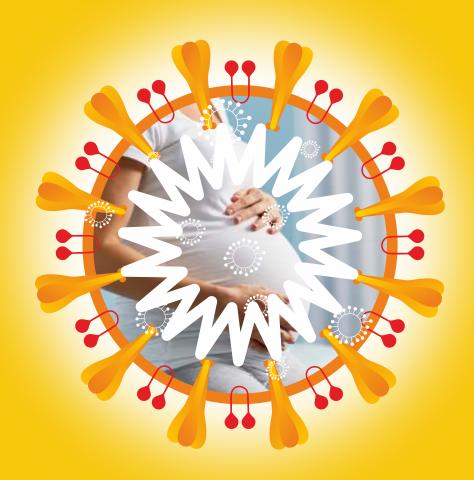




FOGSI GCPR

Good Clinical Practice Recommendation on



PREGNANCY with COVID-19 Infection

Editors

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Disclaimer: The recommendations in this document are based on limited evidence as on the date of publication. As new evidence accumulates, some of the recommendations may change. This would be guided by growing global and Indian experience, published literature, guidelines from international and national professional bodies, and government guidelines. Users should use these guidelines in accordance with the latest government regulations and advisories.

FOREWORD

We are well into the coronavirus COVID-19 pandemic. This is a crisis of global proportions and is transforming our world view. There are still uncertain aspects of this novel infection even as research and medical trials are progressing furiously. Knowledge is evolving in every aspect of the infection and its spread.

It was declared as a pandemic by the World Health Organization on 11 March 2020. Most countries across the globe have recognized this as a national emergency and have started taking measures against the infection. The pandemic is at different states of spread in different countries. At the point of writing this, it has reached 190 countries with more than 28 lakhs cases and over 2 lakh deaths.

India declared the first diagnosed case on 30 January 2020. The first few cases were related to travel from the Middle East and Italy. As on 24th April 2020 there were 24434 confirmed cases in the country and 780 deaths have occurred. Nearly 5500 people have recovered from the infection. At present, in India, it appears that the infection spread is limited to clusters.

Community spread looms large and there is a possibility that large outbreaks may happen in the next few weeks in India. The Government is trying its best to prevent the spread by lockdowns, self isolation, awareness, testing on a mass scale and prophylaxis. Healthcare workers and facilities are gearing up to meet the challenge. Given the propensity of this virus to affect large numbers, it will be inevitable that we will be caring for significant numbers of women infected with COVID-19 in pregnancy and for childbirth. Pregnant women with COVID-19 infection have been cared for and delivered in our country. Fortunately, the numbers are small at present and the best estimates indicate this to be under fifty. However, maternity healthcare providers and facilities need to prepare for the situation with a view to prevent the consequences of the infection on the mother and her newborn. The other aspects that are vital are to prevent the spread of the infection from the infected woman to other pregnant women and the public at large. Healthcare providers need to keep themselves safe while they do take care of pregnant women.

Healthcare systems everywhere in the world are under pressure. The pressure is not only of numbers and heavy workload but also dealing with an unknown pathogen. There are limitations of infrastructure, supply chains and availability of equipment and medications which have occurred, gotten corrected but will inevitably occur in the future too. In times of a lockdown, even transport of healthcare providers to and from the hospital is a challenge. The guidance in the next few pages is our attempt to present the ideal options and some real world experiences and alternatives. Team FOGSI hopes that it will be a useful resource to every FOGSIan and healthcare worker.

Dr Alpesh Gandhi

President FOGSI



EXECUTIVE SUMMARY



Measures for Pregnant Women to Prevent COVID-19 infection

Social Distancing – could be the single most important intervention at population level Do the Five – Staying at home, Hand hygiene, Respiratory hygiene, Avoiding touching the face and Keeping distance should be practiced. Wearing a mask is recommended.



Precautions for healthcare workers (HCW)

HCW are at high risk of getting infected. Precautions are necessary to protect themselves and prevent spread to others.

Distancing – where possible, HCW should keep a distance and practice hand hygiene Personal Protective Equipment (PPE) – use should be according to clinical situation. Covering of all surfaces especially hands and face is vital. Proper technique to wear and remove PPE is essential.

Chemoprophylaxis – is recommended with Hydroxychloroquine only for HCW with known contact of COVID-19 positive patients. In case of accidental exposure, complete protocol should be followed.



Clinical Presentation and maternal effects of COVID-19 in Pregnancy

A history of travel abroad, contact and respiratory symptoms should be elicited at every clinical interaction. Most pregnant women will present with mild symptoms and have a similar course to other adults with COVID-19 infection. Maternal diseases may get agravated if associated with co-morbitites. COVID-19 infection could exaggerate the hypercoagulable state. Mental health issues and domestic violence should be considered in assessing the woman.



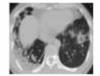
Effects of COVID-19 infection on the fetus

There is emerging evidence from immunological assessment that in-utero transplacental infection to the fetus may occur. The virus has not been isolated in amniotic fluid or vaginal secretions. The neonatal effects seem to be minimal.



Testing for COVID-19 in Pregnancy

The criteria for testing non-pregnant persons are applicable to pregnant women. In addition, there are some special criteria for testing with regards to pregnancy. It is essentially meant for acute respiratory illness with exposure, travel, contact or a HCW or requiring hospitalization. Asymptomatic individuals should be tested between 5 to 14 days of exposure to a known contact. Symptomatic individuals with influenza like illness from hotspots should be tested by RT-PCR (within 7 days) or serology (after 7 days). Pregnant women residing in cluster/containment areas or in large migration gatherings/evacuees centre from hotspot districts presenting in labour or likely to deliver in next 5 days should be tested even if asymptomatic. There is no recommendation for testing every pregnant woman.



Test methods and facilities – presently the RT-PCR test from nasopharyngeal swab is used for diagnosis.

Other investigations – supportive investigations include blood studies for infection and systemic assessment and imaging by X-ray or CT scan chest with abdominal shielding



Notification of COVID-19 cases is mandatory

Quarantine for pregnant women – should be followed as per general population depending on contact tracing or diagnosis.



Arrangements in existing healthcare facilities

COVID and non-COVID facilities need to be defined. There has to be comprehensive maternity services available at COVID hospitals. COVID positive mothers should be delivered in a separate and dedicated Labour Room and Operation Theatre. In case of an emergency where these facilities are not available, the LR and OT should be properly fumigated. Non-COVID hospitals need to make changes such as triage, checklist and referral pathways to minimize accidental infection transmission risk.



COVID Checklist Tool

A checklist should be used to identify suspect patients. They should be referred for testing. This may not be a foolproof method but in the absence of rapid testing, it is a useful approach.



Termination of pregnancy (MTP), sexual and reproductive healthcare

services are time sensitive and their provision is essential during the pandemic for all women.



Antenatal Care

Visits should be optimized and timed. PPE, distancing and hygiene precautions are necessary. Clinic organization is important to reduce transmission risk. Clinic fomites should be disinfected. At the end of the day, the room should be disinfected or fumigated. Telemedicine should be used as appropriate.



Obstetric Ultrasound

Due to prolonged examination time, small room size and proximity, transmission risk is high with obstetric ultrasound. Minimum number of probes should be used. In a hospitalized woman, bedside ultrasound is preferable. Ultrasound machine and fomites should be disinfected. The probe should be washed, dried and disinfected. At the end of the day, the room should be disinfected or fumigated



Assessment of Pregnant women (not in labour)

Recognizing the critically ill woman – Most women will not need hospitalization or critical care. Tachypnoea (>30/min), hypoxia (Sp02 < or = 93%) and imaging showing > 50% lung involvement indicate a need for critical care.



Medical management and drugs used in the treatment of COVID-19 infection in pregnancy

Hydroxychloroquine 600 mg (200 mg thrice a day with meals) and Azithromycin (500 mg once a day) for 10 days has been used successfully. Antiviral therapy (Lopinavir + Ritonavir or Oseltamavir) may be used in high risk groups (immunocompromised, chronic disease, uncontrolled diabetes). Other supportive care should include rest, supplemental oxygen and paracetamol. Plasma therapy is being assessed in trials.





Management of Labour and Delivery in women with COVID-19 infection

There is no rationale to induce labour or deliver a woman early because of COVID-19 infection. Decisions regarding route of delivery should be as per standard obstetric practice or as per the maternal condition.



Labour Analgesia and Anesthesia in Pregnant Women with COVID-19 infectionRegional analgesia and anesthesia can be used in women with COVID-19 infection.
Specialized techniques can be adopted for general anesthesia.



Newborn care should be practiced as per routine. At present, testing is recommended if the mother has COVID-19 infection or if the baby is symptomatic. Breastfeeding is encouraged with good hygiene practices.



Cleaning, maintenance of facilities and medical equipment

should be done with adequate PPE to the HCW. 1% sodium hypochlorite solution with contact time of 30 minutes can be used.



Postnatal Care and Advice to the mother infected with COVID-19 should follow routine practice. If the woman is isolated from the neonate, she should be offered psychological assessment and support.



Diet for the pregnant woman and COVID-19 infection

should be as per routine. There are no special diets. Rumors related to diet should be dispelled. A nutritious diet helps to build immunity.



Training and managing the healthcare cadre is essential to prevent them from getting infected. Training should include donning and doffing. Duty allocation and duration of shifts should be regulated. It is important to keep up morale.



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Introduction

This is an unprecedented global war, and all of mankind is facing the same enemy, the novel coronavirus. And the first battlefield is the hospital where our soldiers are the medical workers.

Novel coronavirus (SARS-COV-2) is a new strain of coronavirus causing COVID-19, first identified in Wuhan City, China. Its characteristics especially those of person to person transmission were documented in December 2019.(1) Shortly after, it was declared as a pandemic.(2) The global figures have been steadily climbing ever since then.(3) The number of cases in India is also growing. (4)

There are a number of other coronavirus infections that have been identified and are pathogenic to humans including the common cold, and the viruses that cause MERS (Middle Eastern Respiratory Syndrome) and SARS (Severe Acute Respiratory Syndrome). The COVID-19 strain of coronavirus infection has a high rate of transmission by droplet and through fomites(1). A study showed that stool samples continued to show presence of viral particles for a mean of 29 days after the first symptoms. This is longer than that of samples from the respiratory tract. (5) We need more such studies to assess feco-oral transmission, but this reiterates the need for hygiene and safe sanitation in general.

On reviewing the scientific literature, 1794 articles on the Coronavirus infection, 36 addressed the issue in pregnant women. A total of eight studies (10 case series/reports and 1 retrospective cohort study) reported outcome in 73 women with pregnancy and COVID-19 infection. Much of the inferences that we are drawing comes from this cohort of pregnant women(6). In India, a handful of pregnant women have been cared for and delivered with COVID-19 infection. Our experience is evolving.

This Good Clinical Practice Recommendation (GCPR) is based on international experience and from the statements and guidance from the Government of India and WHO. As knowledge evolves, some aspects of this recommendation will change. Newer versions will be released as new evidence emerges.

Measures for Pregnant Women to Prevent COVID-19 infection

The greatest tool to prevent COVID-19 Infection in the general population and for pregnant women is Social Distancing. As per the Government of India advisory, this is a non-pharmaceutical infection prevention and control intervention implemented to avoid contact between those who are infected with a disease and those who are not, so as to stop or slow down the rate and extent of disease transmission in a community(7). Some important aspects for the pregnant woman in India from this advisory are:

- Disinfection of surfaces to reduce fomites related spread.
- For women working outside the house, it is preferable to take work from home.
- Keeping a distance of at least one metre in various necessary interactions and activities
- Avoid non-essential travel. If travel is undertaken, it is preferable to use a private vehicle. If public transport is used, distance should be maintained.
- Avoid gatherings and functions such as to celebrate the 7-month milestone and others, which is a common cultural
 practice.
- Minimize visitors from coming to meet the mother and newborn after delivery.

Pregnant women are a special category in terms of healthcare. They should therefore, follow these guidelines fastidiously. They can protect themselves by the motto "Do the Five". The principle elements of this are:



Home	 Stay at home as much as possible unless there is a medical need related to development of symptoms of infection or related to pregnancy. Routine antental visits are to be deferred. If there is a minor query, it can be sorted out telephonically. Keep the traffic of home visitors including homecare personnel, maids, and staff members to a minimum or avoid completely if possible.
Hands	Washing hands frequently and properly with a soap and water or an alcohol-based hand rub for minimum 20 seconds
Elbow	Covering mouth and nose with their bent elbow, handkerchief or tissue while coughing or sneezing. Then the used tissue should be disposed immediately. This is an important component of respiratory hygiene.
Face	Avoid touching face, eyes, nose and mouth with hands.
Space	Keep a distance of at least 1 meter from the next person outside and in the house.

