

Clinical Practice Guideline

Perinatal-Neonatal management of COVID-19 infection

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Federation of Obstetric & Gynecological Societies of India
National Neonatology Forum, India
Indian Academy of Pediatrics

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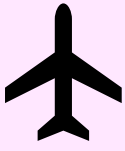
Annexure: [Evidence profiles](#)

Disclaimer

The guidelines in this document are based on limited evidence as available now. As new evidence accumulates, some of the recommendations may change. Users should use these guidelines in accordance with the latest government regulations and ICMR advisories.

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Perinatal-Neonatal Management of COVID-19 Infection



Pregnant women with a history of overseas travel or with exposure to a confirmed/suspected case of COVID-19 should be isolated by using the guidelines for non-pregnant adults.

In the absence of community spread, isolation at the designated facility and in the presence of community spread, isolation by home quarantine may be preferred.



The criteria for offering a laboratory test are the same for pregnant women and the non-pregnant population.

Pregnant women with active COVID-19 infection should be managed with supportive and specific therapy as recommended for non-pregnant adults.

Currently recommended management includes: - oxygen therapy/respiratory support, fluid therapy, antibiotics, shock management, and specific drugs in severe cases.

Options

- Hydroxychloroquine 200 mg thrice a day with meals x 10 days OR 400 mg twice a day on day 1 and 400 mg once a day x 4 days ± Azithromycin 500 mg twice a day x 7 days

Weak recommendation; Low quality evidence

- Lopinavir/ Ritonavir if any of the following criteria are met : hypoxia, hypotension, new onset organ dysfunction (one or more of Increase in creatinine by 50% from baseline, GFR reduction by >25% from baseline or urine output of <0.5 ml/kg for 6 hours), Reduction of GCS by 2 or more, or Any other organ dysfunction

➤ High Risk Groups:

- Age > 60 years
- Diabetes Mellitus, Renal Failure, Chronic Lung disease
- Immunocompromised persons

Dosage:

- Lopinavir/ Ritonavir (200 mg/ 50 mg) – 2 tablets twice daily Or Lopinavir 400mg/Ritonavir 100 mg – 5mL suspension twice daily
- Duration: 14 days or for 7 days after becoming asymptomatic

The choice of specific antiviral therapy is likely to change with rapidly emerging evidence and updated national guidance should be consulted.



- When providing healthcare to woman in labor with confirmed or suspected COVID-19 infection, follow standard universal precautions to prevent contact with body fluids. In addition, use personal protective equipment (PPE) to prevent acquiring infection through respiratory droplets. The PPE should include masks such as the N95 masks and face protection by a face shield or at least goggles.**

- Reception and triage should be in the same room as to be used for admission in labor and delivery. Ideally, this should be a room with negative pressure (If not available, exhaust fans can be installed).
- Keep the room free from any unnecessary items which could act as infected fomites later.
- Restrict entry of visitors and staff into the room to only essentials.
- There should be facilities for health care providers to remove and safely discard PPE at the exit of the room in which the patient is being cared for.



- Separate delivery room and operation theaters 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.



- Mode of delivery in a pregnant woman infected with COVID-19 should be guided by her obstetric assessment and her physiological stability (cardiorespiratory status and oxygenation). **COVID-19 infection itself is not an indication for induction of labor or operative delivery.**

- Continuous electronic fetal monitoring should be done during labor. If facilities for the continuous electronic fetal monitoring are not available, manual monitoring by frequent auscultation of fetal heart rate should be done during the labor as indicated for a high-risk delivery.
- Adequate equipment and trained healthcare providers should be available for intrapartum monitoring and obstetric interventions as indicated in the separate childbirth facilities for infected pregnant women.
- Oxygenation status of women during labor should be monitored by a pulse oximeter and oxygen therapy should be titrated to maintain oxygen saturation of more than 94%.

Recommendations for neonatal resuscitation:

- **If possible, resuscitation of neonate can be done in a physically separate adjacent room earmarked for this purpose. If not feasible, the resuscitation warmer should be physically separated from the mother's delivery area by a distance of at least 2 meters.**
- **Minimum number of personnel should attend** (one in low-risk cases and two in high-risk cases where extensive resuscitation may be anticipated) **and wear a full set of personal protective equipment including N95 mask.**
- **Mother should perform hand hygiene and wear triple layer mask.**
- The umbilical cord should be clamped promptly and skin-to-skin contact avoided.
- Delivery team member should bring over the neonate to the resuscitation area for assessment by the neonatal team.
- **Follow standard NRP guidelines. If positive-pressure ventilation is needed, self-inflating bag and mask may be preferred over T-piece resuscitator**



- **Stable neonates exposed to COVID-19 infection from mothers or other relatives should be roomed-in with their mothers and be exclusively breastfed.**
- **If rooming-in is not possible because of the sickness in the neonate or the mother, the neonate should be fed expressed breast milk of the mother by a nurse or family member who has not been in contact with the mother or other suspected/proven case**



Scenario 1: Resources for isolation of normal, suspected to be infected and infected mothers not available OR healthcare facilities are overwhelmed because of large number of COVID-19 infections OR evidence of community spread is present

Healthy neonate may be roomed-in with mother. The mother-baby dyad must be isolated from other suspected and infected cases and healthy uninfected mothers and neonates.

1. **Direct breastfeeding can be given. Mother should wash hands frequently including before breastfeeding and wear mask. If not feasible due to maternal or neonatal condition, expressed breast milk can be fed.**
2. If safe, early discharge to home followed by telephonic follow-up or home visit by a designated nurse may be considered.



Scenario 2: If resources for isolation of normal, suspected to be infected and infected mothers can be made available AND there is no evidence of community spread

1. **After immediate cord clamping, the neonate should be isolated from the mother.**
2. **During isolation, healthy neonates should preferably be cared for by family member not in contact with mother or other suspected/proven case.** Such care can be provided in usual postnatal wards taking care that persons with suspected/proven infection are not allowed in the area. If safe, while mother is in isolation early discharge to home with healthy family member followed by telephonic follow-up or home visit by a designated nurse may be considered.
3. **Mother can express milk after washing hands and breasts and while wearing mask. This expressed milk can be fed to her own baby without pasteurization.**
4. Mother and baby can be roomed-in once mother has been tested and declared to be clear of infection.

To facilitate early rooming-in, viral testing in mothers with suspected infection should be conducted and reported on priority.

- **If symptomatic, neonates born to a mother with suspected or proven COVID-19 infection should be managed in separate isolation facility.**
- Suspected COVID-19 cases and confirmed COVID-19 cases should ideally be managed in separate isolations.
- If not feasible to have separate facilities and the neonates with suspected and confirmed infection are in a single isolation facility, they should be segregated by leaving enough space between the two cohorts.
- **Negative air borne isolation rooms are preferred for patients requiring aerosolization procedures (respiratory support, suction, nebulization). If not available, negative pressure could also be created by 2-4 exhaust fans driving air out of the room.**
- Isolation rooms should have adequate ventilation. If room is air-conditioned, ensure 12 air changes/ hour and filtering of exhaust air. These areas should not be a part of the central air-conditioning. The doctors, nursing and other support staff working in these isolation rooms should be separate from the ones who are working in regular NICU/SNCU. The staff should be provided with adequate supplies of PPE. The staff also needs to be trained for safe use and disposal of PPE.



- **Respiratory support for neonates with suspected/proven COVID-19 infection is guided by principles of lung protective strategy including use of non-invasive ventilation.**
- NIPPV and High Flow Nasal cannulas should preferably be avoided.
- Healthcare providers should practice contact and droplet isolation and wear N95 mask while providing care in the area where neonates with suspected/proven COVID-19 infection are being provided respiratory support.
- The area providing respiratory support should be a negative air pressure area.



