Perinatal-Neonatal Management of COVID-19

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Federation of Obstetric & Gynaecological Societies of India
National Neonatology Forum, India
Indian Academy of Pediatrics
Guideline Development Group (Alphabetical)

Deepak Chawla, Professor, Dept. of Neonatology, GMCH Chandigarh
Praveen Kumar, Professor, Dept. of Pediatrics, PGIMER, Chandigarh (Chairperson)

Dinesh Chirla, Director Intensive Care Services, Rainbow Children’s hospital group
Pratima Mittal, Professor, Dept. of Obstetrics & Gynaecology, VMMC and SJH, New Delhi

Samir Dalwai, National Joint Secretary IAP, Consultant Pediatrician, Nanavati and Hinduja Hospitals, Mumbai
Bakul Jayant Parekh, National President IAP

Ashok K Deorari, President NNF, Head, Department of Pediatrics, AIIMS, New Delhi
M Jeeva Sankar, Assistant Professor, Dept. of Pediatrics, AIIMS, New Delhi

Atul Ganatra, Vice-President FOGSI, Director, Dr. R J Ganatra’s Nursing Home
Tanu Singhal, Consultant, Dept. of Pediatrics and Infectious Diseases, KDAHMRI, Mumbai

Alpesh Gandhi, President FOGSI, Sr. Consultant Obstetrics & Gynaecology, Arihant Women’s hospital, Ahmedabad
Sindhu Sivanandan, Assistant Professor, Dept. of Neonatology, JIPMER, Puducherry

Nandkishor S Kabra, Director NICU, Surya Hospital, Mumbai
Parikshit Tank, Joint Treasurer, FOGSI, Consultant Obstetrician and Gynaecologist, Ashwini Maternity and Surgical Centre, Mumbai

Annexure: Evidence profiles ; Web-Table 1

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.

Contact : secnnf@nnfi.org

Perinatal-Neonatal Management of COVID-19

- Pregnant women with exposure to COVID-19 or travel to a red zone / containment area during last 2 weeks 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. For home quarantine, the guidelines issued by ICMR/MoHFW should be adhered to.
- Testing for pregnant women should be done as per ICMR testing strategy.
- In addition, pregnant women residing in clusters/containment area or in large migration gatherings/evacuation centres from hotspot districts presenting in labor or likely to deliver in next 5 days should be tested even if asymptomatic.
- Pregnant women with confirmed COVID-19 should be managed with supportive care recommended for non-pregnant adults. Current guidelines by the Government of India do not recommend use of hydroxychloroquine, chloroquine or antiviral drugs in pregnant women.
- Currently recommended management includes: - oxygen therapy/respiratory support for treatment of hypoxemic respiratory failure, fluid therapy, antibiotics and management of shock.
  The choice of specific antiviral therapy and immunomodulatory agent is likely to change with rapidly emerging evidence and updated national guidance (available at the website of Ministry of Health and Family Welfare) should be consulted.
- When providing healthcare to women in labor with suspected or confirmed COVID-19, follow the 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 N95 and face protection by a face shield or at least goggles.
  - Reception and triage should be in the same room that is to be used for admission in labor and delivery. Ideally, this should be a room with negative pressure.
  - Keep the room free from any unnecessary items 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.
- COVID care facilities should be identified in the public and private sector. These would be large multispecialty hospitals with adequate space, infrastructure and logistics. Referral pathways from non-COVID facilities should be well established.
- In such COVID care facilities, three demarcated zones (clean, potentially contaminated, contaminated), each housing all the needed equipment and services for women and neonates are required for management of non-COVID, suspected and confirmed COVID-19 mothers.
- 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.
- Every pregnant woman should be triaged at entry and then allotted into one of the zones.
  - If a case who delivers in a non-COVID facility turns out to be Covid-19 positive, actions should be taken as per the MOHFW’s Guidelines to be followed on detection of suspect/confirmed COVID-19 case in a non-COVID Health Facility.
- Mode of delivery in a pregnant woman with suspected or confirmed COVID-19 should be guided by her obstetric assessment and her physiological stability (cardiorespiratory status and oxygenation). COVID-19 itself is not an indication for induction of labor or cesarean section.
  - 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, but may be difficult with full PPE.
  - 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 should 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 and wear a full set of PPE including N95 mask.**
- **Mother should perform hand hygiene and wear triple layer mask.**
- **Neonatal resuscitation should follow standard guidelines.**
- **Endotracheal administration of medications should be avoided.**
- **Indications for intubation shall not change** because of maternal COVID-19 status.  
- **Bathing is not recommended in view of risk of hypothermia and hospital acquired infections.**