Masks

The WHO has substantially changed its recommendations on the use of masks. In the early part of the pandemic, masks were thought to be necessary only for symptomatic individuals. However, more recent guidance suggests that every individual should wear a mask to curtail the risk of infection.(9) The ideal mask is the FFP3 mask. However, there is very limited availability of these. Therefore, a practical solution could be that FFP3 masks or N95 (FFP2) masks should be worn only by healthcare providers, patients and those caring for infected people directly. The public at large can use simple masks. In some cities in India, the civic authorities have issued notice that mask use is mandatory in public places. (10)

Precautions for healthcare workers

Why are precautions necessary for healthcare workers?

Healthcare workers are at high risk of acquiring the COVID-19 infection when they are caring for patients. This is because of the contact with large numbers of patients, close contact and procedures where there is spray/aerosolization (resuscitation, ventilation) or splash of body fluids (labour, delivery, surgical procedures). The reason to take universal precautions and use appropriate precautions is therefore, obvious. There is a risk of spread of infection from an infected patient to the healthcare provider and then onward spread to more patients and the population at large. As of early March, it was estimated that 3300 healthcare workers have been infected and at least 22 had died.(11) This number has risen fast to about 9000 infected healthcare workers in the United States itself by the middle of April. Of these, 27 have died.(12) It has been estimated that about 20% of healthcare workers who cared for COVID-19 infected patients in Italy acquired the infection(11). In Mumbai, it is estimated that over 200 healthcare workers have been infected with the novel coronavirus.(13) It is also important to note that this is not always the case. With thorough and adequate use of PPE and other protective measures, the experience in Singapore and Hong Kong has been that there was no transmission to healthcare workers(14).

The three principles that healthcare workers should follow are distancing, use of appropriate PPE correctly and chemoprophylaxis.



As for the general population, the healthcare worker should also consider Social distancing as the cornerstone of prevention whenever possible. The following measures may be useful in addition to appropriate gear.

- Maintain a distance of at least 1 meter from patients and other healthcare workers. This is possible in clinic settings. However, this may not be feasible during examination, inpatient care and procedures.
- Remove non-essential items from the consulting or examination room to facilitate cleaning and disinfection and reduce the risk of fomites related spread.
- Regular hand cleaning with soap and water or alcohol based rubs for at least 20 seconds.

Personal Protective Equipment (PPE)

The term "universal precautions" (from the 1980s), refers to the measures taken to prevent the transmission of blood borne infections to health workers. This was later called "standard precautions" to cover the risk of transmission through all body fluids.(15) In settings where the pregnant woman is confirmed to have COVID-19 infection and presents in labour or is undergoing a surgical procedure, there is a need to follow these and some enhanced measures using personal protective equipment (PPE) to prevent acquiring infection through respiratory droplets. The PPE should therefore include masks such as the N95 respirator (ideally fitted to size) and face protection by a face shield or at least goggles, gloves and other measures (16)

In the event that appropriate gear for PPE is not available at a particular unit, consider transferring the patient to a centre which is better equipped. If it is an emergency situation and there is limited PPE, it should be allocated to the workers who are caring for pregnant women who are confirmed cases or those who present with symptoms suggestive of acute respiratory illness or those who are close contacts of confirmed cases.

The following recommendations are available from the Handbook of COVID-19 Prevention and Treatment from the Zhejiang University School of Medicine (17)

Personal Protective Equipment in relation to COVID-19 infection management

Protection Level	Protective Equipment	Scope of Application
Level I protection	Disposable surgical cap Disposable surgical mask Work uniform Disposable latex gloves and/or disposable isolation clothing	 Pre examination triage, General Outpatient Department
Level II protection	Disposable surgical cap Medical protective mask (N95) Work uniform Disposable medical protective uniforn Disposable latex gloves Goggles	 Fever outpatient department Non-respiratory specimen examination of suspected/ confirmed patients Imaging examination of suspected/confirmed patients



		 Cleaning of surgical instruments used with suspected/confirmed patients
Level III protection	Disposable surgical cap Medical protective mask (N95) Work uniform Disposable medical protective uniform Disposable latex gloves Full face respiratory protective devices or powered air-purifying respirator	 Intubation, resuscitation of suspected/confirmed patients where there is a risk of spray or splash of respiratory secretions of body fluids or blood Surgery, procedures, delivery of suspected / confirmed patients Autopsy of suspected/confirmed patients

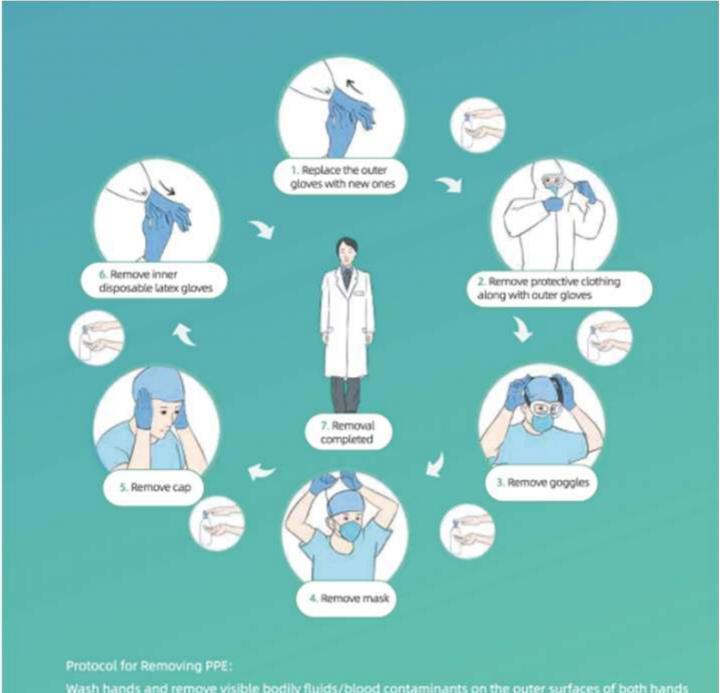
The procedure of wearing (donning) and removing (doffing) of the PPE should be strictly followed as has been illustrated in the following two figures.



Guidance on Donning & Removing Personal Protective Equipment (PPE) to manage COVID-19 Patients







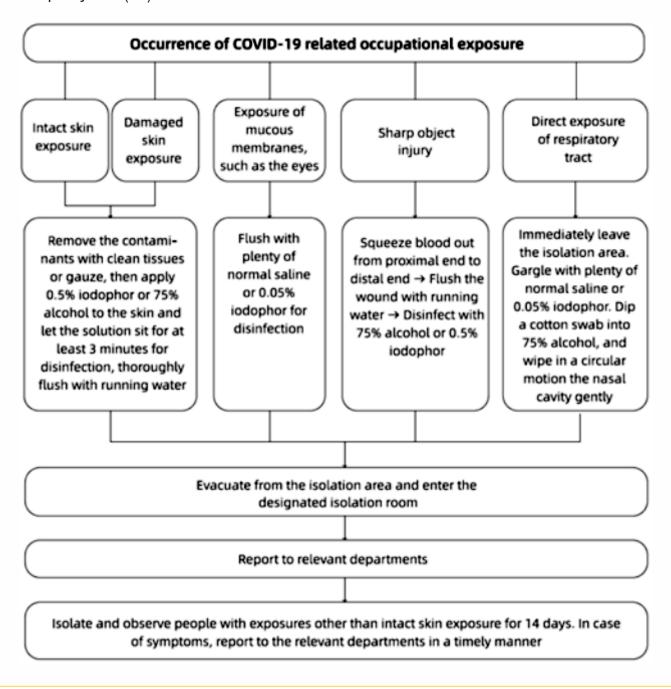
Wash hands and remove visible bodily fluids/blood contaminants on the outer surfaces of both hands \rightarrow Wash hands replace outer gloves with new gloves \rightarrow Remove powered air-purifying respirator or self-priming filter-type full-face mask/mask (if used) \rightarrow Wash hands \rightarrow Remove disposable gowns along with outer gloves (if used) \rightarrow Wash hands and put on outer gloves \rightarrow Enter Removal Area No. ① \rightarrow Wash hands and remove protective clothing along with outer gloves (for gloves and protective clothing, turn inside out, while rolling them down) (note: if used, remove the waterproof boot covers with clothing) \rightarrow Wash hands \rightarrow Enter Removal Area No. ② \rightarrow Wash hands and remove goggles \rightarrow Wash hands and remove mask \rightarrow Wash hands and remove cap \rightarrow Wash hands and remove inner disposable latex gloves \rightarrow Wash hands and leave Removal Area No. ② \rightarrow Wash hands, take a shower, put on clean clothes and enter the clean area



Chemoprophylaxis

In addition to the above two measures, the Indian Council of Medical Research (ICMR) also recommends the use of hydroxychloroquine as prophylaxis for asymptomatic healthcare workers caring for suspected or confirmed COVID-19 infected patients (18). The recommended regimen is to take the tablet of 400 mg hydroxychloroquine twice a day on day 1 and then once weekly for 7 weeks. The medicine should be taken with meals. It is contraindicated in case of known sensitivity to the drug or if a healthcare worker suffers from G6PD deficiency, heart disease or retinopathy. An ECG should preferably be done before starting hydroxychloroquine to rule out cardiac problem. The healthcare worker should not fall into a false sense of security when pharmacoprophylaxis is being used and the other preventive measures should be followed.

In case of accidental occupational exposure, the following protocol should be followed in addition to pharmacoprohylaxis (17).





Clinical Presentation and Effects of COVID-19 on the Mother

The mean incubation period (from exposure to the appearance of clinical features) is 5 to 7 days. Most people who are infected will show features latest by 11 days of exposure(19). Pregnant women are no more likely to get infected than the general population. It has long been held that pregnant women may have an altered immune response to viral infections. This could be associated with more marked symptoms and a worse course of disease especially towards the end of pregnancy. However, at present, the risk appears to be the same as the general population in various studies. At present, it appears that pregnant women do not have worse outcomes or consequences of infection with COVID-19 than the general population(20),(21)

The majority of people (pregnant and general population) may be asymptomatic or present with respiratory symptoms of COVID-19 infection. Most pregnant women will have mild to moderate flu-like symptoms of cough, sore throat, and fever. Few may have difficulty in breathing or shortness of breath. These have been classified as features of severe acute respiratory illness (SARI) by the WHO. As seen with the general population, if the pregnant woman has co-morbid conditions such as diabetes, hypertension, obesity, respiratory disease or is of advanced age, she is more likely to have a severe form of respiratory disease. Pregnant women with associated medical risk factors may present with pneumonia and marked hypoxia or may progress rapidly to this state. Immunocompromised and elderly pregnant women may present with atypical features such as fatigue, malaise, body ache and/or gastrointestinal symptoms like nausea and diarrhea (22).

At the time of every patient contact, irrespective of the reason for the clinical meeting with a pregnant woman, healthcare workers should enquire about features of SARI, travel abroad and/or contact with a known or possible COVID-19 infected person through household contact, visitors or attending events where such a person was present, or residing in a hotspot/cluster/containment zone or with evacuees from such areas.

Given that pregnancy is known to be a hypercoagulable state, and emerging evidence suggests that individuals admitted to hospital with COVID-19 are also hypercoagulable, it follows that infection with COVID-19 is likely to be associated with an increased risk of maternal venous thromboembolism (VTE). Reduced mobility resulting from self-isolation at home, or hospital admission, is likely to increase the risk further. The diagnosis of PE should be considered in women with chest pain, worsening hypoxia (particularly if there is a sudden increase in oxygen requirements) or in women whose breathlessness persists or worsens after expected recovery from COVID-19. (23)

Isolation, bereavement, financial difficulties, insecurity and inability to access support systems are all widely recognised risk factors for mental ill-health. (20) The coronavirus epidemic also increases the risk of domestic violence. The National Commission for Women in India has reported an increase in the number of calls seeking help in the first two weeks of the lockdown. (24)



Effects of COVID-19 infection on the fetus

Preliminary research had suggested that the infection is not transmitted from the mother to child by placental transfer. However, there is emerging evidence that now suggests that vertical transmission is probable.(25) Two reports have published evidence of IgM for SARS-COV-2 in neonatal serum at birth. Since IgM does not cross the placenta, this is likely to represent a neonatal immune response to in utero infection. (26) (27) The proportion of pregnancies affected and the significance to the neonate has not been determined. At present, there seems to be no clinically significant effect on the neonate even when infected. (28)

In other reports including a total of 18 pregnant women with suspected or confirmed COVID-19 pneumonia, all of the newborns, who were delivered via cesarean section, tested negative for the corona virus, and there were no traces of the virus in the mother's amniotic fluid, cord blood or breast milk. (29) (30)

With the limited number of deliveries to COVID-19 infected women, at present, there is no evidence of any fetal effects of the infection in terms of fetal abnormalities or other fetal parameters of growth, amniotic fluid or doppler indices. There is no rationale for recommending amniocentesis to detect fetal infection at this time. An ultrasound 14 days after the infection can be considered for the pregnant woman who has recovered from infection. At present, there is no evidence of higher risk of abortion with COVID-19 infection. At present, there is no evidence of higher risk of preterm labour with COVID-19 infection. However, as with systemic disease which can compromise maternal health, there is a possibility that preterm labour may occur in these situations.