- **Antivirals or chloroquine/hydroxychloroquine – are NOT recommended in symptomatic neonates with confirmed or suspected COVID-19.**
- **Use of adjunctive therapy such as systemic corticosteroids and intravenous gamma globulin is NOT recommended in symptomatic neonates with confirmed or suspected COVID-19**



Disinfection of Surfaces in the childbirth/neonatal care areas for patients with suspected or confirmed Coronavirus infection are not different from those for usual Labor room/OT/NICU/SNCU areas and include the following:



- Wear personal protective equipment before disinfecting.
- If equipment or surface is visibly soiled first clean with soap and water solution or soaked cloth as appropriate before applying the disinfectant.
- 0.5% sodium hypochlorite (equivalent to 5000 ppm) can be used to disinfect large surfaces like floors and walls at least once per shift and for cleaning after a patient is transferred out of the area.
- 70% ethyl alcohol can be used to disinfect small areas between uses, such as reusable dedicated equipment.
- Hydrogen peroxide (dilute 100 ml of H₂O₂ 10% v/v solution with 900 ml of distilled water) can be used for surface cleaning of incubators, open care systems, infusion pumps, weighing scales, standby equipment-ventilators, monitors, phototherapy units, and shelves. Use H₂O₂ only when equipment is not being used for the patient. Contact period of 1 hour is needed for efficacy of H₂O₂.

Minimal composition of a set of PPE for the management of suspected or confirmed cases of COVID-19



Protection	Suggested PPE
Respiratory protections	Triple layered surgical mask N95 facemasks are needed only when performing an aerosol-generating procedure or in an area where neonates are being provided respiratory support by CPAP device/ ventilator.
Eye protection	Goggles or face shield
Body protection	Long-sleeved water-resistant gown
Hand protection	Gloves



- **Follow routine biomedical waste disposal handling, segregation, transport and final disposal guidelines as prescribed by the Government of India.**



- **Parents and families of the COVID-19 exposed, suspected and infected mothers and neonates should receive informed healthcare. They should be aware of and understand the isolation, monitoring, diagnostic and treatment plans of the mothers/babies and be given a periodic update about the health condition.**
- Visitors to both routine and COVID-19 specific childbirth/neonatal care areas should be screened for symptoms of COVID-19 infection.
- Persons (including parents) with suspected or confirmed COVID-19 infection should not be allowed entry in the childbirth/neonatal care area where care to parturient women/sick neonates is being provided.
- For neonates roomed in with mother with suspect/confirmed COVID-19 infection, one healthy family member following contact and droplet precautions should be allowed to stay with her to assist in baby care activities.



- **Stable neonates exposed to COVID19 and being roomed-in with their mothers may be discharged together at time of mothers' discharge.**
- **Stable neonates in whom rooming-in is not possible because of the sickness in the mother and are being cared by a trained family member may be discharged from the facility by 24-48 hours of age.**



- Healthcare professional working in any childbirth or neonatal area should report to their supervisor if they have respiratory or other symptoms suggestive of COVID-19 infection. Such healthcare professional should not be put on clinical duty and should be replaced by a healthy healthcare professional to maintain appropriate patient-provider ratio.
- **Healthcare professional directly involved in the care of patients with suspect/proven COVID-19 infection may consider taking hydroxychloroquine (HCQ) prophylaxis as advised by Government of India, on medical prescription. However, this advisory is based on low-quality evidence and may change in near future.**



- **Follow routine immunization policy in healthy neonates born to mothers with suspected/proven COVID-19 infection.**
- **In neonates with suspected/proven infection, vaccination should be completed before discharge from the hospital as per existing policy.**

Developed jointly by



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Last updated: 26-03-2020

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Importance

During the currently rapidly evolving pandemic of COVID19, guidelines, recommendations and advisories are being issued almost every day by the health authorities. All preparations at various levels are focused on adults and to some extent children. Pregnant women and their newborn infants so far have not received attention. Pregnant women with suspected or confirmed COVID19 and their newborn infants form a special vulnerable group which needs immediate attention.

Unlike other elective medical and surgical problems for which care can be deferred in view of the pandemic situation, pregnancies and deliveries will continue. Newborn infants born to suspected or confirmed COVID19 women pose unique challenges and care of these mother-baby dyads requires special resources. The neonate has to be protected from transmission during delivery and in the post-natal period from mother, possibly exposed family members as well as health care providers.

This evidence based rapid clinical practice guideline jointly from Federation of Obstetric and Gynecologic Societies of India (FOGSI), National neonatology Forum India (NNF) and Indian Academy of Pediatrics (IAP) provides guidance to clinicians and policy makers for the management of pregnant women exposed to COVID19 and their neonates.

As the situation is rapidly evolving and new evidence is emerging virtually every day, the users must check for latest updates from authentic sources like ICMR, Ministry of Health and family welfare (MOHFW), World health Organization (WHO) and Centre of Disease Control (CDC).

Background

Coronaviruses are RNA viruses with glycoprotein spikes that give them a crown like appearance. Four species have been in circulation for a long time and cause mild respiratory disease. They have a lot of genetic diversity and have jumped the species barrier leading to severe respiratory disease (the SARS virus in 2002-2003 and the MERS virus in 2012-2013). In December 2019, a novel coronavirus emerged in Wuhan City of Hubei Province; this was later termed as SARS-CoV-2 or COVID-19. This virus has subsequently spread throughout the world causing more than 300000 cases and 12000 deaths (till 25/3/2020). More than 500 cases and 10 deaths have been reported from India.

The disease spreads by droplets generated by infected people during sneezing and coughing. These are large droplets that travel for 1-2 m and settle on surfaces on which they remain alive for hours or days. Infected person can also spread the infection even before the onset of symptoms. Infection is acquired by either inhalation of infected droplets or touching surfaces/fomites contaminated with the infected droplets and then touching the eyes, nose and mouth. Incubation period varies from 2-14 days with a median of 5 days. The average number of people infected by one infected individual is between 2-3.

The clinical symptoms are variable ranging from asymptomatic state to acute respiratory distress syndrome and multi organ dysfunction. In adults, common symptoms include fever, cough, breathlessness, fatigue, myalgia, headache and sore throat while vomiting, diarrhea, sneezing and conjunctivitis are uncommon. Current evidence suggests that 80-85% of cases are mild, 10-15 % are severe with lower respiratory tract involvement and 5% are critical needing ICU care. The fatality rate is reportedly between 2-3% but can vary from 0.5-10% depending on the number tested, the percentage of elderly people in the population and

availability of critical care support in the hospitals. The severity and fatality are higher in the elderly especially above the age of 60 (among those aged more than 80 years, fatality rate was 15%) and those with comorbidities like heart disease, hypertension, diabetes etc.

There is paucity of data on COVID-19 in pregnancy and neonates. Available data suggests that in general the outcome among pregnancy women and neonates is good. In one case series only, neonatal outcomes were adverse; whether these were due to COVID-19 or other neonatal problems is uncertain. There is no clear evidence of intrauterine transmission till date, but it is based on a very small number of cases studied.

Maternal-fetal transmission and neonatal cases

Schwartz et al described a series of 38 Chinese women in labor and delivery who tested positive for COVID-19. All women were in the 3rd trimester of pregnancy, and SARS-CoV-2 positivity was confirmed by rt-PCR. These pregnancies resulted in 39 infants (one set of twins); detailed clinical information, obstetrical outcomes and SARS-CoV-2 status were available for 30 neonates. Among these 30 neonates, there were no cases of rt-PCR-confirmed SARS-CoV-2 infection, despite the existence of perinatal complications in some of the infants. The virus was not identified in the amniotic fluid, placenta, breast milk of 6 mothers or in the nasal secretions of their neonates tested so far.