- **Stable neonates exposed to COVID-19 from mothers or other relatives should be roomed-in with their mothers and be exclusively breastfed.** For supporting lactation, nurses trained in essential newborn care and lactation management should be provided. A healthy asymptomatic willing family member who is not positive for COVID-19, and has not been in direct contact with suspected or confirmed COVID-19 person may be allowed to provide support for mother and neonate.
- **Mother should wash hands frequently including before breastfeeding and wear mask.**
- **The area providing respiratory support should be a negative air pressure area.**
- **Intubation should be managed in separate isolation facility preferably in single closed rooms.**
- **In case enough single rooms are not available, closed incubators (preferred) or radiant warmers could be placed in a common isolation ward for neonates, at a distance of at least 1 meter from each other.** Suspected and confirmed COVID-19 cases should ideally be managed in separate isolation. If it is not feasible, they should be segregated by leaving enough space between the two cohorts.
- **Negative air borne isolation rooms are preferred for patients requiring aerosolization procedures.**
- **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.”

**Neonates who are symptomatic/ sick and are born to a mother with suspected or confirmed COVID-19 should be managed in separate isolation facility, preferably in single closed rooms.**

- In case enough single rooms are not available, closed incubators (preferred) or radiant warmers could be placed in a common isolation ward for neonates, at a distance of at least 1 meter from each other. Suspected and confirmed COVID-19 cases should ideally be managed in separate isolation. If it is not feasible, they should be segregated by leaving enough space between the two cohorts.
- **Negative air borne isolation rooms are preferred for patients requiring aerosolization procedures.**
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**Testing Strategy for neonates**

1. **History of exposure to COVID-19 positive adult (irrespective of symptoms):**
   - **Mother had COVID-19 infection within 14 days before birth,** or
   - **History of contact with COVID-19 positive persons (including mother, family members in the same household or direct healthcare provider) in the postnatal period**

   **Timing of test:** At birth (if mother had COVID-19) or at detection of the history of contact with COVID-19 positive person (postnatal exposure). If a sample is not obtained at birth due to logistic reasons, it should be obtained as soon as possible. Rooming-in should not be postponed if testing is delayed.

   If the first test is negative, a repeat test should be done after 5-14 days of birth/exposure. However, the test should be done immediately, if new symptoms (respiratory distress, lethargy, seizures, apnea, refusal to feed, diarrhea) appear.

2. **Irrespective of history of exposure:**
   - **Presenting with pneumonia or SARI that requires hospitalization, with onset at more than 48-72 h of age, unless there is another underlying illness that completely explains the respiratory signs and symptoms.**

   **Features that suggest acute respiratory illness in a neonate are respiratory distress, with or without cough, with or without fever.**

**Respiratory support for neonates with suspected/confirmed COVID-19 is guided by principles of lung protective strategy including use of non-invasive ventilation.**

- **CPAP should be preferred over NIPPV and High Flow Nasal cannuas.**
- **Healthcare providers should practice contact and droplet isolation and wear N95 mask while providing care in the area where neonates with suspected/confirmed COVID-19 are being provided respiratory support.**
- **Intubation should be only for usual indications.**
- **Consider use of pre-medication for non-emergent intubation and intubation should be performed by the most experienced person.**
- **Consider use of aerosol box during intubation and suction, in-line suction device, HEPA filters.**
- **The area providing respiratory support should be a negative air pressure area.**

