observed in non-pregnant populations with COVID-19, notably in the USA.<sup>11</sup> Factors such as social behaviour, health-seeking behaviour, comorbidities and unknown genetic influences could be possible causes of differences in presentation and outcomes of COVID-19. This highlights a need for population-specific data of pregnant women, to gain an insight into social-epidemiological and clinical determinants of outcomes in COVID-19.

Currently, in India, the number of COVID-19 cases is on rising. The Ministry of Health and Family Welfare (MoHFW), Government of India, reported more than 10.4 million total confirmed cases with more than 0.1 million deaths as of 4 February 2021.<sup>12</sup> Out of these, Maharashtra state contributed 1.9 million cases with 51 169 deaths due to COVID-19.<sup>12</sup> COVID-19 affected Indian states including Maharashtra which need special attention in planning the strategies for combating COVID-19, especially in the vulnerable population such as pregnant women. Our preliminary observations suggest that nearly 12% of pregnant women in Maharashtra State have SARS-CoV-2 infection and about 10% of these are symptomatic, highlighting the emergency nature of the situation.<sup>13</sup> Currently, there is no epidemiological, demographic and clinical information on pregnant women with COVID-19 in India. Additionally, the outcomes of neonates born to mothers with COVID-19 were not documented in the Indian population.

To address the knowledge gaps, ICMR-National Institute for Research in Reproductive and Child Health (NIRRCH) has initiated a hospital-based pregnancy registry to capture sociodemographic, clinical presentations, treatment outcomes, obstetric and neonatal outcomes in Indian women with COVID-19. Herein, we describe the protocol and the characteristics of this registry.

## MATERIALS AND METHODS

The PregCovid registry is a prospective, hospital-based study designed to capture hospital data of pregnant and post-partum women with COVID-19 and their newborns. The PregCovid study aims to establish a network of COVID-19 hospitals in India to systematically capture data of pregnant and postpartum women with COVID-19 and their newborns. The objectives of the study are as follows: (1) to study epidemiological, clinical, maternal characteristics of pregnant and post-partum women with SARS-CoV-2 infection; (2) to study the severity of COVID-19, pregnancy complications including miscarriage, ectopic pregnancy, stillbirth, fetal growth restriction, preterm births, maternal, neonatal morbidity and mortality; (3) To study the impact of COVID-19 on maternal and neonatal outcomes during the different waves of COVID-19 pandemic in Indian women and (4) To study mother-to-child transmission of SARS-CoV-2 infection.

### Identification of study sites for data capturing

Since Maharashtra is a hotspot region for COVID-19, it was decided initially to launch the registry to capture the data in the Maharashtra state. Towards that, the Medical Education and Drugs Department (MEDD) Government of Maharashtra and Municipal Corporation of Greater Mumbai were consulted, and primary data on COVID-19 and pregnant women were collected by a rapid survey. We have provided the details of the PregCovid registry in the public domain to expand our network all over India.

### Data collection instrument

An a priori requirement of the registry was the development of the case record form. Towards this RG and DM carried out a situational analysis of the current evidence on the impact and outcomes of COVID-19 on pregnant women.<sup>14</sup> Based on the outcomes of the systematic review of the baseline data of more than 400 women from different parts of the world and also reviewing the USA registry PRIORITY: Pregnancy Coronavirus Outcomes Registry,<sup>15</sup> we shortlisted the key parameters about which the information should be collected.

In the next step, the case record form was independently reviewed by a team of gynaecologists and paediatricians. Their inputs were recorded and the case record form was modified by a consensus. The modified case record form was circulated to the site investigators (Professor & Head, Obstetrics and Gynaecology Departments, and Professor & Head Paediatrics/Neonatology Department) of the PregCovid Registry Network for further feedback and its feasibility as they have experience of treating the COVID-19 cases. RG coordinated with the site investigators of the PregCovid Registry Network Hospitals for pilot testing of the case record form. Based on the feasibility and pilot testing, the case record form was modified and finalised by the consensus of investigators (table 1).