Early in the epidemic, two cases of neonatal SARS-CoV-19 infection were reported. One was an infant diagnosed at 17 days of life having a history of close contact with two confirmed cases of SARS-CoV-2 infection (mother and nanny), and the other was a neonate who was found to be infected 36 hours following delivery. In both infants there was no direct evidence for vertical transmission, and because viral testing was delayed, a postpartum neonatal infection acquired through an infected contact could not be eliminated.

Neonatal exposure: As per Chinese consensus guidelines, neonates are said to be exposed to COVID-19 if they are born to the mothers with a history of COVID-19 infection diagnosed 14 days before delivery or 28 days after delivery, or if the neonate is directly exposed to close contacts with COVID-19 infection (including family members, caregivers, medical staff, and visitors). They should be managed as patients under investigation (PUI) irrespective of whether they are symptomatic or not.

Implications of available literature

Though in-utero or vertical transmission has not been demonstrated so far, the probability cannot be excluded currently. Postnatal transmission from infected mother or care givers to the neonate is definitely possible. A delay in testing can make it difficult to differentiate a mother to fetal transmission (or at birth) from postnatal (contact / droplet) transmission. Lastly, fetal effect of maternal infection during first and second trimester of pregnancy is not known.

Methods used to develop the guideline

The GRADE approach recommended by WHO was used to develop the guideline. A Guideline Development Group (GDG) comprising of obstetricians, neonatologists and pediatricians was constituted. The GDG drafted a list of questions which are likely to be faced by clinicians involved in obstetric and neonatal care. An e-survey was carried out amongst a wider group of clinicians to invite more questions and prioritize. Literature search was carried out in Pubmed using search terms like ("coronavirus"[MeSH Terms] OR "coronavirus"[All Fields])) AND 2019/12[PDAT] : 2030[PDAT]) OR 2019-nCoV[All Fields] OR 2019nCoV[All Fields] OR COVID-19[All Fields] OR SARS-CoV-2[All Fields]. In addition, websites of all relevant international and national organizations were searched. Guidelines, systematic reviews, trials, reviews and other

descriptive reports were reviewed. For PICO questions, the evidence was extracted into evidence profiles., The context, resources required, values and preferences were considered for developing the recommendations.

Clinical Practice Questions for obstetricians and neonatologists

Following questions were short-listed:

Pregnant women with travel history, clinical suspicion or confirmed case

1. What should be the care of pregnant women with history of travel to designated countries or with exposure to a confirmed/suspected case of COVID-19?
2. Which pregnant women need testing for COVID-19?
3. Where in a healthcare facility should a pregnant woman with suspected or active COVID-19 infection deliver?
4. What infection control measures should be taken in triage, labor and delivery of a pregnant woman with active or suspected COVID-19 infection?
5. What should be the method of labor induction and mode of delivery in pregnant women with active or suspected COVID-19 infection?
6. What should be the specific care of pregnant women with active COVID-19 infection?

Neonatal Care

7. What precautions should the neonatal resuscitation team take when attending the delivery of a woman with suspected or confirmed COVID-19 infection?
8. What should be the feeding policy for stable neonates born to COVID-19 mothers?
9. Is it necessary to separate the mother and baby if mother is suspected or confirmed to be COVID-19 positive?
10. Should symptomatic neonates needing intensive or special care be nursed in common room NICU/SNCU or isolation facility?
11. What are the special precautions to be taken while providing respiratory support to neonates exposed to COVID-19 infection?
12. In symptomatic neonates, what is the role of specific treatment in case of perinatal exposure and in case of confirmed infection with COVID-19?

Prevention and Infection Control

13. What should be the specific disinfection practices in NICU /SNCU?
14. When should Personal protective equipment (donning and doffing) be used?
15. What should be the biomedical waste disposal protocol while managing a suspected or confirmed case of COVID-19?

Diagnosis

16. What should be the testing protocol for neonates born to mothers with suspected or confirmed COVID-19?

General questions

17. What should be the visitation policy and preventive measures for visitors during the COVID-19 outbreak?
18. What should be the discharge policy of neonates born to suspected or confirmed COVID-19 mothers?
19. What should be the occupational health policy specific to COVID-19 pandemic?
20. What should be the immunization policy for neonates born to suspected or COVID-19 positive women?

Practice question 1: What should be the care of pregnant women with history of overseas travel or with exposure to a confirmed/suspected case of COVID19?*PICO question*

Among asymptomatic pregnant woman with history of contact with Covid-19 infected person or history of overseas travel, which is better: isolation/quarantine as recommended for non-pregnant individuals versus specific isolation/quarantine practice (hospitalization/special designated facility/longer or shorter isolation)?

Summary of Evidence

Of the 1794 articles on the Coronavirus infection, 36 addressed the issue in pregnant women. No clinical trials have compared specific care including isolation strategies 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 Coronavirus infection. Due to absence of comparative group it is not possible to estimate the effect of Covid-19 infection in pregnancy. However, almost all pregnant women had mild infection. One (1.4%) of 73 died due to severe disease.

Values and preferences

No evidence is available about preference of pregnant women, families, healthcare provider or policymakers about isolation of exposed women during the postnatal period. Due to non-severe nature of disease, it is unlikely that women will prefer to remain away from home during the isolation

Resources required

Significant resources including provision of appropriate nutrition and antenatal check-ups will be required if exposed pregnant women are isolated in special facilities.

RECOMMENDATION 1

Pregnant women with a history of overseas travel or with exposure to a confirmed/suspected case of COVID-19 should be isolated by using the guidelines for non-pregnant adults.

In the absence of community spread isolation at the designated facility and in the presence of community spread, isolation by home quarantine may be preferred.

Practice Question 2: Which pregnant women need testing for COVID-19?

The criteria for offering a laboratory test are the same for pregnant women and the non-pregnant population. Currently, as per the guidance given by the Indian Council for Medical Research (ICMR) pregnant women should be tested in the following circumstances:^a

1. A pregnant woman who has acute respiratory illness with one of the following criteria:
 - a history of travel abroad in the last 14 days (6 March 2020 onwards). In addition to testing, these individuals (with or without symptoms) and their household contacts should home quarantine for 14 days.
 - is a close contact of a laboratory proven positive patient or
 - she is a healthcare worker herself or
 - hospitalized with features of severe acute respiratory illness.

As per the World Health Organization (WHO), features which suggest acute respiratory illness are fever and a respiratory symptom such as cough, shortness of breath, congestion or sore throat. Immunocompromised and elderly pregnant women may present with atypical features such as fatigue, malaise, body ache and/or gastrointestinal symptoms.^b

2. A pregnant woman who is presently asymptomatic should be tested between 5 and 14 days of coming into direct and high-risk contact of an individual who has been tested positive for the infection.

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.^c

RECOMMENDATION 2

- **The criteria for offering a laboratory test are the same for pregnant women and the non-pregnant population.**

^a https://icmr.nic.in/sites/default/files/upload_documents/2020-03-20_covid19_test_v3.pdf

^b [https://www.who.int/publications-detail/global-surveillance-for-human-infection-with-novel-coronavirus-\(2019-ncov\)](https://www.who.int/publications-detail/global-surveillance-for-human-infection-with-novel-coronavirus-(2019-ncov))

^c <https://www.mohfw.gov.in/pdf/GuidelinesonClinicalManagementofCOVID1912020.pdf>

Practice Question 3: Where in a healthcare facility should a pregnant woman with suspected or active COVID-19 infection deliver?

Pregnant women with suspected/proven infection need to be cared for in separate areas like other adults with suspected/proven infection.

RECOMMENDATION 3

- **Separate delivery room and operation theaters are required for management of suspected or confirmed Covid19 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.