**Specific anti-COVID-19 treatment is not recommended in symptomatic neonates.**

- **Use of adjunctive therapy such as systemic corticosteroids, intravenous gamma globulin and convalescent plasma is NOT recommended in symptomatic neonates with suspected or confirmed COVID-19.**
Disinfection of surfaces in the childbirth/neonatal care areas for patients with suspected or confirmed COVID-19 are not different from those for usual labor room/OT/NICU/SNCU areas and include the following:

- Wear PPE before disinfecting.
- If equipment or surface is visibly soiled first clean with soap and water solution or soaked cloth.
- 0.5% sodium hypochlorite 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 and equipment between uses.
- Hydrogen peroxide 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. For ensuring the efficacy of disinfection with H2O2 use the contact period recommended by manufacturer. Usually a contact period of 1 hour is required.

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

<table>
<thead>
<tr>
<th>Protection</th>
<th>Suggested PPE</th>
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| Respiratory protection | Triple layered surgical mask  
                        | N95 facemasks are needed 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     | Full-sleeved water-resistant gown including head and complete shoe cover.    |
| Hand protection     | Well-fitting Gloves                                                          |

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

- Families of suspected and confirmed COVID-19 mothers and neonates should receive informed healthcare.
- Visitors to routine childbirth/neonatal care areas should be screened for symptoms of COVID-19.
- Persons (including parents) with suspected or confirmed COVID-19 should not be allowed entry in the childbirth/neonatal care area.
- For neonates roomed-in with mother having suspect/confirmed COVID-19, one healthy family member following contact and droplet precautions should be allowed to stay with her to assist in baby care activities.
- COVID-19 mother may be allowed to visit her neonate admitted in NICU if she fulfills all of these:
  - Resolution of fever without the use of antipyretics for at least 72 hours AND
  - Improvement (but not full resolution) in respiratory symptoms AND
  - Negative results of a molecular assay for detection of SARS-CoV-2 in case of severe disease

### Suspect neonates

- Stable neonates exposed to COVID19 and being roomed-in with their mothers may be discharged together at the same time.
- 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.

#### COVID-19 positive neonates

- Asymptomatic neonates or those with mild to moderate clinical course whose symptoms and need of oxygen abate within 3 days can be discharged from the hospital after 10 days without repeating RT-PCR test.
- In severe cases, a single negative RT-PCR should be demonstrated after resolution of symptoms, prior to discharge.

### Discharge Policy

- 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.
- Healthcare professional directly involved in the care of patients with suspect/confirmed COVID-19 infection may consider taking hydroxychloroquine (HCQ) prophylaxis as advised by Government of India, on medical prescription.

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

**Developed jointly by**

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*Version 2.0 Last updated: 07-05-2020*  
*Contact: secnn@mnfi.org*  
*Design by Dr. Deepak Chawla*
Operational flow chart

To be managed in usual care areas for neonates (not applicable if it is an exclusive COVID hospital)

Neither suspect not positive

COVID status

Suspect

Positive

Sick or gestation <34 weeks

No

Yes

A

COVID suspect
stable neonate

B

COVID positive
stable neonate

C

COVID suspect
neonate with Gestation<34 weeks or sick

D

COVID positive
neonate with Gestation<34 weeks or sick

Classify at admission and periodic assessment during course of illness

A

Mother sick

No

Yes

Room-in with mother in "COVID postnatal ward"
Allow breastfeeding with droplet and contact precautions.

Shift to "Well-baby COVID ward"
Give EBM if can be given safely. Else give formula feed.

Shift to "COVID suspect area" in SNCU/NICU

If neonate in suspect area tests positive, shift to COVID positive ward/NICU
If neonate in neonatal ward becomes sick shift to SNCU/NICU

Area characteristics

Healthcare provider

Equipment needed

PPE

Mother should wear mask perform hand hygiene before breastfeeding

H

Keep suspect and positive neonates/mothers in separate areas/rooms
If not possible keep in separate corners in the same ward. May create a temporary physical barrier to ensure separation.