Testing for COVID-19 in Pregnancy

Indications (Criteria)

The currently recommended indications for testing for the general population (*which also apply to pregnant women*) as per the ICMR given on 09 April 2020 are as follows (31):

- 1. All symptomatic individuals who have undertaken international travel in the last 14 days
- 2. All symptomatic contacts of laboratory confirmed cases
- 3. All symptomatic health care workers

Note — The term "symptomatic" is interpreted as symptoms of acute respiratory illness (fever with a respiratory symptom such as cough, congestion, sore throat or shortness of breath).

- 4. All patients with Severe Acute Respiratory Illness (fever AND cough and/or shortness of breath). *These are patients who have a severe illness which requires hospitalization.*
- 5. Asymptomatic direct and high-risk contacts of a confirmed case should be tested once between day 5 and day 14 of coming in his/her contact

As per the guidance from the Government of India, direct and high risk contact is defined as those living in the same household, traveling together by any conveyance, working together in close proximity (same room), or healthcare workers providing direct care. (32)



In hotspots/cluster (as per MoHFW) and in large migration gatherings/ evacuees centres:

- 6. All symptomatic ILI (fever, cough, sore throat, runny nose). (ILI is an abbreviation for Influenza Like Illness.)
 - a. Within 7 days of illness RT-PCR
 - b. After 7 days of illness Antibody test (If negative, confirmed by RT-PCR)

Recently, pregnant women have been classified as a special category for testing and the current specific recommendations which have been added for them are:

7. Pregnant women residing in cluster/containment areas or in large migration gatherings/evacuees centre from hotspot districts presenting in labour or likely to deliver in next 5 days should be tested **even if asymptomatic.** (33) The guidance further states that the testing should be carried out in the center where the woman is admitted for delivery and she should not be referred out for testing.

Note — Healthcare providers should be updated about the local conditions and the hotspots/clusters in their area. These change as per contact tracing and are updated regularly at https://www.mohfw.gov.in/

This testing strategy may evolve and recommendations may change.

We believe that a pregnant woman who is in labour with any (not all) of the symptoms of SARI will be benefited if tested for COVID-19 infection. At present, this is not recommended by ICMR, but may be included in future in the testing criteria, once the rapid tests are available, which maybe useful to the mother, neonate and healthcare workers.

Test methods and facilities

The current diagnostic approach to confirming the diagnosis of COVID-19 infection in India is to detect the presence of viral nucleic acid. This is carried out by lysing the virus in the specimen and amplifying the quantity of nucleic acid available (Nucleic Acid Amplification Testing or NAAT). The NAAT technique that is used is a real time reverse-transcription polymerase chain reaction (RT-PCR) which amplifies the viral nucleic acid. Certain specific genes are then detected in the specimen using fluorescence to confirm the diagnosis.

The CDC recommends collection of a nasopharyngeal swab specimen to test for COVID-19 (34). An oropharyngeal swab can be collected but is not essential; if collected, it should be placed in the same container as the nasopharyngeal specimen. Sputum should only be collected from patients with productive cough; induction of sputum is not indicated.

The test should be performed from a center which is authorized by the government of India and state governments. The government has allowed testing to be conducted at private laboratories from 22 March 2020. The detailed guidelines on testing are available on the ICMR website (35) (36).



It highlights the preference for home collection of samples, maintaining safety during transport and disposal, guidance on disclosing results and fees. The cost of the test has been capped in private labs at Rs 4500/-. Reports should generally be available in 24 hours. Repeat test is indicated only if clinically warranted. There are 362 centers for testing in India. The details are updated regularly and available on the ICMR website. (37)

At present, the RT-PCR test is recommended by the ICMR. However, false negative tests are known to occur to the rate of 10-30% even with two serial swabs tested by the RT-PCR technique. The results of RT-PCR are dependent heavily on viral load and nature of the specimen as illustrated in the table below. (38)

Coronavirus Testing Positivity Rates		
Bronchoalveolar lavage fluid	93%	
Sputum	72%	
Nasopharyheal swab	63%	
Fibrobronchoscope brush biopsy	46%	
Pharyngeal swab	32%	
Feces	29%	
Blood	1%	
Urine	0%	

More rapid molecular diagnostic tests (TrueNat beta CoV test) FDA and ICMR which can give results in 2-3 hours may be available soon. These could be adapted to becoming point-of-care tests in the future as the laboratory set-up is minimized with this technology.

ICMR has also issued an advisory on pooled sample testing using RT-PCR. In this approach, 2 to 5 samples of nasopharyngeal swabs are pooled. It is currently recommended for situations where the prevalence is likely to be lower than 2%. Pooled samples should not be used for known contacts and individuals in the high-risk category. It may be a useful approach for healthcare worker screening and for population based surveys. (39)

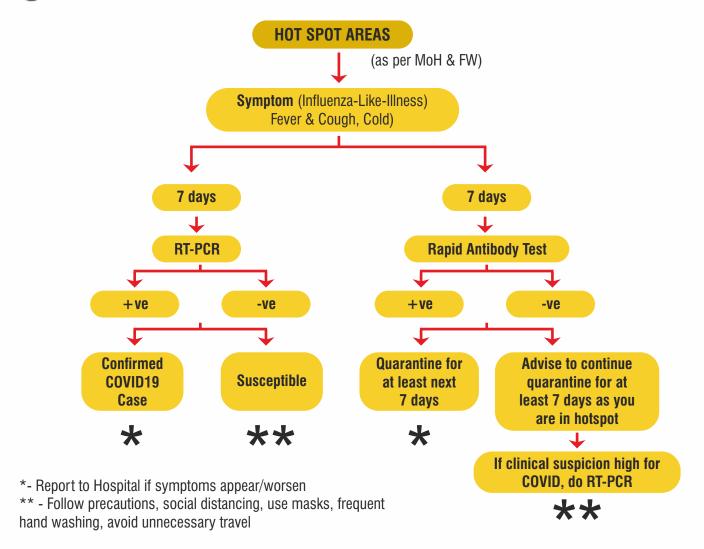
In the near future, serological testing is likely to be available in India. It is faster and cheaper as compared to RT-PCR. At a population level, serological testing may be more feasible to see the prevalence. Also, after 3 weeks of infection, the RT-PCR would be negative, but serology would give the diagnosis. (17) There are various types of test kits available for detecting the immune response to COVID-19 infection. The possible results, interpretation and action are summarized below. (40)



Finding	IgG negative, IgM negative	IgM positive, IgG negative	IgM positive, IgG positive	IgM negative, IgG positive
Interpretation	No exposure to infection or exposure to infection has occurred less than 5-7 days ago	Recent exposure to infection (7 to 14 days ago)	Exposure to infection was about 14 to 21 days ago	Exposure to infection was more than 21 days ago and immunity has developed
Clinical status and steps	No medical treatment needed as they are usually healthy or asymptomatic. If symptoms develop, test should be repeated.	Confirm the diagnosis by RT-PCR of nasopharyngeal swab. Medical care depends on clinical symptoms.	Confirm the diagnosis by RT-PCR of nasopharyngeal swab. Usually they are on the road to recovery and will not need medical care.	These are individuals who have recovered from a clinical or sub-clinical infection. They do not need medical care.
Risk of transmission to others	Not infectious, but can get infected themselves if exposed to a carrier or infected person. They should take all precautions to avoid getting infected.	This individual is infectious to others and needs to be isolated.	Risk of transmission of infection from these individuals is low especially if they are asymptomatic.	They are not likely to be carriers or transmit infection.

The recommended approach to the use of serological testing in India is for testing in hot spots. These areas are identified by the Ministry of Health and Family Welfare as Hotspots or Red Zones. The red zones are the ones which contribute to more than 80% of the case load in the country or state or which have a doubling time shorter than 4 days. On the other hand, districts are said to be in the green zone if there is no new confirmed case for 28 days. (41) The ICMR protocol is outlined below. (42) The recommended test for clinical confirmation is the RT-PCR. The serological tests are a supplementary tool to be used only for specific areas.





Other investigations

Other laboratory findings that have been seen with COVID-19 infection are leucopenia, lymphocytopenia, mild thrombocytopenia, mild elevation of liver enzymes and other acute infection markers. Some laboratory markers such as elevated levels of ferritin, C-Reactive Protein, Procalcitonin and a NLR (N:L ratio) i.e. absolute neutrophil count: absolute lymphocyte count > 3.5 predict poor outcomes for patients in critical care. They may be used to grade the severity of the infection. Co-infection with other common respiratory pathogens and the common cold virus are often seen with COVID-19. (17)

CT scan Chest and X-Ray Chest usually show patterns consistent with atypical pneumonia. The typical findings are bilateral multifocal consolidations or ground glass opacities which may progress to involve the entire lung and small pleural effusions. Imaging results vary and they may not always correlate with the clinical picture. X-Rays are more practicable than CT scans in our country and could be the primary imaging modality. The intravenous contrast medium in case CT scan is performed should be limited or used with caution where the systemic illness has a renal component. A study from China of over 1000 patients showed that Chest CT has a high sensitivity for diagnosis of COVID-19. Chest CT may be considered as a primary tool for the current COVID-19 detection in epidemic areas.(43) In cases where an X-Ray is taken or a CT scan is needed for a pregnant woman, there should be provision of an abdominal shield to protect the fetus from radiation exposure. An informed consent for the imaging should be taken from the pregnant woman and her relatives.



Notification of COVID-19 cases

Guidelines for notifying COVID-19 affected persons by Private Institutions have been given by the Government of India (44). It shall be mandatory for all hospitals (Government and Private), Medical officers in Government health institutions and registered Private Medical Practitioners including AYUSH Practitioners, to notify such person(s) with COVID-19 to concerned district surveillance unit.

All practitioners shall also get the self-declaration forms (enclosed) for those who, within their knowledge, are having travel history of COVID-19 affected areas. In case the person has any such history in the last 14 days and is symptomatic as per case definition of COVID-19, the person must be isolated in the hospital and will be tested for COVID-19 as per protocol. Information of all such cases should be given to the State helpline number (list enclosed) and also to national helpline 1075. Email may also be sent at ncov2019@gov.in.

Quarantine for pregnant women in COVID-19 pandemic

The term Quarantine is used to separate and restrict the movement of well persons who are known to be exposed (directly or indirectly) or suspected to be exposed to a communicable disease to see if they become ill. These people may have been exposed to a disease and remain asymptomatic. Quarantine may be at home or in a facility designated by the state which includes hotels, hostels, guesthouses or hospitals. This has been shown to be an effective measure against the spread of infection. On the other hand, Isolation refers to the separation and restriction of movements of ill persons who have a contagious disease in order to prevent its transmission to others. It typically occurs in a hospital setting or a special facility. At present, in India, all symptomatic patients who have a positive test for COVID19 are being isolated.

The criteria for quarantine are the same for pregnant women and the general population. These criteria, duration and measures may be changed with the passage of time as per advice of the Government of India (46). A contact in the context of COVID-19 is:

A person living in the same household as a COVID-19 case

- A person having had direct physical contact with a COVID-19 case or his/her infectious secretions
- without recommended personal protective equipment (PPE) or with a possible breach of PPE
 A person who was in a closed environment or had face to face contact with a COVID-19 case at a
- distance of within 1 meter including air travel.

In India, all suspected (awaiting test results) and confirmed cases of COVID-19 disease are currently being isolated and managed in a hospital setting with the intent to break the chain of transmission. The scope of home isolation has been extended to individuals with very mild to mild symptoms of infection as certified by the treating medical officer. Certain criteria should be fulfilled such as having facilities at one's own residence for isolation for the patient and facilities for quarantine for other family members. A caregiver has to be available. The caregiver and home contacts should take prophylactic hydroxychloroquine. The care giver should wear disposable gloves and three layer mask, preferably N 95 mask while taking care and the patient should wear N 95 mask. The patient should agree to monitoring by keeping active the Aarogya Setu app and to keep the local health authorities informed.



The patient has to give an undertaking in a prescribed format. If the health condition worsens, the patient should seek medical care. Home isolation may be stopped when the symptoms resolve and the medical officer certifies her to be free of infection after laboratory testing. (46a)

Instructions for individuals in home isolation and quarantine

The home quarantined person should:

- Stay in a well-ventilated single-room preferably with an attached/separate toilet.
- If another family member needs to stay in the same room, it's advisable to maintain a distance of at
- least 1 meter between the two.
- · Needs to stay away from elderly people, pregnant women, children and persons with co-morbidities
- within the household.
- · Restrict his/her movement within the house.
- Under no circumstances attend any social/religious gathering e.g. wedding, condolences, etc.

General health measures to be followed in quarantine include hand washing, avoiding sharing fomites. The patient should wear 3 layer mask or N95 mask if not possible he should wear a surgical mask & change it every 6 to 8 hours with correct disposal in 1% hypochlorite solution. If symptoms appear during quarantine, the pregnant woman should contact a health facility by telephone and follow the given advice.