Practice Question 4: What infection control measures should be taken in triage, labor and delivery of a pregnant woman with active or suspected COVID-19 infection?

The term “universal precautions” 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. In settings where the woman in labor is confirmed or suspected to have COVID-19 infection, 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 and face protection by a face shield or at least goggles.^d

In India, as the numbers start rising and women with pregnancy and labor start emerging with COVID-19 infection, infrastructure preparedness will have to come into play. An elaborate advisory to this effect has been issued by the Ministry of Health and Family Welfare on hospital and institutional preparedness^e and for the conduct of mock drills and standard operating procedures.^f

For a woman who is confirmed or suspected to have COVID-19 infection, given recommendations should be followed to minimize the risk to health workers.^g

^d <https://www.cdc.gov/hai/pdfs/ppe/ppeslides6-29-04.pdf>

^e <https://www.mohfw.gov.in/pdf/AdvisoryforHospitalsandMedicalInstitutions.pdf>

^f <https://www.mohfw.gov.in/pdf/MockDrill.pdf>

^g <https://www.rcog.org.uk/globalassets/documents/guidelines/coronavirus-covid-19-infection-in-pregnancy-v3-20-03-18.pdf>

RECOMMENDATION 4

- When providing healthcare to woman in labor with confirmed or suspected COVID-19 infection, follow standard universal precautions to prevent contact with body fluids. In addition, use personal protective equipment (PPE) to prevent acquiring infection through respiratory droplets. The **PPE should include masks such as the N95 masks and face protection** by a face shield or at least goggles.
- The woman should inform the facility in advance of her arrival if possible, in order to allow time for preparation.
- Reception and triage should be in the same room as to be used for admission in labor and delivery. Ideally, this should be a room with negative pressure (If not available, exhaust fans can be installed).
- 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 and non-essential staff into the room.
- There should be facilities for health care providers to remove and safely discard PPE at the exit of the room in which the patient is being cared for.

Practice question 5: What should be the method of labor induction and mode of delivery in pregnant women with active or suspected COVID-19 infection?*PICO question*

Among pregnant woman with active COVID-19 infection what is labor induction method and mode of delivery as recommended for non-infected pregnant women versus specific intervention (e.g. early induction or operative delivery)?

Summary of Evidence

Literature search revealed 1794 articles on Coronavirus infection, 36 addressed the issue in pregnant women. In addition, web resources available on websites of different professional organizations were accessed. No clinical trials have compared specific care including isolation strategies 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 Coronavirus infection. Majority of women in these studies were delivered by C-section, however, in the only case-control study, all controls also delivered by C-section. Incidence of C-section is high in China from where all studies have originated, and it is not possible to infer that Covid-19 infection increases the probability of C-section. Literature indicates possibility of higher incidence of fetal distress in infected pregnant women. However, due to small sample size and lack of comparison group, no definite inference can be made. As pneumonia has been reported in the case reports, pregnant women with infection need to be monitored for respiratory compromise during childbirth.

Values and preferences

No evidence is available about preference of pregnant women, families, healthcare provider or policymakers about mode of delivery in the infected pregnant women.

Resources required

Pregnant women with suspected/proven infection need to be cared for in separate areas like other adults with suspected/proven infection. Apart from the resources required to care for such patients, adequate resources including space, equipment, supplies and trained healthcare providers are required for delivery, caesarean section and neonatal resuscitation.

RECOMMENDATION 5

- Mode of delivery in a pregnant woman infected with COVID-19 should be guided by her obstetric assessment and her physiological stability (cardiorespiratory status and oxygenation). **COVID-19 infection itself is not an indication for induction of labour or operative delivery.**
- Continuous electronic fetal monitoring should be done during labor. If facilities for the continuous electronic fetal monitoring are not available, manual monitoring by frequent auscultation of fetal heart rate should be done during the labour as indicated for a high-risk delivery.
- Adequate equipment and trained healthcare providers should be available for intrapartum monitoring and obstetric interventions as indicated in the separate childbirth facilities for infected pregnant women.
- Oxygenation status of women during labor should be monitored by a pulse oximeter and oxygen therapy should be titrated to maintain oxygen saturation of more than 94%.

Practice question 6: What should be the specific care of pregnant women with active COVID-19 infection?*PICO question*

Among pregnant woman with active COVID-19 infection, treatment as recommended for non-pregnant individuals versus specific antiviral/supportive therapy?

Summary of Evidence

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 in a dose of 600 mg (200 mg thrice a day with meals) and Azithromycin (500 mg once a day) for 10 days has been shown to give virological cure on day 6 of treatment in 100% of treated patients in one study. The study included 20 treated patients with upper and lower respiratory symptoms. In this study, 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. 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 of care alone.

Other agents such as Remdesivir are being evaluated in a randomized trial.

Clinicians should follow the latest updated national guidelines released by ICMR/MoHFW and FOGSI. The currently recommended treatment strategy is described in recommendation box below.

Values and preferences

No evidence is available about preference of pregnant women, families, healthcare provider or policymakers about choice of therapy during active infection.

Resources required

Availability of specific antivirals in India is not easy. On the other hand, hydroxychloroquine and azithromycin are easily available and cheap. In absence of specific literature, resources needed for management of pregnant women with active Covid-19 infection can be assumed to similar to those required for other adults. However, arrangements (place, equipment, staff,

and supplies) for delivery, neonatal resuscitation and neonatal care would have to be created in the same area.

RECOMMENDATION 6

Pregnant women with active COVID-19 infection should be managed with supportive and specific therapy as recommended for non-pregnant adults.

Currently recommended management includes: - oxygen therapy/respiratory support, fluid therapy, antibiotics, shock management, and specific drugs in severe cases.

Options:

- Hydroxychloroquine 200 mg thrice a day with meals x 10 days OR 400 mg twice a day on day 1 and 400 mg once a day x 4 days
± Azithromycin 500 mg twice a day x 7 days

Weak recommendation; Low quality evidence

- Lopinavir/ Ritonavir if any of the following criteria are met:
 - 1) hypoxia,
 - 2) hypotension,
 - 3) new onset organ dysfunction (one or more)
 - a) Increase in creatinine by 50% from baseline, GFR reduction by >25% from baseline or urine output of <0.5 ml/kg for 6 hours.
 - b) Reduction of GCS by 2 or more
 - c) Any other organ dysfunction
 - 4) High Risk Groups:
 - a) Age > 60 years
 - b) Diabetes Mellitus, Renal Failure, Chronic Lung disease
 - c) Immunocompromised persons

Dosage:

- Lopinavir/ Ritonavir (200 mg/ 50 mg) – 2 tablets twice daily
- For patients unable to take medications by mouth: Lopinavir 400mg/Ritonavir 100 mg – 5mL suspension twice daily
- Duration: 14 days or for 7 days after becoming asymptomatic

The choice of specific antiviral therapy is likely to change with rapidly emerging evidence and updated national guidance should be consulted.

Updated guidance can be accessed at the website of Ministry of Health and Family Welfare: <https://www.mohfw.gov.in/>

Practice Question 7: What precautions should the neonatal resuscitation team take when attending delivery of a woman with suspected or confirmed COVID-19 infection?

Rationale: Around 10% of neonates are anticipated to require resuscitation including oro-nasal suction or positive pressure ventilation and a few may require intubation. These are potentially aerosol generating procedures. Hence, N95 masks should be worn along with PPE.

There is insufficient evidence regarding whether delayed cord clamping increases the risk of infection to the newborn via direct contact. The Royal College of Obstetricians and Gynecologists of UK (RCOG)³ and Society of Obstetricians and Gynecologists of Canada⁴ recommend delayed cord clamping unless there are other contraindications while American College of Obstetrics and Gynecologists (ACOG)² and Chinese guidelines⁵ recommend immediate cord clamping.