**Table 1** Maternal and newborn information with respect to different parameters captured by Electronic Patient Record for PregCovid registry

Maternal information	Parameters
Sociodemographic and epidemiological data	Age, religion, occupation, education, financial status, residential area (red zone, orange, green)
Medical history	Anaemia, diabetes mellitus, chronic hypertension, blood disorders, chronic obstructive disease, asthma, tuberculosis, cardiac disorders, psychiatric disorders, thyroid disorders, kidney disorder, rheumatoid arthritis, malignancy, immunocompromised state, surgical history, H/o contact in community, exposure while caring for COVID-19 patient and foreign travel, COVID-19 vaccination details.
Obstetric history	Gestational age, and conception history, gravida, parity, mode of delivery, living children, abortions, stillbirth, ectopic pregnancy, molar pregnancy, preterm birth
Clinical presentation of COVID-19	Asymptomatic or symptomatic, details of symptoms, duration of symptoms, intervals–symptoms onset to admission, exposure/contact to diagnosis, atypical symptoms, complications of COVID-19 (Acute respiratory distress syndrome (ARDS), consolidation, heart failure, septic shock, acute renal injury, etc)
General physical examination	BMI, stability of vitals, oxygen saturation at time of admission, lowest oxygen saturation during hospitalisation, date and method of COVID-19 testing, type of sample for COVID-19 testing, indications of COVID-19 testing, X-ray, CT scan, other laboratory investigations, coinfections like malaria, dengue, etc
Delivery details	Pregnancy outcomes: delivered (singleton/multifetal), undelivered, spontaneous abortion, stillbirth, ectopic pregnancy, MTP Delivery details: mode of delivery, duration of labour, induction, CS details, complications Pregnancy complications: pre-eclampsia, eclampsia, placenta previa, placenta abruption, uterine rupture, premature rupture of membranes, oligohydramnios, polyhydramnios, antepartum postpartum haemorrhage, gestational hypertension, gestational diabetes/ pregestational diabetes mellitus, preterm labour, chorioamnionitis, fetal growth restriction, congenital malformation, haematoma, surgical site infection
Treatment	Antibiotics, antivirals, hydroxychloroquine, steroids, heparin, high-flow nasal cannula oxygen therapy, NIV, any other treatment and outcomes, hospital and intensive care unit (ICU) stay, blood transfusion, convalescent plasma therapy, monoclonal antibodies.
Newborn Information	<b>Parameters</b>
Basic demographic and clinical investigations	Date of birth, 5 min APGAR score, gender, congenital anomalies, birth weight, feeding details, neonatal intensive care unit (NICU) admission, neonatal complications, indications and duration of NICU admission, vaccination details, testing for COVID-19, cord blood testing for COVID-19 (if available), laboratory investigations, treatment and outcomes.

APGAR, Appearance, Pulse, Grimace, Activity and Respiration; BMI, body mass index; CS, Caesarean section; MTP, medical termination of pregnancy; NIV, non-invasive ventilation.

### Tools for real-time data capture

To capture the real-time data, an online electronic patient record (EPR) software was developed by an outsourced team of experts. The developed software was first tested using dummy data by a team of obstetricians and paediatricians from the participating study sites. The time for data entry was recorded for obstetrics and paediatrics sections. Based on the inputs received from the user team, the software was modified and pilot testing was carried out before the actual start of the data entered into the software.