Family members of the pregnant woman quarantined at home should keep a distance from her at all times and avoid direct contact with her and her fomites. The care giver should use disposable gloves & minimum 3 layer mask. Visitors should not be allowed. Clothes should be washed separately.

The duration of home quarantine is 14 days from the time of exposure to a confirmed case or earlier if a test is performed on a suspect case and it is negative.

Arrangements in existing healthcare facilities to manage COVID-19 exposed and infected pregnant women

Organization of healthcare in general during the pandemic

The pandemic represents a challenging situation where the medical practitioner will have to deal with a mix of patients and attendants who may be uninfected by coronavirus, asymptomatic carriers, primarily presenting with features of the infection, or seeking healthcare for other reasons and coincidentally have infection (with or without symptoms). As healthcare providers for women and particularly those in pregnancy, this documentation focuses on the organization and arrangements for pregnant women with or without infection.

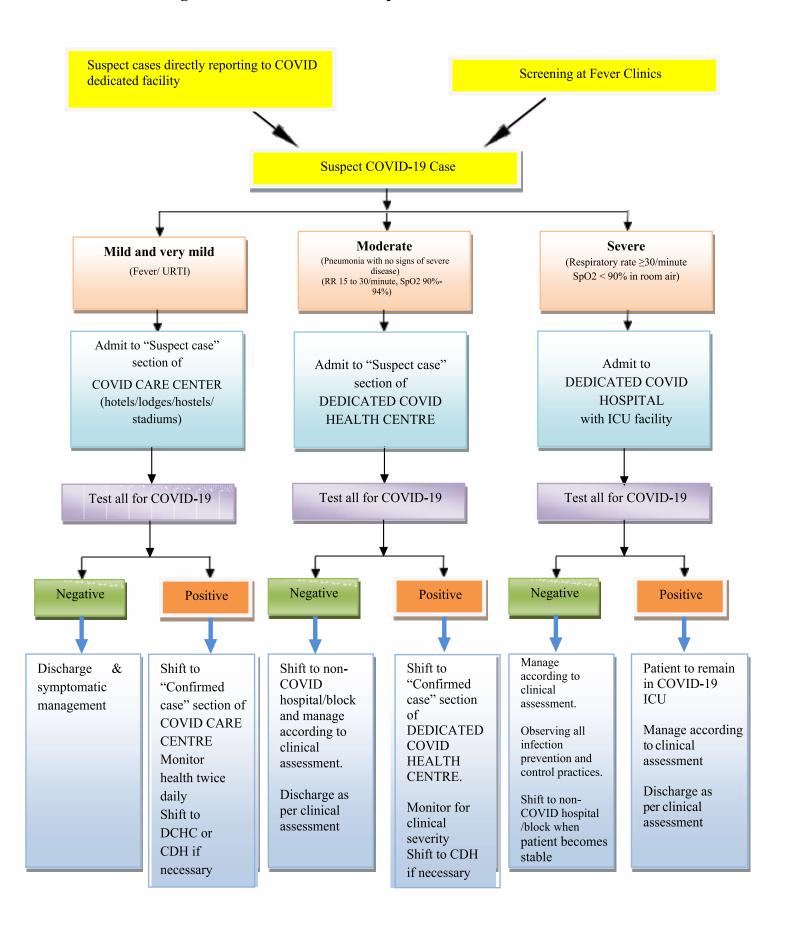


Government institutions have been advised regarding preparation and conduct of mock drills by elaborate advisories. (47) (48) The current recommendation is to organize public and private health care essentially into non-COVID and COVID facilities. Further, COVID facilities would be designated to represent various levels of care as follows. (49) (50)

	Purpose	Staffing and Facilities
Fever clinics	Outpatient assessment	
COVID Care Centres (CCC)	Observation and treatment of very mild or mild cases	Existing quarantine facilities or makeshift facility such as a hostel, stadium, lodges etc. Functioning hospitals or part of hospitals may also be used, but only as a last resort as these facilities are better utilized for DCHC and DCH. These centres may be manned by AYUSH doctors working under the guidance of an allopathic doctor
Dedicated COVID Health Centre (DCHC)	Observation and treatment of moderate cases or mild cases with high risk factors such as old age, diabetes, heart disease, respiratory disease.	Existing hospital with beds where there is facility to provide oxygen continuously. Allopathic doctors and postgraduate trainees.
Dedicated COVID Hospital (DCH)	Observation and treatment of severe cases	Hospitals with oxygen, intensive care and ventilators being available. These centers should also have facilities for maternity care and other subspecialties. Allopathic doctors and postgraduate trainees.



Algorithm for isolation of suspect/confirmed cases of COVID-19





In Dedicated Covid Health Centres (DCHC) and Dedicated Covid Hospitals (DCH), there should be three demarcated zones — clean, potentially contaminated and contaminated with exclusive passageways to minimize exposure of individuals to each other once they have been allotted into these zones. Each of these zones would then have its own facility to deal with outpatient, inpatient care and intensive care management. Wherever possible, it may be beneficial for the entire contaminated zone (wards, labour rooms, operation theatres and ICU) to have a negative pressure system to limit the spread of infection.

However, it may not be feasible to create such facilities everywhere. Therefore, the same principles should be applied to the existing facilities as far as possible. The purpose is to minimize the chance of contact between infected and non-infected pregnant women.

Every pregnant woman should be triaged at entry and then allotted into one of the zones depending on the presentation.

Infected	Potentially infected	Clean
Tested and shown to be positive for COVID-19	 Symptoms of SARI Contact with infected individual Travel abroad in the last 14 days Healthcare worker caring for COVID-19 infected individuals Test result is awaited Residing in hotspot/cluster/containment zone/with evacuees from this areas 	 No symptoms of SARI No contact with infected individual No travel history Not residing in hotspot/cluster/containment zone/with evacuees from this areas

The infected and potentially infected pregnant women should be kept in separate isolation areas. Each isolation area includes isolation wards, and an isolation ICU area. If possible, each patient should be kept in a separate room with an attached toilet and bathroom.

Access to isolation areas should be strictly limited. Family visits shall be declined. Patients should be allowed to have their electronic communication devices to facilitate interactions with the family and friends.

Organization of maternity care (specifically private sector) during the pandemic

The continuity of ongoing care for time sensitive health matters such as maternity care is essential. In India, a significant proportion of maternity care is provided by the private sector and it needs to continue to provide services so that the public healthcare infrastructure does not get overburdened.

In the private sector, large multispecialty hospitals can be organized according to the guidance given for the public sector as facilities, infrastructure and finances are feasible. However, this does not hold true for the nearby small to medium sized private healthcare facility which is usually a doctor-owned and operated single specialty (maternity care) facility. The guidance in this GCPR addresses the needs of this group of centres under the following headings to continue essential maternity care to be provided safely. Certain considerations of staff management, cleaning and maintenance of facilities are common for all hospitals.

- What are the facilities for maternity care at COVID and non-COVID hospitals
- Checklist to identify suspected cases and referral pathways
- Organization of facilities and administrative aspects



	COVID Maternity Hospital in private sector	Non-COVID Maternity Hospital in private sector
Typical set up in private sector	Large multispecialty hospitals	Small to medium single speciality (maternity care) hospitals or nursing homes
Infrastructure	Separate building with multiple entry and exit facilities, multiple staircases or elevators where some of these can be kept separate for suspect or confirmed cases Separate dedicated Labour Room and Operation Theatre	Part of a building where there is a single entry or exit and segregation is not possible Separate dedicated Labour Room and Operation Theatre are not possible
Medical facilities	Equipped to manage maternity care and medical issues related to the infection. Should have facilities similar to a DCH as outlined above.	Equipped to manage maternity care and has back-up facilities for emergencies.
Personal Protective Equipment	Should have adequate stock of various levels of PPE to cater to the requirements of treating large numbers of suspected or infected patients.	Should have stock enough to cover for a few cases for rendering first aid or emergency treatment for suspected or confirmed cases before they are referred or if they are not in a state to be referred.

COVID-19 Checklist tool to identify suspected cases

The checklist tool should be used in advance of a patient's physical visit. It should be administered remotely by telemedicine pathways. These are essential criteria for testing for COVID-19 infection given by ICMR. If the pregnant woman falls into the group which needs testing, she should be labelled as a suspect case until the test report is obtained in the negative. If there is a suspicion, the patient should be directed to a COVID hospital for further care and management. If a patient does not have an appointment and has walked-in for a consultation, they can complete the checklist tool by phone, standing outside the premises. If the checklist tool has not been administered in advance, it should be done at the point of triage. Referral pathways should be established and every private sector Non-COVID maternity hospital should be mapped to a private sector COVID hospital providing maternity care as well as having linkages to a public sector COVID hospital for the same.

COVID-19 SCREEING CHECKLIST TOOL

- Do you have fever?
- Do you have features of respiratory disease (runny nose, altered smell sensation, blocked nose, cough, sore throat, difficulty in breathing or feeling breathless)?
- Do you have travel abroad / interstate in the last 14 days?
- Have you travelled from anywhere outside your locality in the last 14 days? If yes, was this area a hotspot?
- Do you have household or close and direct contact with a person who meets the above two criteria of travel?
- Do you have household or close and direct contact with a person who is confirmed to have COVID-19 infection or who
 is suspected and undergoing testing?



- Do you reside in a hotspot/containment area/cluster/with migrants/with evacuees from such areas?
- Are you a healthcare provider who has been to work in the last 14 days?
- Have you been hospitalized in the last 14 days?

Organization of facilities in Non-COVID Maternity Hospital in private sector to reduce transmission risk

Designation of a triage area:

As far as possible, patients and their relative should be triaged remotely by telemedicine. If this is not possible, there should be a segregated area of the hospital premises which is used for triage. This area could be at the entry gate of the building in which the hospital is located. It should be staffed by paramedical personnel. Triage may include use of the checklist tool, remote temperature screening and a finger oxygen pulseoximeter if available. The triage criteria should also be applied to the attendant with the patient.

Application of Triage:

If there is suspicion of infection on checklist and the patient is stable, she should be given an N95 mask and referred to a fever clinic or COVID Hospital.

If there is suspicion (or confirmed case) but it is an emergency, the patient should be given basic care with wearing full PPE and then referred to a COVID Hospital.

If there is no suspicion and patient is stable, care can proceed as usual.

Creation of isolation area:

Patients who are suspected or confirmed cases admitted into the hospital premises for emergency or basic care before referral will need to be kept in an isolated area of the hospital. This area should be near the entry and at triage room of the hospital. It should be a room with an attached bathroom to minimize movement and to allow hygiene to be maintained. The staff entering this area should compulsorily use appropriate PPE. After the patient leaves the premises, the isolation area should be fumigated. and disinfected with 1% sodium hypochlorite. In case the labour ward or operation theatre has been used, it should be fumigated. Another patient should not be taken for labour care or surgery in these areas until one hour after fumigation and disinfection are completed. The staff that has had an exposure should be counseled, managed and quarantined as per the flow chart mentioned earlier and as per advice of the local health authority.

Administrative aspects:

Only one attendant should accompany the woman and the same person should stay with her for the duration of the

- admission.
 - Visitors should be prohibited entry. This minimizes the traffic to the hospital.
- Administrators may facilitate remote communication by providing devices, adequate charging points and wi-fi.
- There should not be any health camps, health education seminars or hospital gatherings.
- Visits by medical representatives should be stopped.
- The hospital mess/canteen should cater only to patients, single attendant and hospital staff.
- In case of a suspected or confirmed case being admitted to a Non-COVID hospital, notification has to be made to the
- local health authority.



By far and large, local health authorities have now agreed that hospitals will not be sealed in the circumstances of a suspected or confirmed COVID case being treated or admitted there as it will result in a marked reduction in facilities from sealing and also from the fear that the premises will be sealed, earning it disrepute.

Telemedicine during the pandemic

Telemedicine has been permitted by the Medical Council of India at the present time (52). Below are some pointers towards safe telemedicine practice.

- The same ethical and professional standards should be practiced as per usual practice.
- Various forms of communication can be used as per the choice of both parties. This may be in the form of video (specialized telemedicine platforms or general platforms such as WhatsApp, Zoom, FacebookLive, Skype, etc.), audio (telephone or any other voice-over-Internet-protocol) or written communication (email, messages on various applications).
- First consultations should preferably be via a video format to build rapport.
- Emergency consultations should be limited to directing the patient or care giver to the appropriate site for physical care and advice about first aid until reaching such a site.
- Interventions by the doctor could be health education, counselling or prescription of medications.
- Prescriptions should be provided in a standard format.
- Medications are grouped as per the mode of consultation, feasibility and safety of telemedicine. List 0 includes drugs which are available over the counter such as paracetamol, oral rehydration solutions, etc. They may be advised by any mode of consultation. List A includes drugs that can be prescribed only after video consultation such as eye drops for conjunctivitis. List B comprises of drugs that are prescribed for the same condition as add-ons (Eg: ondansetron for severe nausea in pregnancy which is not relieved by first line agents like doxylamine). Certain medications (psychotropic agents, narcotics and schedule X drugs) cannot be prescribed in telemedicine consultations.
- Consent is implied when the patient initiates a consultation with the doctor. However, if the doctor has initiated the consultation (on the request of the patient's caregiver, for example), an explicit consent should be taken. This can be done by recording the patient saying a simple statement such as "I consent to avail consultation via telemedicine."
- At present, doctors do not need any special training to do telemedicine. In the future, the Board of Governors of the National Medical Council will have a telemedicine program. Doctors will be required to complete a course in telemedicine within three years of it being notified.
- Documentation and maintainence of records may be in physical or electronic form.
- Telemedicine may be a chargeable service.