Enter and exit separate from usual neonatal care areas
Donning and doffing areas to be earmarked

Nurse to assist in initiation of breastfeeding. Consider allowing a family member to stay with mother to provide support to mother

Nurse for feeding and other care of well baby.

Equipment and disposables to safely prepare and administer expressed breast milk or formula feed

Crash-cart and resuscitation station, equipment for usual neonatal monitoring and care should be available

All equipment as per standard of care in SNCU or NICU

Health care providers to wear full set of PPE

Suspect include
- Mother COVID-19 positive within 2 weeks prior to delivery
- Neonates born to a mother with suspected infection or to a mother from a containment area
- Postnatal exposure to infected mother or another person including a healthcare worker
- Presenting with respiratory distress with or without fever and cough, onset beyond 48-72 h of age and no other alternative explanation for the illness

Positive means RT-PCR is positive for COVID-19
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Introduction

Importance

Screening, diagnosis, prevention, and management of COVID-19 in the current pandemic are guided by recommendations and advisories based on a rapidly evolving body of scientific evidence. The resilience of the health system is being tested with the focus being on the identification, isolation, and clinical care of COVID-19 infected individuals. Pregnant women with suspected or confirmed COVID-19 and their newborn infants constitute a special vulnerable group. The strained health system not only needs to screen and manage suspected COVID-19 infection among pregnant women and neonates but also needs to ensure uninterrupted clinical care, especially during the high-risk period of childbirth. The neonate has to be protected from transmission during delivery and in the post-natal period from mother and possibly exposed family members. Also, healthcare workers need protection from getting infected while providing perinatal clinical care characterized by close and frequent contact with the patients.

This updated evidence-based rapid clinical practice guideline jointly from Federation of Obstetric and Gynaecological Societies of India (FOGSI), National Neonatology Forum India (NNF India) and Indian Academy of Pediatrics (IAP) provides guidance to clinicians and policymakers for the management of pregnant women exposed to COVID-19 and their neonates. This document updates and overrides the previous guidelines released on March 26, 2020.

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 Indian Council of Medical Research (ICMR), Ministry of Health and Family Welfare (MOHFW), World Health Organization (WHO) and Center for Disease Control and Prevention (CDC).

Background

Coronaviruses are RNA viruses with glycoprotein spikes that give them a crown-like appearance.\(^1,2\) 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 of China; this was later termed as SARS-CoV-2 or COVID-19. This virus has subsequently spread throughout the world causing about 3.7 million cases and 2,64,000 deaths (till 7/5/2020).\(^3\) More than 52,000 cases and 1700 deaths have been reported from India (till 07/5/2020).\(^4\) 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 the virus can remain alive for hours or days. Infected persons 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. The 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. \(^5\) The clinical symptoms are variable ranging from an
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, the fatality rate was 15%) and those with comorbidities like heart disease, hypertension, diabetes, etc. There is a paucity of data on clinical features and outcomes of COVID-19 in pregnancy and neonates. Available data suggest that in general, the outcome among pregnant women and neonates is good. A large proportion of infected pregnant women are likely to be asymptomatic or have mild symptoms. [6] However, severe disease needing admission to the intensive care unit has been reported among pregnant women. Emerging evidence indicates that among women infected with COVID-19 in the third trimester, the risk of vertical transmission is low. Reported clinical features of COVID-19 infection in neonates include fever, lethargy, cough, vomiting, and respiratory distress, thus mimicking the presentation of bacterial sepsis.[2,7,8]

What is new?