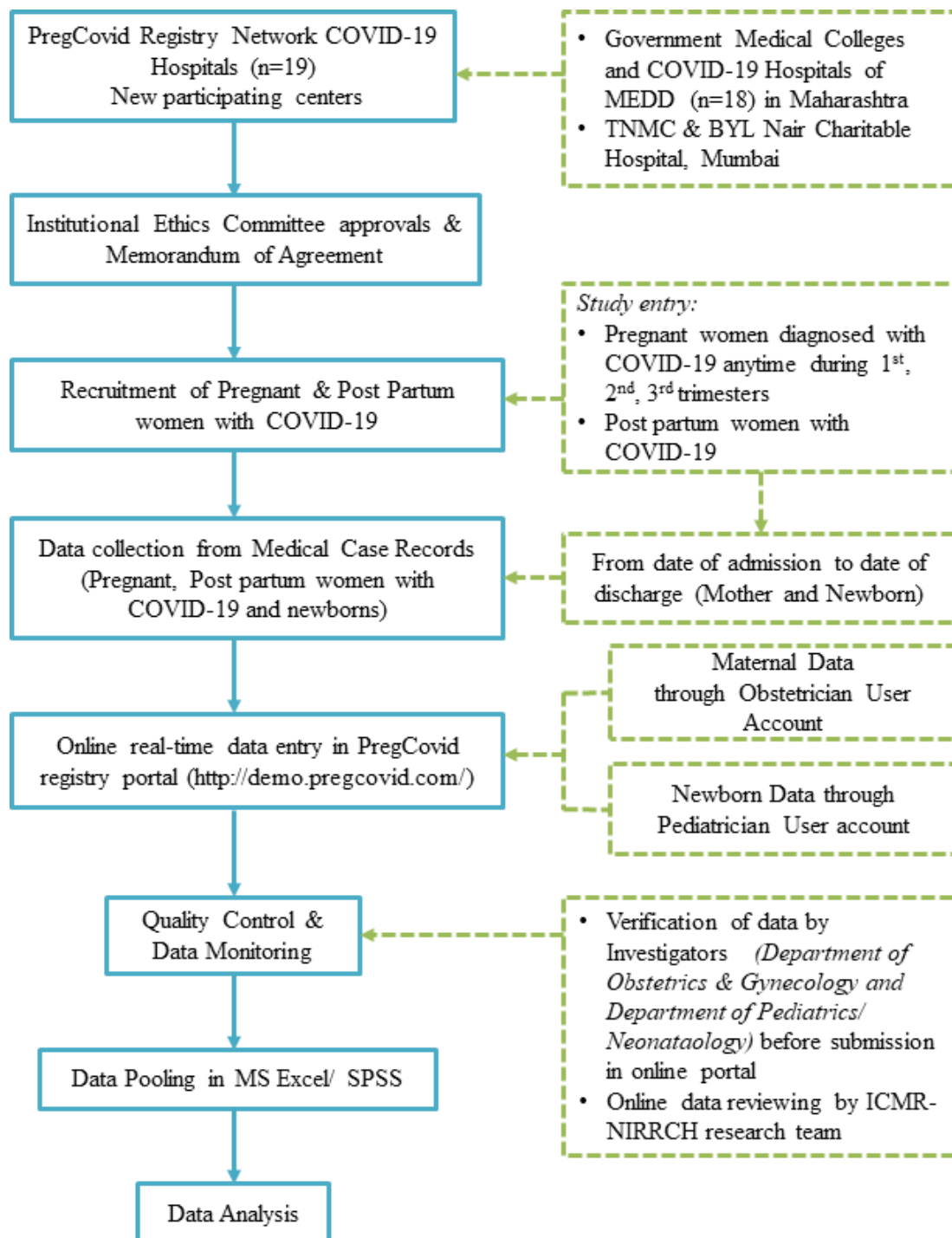
### APPROVAL FORM INSTITUTIONAL REVIEW BOARDS

The protocol was submitted for the Institutional Ethics Committee of ICMR-NIRRH (IEC no. D/ICEC/

Sci-53/55/2020, dated 4 June 2020), common IEC MEDD (BJGMC/IEC/Pharmac/ND-Dept.0422072-072, dated 12 May 2020) and BYL Nair Hospital, Mumbai, India (No. ECARP/2020/63, dated 27 May 2020).<sup>16</sup> The approved protocol was submitted to the ethics committee of the participating centres and approvals of ECs of participating centres were obtained. The IECs granted a waiver of consent as the data are collected from the medical case records.