Termination of pregnancy (MTP), sexual and reproductive healthcare in times of COVID-19

Abortion care is essential healthcare. It is critical to ensure that women who seek abortion and family planning do not suffer from lack of access. It is well established that early abortions are safer for women and the MTP Act places limits on the gestational age for abortions. This makes the provision of abortion time-sensitive. A lack of these services may mean that women seek an abortion from unsafe providers and put themselves in harm's way. The services should therefore continue to be provided by public and private providers.

It should be noted that suspected or confirmed COVID-19 infection by itself is not an indication for termination of pregnancy.

Some important practice recommendations related to termination of pregnancy are outlined below for routine practice.

 All the provisions of the MTP Act including consent, documentation and maintenance of records need to be adhered to.



- Consultation, counseling and prescription of investigations (blood and ultrasound) can be provided by telemedicine.
 They can be reviewed remotely before in-person visit.
- Before the in-person visit, screen the woman as for a standard clinic visit. with the COVID-19 Screening Checklist Tool.
- There is no requirement of mandatory testing for COVID-19 infection in the absence of clinical suspicion for medical or surgical MTP.
- If there is suspicion or confirmed COVID-19 infection, advice the woman to go to a designated COVID facility. The procedure should be deferred for 14 days. If she develops symptoms in this time, appropriate medical care should be sought. Refrain from performing MTP at this time even if it means converting a medicated abortion to a surgical one.
- Give due consideration to limited travel modalities and feasibility of seeking emergency care when prescribing medicated abortion.
- Medicated abortion (MTP pills) cannot be prescribed by telemedicine.
- Follow-up after medicated abortions can be conducted remotely. If the woman is asymptomatic after the medicated abortion and has no complaints, physical visits and ultrasounds to confirm completion may be deferred or avoided.
- In the event that a woman who has been prescribed medicated abortion requires a surgical evacuation some specific considerations should be followed as outlined below. (These would also apply to other emergency uterine evacuation procedures of spontaneous abortions.) For an asymptomatic patient with no risk factors on the screening questionnaire, proceed with the standard surgical and anaesthesia practice with appropriate PPE. For a patient who has answered Yes to any of the questions in the screening questionnaire, take precautions, wear full PPE and treat the situation as a suspected case.
 - If possible, the procedure should be done in a COVID hospital where a separate theatre would be available.
 - If it is an emergency with acute blood loss with the patient presenting to a non-COVID hospital, the theatre should not be used for one hour after fumigation and disinfection.
 - If possible, perform the procedure under local anesthesia with an anesthetist standing by in the operation theatre. If this is not possible, the decision regarding anaesthesia should be taken in consultation with the anesthetist.
 - Have one assistant and one other auxillary staff in the theatre. A full PPE kit should be worn by all the personnel
 in the theatre.
 - Perform the procedure using a manual vacuum aspiration (MVA) kit and sterilize it after treating with sodium hypochlorite solution for 30 minutes. If an MVA kit is not available, all the surgical instruments have to be treated with sodium hypocholorite, washed, dried and then autoclaved.
 - After she is stabilized, testing for COVID-19 should be done (as she had risk factors on the questionnaire). Notify to the local authorities if the test is positive.

Emergency Contraceptive Pills can be prescribed by telemedicine and they can reduce the chance of requiring MTP.

Gynecological and general surgery during pregnancy and COVID-19 infection

In the unusual circumstances that a pregnant woman may need a surgery (ectopic pregnancy not fitting the criteria of medical management or ovarian torsion) or general surgery (appendicitis), the following aspects of care should be kept in mind (53),(54).

Women should be screened clinically and if there is suspicion or a confirmed case of COVID-19 infection, the surgery should be performed at a designated hospital. In such situations, full surgical, anesthesia and PPE protocols will have to be adopted from the point of entry.



Even if there is no suspicion of COVID-19 infection, laparoscopic surgery should be avoided during the pandemic, if possible. If laparoscopy is to be performed, it should be done with due counseling of the patient. Open surgery is preferred as the risk of aerosol generation from creating a pneumoperitoneum is reduced. Also, open surgery is more feasible under regional anesthesia as compared to laparoscopy. This is an important consideration because intubation and ventilation in general anesthesia are aerosol generating procedures. Electrosurgery use should be avoided or minimized. If possible, cautery with smoke extracting devices should be used. Suction use should be minimized to avoid generating aerosol of biological material.

Routine Antenatal Care during the pandemic

Antenatal Care Visits

Following the principles of social distancing, it is advisable to minimize the number of visits that a pregnant woman needs to leave her house. There is a minimum level of antenatal care and investigations which are necessary.

For the low risk, asymptomatic and uninfected woman, at present, the recommended strategy for antenatal care is to onduct antenatal care visits by phone or video call supplemented with home blood pressure monitoring.

Some visits may be deferred. Questions, counselling and minor ailments can be addressed remotely. (51)(55) An ultrasound is advised at 12-13 weeks and at 18-22 weeks as outlined below. Pregnancy visits can be timed with these sonographies. The next visit can be at about 30 to 32 weeks. Vaccinations and antenatal profile (blood and other investigations) can be planned during these visits. Growth scans in the last trimester are advised or performed only if indicated. Women are advised to note fetal movements every day. For women who have high risk factors, the guidance of the HCP (Health Care Provider) is needed.

Providing Antenatal Care

Some useful practices to follow in providing antenatal care are outlined below to enhance safety and ensure smooth functioning of the clinic.

- Appointments should be scheduled to avoid waiting time and exposure. The woman should be screened with the checklist tool on the telephone.
- The patient should make the visit alone or at the most, with one attendant.
- The patient (and attendant) should leave their shoes outside the waiting room.
- At entry, they should use a hand sanitizer correctly.
- They should be given a mask if they are not wearing one.
- If the checklist tool was not administered earlier, it should be done in the waiting room.
- The doctor should wear appropriate PPE (uniform, scrubs or apron with surgical cap, mask-3 layer or N95 preferably and gloves) while examining the patient.
- In the consulting room, avoid air conditioning. An exhaust fan should be switched on or the window should be opened.
- The fan may be a ceiling fan or a standing/table fan blowing air in a direction away from the doctor.
- The consulting room should be kept free from clutter and have the minimum amount of furniture necessary. The furniture should be hard surfaced to facilitate cleaning.
- The patient examination table can have disposable covers where possible.
- The number of fomites (mobile phones, electronic devices, pens, measuring tapes, stethoscopes and BP apparatus) should be kept to a minimum and frequently sanitized.
- Avoid handling paper, files and reports that the patient brings. It can be seen with the patient holding them or by photographs.
- The consulting room should be cleaned regularly. At the end of the clinic, the examination table should be disinfected.
- The room may be fumigated at the end of the day.



Obstetric ultrasound during the pandemic

Ultrasound represents an important part of antenatal care in modern obstetric practice. Though most of the times it is a non-invasive procedure, ultrasound represents a high risk situation for coronavirus transmission. The virus can survive on inanimate surfaces such as an ultrasound machine for 48 to 96 hours and these surfaces are touched repeatedly by the operator. (55), (56) During invasive procedures (amniocentesis or fetal reductions), there is a potential for exposure to body fluids. There is physical proximity of less than a meter and examination time may be prolonged especially for detailed anatomy scans. Ultrasound rooms are typically small, poorly ventilated.

Appointments should be scheduled to avoid waiting time and exposure. The woman should be screened as for a clinical visit. If there is a suspicion, the examination should be deferred. If the visit cannot be deferred, it should be scheduled at the end of the list so that thorough terminal disinfection is possible. The ultrasound room should be cleaned regularly. There should be minimum number of fomites in the room. The furniture should be hard surfaced to facilitate cleaning. The patient bed can have disposable covers where possible.

In case the woman is sick and hospitalized due to the COVID19 infection and requires an ultrasound, it may be desirable to perform it at the patient's bedside rather than transporting the woman to the ultrasound room.

Hand hygiene, respiratory hygiene and mask wear advice as outlined earlier should be followed. The operator should wear non-sterile gloves while performing the examination.

The following is a suggested schedule for obstetric ultrasound examination. (56)

Routine ultrasound examination in pregnant women

Scan	Asymptomatic	Clinical screening is suspicious for COVID-19 exposure	
11+0 to 13+6 weeks Also for dating	Combined test Offer serum / NIPT screening If possible & available	Reschedule combined test in 2 weeks within gestational age window(unless local protocols differ) Offer NIPT/ serum screening If possible & available and detailed scan in 3-4 weeks after quarantine	
18+0 to 19+4 weeks	Anatomical scan	Reschedule after quarantine in 2-3 weeks	
Fetal growth scan in third trimester	Do not perform unless clinically indicated	Do not perform unless clinically indicated	

Modification of routine ultrasound examination in women with suspected/probable/confirmed COVID 19 infection

Scan	Outpatient	Hospitalized	
11+0 to 13+6 weeks Also for dating	Reschedule combined test in 2 weeks if still within gestational age window (unless local protocols differ Offer NIPT/ serum screening and detailed scan 3-4 weeks following recovery	Offer NIPT screening If possible & available Perform at bed side	



18+0 to 19.4 weeks	Reschedule in 3-4 weeks following recovery	Perform at bedside	
Fetal growth scan in third	Reduce frequency with first	Follow up growth every 4	
trimester	scan 2-4 weeks after recovery	weeks or earlier based on	
		findings	

An ultrasound 14 days after the infection can be considered for the pregnant woman who has recovered from infection for reassurance.

Assessment of Pregnant women (not in labour) with COVID-19 infection

If a pregnant woman is confirmed by tests to have COVID-19 infection, the first step is to assess the systemic status.

- 1. If asymptomatic, the woman should be quarantined in the hospital as per current practice. The measures to be taken are discussed in the previous section. If the numbers increase, the Government guidelines on hospital admission for quarantine may change. She should self monitor and report if symptoms arise.
- 2. If symptomatic, a decision needs to be made as to the requirement of hospitalization or further intensive care.

Hospitalization	Intensive Care (to be managed by critical care specialist) (17)
 In a very mild or mild disease if the criteria for home isolation (outlined earlier) are not met, hospitalization is necessary. Worsening of features of an individual who was in home isolation. Presentation with moderate or severe illness. 	 Pregnant women who meet any of the following criteria: respiratory rate > 30 breaths/min; oxygen saturation < or = 93% at a rest; arterial partial pressure of oxygen (PaO2)/oxygen concentration (FiO2) < 300 mm Hg Patients with > 50% lesions progression within 24 to 48 hours in lung imaging Quick Sequential Organ Failure Assessment Score (qSOFA) score can be a useful adjunct to decision making for ICU management.

Most publications have the oxygen saturation mentioned a level of < or = 93%(17). However, one of the Government published guidance mentions this as 90% (50).

A quick bedside assessment tool is also usable for sepsis (typically for bacterial infections) screening in triage called the quick SOFA (qSOFA) score. It includes 1 point for each of 3 criteria.

qSOFA SCORE				Score ≥ 2 is
Number	Criteria		Point	suggestive of
1.	Respiratory rate	≥ 22 breaths/min	1	sepsis and
2.	Mental status	Altered	1	needs intensive
3.	Systolic Blood pressure	≤ 100 mm Hg	1	care



Medical management and drugs used in the treatment of COVID-19 infection in pregnancy

Supportive therapy for COVID-19 infections should include rest, oxygen supplementation, fluid management and nutritional care as needed.

The treatment of COVID-19 viral infection has been attempted by two approaches. The first approach is the use of a combination of Hydroxychloroquine and Azithromycin. These drugs are readily available and cost-effective in India. The other approach has been to use antiviral drugs, some of which are not yet available in India.

Hydroxychloroquine was used in a small study comprising of 24 patients. (57) This study was not much accepted at that time. However, the same group has published the success of the hydroxychloroquine + azithromycin in a larger cohort. (58) They found a rapid fall of nasopharyngeal viral load was noted, with 83% negative at Day 7, and 93% at Day 8. Virus cultures from patient respiratory samples were negative in 97.5% of patients at Day 5. Consequently patients were able to be rapidly discharged from intensive care with a mean length of stay of five days. The regimen used is hydroxychloroquine in a dose of 600 mg (200 mg thrice a day with meals) and Azithromycin (500 mg once a day) for 10 days. In these studies, pregnancy was an exclusion criteria. However, as such, both these drugs have been used in pregnancy and during breastfeeding without significant effects on the mother or fetus. Alternative dosage regimens for hydroxychloroquine are to give 400 mg twice a day on day 1 and then 400 mg once a day for the next four days. Chloroquine can also be used as an alternative. The dose is 500 mg twice a day for 7 days. Some authorities recommend that azithromycin should be added only where there is a clinical suspicion of superadded bacterial infection .