In the radiant warmer designated for resuscitation, the neonatal team shall perform assessment and proceed with initial steps as per NNF/ AAP Neonatal resuscitation program (NRP) guidelines 7th edition.

The use of non-invasive respiratory support like CPAP using T-Piece device in an exposed neonate can result in generation of aerosols. Also, disinfection of T-Piece may be an issue after use. Hence, if neonates have respiratory distress, positive pressure ventilation can be provided using a bag and mask device. Indication for intubation is as per NRP.

Neonates requiring intensive care should be transferred to the designated isolation ward or single room with intensive care facilities. The neonatal resuscitation team should doff the PPE after exiting the delivery area, dispose them as per disposal policy and perform hand hygiene.

Transfer can be performed by another healthcare worker wearing appropriate PPE. If the neonate is intubated or on nasal prong oxygen (CPAP using T-Piece device is not recommended during transfers), N95 mask is recommended.

Resuscitation equipment: A new set should be used for each delivery. Disposables like endotracheal tubes, suction catheter, orogastric tube, tapes for fixing ET tube, umbilical catheter, syringes placed near the resuscitation area should be discarded even if unused. Reusable equipment should be thoroughly disinfected as per hospital protocol. Wear protective clothing when dealing with contaminated equipment.

RECOMMENDATION 7

Recommendations for neonatal resuscitation:

- **If possible, resuscitation of neonate can be done in a physically separate adjacent room earmarked for this purpose. If not feasible, the resuscitation warmer should be physically separated from the mother's delivery area by a distance of at least 2 meters.** A curtain can be used between the two areas to minimize opportunities for close contact.
- **Minimum number of personnel should attend** (one person in low risk cases and two in high risk cases where extensive resuscitation may be anticipated) **and wear a full set of personal protective equipment including N95 mask.**
- **Mother should perform hand hygiene and wear triple layer mask.**
- The umbilical cord should be clamped promptly and skin to skin contact avoided.
- Delivery team member should bring over the neonate to the resuscitation area for assessment by the neonatal team.
- **Neonatal resuscitation should follow standard guidelines. If positive-pressure ventilation is needed, self-inflating bag and mask may be preferred over T-piece resuscitator.**

Practice question 8: What should be the feeding policy for stable neonates born to COVID-19 mothers ?

PICO question

For well neonates exposed to COVID19 infection from mothers/other relatives/healthcare providers and requiring *routine essential newborn care*, does feeding expressed breastmilk, donor milk, or formula milk reduce the risk of transmission as well as the incidence of critical outcomes such as neonatal mortality when compared to direct breastfeeding ?

Summary of evidence

Literature was searched for articles on the effect of COVID19/SARS-CoV-2 infection in neonates or pregnant women or breast feeding. The group also accessed the web resources available on websites of different professional organizations.

Of the 1629 articles retrieved, 34 addressed the issue of perinatal and neonatal management of COVID-19. No clinical trials have compared the effect of direct breastfeeding with that of feeding expressed breastmilk (EBM), human donor milk, or formula milk in neonates exposed to SARS-CoV-2 infection.

A total of eight studies (7 case series/reports and one retrospective cohort study) reported outcomes in 42 women with pregnancy and Coronavirus infection. Almost all (41 of 42) delivered by C-section and the neonates were isolated from their infected mothers. There was no evidence of vertical transmission of the infection from mother to fetus/neonate. The virus was not detected in expressed breastmilk either. Out of the eight studies, four did not provide any details of the feeding policy; breastfeeding was not allowed in the remaining four studies.

The group also searched the literature for existing guidelines on postnatal care, including breastfeeding in neonates born to mothers with suspected/confirmed Coronavirus infection. Recommendations vary across different guidelines.

Values and preferences

No evidence is available on the preferences of mothers, families, healthcare providers, or policymakers regarding the mode of feeding in asymptomatic exposed neonates in the postnatal period. The preferences and values are likely to be varied given that (a) the SARS-CoV-2 virus has not been detected in the breastmilk in the limited studies so far and (b) the disease is unlikely to be severe in neonates and children and (3) the potential benefits of direct breastfeeding in reducing the neonatal and infant mortality, particularly in low- and middle-income country settings. The variation is also evident in the existing guidelines, which prescribe approach varying from complete isolation to continuing rooming-in, skin-to-skin contact, and breastfeeding.

Resources required

Significant resources are required if neonates are to be separated from their mothers with suspected/confirmed infection. At least three types of areas will need to be maintained with all needed equipment, disposable supplies, medicines, and trained healthcare providers in each area to make isolation possible – 1) for mothers and neonates without suspected/confirmed infection; 2) mothers and neonates with suspected infection (each mother and each neonate in a different air isolation unit) and 3) mothers with confirmed infection (each mother and each neonate in a different air isolation unit). Besides, arrangements need to be made for either safe expression of breastmilk or safe formula milk preparation and administration. It will entail a significant burden on the available resources.

On the other hand, if neonates are roomed-in with the mothers and are allowed to breastfeed directly, a few may get infected. Based on the limited evidence available, it seems that the disease is unlikely to be severe in the neonates. Given the high incidence of asphyxia, prematurity, and sepsis in India, a large proportion of neonates may be symptomatic otherwise and not necessarily due to COVID-19.

RECOMMENDATION 8

- A. Stable neonates exposed to COVID-19 infection from mothers or other relatives should be roomed-in with their mothers and be exclusively breastfed.**
- B. If rooming-in is not possible because of the sickness in the neonate or the mother, the neonate should be fed expressed breast milk of the mother by a nurse or family member who has not been in contact with the mother or other suspected/proven case, provided the neonate can tolerate enteral feeding.**

Weak recommendation, based on consensus among experts in the absence of evidence for any beneficial effect or harm in the risk of COVID-19 following direct breastfeeding or expressed breastmilk feeding

Conditions to be met

- *Mothers should perform hand hygiene frequently, including before and after breastfeeding and touching the baby.*
- *Mothers should practice respiratory hygiene and wear a mask while breastfeeding and providing other care to the baby; they should routinely clean and disinfect the surfaces.*
- *Mothers can express milk after washing hands and breasts and while wearing a mask. If possible, a dedicated breast pump should be provided. If not, it should be decontaminated as per protocol. This expressed milk can be fed to the baby without pasteurization. The collection and transport of EBM to the baby should be done very carefully to avoid contamination.*

Practice question 9: Is it necessary to separate the mother and baby if mother is suspected or confirmed to be COVID-19 positive?*PICO questions*

- Among neonates born to mothers with suspected or confirmed COVID-19 infection, should routine postnatal care be provided in isolation or by rooming-in with mother?
- If isolation from mother is advised, should the isolated routine postnatal care be provided in a hospital care area or at home with an unexposed health family member?

Summary of Evidence

No clinical trials have compared isolation versus rooming-in of neonate with mother. Two neonates have been reported to have infection, one at 36 h of birth and second at 17 days of life. In the first case, baby was immediately isolated from the mother wearing N-95 mask during C-section. However, postnatal contact with another infected human could not be ruled out; therefore, postnatal infection was considered most likely. In the second case, household contact with two persons including mother was present. An estimation of the risk of transmission of the Coronavirus has shown basic reproduction number (R_0) of 2.24 to 3.58 indicating high risk of infection on contact with an infected human. There is no evidence that this risk estimate does not apply to neonates in the postnatal period.

Values and preferences

No evidence is available about preference of mothers, families, healthcare provider or policymakers about separation of mother and baby in the postnatal period in case of COVID19 infection. There is expected to be variation in the preferences as disease is known to be milder in neonates and children. The variation is also evident in existing guidelines which prescribe approach varying from complete isolation to continuing rooming-in, skin-to-skin contact and breastfeeding.