7 May 2020

- Updated number of infections and deaths on 07/05/2020
- Added number of infections and deaths in India on 07/05/2020
- Updated the literature section to include literature up to 30/4/2020
- Practice question 2: Recommendation is updated based on current evidence and ICMR recommendations
- Practice question 3: Recommendation is updated based on the current epidemiology of infection in India
- Practice question 4: Recommendation is updated based on current epidemiology of infection in India and knowledge of transmission of the virus
- Practice question 6: Recommendation is updated based on current ICMR guidelines.
- Practice question 7: Added in the recommendation about the use of HEPA filter and the need to discard unused disposables. Modified the recommendation about the use of a T-piece, transport after resuscitation, and bathing of the neonate.
- Practice question 8: Added a paragraph about milk donation.
- Practice question 9: Modified the recommendation removing the choice of isolating neonate from the mother.
- Practice question 11: Added section on intubation.
- Practice question 12: Added section on the use of convalescent plasma.
• Practice question 15: Added disinfection in the hospital area where healthy/asymptomatic neonates born to mothers with suspected/confirmed COVID-19 infection are cared for.
• Practice question 16: Recommendation is updated based on current evidence and ICMR recommendations
• Practice question 17: Added recommendation for visitation policy of infected mother to NICU
• Practice question 18: Added need to protect elderly grandparents from contact with infected neonates
• Practice question 20: Added text and reference to the ACVIP statement.

A brief review of the literature

Maternal-fetal transmission and neonatal cases

COVID-19 has been reported in a total of 809 pregnant women till 30th April 2020. Of these, 305 had pneumonia, 20 needed ICU admission, and 2 died. Among 656 women who delivered by the time studies were reported, the cesarean section was the mode of delivery in 468 (71.3%). Among 707 neonates born to these women, 111 (15.7%) were admitted to NICU, 20 had pneumonia and 3 died. However, in the majority of neonates, the reason for admission to NICU was isolation from the infected mother or other morbidities unrelated to COVID-19. Among the 707 births, the vertical transmission was suspected in 17 neonates (pooled rate of 2.4%), based on virologic and serological reports. [9-17] However two individual case series have reported higher transmission rates of 7.1% (3 of 42) and 9.1% (3 of 33). [14,15]

Of 17 neonates with suspect vertical transmission, the infection was confirmed by a positive RT-PCR in 11 (Web-Table 1). In 3 neonates, the infection was suspected based on elevated anti-COVID-19 IgM and IgG levels at birth.[12,13] In another 3 neonates, only IgG levels were elevated.[12] In these 6 neonates with elevated antibodies, the RT-PCR was repeatedly negative indicating the possibility of intrauterine infection of the fetus. Pneumonia was the most common manifestation of infection with 9 neonates of 11 with positive RT-PCR showing clinical and/or radiological evidence of pneumonia. Other clinical features included fever, lethargy, and gastrointestinal symptoms. However, the disease was mild in most neonates with only 1 neonate needing short duration respiratory support and all being discharged alive from the hospital.

Isolation from mother was practiced in all but 2 of these 17 neonates.[14] Maternal infection was confirmed only in the postnatal period in mothers of these 2 neonates. Breastfeeding was given by these mothers without wearing masks. In one neonate RT-PCR was positive on day 1 and in the second neonate, it was positive on day 3.
The main studies reporting maternal and neonatal outcomes are summarized below.

Schwartz et al described a series of 38 Chinese women in labor and delivery who tested positive for COVID-19.[18] 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 the nasal secretions of their neonates.

Early in the epidemic, two cases of neonatal SARS-CoV-19 infection were reported.[18] 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.

Zeng et al describe a large cohort of 33 neonates born to Covid-19 positive mothers in Wuhan, among which three tested positive.[19] All neonates were admitted to NICU, one neonate even requiring non-invasive ventilation, and treatment for respiratory distress syndrome and sepsis. The authors commented that strict infection control and prevention procedures were followed during the delivery. However, no information is provided in the publication about the use of exclusive breastfeeding or expressed breast milk. Since all infected neonates were tested latest by day 2 of life, the possibility of transmission from mother either in-utero or during delivery could not be ruled out.