### Characteristics of the PregCovid registry network and requirements of additional participating centres

The overall flow of the study protocol is outlined in [figure 1](#). The registry is presently initiated with 19 participating centres; it is open for all public and private



**Figure 1** Flow chart showing details on data collection, quality control, data analysis to be used for PregCovid registry. MEDD, Medical Education and Drugs Department. Topiwala National Medical College (TNMC) and Bai Yamunabai Laxman (BYL) Charitable Hospital, Mumbai

COVID-19 hospitals all over India. A dedicated PregCovid portal for data entry (<http://app.pregcovid.com/login>) is developed along with a website for giving information about the registry for prospective collaborators, publications and any breakthrough information related to the registry (<https://pregcovid.com/>).

Maharashtra state is the second most populous state in India with 112million of which male and female are 58million and 54million, respectively.<sup>17</sup> The first

case of COVID-19 in Maharashtra State was detected in Pune on ninth March 2020 and since then Maharashtra is harbouring around 30% of the total cases of COVID-19 burden in India.<sup>18</sup> To respond to this public health emergency, phase I of implementation of the registry will be carried out through the 19 participating centres within Maharashtra and further expansion will be carried out to other states all over India. The registry is open to other collaborating centres all over India who

wish to become a part of this network. The approaching centres must contact the Coordinator or the Principal Investigator of the registry at ICMR-NIRRH. They will need to obtain approval from their Institutional Ethics Committee and sign a Memorandum of Agreement with ICMR-NIRRH, Mumbai. For further details, the centres can visit the PregCovid website (<https://pregcovid.com/for-covid19-hospitals/>).

### Timelines

The registry will collect anonymised real-time data of pregnant women diagnosed with COVID-19 and admitted until May 2022. The date is extendable depending on the duration of the pandemic. Interim analysis may be conducted at the discretion of the investigators in consultation with other stakeholders. The final analysis will be done after collecting all the data.

### Study instruments

The registry is implemented through an app-based EPR, which is shared with participating centres and the site principal investigator (PI) will be responsible for data entry. Software is developed for online real-time data entry. The data will be entered online in the EPR from the original medical records of pregnant and post-partum women with confirmed COVID-19 admitted in the network hospitals of the PregCovid registry.

### Case record form

The case record form is designed to include socio-demographic, epidemiological, clinical presentations, laboratory investigations, past medical and surgical history, current pregnancy details, pregnancy complications, treatment details, and outcomes. New-born data collection tool includes date and time of delivery, mode of delivery, birth weight, sex of infant, whether live birth/stillbirth, diagnosis with SARS-CoV-2 infection (if any), morbidity and mortality data (table 1).

### Training for data entry, monitoring and quality control

The site PIs and their team will be provided online training for data entry, quality control measures to ensure the accuracy of the data entered from the study sites. A training manual and a video of detailed instructions on the use of the software will be provided to all participating study sites. The site PI will ensure that the data are entered in a near real-time manner. The site PIs will monitor individual data entry and ensure its accuracy. The team at NIRRH will periodically review the data entered for gaps and discrepancies and provide regular feedback to the team at PregCovid registry network hospitals.

The study participants will be given a unique ID. The name and ID of the study participants will be kept confidential with the site investigators. The names of the COVID-19 patients will not be entered into any of the documents. None of the details of study participants revealing their identity will be used in any reports and publications arising from this study. The information as per the case record form will be captured electronically

in a central database created, maintained, and regularly updated at ICMR-NIRRH. Data entry and data access will be independently controlled and held behind secure firewalls. Data collected from different study sites will be kept separately and only specific individuals within a research team will be able to access and edit the data. The quality of the electronic data will be regularly monitored by the PI and research team at ICMR-NIRRH.

### STATISTICAL ANALYSIS

The data analysis will be carried out for symptoms, the severity of COVID-19, pregnancy complications, maternal morbidity and mortality, neonatal complications, etc. Data analysis will be carried out for different waves of the COVID-19 pandemic for rapid response and developing strategies well in advance to manage pregnant women infected with SARS-CoV-2. The mother-to-child transmission data will be analysed from the RT-PCR and/ antibody data of neonatal and maternal samples tested wherever the information is available. Statistical analysis will be carried out using MS Excel and SPSS V.26 (SPSS).