Resources required

Significant resources are required as described above in practice question 8.

RECOMMENDATION 9

Scenario 1 : Resources for isolation of normal, suspected to be infected and infected mothers not available OR healthcare facilities are overwhelmed because of large number of Coronavirus infections OR evidence of community spread is present

1. **Healthy neonate may be roomed-in with mother. The mother-baby dyad must be isolated from other suspected and infected cases and healthy uninfected mothers and neonates.**
2. **Direct breastfeeding can be given. Mother should wash hands frequently including before breastfeeding and wear mask. If needed due to neonatal condition, expressed breast milk may also be fed.**
3. If safe, early discharge to home followed by telephonic follow-up or home visit by a designated nurse may be considered.

Scenario2 : If resources for isolation of normal, suspected to be infected and infected mothers can be made available AND there is no evidence of community spread (see 'Resources required section')

1. **After immediate cord clamping, the neonate should be isolated from the mother.**
2. **During isolation, healthy neonates should preferably be cared for by family member not in contact with mother or other suspected/proven case.** Such care can be provided in usual postnatal wards taking care that persons with suspected/proven infection are not allowed in the area. If safe, while mother is in isolation early discharge to home with healthy family member followed by telephonic follow-up or home visit by a designated nurse may be considered.
3. **Mother can express milk after washing hands and breasts and while wearing mask. This expressed milk can be fed to her own baby without pasteurization.**
4. Mother and baby can be roomed-in once mother has been tested and declared to be clear of infection.
5. To facilitate early rooming-in, viral testing in mothers with suspected infection should be conducted and reported on priority.

Practice Question 10: Should symptomatic neonates needing intensive or special care be nursed in common room NICU/SNCU or isolation facility?

As discussed in previous questions, no vertical transmission from mother to fetus has been reported. However, the guideline group feels that the evidence is limited and precautions need to be taken to prevent potential transmission of infection from neonates born to suspected/infected mothers to other neonates.

RECOMMENDATION 10

- **Neonates who are symptomatic/ sick and are born to a mother with suspected or proven COVID-19 infection should be managed in separate isolation facility.**
- This area should be separate from the NICU/SNCU with a transitional area in-between. These single rooms can be single closed rooms.
- In case if enough single rooms are not available, closed incubators (preferred) or radiant warmers could be placed in a common isolation ward for neonates. The neonatal beds should be at a distance of at least 1 meter from one another. Suspected COVID-19 cases and confirmed COVID-19 cases should ideally be managed in separate isolations. If not feasible to have separate facilities and the neonates with suspected and confirmed infection are in a single isolation facility, they should be segregated by leaving enough space between the two cohorts.
- The isolation ward should have a separate double door entry with changing room and nursing station. It should be away from routine NICU/SNCU/labor room/postnatal ward in a segregated area which is not frequented by other personnel. The access to isolation ward should be through dedicated lift or guarded stairs.
- **Negative air borne isolation rooms are preferred for patients requiring aerosolization procedures (respiratory support, suction, nebulization). If not available, negative pressure could also be created by 2-4 exhaust fans driving air out of the room.**
- Isolation rooms should have adequate ventilation. If room is air-conditioned, ensure 12 air changes/ hour and filtering of exhaust air. These areas should not be a part of the central air-conditioning.
- The doctors, nursing and other support staff working in these isolation rooms should be separate from the ones who are working in regular NICU/SNCU. The staff should be provided with adequate supplies of PPE. The staff also needs to be trained for safe use and disposal of PPE.

If the facilities of isolation intensive care are not available in the hospital where symptomatic or sick newborn is born or referred with COVID 19 infections, the newborn should be immediately shifted to State designated closest hospital where such facilities are available. Complete safety and PPE policies and precautions must be followed during transport.

Practice Question 11: What are the special precautions to be taken while providing respiratory support to neonates exposed to COVID-19 infection?

- Personnel performing aerosol generating medical procedures (AGMPs) must wear full PPE with N95 masks and eye and face protection. The AGMPs include endotracheal intubation, extubation, non-invasive ventilation, cardiopulmonary resuscitation, manual ventilation before intubation, bronchoscopy, suction etc.
- Non-invasive ventilation especially NIPPV and High Flow Nasal cannulas should be avoided because of propensity for aerosol generation. CPAP may also generate aerosols but on the other hand has numerous well-proven advantages over intubation for neonate's esp. preterm. Hence, CPAP may be used with lowest possible flows and neonates may be intubated only as per indication.
- If intubating, cuffed endotracheal tubes may offer advantage and In-line suction devices should be preferred.
- Viral filters are recommended to prevent cross-contamination of pathogens between different patients.

RECOMMENDATION 11

- **Respiratory support for neonates with suspected/proven COVID-19 infection is guided by principles of lung protective strategy including use of non-invasive ventilation.**
- **NIPPV and High Flow Nasal cannulas should preferably be avoided.**
- **Healthcare providers should practice contact and droplet isolation and wear N95 mask while providing care in the area where neonates with suspected/proven COVID-19 infection are being provided respiratory support.**
- **The area providing respiratory support should be a negative air pressure area.**

Practice question 12: In symptomatic neonates, what is the role of specific treatment in case of perinatal exposure and case of confirmed infection with COVID-19?

PICO questions

- a. Among symptomatic neonates born to mothers with suspected or confirmed COVID19, what is the effect of treatment with one or more of antiviral drugs on critical outcomes such as in-hospital mortality and neonatal mortality, when compared to only supportive care?
- b. Among symptomatic neonates born to mothers with suspected or confirmed COVID19, what is the effect of treatment with chloroquine or hydroxychloroquine on critical outcomes such as in-hospital mortality and neonatal mortality, when compared to only supportive care?
- c. Among symptomatic neonates born to mothers with suspected or confirmed COVID19, what is the effect of treatment with adjuvant therapies (corticosteroids, intravenous

gamma globulin, interferon, and others) on critical outcomes such as in-hospital mortality and neonatal mortality, when compared to only supportive care?

Summary of evidence

No clinical trials have compared the effect of different antivirals, other drugs like chloroquine or hydroxychloroquine or adjuvant treatment like corticosteroids and intravenous gamma globulin in neonates.

A total of eight studies (7 case series/reports and 1 retrospective cohort study) reported outcomes in 42 women with pregnancy and suspected or confirmed COVID-19. Most of them had an uneventful clinical course after birth. Only one infant died during the birth hospitalization. None of the infants received any specific treatment with antivirals or chloroquine/hydroxychloroquine. Two neonates were detected to have the infection, one at 36 h of birth and second at 17 days of life. Both improved with only supportive care.

RECOMMENDATION 12

Specific anti-COVID-19 treatment - antivirals or chloroquine/hydroxychloroquine - is NOT recommended in symptomatic neonates with confirmed or suspected COVID-19.

Weak recommendation, based on consensus among experts in the absence of evidence for any beneficial effect or harm with the use of any of the options available

Use of adjunctive therapy such as systemic corticosteroids and intravenous gamma globulin is NOT recommended in symptomatic neonates with confirmed or suspected COVID-19.

Weak recommendation, based on consensus among experts in the absence of evidence for any beneficial effect or harm with the use of any of the options available

Practice question 13 : What should be the specific disinfection practices in NICU/SNCU?

PICO question

In neonatal care areas (NICU/SNCU/isolation areas) where neonates with suspected or confirmed COVID-19 infection are cared for, routine cleaning versus chemical disinfection versus fumigation?