Antiviral therapy

Lopinavir-ritonavir was the first antiviral combination used in an attempt to treat COVID-19 infection. This may be considered as a possible line of treatment for those who have chronic disease, immunocompromise or uncontrolled diabetes. However, there was no difference in time to clinical improvement or mortality at 28 days in a randomized trial of 199 patients with severe COVID-19 given lopinavir-ritonavir (400/100 mg) twice daily for 14 days in addition to standard care versus those who received standard care alone (60) .

Other agents such as Remdesivir(59), Favipriavir (61) are being evaluated in a randomized trials.

In India, some health authorities have prescribed a regimen of Oseltamavir 75 mg twice a day for five days in conjunction with hydroxychloroquine(62). The recommendation is based on the experience of the H1N1 (swine flu) experience. At present, data on this regimen is limited. The regimen is simple, cost effective and the drug is available easily.

Other Drugs

A number of other drugs that are used in the management of pregnant women with COVID-19 infection are discussed below.

NSAIDs: These are the drugs used most often in the care of COVID-19 infected pregnant women for symptomatic relief of fever and myalgia. Paracetamol is the preferred drug. If possible, Ibuprofen and other NSAIDs may be avoided because there are concerns about potentiating ACE receptors.

Antenatal Steroids (fetal maturity): Steroids are recommended for enhancing fetal lung maturity in situations where preterm delivery is likely between 24 to 34 weeks of gestation.

Antihypertensives: There is controversy surrounding the use of ACE (Angiotensin Converting Enzyme) inhibitors and ARBs (Angiotensin Receptor Blockers) in the general population, especially the elderly with hypertension. In pregnancy, these drugs are not to be used due to their known deleterious effects on the fetus. The point of using them in pregnant women, therefore, does not arise.

Antibiotics: If there is a suspicion of secondary bacterial infection, appropriate antibiotics which are considered safe in pregnancy should be added.



Oxygen: If there is difficulty in breathing, oxygen supplementation by nasal prongs or mask may be added. High flow nasal oxygen at 4 to 6 liters per minute should be immediately administered. Non invasive ventilation can also be used. At this point, there should be a reevaluation of the patient's status and consideration should be given to the need for intensive care.

Intensive Care Management

It is estimated that about 15% of COVID-19 infected individuals will need care in hospital and 5% will need intensive care. (1) The outcome of such individuals is largely determined by the underlying co-morbidities and the availability of ICU facilities. In the public sector, India has a hospital bed availability of about 5 per 1000 population and intensive care bed availability of 1.3 per 100000 population. The number of ventilators are about half of what is estimated to be needed if there is a full-blown epidemic in the country (64). Western countries are also facing similar shortages or space, beds, personnel and infrastructure. This has resulted in a triage where care is being accorded only to infected individuals with a good prognosis of survival.

If a woman is identified to need intensive care, it should be done in conjunction with a team of ICU experts. Caring for critically ill pregnant women patients with COVID -19 is based on management of viral pneumonia with respiratory failure with additional precautions to reduce risk of transmission. The principle guidelines for ARDS in these circumstances include:

- Conservative Intravenous fluid strategies
- Empirical early antibiotic for possible bacterial pneumonia
- Early invasive ventilation may be needed
- Lung protective ventilation strategies
- Periodic prone positioning during mechanical ventilation. There is little evidence on prone positioning in pregnant women. Pregnant women may benefit from being placed in the lateral decubitus position.
- Extracorporeal membrane oxygenation where needed

Plasma Therapy

One of the experimental approaches been attempted for critically ill patients is the infusion of plasma from individuals who have recovered from the COVID-19 infection. This approach is based on the passive transfer of antibodies from the recovered person to the critically ill person. The initial reports of the treatment are encouraging. (65) In India, the ICMR has published a letter of intent calling for participation of institutions in a randomized controlled study on Therapeutic Plasma Exchange in COVID-19 and published a protocol for the same. The ICMR emphasizes that this is an experimental treatment to be performed only in settings of a clinical trial and not for routine use, even for individuals in critical care with COVID-19 infection. (66)

Vaccine

At present, a number of organizations in the public and private sector are working towards the development of a vaccine. Some safety trials have been initiated. However, it is estimated that a vaccine would be available to use only after 6-12 months. (63)

Labour Triage for women with COVID-19 infection

A protocol should be in place in every maternity unit to receive pregnant women in labour or suspected labour with confirmed or suspected COVID-19 infection. The outline of the arrangements for healthcare facilities has been mentioned in an earlier section. The same principles should be followed. The following aspects should be borne in mind in planning for this triage process (9).

- The woman should call in advance to alert the maternity unit about her arrival whenever this is possible. This will give some time to the healthcare workers to prepare in triage and don the PPE.
- The woman should use private transport or an ambulance when possible to reach the maternity unit.
- She should be met with appropriately donned PPE at reception itself.
- Reception and triage in the same room as to be used for admission in labour and delivery. This should be a room with negative pressure. But it is not available everywhere.



- Keep the room free from any unnecessary items (decorations, extra chairs, etc) which could act as infected fomites later.
- There should be a restriction on the number of attendants allowed with the woman. There should be a restriction on the entry and exit of non-essential staff into the room. The companion of the woman should be treated as infected and all precautions should be taken.

In the future, if the number of COVID-19 infected patients rises, it is expected that there would be some who would be recognized to have the infection for the first time when they present in labour. Anticipating this, an elaborate advisory to this effect has been issued by the Ministry of Health and Family Welfare on hospital and institutional preparedness (47) and the conduct of mock drills and standard operating procedures (48).

Management of Labor and Delivery in women with COVID-19 infection

In all circumstances, maternity care providers should continue to provide client-centred, respectful skilled care and support. Birth attendants should be limited to one named contact. There should be adequate counselling of the mother about the infection.

Separate delivery room and operation theatres are required for management of suspected or confirmed COVID-19 mothers. Both should have neonatal resuscitation corners located at least 2 m away from the delivery table. Resources required include space, equipment, supplies and trained healthcare providers for delivery, caesarean section and neonatal resuscitation. The standards and facilities required for infection control in these areas should be same as that for other adults with suspected or confirmed COVID-19 infection.

Following the principles in earlier sections on recognition, offering testing, PPE use and principles of isolation of COVID-19 infected women, this section is restricted to the management of labour and delivery and the modifications necessary in women with COVID-19 infection. Depending on the clinical picture and severity of the condition, a multispeciality team may be involved in caring for the pregnant woman in labour. The anaesthetist and neonatologist should be informed of such a woman presenting in labour.

If a woman presents in preterm labour, tocolysis is contraindicated in following the general principles of avoiding such an intervention with systemic disease. This decision should be individualized depending on the degree of clinical severity of the infection. If there is pulmonary involvement, beta-mimetic agents should be avoided. For a woman in preterm labour or where preterm birth is anticipated, antenatal corticosteroids should be used as routine. This is safe for the woman with COVID-19 infection.

Timing of delivery should not be altered on the basis of COVID-19 infection. The presence of infection is not an indication to induce labour or deliver the woman. At present, there is no evidence of transplacental vertical transmission. There would be no rationale in doing so. The exception to this would be the critically ill pregnant woman where delivery may be indicated to relieve the extra metabolic and pulmonary load. However, the possible benefits of this need to be weighed against the possible risks of worsening the systemic status with a surgical intervention. Such a decision has to be guided by individual circumstances including the degree of clinical stability, gestational age, available infrastructure and the couple's wishes.

In labour, monitoring should include the periodic evaluation of the respiratory status with a watch for symptoms of difficulty or shortness of breath, respiratory rate, pulse rate and oxygen saturation on pulseoximetry. If there is a deterioration of these features, intensive care measures would be required including ventilation.

As such, the pregnant woman with COVID-19 infection can be allowed to labour and indications for interventions should follow standard obstetric practice. A prolonged labour may be detrimental to the general condition of a woman who has systemic illness. There could be further maternal deterioration. Prolonged oxytocin infusion and volume overload should be avoided. With every examination and contact, healthcare workers should be mindful of adequate protective gear. An intravenous access should be established and fluids should be restricted in labour. It may be prudent to offer continuous electronic fetal monitoring in labour for women with COVID-19 infection wherever such facilities are available.



At present, pregnant women have almost universally been delivered by caesarean section when they present in labour with COVID-19 infection. There is no proven scientific rationale for this. It could reflect local preference and practices (67). Operating with PPE gear can be a formidable task as has been described from some personal experiences. There can be difficulty with communication (hearing is reduced). Therefore it is good to have a set operating team which is generally familiar with standard operative steps of a particular procedure. Also, tactile sensation is diminished. This may lead to increase in operative time. Airconditioning has to be switched off to prevent the spread of the virus into the atmosphere and the operating team is faced with heat, perspiration and humidity. These challenges require fortitude and preparation to overcome them.

If a woman with COVID-19 infection has respiratory features, and has PPH, carboprost should be avoided. Methylergometrine can be used with caution. Oxytocin, misoprostol and tranexamic acid can be used as usual.

The maternal profiles and neonatal outcome of labour has been described in a study of 33 pregnant women who delivered with COVID-19 infection in Wuhan(28). The study describes the presentation of the women in labour. Three of the 33 neonates were found to be infected in this study. They had mild features of the infection. Excerpted data from this study is presented below.

	Neonates with SARS-CoV-2, No. (%)	
	No (n = 30)	Yes (n = 3)
Preterm	3 (10)	1 (33)
Small for Gestational Age	2 (7)	1 (33)
Asphyxia	1(3)	1(33)
Maternal Features		
Fever on admission	7 (23)	1(33)
Postpartum fever	4 (13)	1(33)
Cough	9 (30)	1(33)
ICU admission	0	0
Pneumonia on CT scan	30(100)	3 (100)
Nasopharyngeal swab	30(100)	3 (100)
Delivered by caesarean	23 (77)	3 (100)
Premature rupture of	2 (7)	1 (33)
membranes		

Labour Analgesia and Anesthesia in Pregnant Women with COVID-19 infection

Following the principles in earlier sections on recognition, PPE use and principles of isolation of COVID-19 infected women, this section is restricted to the specific aspects of anesthesia in labour and delivery. A team of anesthetists should be available with a senior anesthetist taking the clinical lead. There is interim guidance on the subject of obstetric analgesia and anesthesia with COVID-19 infection(68) .

There is no evidence that epidural or spinal analgesia or anaesthesia is contraindicated in the presence of coronaviruses. Therefore, a COVID-19 infected woman who is fit enough to labour can be offered epidural analgesia. If she requires a cesarean delivery, the same epidural can be continued and a general anesthesia can be avoided.

If a woman who has not had an epidural anesthesia requires a cesarean birth, the choice of anesthesia is governed by the general health status of the woman. For most women, spinal anesthesia by standard techniques is suitable. However, in the situation where there is respiratory compromise, general anesthesia and subsequent ventilation will be needed.

If general anaesthesia is administered, preoxygenate the patient for five minutes with $100\%~O_2$ and perform rapid sequence induction (RSI) to avoid manual ventilation of the patient's lungs. Use a video-laryngoscope to improve intubation success and avoid awake fiberoptic intubations, when possible. This is a procedure that induces aerosolization. The need for using full PPE is reiterated. Place a high efficiency hydrophobic filter between the facemask and breathing circuit or between the facemask and reservoir bag to avoid contaminating the atmosphere.



Testing for the Newborn

The care of the newborn should be in the hands of a neonatologist or pediatrician. Some areas of concern regarding testing of the newborn are mentioned below to help with counseling the mother and family(6). At present, there are no new recommendations about neonatal testing. There could be some changes in the near future.