### SAMPLE SIZE

The sample size is not calculated as PregCovid is an observational study to capture the data of all the pregnant and post-partum women diagnosed with COVID-19; admitted at the network hospitals of the PregCovid registry. The data collection will start from March 2020 and will continue till May 2022. The date is extendable depending on the duration of the COVID-19 pandemic.

### Patient and public involvement

We have not involved patients or the public in the conceptualisation of the PregCovid registry, and the study design, due to the quick response required at the beginning of the COVID-19 pandemic. The patients and general population will be informed of the results through the study website (<https://pregcovid.com>), and social media platforms.

### DISCUSSION

To the best of our knowledge, this is the first registry on pregnant women with COVID-19 in India for capturing data on clinical presentation, maternal and neonatal outcomes, response to treatment and mother to child transmission of SARS-CoV-2 infection. While the initial focus is on Maharashtra, as the pandemic unfolds, we anticipate collaborations from different states representative of the Indian population. In its present form, it is geared to generate data of the worst affected state in India in a very systematic manner. Its interim analysis would help other states plan their strategies well in advance to manage pregnant women infected with SARS-CoV-2.

The study will also generate information on the ethnic and socio-demographic determinants of the clinical



presentation, and outcomes of pregnant women with COVID-19. Together, this data will aid in planning the strategies to handle the epidemic of COVID-19 and pregnancy. This data is extremely important to develop rational management strategies for protecting pregnant women against possible adverse effects of COVID-19. This information will be also of importance not just for COVID-19 but also provide a broad framework to deal with the entire group of coronaviruses that lead to common respiratory infections in general.

The preliminary findings of the registry data are useful for improved management of pregnancy with COVID-19. ICMR recommends universal testing of pregnant women in India. Accordingly, women residing in clusters/containment areas or in large migration gatherings/evacuees centres from hotspot districts in India and presenting in labour or likely to deliver in the next 5 days were recommended to be screened for SARS-CoV-2.<sup>19</sup> We observed a 12% prevalence of SARS-CoV-2 in pregnant women with the presence of one symptomatic to every nine asymptomatic pregnant women.<sup>13</sup> These findings of the universal testing strategy of pregnant women are useful for planning strategies to prevent the spread of the virus to newborns, healthcare workers, and others in the community. The study also highlights that pregnant women should be paid special attention to their health. The significance of detecting asymptomatic pregnant women is useful for ensuring safe obstetric and neonatal services and assessing the burden of COVID-19 in the region to plan strategies on strengthening or relaxing mass physical distancing measures.

Detection of dengue and malaria coinfection with COVID-19 in pregnant women is useful for formulating the strategies for pregnant women living in malaria and dengue-endemic zones.<sup>20</sup> Considering the COVID-19 reaching the tribal and rural parts of India, both public and private healthcare systems should be strengthened for diagnosis and appropriate management of co-infections. Documentation of post-partum psychosis in mothers with COVID-19<sup>21</sup> is useful for creating awareness and providing appropriate mental healthcare for pregnant and postpartum women with COVID-19.

Globally, there are several National, Regional and International registries being established for pregnant women with COVID-19.<sup>22</sup> The objectives and the protocol of the PregCovid registry are at par with these international registries and will open up an opportunity at the international level for data comparison and assimilation. Eventually, collaborations with an international consortium with global experts having experience in managing COVID-19 pregnant women would be useful for developing a global strategy on COVID-19 in pregnancy.

## ETHICS AND DISSEMINATION

The study was approved by the Institutional Ethics Committee of ICMR-NIRRH (IEC no. D/ICEC/Sci-53/55/2020, dated 4 June 2020), common IEC MEDD

(BJGMC/IEC/Pharmac/ND-Dept.0422072-072, dated 12 May 2020) and BYL Nair Hospital, Mumbai, India (No. ECARP/2020/63, dated 27 May 2020). IECs granted a waiver of consent.

The evidence generated from the registry will be regularly shared with the appropriate authorities for policy decisions. Several publications will be submitted to international peer-reviewed journals on findings that emerged from the data of the PregCovid study. Press releases and articles for the lay audience will also be prepared for important findings.

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**Patient consent for publication** Not applicable.

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