Summary of Evidence

Of the 1742 articles on the Coronavirus infection, 15 were shortlisted. No clinical trials comparing different disinfection procedures were found. Only one study relevant to the question was a review of previous publications on effectiveness of different disinfectants. Coronavirus was observed to be inactivated by surface disinfection with 62-71% ethyl alcohol, 0.5% hydrogen peroxide or 0.1% sodium hypochlorite. World Health Organization recommends the use of 70% ethyl alcohol to disinfect small areas between uses, such as reusable dedicated equipment) and 0.5% sodium hypochlorite (equivalent to 5000 ppm) for disinfecting surfaces. CDC refers to the products approved by Environmental Protection Agency for disinfection.

These products include ethyl alcohol, hydrogen peroxide or sodium hypochlorite . Role of fumigation is not supported by existing literature or guidelines.

Values and preferences

No evidence is available about preference of nurses, sanitation workers, healthcare provider or policymakers about preference for a specific disinfectant. The recommended preparations are used routinely, and it can be presumed that their use is acceptable.

Resources required

No new disinfectants or related resources are required. Healthcare facilities need to ensure adequate supply of the recommended disinfectants. Although healthcare workers have previous experience of using these disinfectants, refresher training, supervision and ready reference tools (like posters) should be ensured.

RECOMMENDATION 13

Disinfection of Surfaces in the childbirth/neonatal care areas for patients with suspected or confirmed Coronavirus infection are not different from those for usual Labor room/OT/NICU/SNCU areas and include the following:

1. Wear personal protective equipment before disinfecting
2. If equipment or surface is visibly soiled first clean with soap and water solution or soaked cloth as appropriate before applying the disinfectant
3. 0.5% sodium hypochlorite (equivalent to 5000 ppm) can be used to disinfect large surfaces like floors and walls at least once per shift and for cleaning after a patient is transferred out of the area.
4. 70% ethyl alcohol can be used to disinfect small areas between uses, such as reusable dedicated equipment.
5. Hydrogen peroxide (dilute 100 ml of H₂O₂ 10% v/v solution with 900 ml of distilled water) can be used for surface cleaning of incubators, open care systems, infusion pumps, weighing scales, standby equipment-ventilators, monitors, phototherapy units, and shelves. Use H₂O₂ only when equipment is not being used for the patient. Contact period of 1 hour is needed for efficacy of H₂O₂.

Practice Question 14: When should personal protective equipment (donning and doffing) be used?

Users should refer to updated guidelines by the Ministry of Health and Family welfare.^h

A brief description of methods and indications of the use of PPE are given below:

- Personal protective equipment, or PPE, as defined by the Occupational Safety and Health Administration, or OSHA, is "specialized clothing or equipment, worn by an employee for protection against infectious materials."

^h <https://www.mohfw.gov.in/pdf/GuidelinesonrationaluseofPersonalProtectiveEquipment.pdf>

- The protection of healthcare personnel from infectious disease exposures in the workplace requires a combination of controls, one of which is the use of PPE. It is important to recognize that protection of healthcare worker also involves other preventive strategies.
- The CDC recommends that all health care personnel who enter the room of a patient with known or suspected COVID-19 (persons under investigation) should adhere to Standard, Contact, and Droplet precautions.
- PPE prevent contact with the infectious agent, or body fluid that may contain the infectious agent, by creating a barrier between the worker and the infectious material.
 - Gloves protect the hands
 - Gowns or aprons protect the skin and/or clothing
 - Masks and respirators protect the mouth and nose. The respirator has been designed to also protect the respiratory tract from airborne transmission of infectious agents
 - Goggles protect the eyes
 - Face shields protect the entire face

RECOMMENDATION 14

Minimal composition of a set of PPE for the management of suspected or confirmed cases of COVID-19

Protection	Suggested PPE
Respiratory Protection	Triple layered surgical mask N95 facemasks are needed only when performing an aerosol-generating procedure or in an area where neonates are being provided respiratory support by CPAP device/ventilator.
Eye Protection	Goggles or face shield
Body Protection	Long-sleeved water-resistant gown
Hand Protection	Gloves

Sequence of donning : Before wearing the PPE for managing a suspected or confirmed COVID-19 case, proper hand hygiene should be performed. The gown should be donned first. The mask or respirator should be put on next and properly adjusted to fit; remember to fit check the respirator. The goggles or face shield should be donned next and the gloves are donned last. Keep in mind, the combination of PPE used, and therefore the sequence for donning, will be determined by the precautions that need to be taken.

Steps in removing PPE (Doffing)

Wearing the PPE correctly will protect the healthcare worker from contamination. After the patient has been examined or desired procedure is performed, the removal of the PPE is a critical and important step that needs to be carefully carried out in order to avoid self-contamination because the PPE could by now be contaminated.

1. The gloves are removed first because they are considered a heavily contaminated item. Use of alcohol-based hand disinfectant should be considered before removing the gloves. Dispose of the gloves in a biohazard bin.
2. After the removal of gloves, hand hygiene should be performed, and a new pair of gloves should be worn to further continue the doffing procedure. Using a new pair of gloves will prevent self-contamination. Unbuttoning of the backside of the gown, performed by an assistant. Removal of gown to be performed by grabbing the back side of the gown and pulling it away from the body. Single-use gowns can now be disposed of; reusable gowns have to be placed in a bag or container for disinfection
3. After the gown, the goggles should be removed and either disposed if they are single-use, or placed in a bag or container for disinfection. In order to remove the goggles, a finger should be placed under the textile elastic strap in the back of the head and the goggles taken off. Touching the front part of the goggles, which can be contaminated, should be avoided. If goggles with temples are used, they should be removed as per manufacturer's recommendations.
4. The respirator/ mask should be removed next. In order to remove the respirator/mask, a finger or thumb should be placed under the straps in the back and the respirator taken off. The respirator (or the surgical mask) should be disposed of after removal. It is important to avoid touching the respirator/mask with the gloves (except for the straps) during its removal.
5. The last PPE items that should be removed are the new set of gloves that were worn after disposal of the contaminated gloves. Use of alcohol-based solution should be considered before removing the gloves. The gloves should be removed Dispose of the gloves in a biohazard bin.
6. After glove removal, hand hygiene should be performed.

Practice Question 15: What should be the biomedical waste disposal protocol while managing a suspected or confirmed case of COVID-19?

As per the latest notification by Ministry of Health and Family Welfare (MOHFW¹), dated 21/3/2020, all biomedical waste should be disposed of in accordance with the national guidelines, 2016.ⁱ

- a. Only pre-treatment and segregation will be done in the hospital and the final disposal will be done by common biomedical waste treatment and disposal facility.
- b. Biomedical waste devices, articles generated during diagnosis, treatment, management, immunization etc. from patients with COVID-19 and HCW working in such ward/OPD should be managed in accordance with safe routine procedures and rules.

RECOMMENDATION 15

Follow ***routine*** biomedical waste disposal handling, segregation, transport and final disposal guidelines as prescribed by the Government of India.

ⁱ<https://www.mohfw.gov.in/pdf//National%20Guidelines%20for%20IPC%20in%20HCF%20-%20final%281%29.pdf>

Practice Question 16 : What should be the testing protocol for neonates born to mothers with suspected or confirmed COVID-19 ?