Which neonates to test?	Neonates born to mothers with COVID-19 infection within 14 days of delivery or up to 28 days after birth
	Symptomatic neonates exposed to close contacts with COVID-19 infection
When should the	If symptomatic, specimens should be collected as soon as possible
neonate be tested	If asymptomatic and roomed-in, test only if and when mother's test comes
	positive. If mother is COVID-19 positive and baby's initial sample is negative, another sample should be repeated after 48 hours.
What sample	Not mechanically ventilated - Upper respiratory nasopharyngeal swab (NP).
should be	Collection of oropharyngeal swabs (OP) is a lower priority and if collected
collected of the	should be combined in the same tube as the NP.
neonate?	Mechanically ventilated - Tracheal aspirate sample should be collected and
	tested as a lower respiratory tract specimen
How to	Upper nasopharyngeal swab
collect?	Use only synthetic fiber swabs with plastic shafts. Do not use calcium
	alginate swabs or swabs with wooden shafts, as they may contain
	substances that inactivate some viruses and inhibit PCR testing.
	Insert a swab into nostril parallel to the palate. Swab should reach
	depth equal to distance from nostrils to outer opening of the ear.
	Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it.
	Place swabs immediately into sterile tubes containing 2-3 ml of viral transport media.
	Oropharyngeal swab (e.g., throat swab): Swab the posterior pharynx,
	avoiding the tongue.
	Nasopharyngeal wash/aspirate or nasal aspirate
	Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup
	or sterile dry container.
	Other samples: Currently not advised; stool, urine and blood specimens,
	since the isolation is less reliable than from respiratory specimens. Do not
	take these specimens for testing (based on current advisory
	recommendations)

Breastfeeding and the COVID-19 infected mother

Some viral infections such as cytomegalovirus and HIV are transmitted through breast milk. The CDC states that "we do not know whether mothers with COVID-19 can transmit the virus via breast milk".(69) The initial data from a Chinese study in 6 women shows that there is no secretion of viral particles in breast milk.(29) As present knowledge stands, there is no evidence that COVID-19 is secreted in breast milk. As breast milk is the best source of nutrition and general immunity for the infant, WHO encourages it.(70) In the light of the current evidence, we advise that the benefits of breastfeeding outweigh any potential risks of transmission of the virus through breast milk. Early and exclusive breastfeeding should be initiated for these mothers.



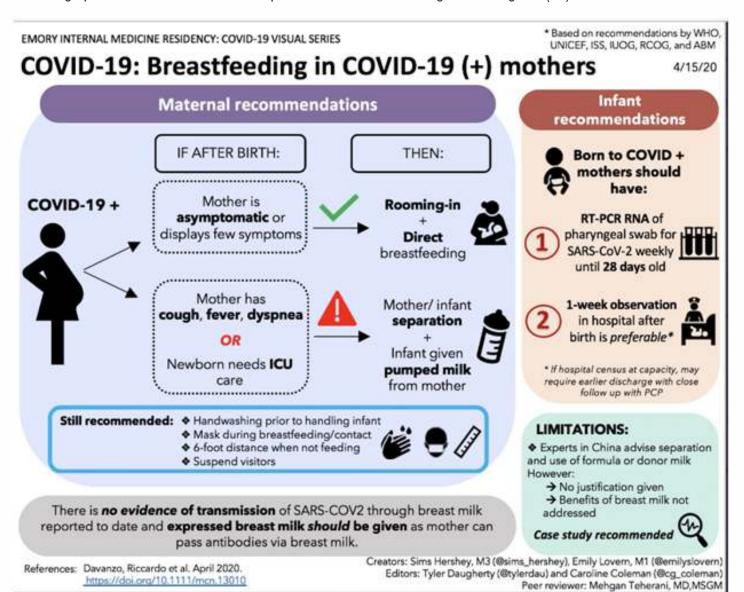
The main risk for infants of breastfeeding is the close contact with the mother, who is also likely to share infective airborne droplets. The following precautions should be taken to limit spread to the baby:

- If the baby is roomed-in, it is better to keep the bay at adistance of more than one metre from the mother except for the time of breastfeeding.
- Pregnant woman should wash her hands before and after touching her baby
- She should wear a mask (preferably a FFP3 or FFP2/N95)
- She should avoid coughing or sneezing while breastfeeding
- All surfaces should be kept clean and disinfection should be done

If a mother does not wish to feed the child directly, she can express her breast milk by hand or by a pump. If a pump is used, it should be kept separate and instructions on keeping it clean should be followed. The mother should follow hand hygiene. The expressed milk should be fed to the baby by another individual who is not infected.

If a mother is too unwell to feed the baby or express milk, formula feeding is needed and this should be provided with strict adherence to sterilization guidelines. (69)

The inforgraphic below illustrates the above points and is a useful learning and training tool. (71)





Cleaning, maintenance of facilities and medical equipment

The isolation areas, procedure and surgical areas and medical equipment should all be handled as potential sources of infection if a COVID-19 pregnant woman has been cared for in those areas. (17) While this is being carried out, the worker should wear PPE.

For surface cleaning and disinfection, agents that are useful are alcohol or chlorine based. Alcohol based agents should contain 70% isopropyl alcohol. Chlorine based solutions are prepared by diluting liquid chlorine (1000 mg/L strength) or freshly prepared 1% sodium hypochlorite solution. The appropriate concentration of sodium hypochlorite for disinfecting general liquid biological waste is approximately 1%. Household bleach is 5 - 6% sodium hypochlorite; therefore a 1:5 (v/v) dilution of bleach to liquid biological waste is appropriate. The contact time of these solutions should be at least 30 minutes.

- Floors, walls and object surfaces should be wiped 2-3 times a day or if there is visible contamination.
- Air can be sterilized by fumigation, plasma air sterilizers or ultraviolet lamps.
- After a procedure, the biological fluids, blood, and fecal matter should be treated with the above solutions before disposal.
- If there is a large fluid spill, sodium hypochlorite powder should be spread over the spill and left in contact for 30 minutes before swabbing or cleaning it.
- Reusable medical equipment, linen, fabric and clothes should also be treated with sodium hypochlorite before they
 are processed further.

Postnatal Care and Advice to the mother infected with COVID-19

Postnatal care of the mother infected with COVID-19 should include continued medical evaluation for respiratory status and symptoms and standard practices of routine postnatal care. She should be encouraged to maintain the good practices of hygiene related to the puerperium and hand hygiene. Advice should include management of engorged breasts when feeding has not been established and measures to enhance breastfeeding after the isolation period is completed. She should consume a healthy, nutritious diet to recover from the infection and build immunity.

The discharge card from the maternity unit should have advice about COVID-19 infection in addition to the usual post-delivery instructions. It should emphasize social distancing and need for evaluation if symptoms of acute respiratory illness (SARI) arise after delivery.

The mother who is recovering from an acute illness and/or is isolated from the infant may be at risk for developing anxiety, postpartum depression and other mental health issues. She should be offered counseling and psychological support. Some women may need a psychiatrist's consultations. These interventions can be safely provided by teleconsultation by remote electronic media. After an individual (and especially a pregnant woman) recovers, they may face stigma of the disease. There should be widespread community awareness of recovery and destigmatization campaigns. This is important for pregnant women, healthcare workers and for health facilities where treatments are provided.

Further into the puerperium, the couple should follow contraceptive practices as per their informed choice.

Diet for the pregnant and postpartum woman and COVID-19 infection

Diet has been the subject of numerous controversies in the wake of the COVID-19 pandemic. It is essential to understand and we state clearly at the outset that there is no particular diet that is recommended to treat or use as part of the treatment against COVID-19 infection in a pregnant woman or in the general population. There is also no evidence that consumption of meat, chicken or eggs leads to a higher risk of acquiring COVID-19 infection.



Certain populations of pregnant women who are at risk may have some benefits from dietary modifications in terms of lowering infection risk such as women who are diabetic, obese or have other metabolic abnormalities. For other pregnant women, there is limited evidence that any dietary substances may improve immune status and reduce infection risk. Based on such limited evidence, dietary advice is generic and would include a high protein diet and vitamin and micronutrient supplementation. Natural sources of these are called superfoods in common parlance and include citrus fruits, ginger, garlic, broccoli, turmeric, oregano oil and spinach. Liver detoxification is essential to reduce toxins burden on our body. While most of the above lack robust evidence, taking these measures will not do any harm, so they should be judiciously used in consultation with the treating doctor.

Training and managing the healthcare cadre

Medical staff (doctors, nurses and auxillary staff) are the frontline workers in the battle against COVID-19 infections. In regards to their management and organization, we have to consider their training, arrangement of duties and logistics for them to commute.

Staff training: In addition to the general advice on hygiene, social distancing and mask use that has been described in earlier sections; some aspects of COVID-19 necessitate special training(14)(16). A baseline sensitization should be carried out for every staff member to make them aware of the risk of infection and dispel undue myths and rumors. The type of training and measures will depend on the type of work that a staff member performs in the hospital.

All staff members should be instructed regarding fomites. They should avoid wearing jewelry, ornaments and other accessories when going to the hospital. They should reach the hospital in street clothes. A changing area with privacy should be designated where the street clothes are removed and kept securely in a plastic bag. Staff members should change into scrubs and cover their hair and wear masks. The number of fomites (mobile phones, electronic devices, pens, measuring tapes, stethoscopes and BP apparatus) should be kept to a minimum and frequently sanitized.

When the duty shift is over, staff members should change back into street clothes in the changing room keeping the two sets of clothes apart. If facilities are available, they should shower/bath just before leaving. As soon as they reach home, shoes should be removed outside. Staff members should avoid touching any objects (including doorbells), furniture or surfaces in the home premises and head immediately for a shower/bath. Personal objects which may have been exposed at the hospital such as purses, wallets, mobile phones, keys, belts, etc. should be disinfected. If the staff member is exposed with inadequate PPE, they should self quarantine themselves.

In COVID Hospitals, before working in a ward, delivery room, or operation theatre, staff (including doctors – junior and senior) must undergo training to ensure that they know how to put on and remove personal protective equipment.

Staff duties and allocations: Staff members who are older than 60 years and have co-morbid conditions (diabetes, obesity, heart or respiratory disease) or are pregnant should preferably be given leave with pay or allotted non-contact duties during the pandemic to whatever extent it is feasible.

In Non-COVID hospitals, staff duties should be managed with the considerations that workload is reduced and travel may be difficult. Staff may be divided into teams and facilities can be made for them to stay in the hospital premises for a few days at a time especially during the lockdown period.

In COVID hospitals, if case loads increase, the staff should be divided into different teams. Each team should be limited to a maximum of 4 to 6 hours of working in an isolation ward. The teams shall work in the isolation wards (contaminated zones) at different times. Arrange treatment, examination and disinfection for each team as a group to reduce the frequency of staff moving in and out of the isolation wards. Before going off duty, staff must wash themselves and conduct necessary personal hygiene regimens to prevent possible infection of their respiratory tracts and mucosa. In non-COVID hospitals, the shifts could be extended to 6 to 8 hours.

In case of exposure, the measures outlined earlier should be followed and consideration should be given to the prophylactic use of hydroxychloroguine as per the ICMR protocall.



Staff logistics: Staff members should be given identification letters or cards and be exempted from restrictions on travel. Staff members have faced stigma in the localities where they live. There have been some incidents of violence against them by others in the area with the false fear that they would spread infection. In such situations, police protection and action is necessary. The Home Secretary has issued orders to Chief Secretaries of states, Administrators of Union Territories, Directors General of Police to ensure adequate protection of healthcare workers, medical staff and frontline workers.

Keeping up the team spirit is essential:

- Workforce safety is a high priority, active training in the proper use of barrier precautions and hygiene practices is important.
- Presence of adequate stocks of material and PPE is important to prevent insecurity of shortages.
- Psychological stress and burnout of healthcare workers is common so provide emotional support, encouragement and appreciation
- Reduce stigmatization by ill-informed members of the public
- Special provision of meals to boost morale; laundry service for used scrubs
- Provision of frequent updates and encouragements
- Health insurance has been announced in India to all frontline healthworkers upto Rs 50 Lakhs.
- Care of workers who may have medical conditions should be given appropriate care themselves.

Consent

In addition to routine consent taken at the time of admission, treatment procedures, delivery or surgery, it would be prudent to include aspects related to COVID-19 infection for the time of the pandemic. Such a specific consent is not mandatory as it is a pandemic but it may be taken for the practitioner's safety.

The medical practitioner is required to notify the public health authority about anybody with a communicable disease and disclose the identity of the person for which NO CONSENT is required. Also, the authorities have all powers of inspection of persons travelling by railway or otherwise and the segregation, in hospital, temporary accommodation or otherwise, of persons suspected by the inspecting officer of being infected with the disease and NO CONSENT is deemed necessary.

The points that should be included are the probable chances of COVID-19 infection while in hospital and its consequences and the precautions to be taken to avoid the infection. A sample consent form is given below.

COVID-19 CONSENT FORM

I/we have been explained in detail about prevailing pandemic condition of COVID-19.

I/We had also been explained about possibility of transmission of infection from me/my relative/s who has/have accompanied me/us to doctor, hospital staff, other patients, their relatives and other visitors of hospital and vice-versa from doctor, hospital staff, other patients, their relatives, other visitor of hospital to me and my relative/s who has accompanied me.

I/We also had been explained about incubation period of the infection and its importance.

If I have been asymptomatic carrier or an undiagnosed patient with COVID-19 and if I/we turn positive for COVID-19 infection afterwards or even after discharge from the hospital, I/we give assurance to inform doctor and hospital immediately, failing which may invite serious consequences including legal proceedings against me/us

I/we declare that we neither have concealed nor represented in false or fabricated manner any information I/we was/were asked to provide by doctor and /or hospital staff.

I/We had been explained everything in detail about COVID-19 infection in language we could understand.