Testing guidelines

Which neonates?	<ul style="list-style-type: none"> • 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?	<p>If symptomatic, specimens should be collected as soon as possible</p> <p>If asymptomatic and roomed-in, test only if and when mother's test comes positive.</p> <p>If mother is COVID-19 positive and baby's initial sample is negative, another sample should be repeated after 48 hours.</p>
What sample?	<p><i>Not mechanically ventilated</i></p> <p>Upper respiratory nasopharyngeal swab (NP). Collection of oropharyngeal swabs (OP) is a lower priority and if collected should be combined in the same tube as the NP.</p> <p><i>Mechanically ventilated</i></p> <p>Tracheal aspirate sample should be collected and tested as a lower respiratory tract specimen</p>
How to collect?	<p><i>Upper nasopharyngeal swab</i></p> <ul style="list-style-type: none"> • 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. <p><i>Oropharyngeal swab (e.g., throat swab):</i> Swab the posterior pharynx, avoiding the tongue.</p> <p><i>Nasopharyngeal wash/aspirate or nasal aspirate</i></p> <p>Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.</p> <p>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)</p>
What PPE is needed for sample collection?	<p>Clinicians should wear appropriate personal protective equipment during sampling.</p> <p>Nasopharyngeal swab</p> <ul style="list-style-type: none"> • Hand Hygiene • Disposable single use glove • Disposable Plastic Apron • Surgical facemask

	<ul style="list-style-type: none"> • Eye Protection (surgical mask with integrated visor or full-face shield or visor or goggles / safety spectacles) <p>For any sampling from lower respiratory tract in intubated neonates a full set of PPE is a MUST</p> <ul style="list-style-type: none"> • Hand Hygiene • disposable single use glove • Long sleeved disposable gown • N95 mask or another respirator mask • Eye Protection
Labelling the sample	Label each specimen container with the patient's name, hospital ID number, specimen type and the date the sample was collected. Handle the sample with precautions under biosafety level 3 (BSL-3) conditions until is rendered non-infectious by laboratory.
How to store?	Samples should be collected in viral transport media procured from microbiology laboratory and transported immediately in icepacks. One can use disposable thermocol cartons or plastic bags with ice cubes for in-house transport. If sending to another laboratory, store specimens at 2-8°C for up to 72 hours after collection. Storage can be done in a refrigerator dedicated for this purpose. If a delay in testing or shipping is expected, store specimens at -70°C or below. This requires deep freezers.
How to send?	If transporting by shipping, the samples need to be packed as per instructions Guidance for sample Collection, Packaging and Transportation for Novel Coronavirus. ^j
Where to send?	Authorized laboratories (See MOHFW website for latest list)
What test?	Reverse Transcriptase PCR is a rapid test for detecting COVID-19

Practice Question 17 : What should be the visitation policy and preventive measures for visitors during the COVID-19 outbreak?

RECOMMENDATION 17

- Parents and families of the COVID-19 exposed, suspected and infected mothers and neonates should receive informed healthcare. They should be aware of and understand the isolation, monitoring, diagnostic and treatment plans of the mothers/babies and be given a periodic update about the health condition.
- Visitors to both routine and COVID-19 specific childbirth/neonatal care areas should be screened for symptoms of COVID-19 infection.
- Persons (including parents) with suspected or confirmed COVID-19 infection should not be allowed entry in the childbirth/neonatal care area where care to parturient women/sick neonates is being provided.
- For neonates roomed in with mother having suspect/confirmed COVID-19 infection, one healthy family member following contact and droplet precautions should be allowed to stay with her to assist in baby care activities.

^j https://www.mohfw.gov.in/pdf/5Sample%20collection_packaging%20%202019-nCoV.pdf

Practice question 18: What should be the discharge policy of neonates born to suspected or confirmed COVID-19 mothers?*PICO question*

Among stable neonates exposed to COVID19 infection from mothers/other relatives/healthcare providers and requiring *routine newborn care*, what is the efficacy and safety of early discharge on the incidence of critical outcomes such as neonatal mortality when compared to late discharge from the health facility?

Summary of evidence

No clinical trials have examined the effect or safety of different discharge criteria among neonates exposed to COVID19 infection or with confirmed COVID-19.

A total of eight studies (seven case series/reports and one retrospective cohort study) reported perinatal and neonatal outcomes in 42 women with pregnancy and COVID-19. None of the studies had reported their discharge criteria for stable neonates who were born to mothers with confirmed COVID-19. However, most of the authors have followed the Chinese Expert consensus to isolate such neonates in the health facility soon after birth and to avoid breastfeeding to prevent transmission of infection from the mothers.

None of the guidelines have addressed this issue clearly in their recommendations.

Values and preferences

No evidence is available on the preferences of mothers, families, healthcare providers, or policymakers regarding the discharge criteria of the asymptomatic exposed neonates in the postnatal period. The preferences and values are likely to be varied given the differences in the unit policies regarding isolation of the exposed neonates (home isolation vs. facility isolation, isolation with affected mother vs. with a healthy unexposed family member).

Resources required

Significant resources are required if a decision is made to delay the discharge – to ensure isolation for 14 days – of the exposed neonates from the health facility. Conversely, if the neonates are roomed-in with their mothers or are being cared for by a trained family member, the neonate can be discharged early to home. In both these cases, the resources required will be low, though it may pose additional concerns of continued exposure to infection (in case of rooming-in with the mother) and possible compromise in the care of neonate (if being taken care by the family member and not by the mother).

RECOMMENDATION 18

Stable neonates exposed to COVID19 and being roomed-in with their mothers may be discharged at time of mothers' discharge.

Weak recommendation, based on consensus among experts based on the incubation period of SARS-CoV-2 infection in adults and older children

Stable neonates in whom rooming-in is not possible because of the sickness in the mother and are being cared by a trained family member may be discharged from the facility by 24-48 hours of age.

Weak recommendation, based on consensus among experts in the absence of evidence for any beneficial effect or harm with early discharge following exposure to COVID19

Remarks

- *Early discharge to home may be followed by a telephonic follow-up or home visit by a designated nurse.*
- *Mothers and family members should be counselled regarding the danger signs and advised to report back to the facility if the neonate develops any of the danger signs*
- *If the neonate develops any danger signs or becomes unwell during home isolation, he/she should be taken to a designated hospital facility for assessment as well as COVID-19 testing (if indicated)*
- *Mothers and family members should perform hand hygiene frequently including before and after touching and feeding the baby*
- *Mothers should practice respiratory hygiene and wear a mask while breastfeeding and providing other care to the baby; they should routinely clean and disinfect all the surfaces*

Practice Question 19: What should be the occupational health policy specific to COVID-19 pandemic?

- Healthcare workers directly involved in the care of COVID19 patients are eligible for Hydroxychloroquine (HCQ) prophylaxis as per latest ICMR guideline released on 22 March 2020. Eligible healthcare workers should contact their hospital teams for prescription.
- Health care workers should be asked to avoid domestic travel unless necessary
- Health care workers who have travelled internationally should be home quarantined for 2 weeks from the date of arrival before allowing them to resume work
- Health care workers who have had household members returning from international travel should be asked to maintain social distancing from them
- Health care workers who have fever and/ or respiratory symptoms should get themselves evaluated by the local COVID19 team of physicians. They may be categorized as NOT suspect and advised home quarantine for short period or SUSPECT and advised COVID19 testing with hospital quarantine. These policies are evolving and updated guidance from ICMR and local health authorities should be sought.

RECOMMENDATION 19

- Healthcare professional working in any childbirth or neonatal area should report to their supervisor if they have respiratory or other symptoms suggestive of COVID-19 infection. Such healthcare professional should not be put on clinical duty and should be replaced by a healthy healthcare professional to maintain appropriate patient-provider ratio.
- Healthcare professional directly involved in the care of patients with suspect/proven COVID-19 infection may consider taking hydroxychloroquine (HCQ) prophylaxis as advised by Government of India, on medical prescription. However, this advisory is based on low-quality evidence and may change in near future.

Practice Question 20: What should be the immunization policy with respect to neonates born to women with suspected or confirmed COVID-19 infection?

No clinical trials or specific information is available about vaccination of these neonates.

RECOMMENDATION 20

- Follow routine immunization policy in healthy neonates born to mothers with suspected/proven COVID-19 infection.
- In neonates with suspected/proven infection, vaccination should be completed before discharge from the hospital as per existing policy.

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