I/We have been explained possibility of any further test, involvement of other doctors, change in treatment protocol/ transfer to other hospital/designated center for COVID-19 infection treatment any time during course of treatment



After understanding in detail the above I/we give our free and fair consent in sound state of mind without any pressure, threat, coercion or under influence of any intoxication for admission/treatment/procedure/surgery/operation to

Dr.	
UI	,

Signature/thumb impression of patient	Signature of witness
Name	Name
Age	Age
Address	Address
Date	Date
Signature of doctor	Signature of witness
Name Registration No. Age Address	Name Age Address Date
Date	

FOGSI Registry

We, at FOGSI, are trying to track every pregnancy and delivery process of COVID-19 affected women and learn about the problems faced and their on-ground solutions. The number of cases is small and we have set up a registry which will allow a meaningful analysis of the data in the coming time depending on the number of reported cases.

The format is available on the FOGSI website (https://www.fogsi.org/fogsi-national-registry-on-covid-19-infection-in-pregnancy) and we urge maternity care providers to please report cases as they occur. (72)

The importance of the Registry cannot be overemphasized. We are dealing with a pathogen about which little is known in terms of pathophysiology, maternal and fetal effects. A lot of new data is emerging and there are variations seen from region to region. It is important for each country to establish a platform for data collection to facilitate further research on the very important aspect of the interaction of coronavirus infection and pregnancy. The most important questions that we need to answer are:

- What are the signs, symptoms and presentation of COVID-19 infection in pregnancy?
- What are the outcomes of COVID-19 infection in pregnancy for both mother and infant?
- What are the characteristics of women who are hospitalised with pandemic Covid-19 infection in pregnancy and do these characteristics influence disease outcome?
- How does the treatment of pandemic Covid-19 infection in pregnancy influence outcomes for mother and infant?

Information Sources for Healthcare providers and the Public

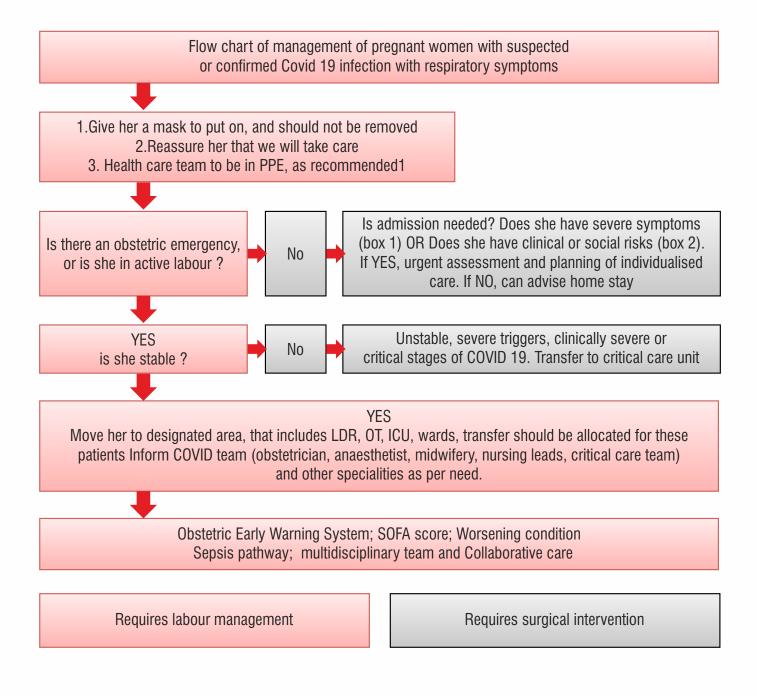
Various government agencies are updating advisories, documents and resources as the pandemic evolves. The ICMR (https://icmr.nic.in/content/covid-19) and Ministry of Health and Family Welfare (https://www.mohfw.gov.in/) are the most important sources for information for healthcare providers and the public. Various state governments, local government bodies such as municipal corporations have their own websites for locally relevant information. Please see the list below. (73) Professional bodies such as FOGSI (https://www.fogsi.org/) regularly provide advisories and guidelines regarding the pandemic relevant to specialties.

In addition to this, information about COVID-19 can be availed by calling the national helpline number 011-23978046 or 1075, by email on ncov2019@gov.in or on chat on https://wa.me/919013151515.

Aarogya Setu is a mobile application developed by the Government of India to connect essential health services and information about risks, best practices and relevant advisories pertaining to the containment of COVID-19. The app can be downloaded from Google Play Store or AppStore for Apple users.



Flow Charts





Management of Labour



Delivery suite designated for these cases with all isolation facilities with well equiped to monitor and care. This should not be a part of the running labour and delivery complex.





Minimise the number of persons in the room.

Healthcare team to be in PPE.

Birth companion to be in PPE*





- 1.Routine monitoring protocol for high risk pregnancy 2.Hourly vitals, intake output charting
 - 3.3. Fetal monitoring as per protocol
 - 4. Minimise interventions, if they can be avoided
 - 5. Entonox use only if with a single use filter 6. Water birth is contraindicated
 - 7. Cut short the second stage if she is
 - getting exhausted 8. Mode of delivery : CS is reserved for those with obstetric indications.1 CS to be considered if she
 - has severe disease**

 9. Delayed cord clamping is recommended*** by

 RCOG1
 - 10. Vertical transmission has not yet been proven

Surgical Procedure



Designated OT

Minimise the number of persons in the OT room

Healthcare team to be in PPE

Plan ahead and minimize the movement of the team in and out of the OT during the procedure





- 1. Anaesthesia : regional is preferred If general anaesthesia is needed then, ensure negative presures in the OT through the procedure and at extubation
 - 2. Antibiotics prophylaxis is recommended
 - 3. Category 1, crash cesarean section may have a delay as the team needs time to put on PPE and prepare the entire team, which may need to be explained. 1





Post Op care as per standards Isolation room principles, barrier nursing with universal standard precautions

* Birth companion is an important support sytem of these women, and hence should not be removed, but given adequate PPE to protect them. ** CS is reserved for those with obstetric indications by the RCOG guideline, but data from China shows a majority having a cesaren section. ***Delayed cord clamping is advocated as vertical transmission is not been proven, and benefits to baby are huge

Note – There is controversy about the timing of cord clamping. The ACOG recommends early (immediate) cord clamping, whereas the RCOG recommends delayed (1 minute) cord clamping.



Box 1

Conduct Illness Severity Assessment

- 1. Does she have difficulty breathing or shortness of breath?
- 2. Does she have difficulty completing a sentence without gasping for air or needing to stop to catch breath frequently when walking across the room?
- 3. Does patient cough blood?
- 4. Does she have new pain or pressure in the chest other than pain with coughing?
- 5. Is she unable to keep liquids down?
- 6. Are there features of hypotension?
- 7. Is she less responsive than normal or does she become confused when talking to her?

Box 2

Assess Clinical and Social Risks

- 1. Comorbidities (Hypertension, diabetes, asthma, HIV, chronic heart disease, chronic liver disease, chronic lung disease, chronic kidney disease, blood dyscrasia, and people on immunosuppressive medications)
- 2. Obstetric issues (eg, preterm labor)
- 3. Inability to care for self or arrange follow-up if necessary

Box 3

Clinical Classification of Covid 19 infection (China)

Mild disease: Clinical symptoms are mild and evidence of pneumonia on imaging

Moderate: Fever + respiratory symtoms + pneumonia manifestations on imaging

Severe: Respiratory rate > 30 / min, Sp02 < or = 93% at rest, pa02/Fi02 < 300 mmHg, Those with 50% lesions progression within 24 to 48 hours of imaging

Critical: Respiratory failure requiring mechanical ventilation, presence of shock, other organ failure that requires ICU care



List of Laboratories approved by ICMR is constantly updated and is available at https://covid.icmr.org.in/index.php/testing-facilities

National and State helpline numbers 1075/1800-112-545/011-23978046

State / UT	State Helpline No.
Andhra Pradesh	0866 - 2410978
Arunachal Pradesh	9436055743
Assam	6913347770
Bihar	104
Chhattisgarh	077122-35091
Goa	104
Gujrat	104
Haryana	8558893911
Himachal Pradesh	104
Jharkhand	104
Karnataka	104
Kerla	0471 - 2552056
Madhya Pradesh	0755 - 2527177
Maharashtra	020 - 26127394
Manipur	3852411668
Meghalaya	108
Mizoram	102
Nagaland	7005539653
Odhisha	9139994859

State / UT	State Helpline No.
Punjab	104
Rajasthan	0141-2225624
Sikkim	104
Tamilnadu	044-29510500
Telangana	104
Tripura	0381- 2315879
Uttarakhand	104
Utterpradesh	18001805145
West Bengal	3323412600
Andaman & Nicobar	03192-232102
Chandigargh	9779558585
Dadra & Nagar Havale	104
Daman & Diu	
Delhi	011 - 22307145
Jammu	0191 - 2520952
Ladakh	01982256462
Lakshwadeep	104
Puducheery	104



Letter from Home Secretary regarding Police Protection of Medical Staff

AJAY BHALLA, IAS



गृह सचिव Home Secretary भारत सरकार Government of India North Block, New Delhi

No. 40-10/2020-DM-I (A)

22nd April, 2020

Dear

Kindly refer to Ministry of Home Affairs advisories issued vide letters No. 11034/01/2020-IS-IV dated 24.03.2020, 04.04.2020 and 11.04.2020 requesting Chief Secretaries/ Administrators/ Directors General of Police of all the State Governments/ Union Territory Administrations to ensure adequate protection to healthcare professionals, medical staff and frontline workers by augmenting their safety and security cover. In spite of the said communications, some incidents of violence have been reported from different parts of the country against healthcare professionals/ frontline workers.

- 2. You are aware that the whole-hearted and untiring services rendered by the entire medical fraternity, while even risking their lives, has enabled the country to resist the spread of the highly infectious COVID-19 virus, that has already been declared as a pandemic by the World Health Organisation (WHO). At this time, any single incident of violence against healthcare professionals is likely to create a sense of insecurity amongst the entire healthcare community.
- I would like to draw your kind attention to the direction of the Hon'ble Supreme Court in WP (Civil) No. 10795/2020 dated 08.04.2020, as under:

"The Government of India, respective States/Union Territories and respective Police authorities are directed to provide the necessary Police security to the Doctors and medical staff in Hospitals and places where patients who have been diagnosed COVID-19 or patients suspected of COVID-19 or those quarantined are housed. Necessary Police security be also extended to Doctors and other medical staff who visit places to conduct screening of people to find out symptoms of disease."

The above direction of the Apex Court was conveyed by MHA to all States/Union Territories vide aforesaid letter dated April 11, 2020.

4. Therefore, it is the responsibility of all State Governments/UT Administrations/ District Administrations and law enforcement agencies to take all necessary measures to ensure adequate protection to healthcare professionals and frontline workers, and to prevent any incident of violence against them. The measures to be taken in this regard should be finalized in consultation with the local chapters of the Indian Medical Association (IMA), and the members of the IMA should be kept apprised of the actions taken to create a sense of security and confidence amongst the health fraternity.

Contd.p.2..



Letter from Home Secretary regarding Police Protection of Medical Staff

-2-

- 5. I would also like to draw your kind attention to Section 51 of the Disaster Management Act, 2005 which provides for strict penalties against any person who obstructs any officer or employee of the Central Government or the State Government, or a person authorised by the National Authority or State Authority or District Authority in the discharge of his functions under this Act or refuses to comply with any direction given by or on behalf of the Central Government or the State Government or the National Executive Committee or the State Executive Committee or the District Authority.
- 6. In line with the provisions of the Disaster Management Act, 2005, I urge upon all State/UT and District authorities to invoke the provisions of the Act, or any other law in force, to take strict penal action against the offenders, who obstruct Government health officials, or other health professionals and/ or related persons, who are authorized under the Disaster Management Act, 2005, in the discharge of their lawful services.
- 7. A few heinous instances of unruly behaviour by people have also been reported in some parts of the country where the family and relatives of medical professionals, suspected to have died due to COVID-19 infection were prevented from performing the last rites of the deceased. In such cases, adequate security should be provided; and, stringent action should be taken against such offenders who obstruct the performance of last rites of medical professionals or frontline healthcare workers, who, unfortunately, succumb to the infection from COVID-19 while discharging their services, or otherwise.
- 8. State Governments/ UT Administrations are also requested to appoint Nodal Officers at State/UT level and at District level, who would be available 24x7 to redress any safety issue on the functioning of medical professionals. They should also take immediate and strict action in case any incident of violence takes place.
- 9. Details of preventive measures taken and appointment of Nodal Officers should be widely publicized amongst the medical fraternity, including the local chapters of the IMA, as well as to the public at large, to ensure compliance at ground level. Further, it is requested that details of action taken by State Governments/UT Administrations should be informed to Ministry of Home Affairs and Ministry of Health and Family Welfare.

With regards,

Yours sincerely

Sd/-

(Ajay Bhalla)

To

- 1. The Chief Secretaries of all States
- 2. Administrators of all Union Territories.
- Directors General of Police of all States/UTs
- 4. Commissioner of Police, Delhi

Copy for information to:

The Secretary, Ministry of Health & Family Welfare

(Ajay Bhalla)



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