Aghdam et al from Iran report a 15-day-old neonate with fever, lethargy, cutaneous mottling, and respiratory distress.[7] Baby’s mother had symptoms but was not tested as per the country norms. Neonate’s nasopharyngeal swab was positive for COVID-19. The neonate was isolated and provided supportive care, antibiotics, and antiviral (Oseltamivir) treatment.

Dong et al report a newborn infant with elevated IgM antibodies to SARS-CoV-2 born to a mother with COVID-19.[20] The RT-PCR test was done five times and turned out to be negative on the baby. In this case, the mother was infected at least 3 weeks before delivery. The authors argue that the elevated IgM antibody levels in the neonate detected as early as two hours of age suggest that the neonate was infected in utero.

Zeng H et al reported serological analyses of 6 pregnant women with confirmed COVID-19 and their infants. [21] Two infants had elevated IgM levels and five had elevated IgG levels. Since IgM is not transferred transplacentally, the possibility of neonatal infection could not be ruled out. In this report, the cord blood, amniotic fluid, and breast milk were not tested.

However, in the absence of virologic proof, caution must be exercised about in-utero transmission based on serological tests alone.[22] The IgM assays can yield both false-positive (e.g. due to cross-reactivity) and false-negative results and are less reliable than molecular diagnostic tests based on nucleic acid amplification and detection.
A systematic review included pregnancy outcomes in COVID-19 published between February 12 to April 4, 2020. [23] Eighteen articles reporting data from 108 pregnancies were included. The majority of the studies originated from China, but cases from Sweden, the USA, Korea, and Honduras were also included. Three maternal intensive care unit admissions were noted but no maternal deaths. One neonatal death (SARS-CoV-2 negative) and one intrauterine death were also reported. The review authors concluded that available literature has found no clear evidence for vertical transmission of COVID-19 from the mother to the fetus.

There is a case report of maternal death with Covid-19 infection from Iran. [24] A 27-year-old woman at 30 weeks presented with respiratory distress, fever, cough, and myalgia for 3 days. There was no contact with anyone diagnosed with COVID-19 as well as no recent travel history (inside or outside of Iran) in the past two weeks. She had respiratory distress and required intubation for low oxygen saturation. RT-PCR for SARS-COV-2 was positive. The fetus could not be resuscitated.

A case series reported 17 infected pregnant women delivering 17 neonates (three of them preterm). [25] There was no fetal or neonatal death. None of the neonates tested with throat swab was positive by RT-PCR. However, intrauterine tissue samples such as placenta, cord blood, or amniotic fluid were not tested. In two neonates, COVID-19 was suspected but viral tests were negative.

**Neonatal exposure definition**

As per Chinese consensus guidelines, neonates are said to be exposed to COVID-19 if they are born to mothers with a history of COVID-19 diagnosed within 14 days before or 28 days after delivery, or if the neonate is directly exposed to close contacts with COVID-19 (including family members, caregivers, medical staff, and visitors). [26,27] They should be managed as patients under investigation (PUI) irrespective of whether they are symptomatic or not.

**Implications of available literature**

The updated literature indicates that in-utero or vertical transmission is infrequent but possible. Postnatal transmission from an infected mother or caregivers to the neonate can also occur. A delay in testing can make it difficult to differentiate a vertical transmission from mother to fetal (or at birth) from postnatal (contact/droplet) transmission. Lastly, fetal effects of maternal infection during the first and second trimester of pregnancy are not known.

**Methods used to develop the guideline**

The GRADE approach recommended by WHO was used to develop the guideline. [28] A Guideline Development Group (GDG) comprising of obstetricians, neonatologists, and pediatricians were constituted. The GDG drafted a list of questions that 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...
Updated search

PubMed was searched between March 14th (search date for the last version of the guidelines) and April 30th, 2020 to identify newly published articles related to pregnancy and neonatal management in the setting of COVID-19 as well as other related articles in the pediatric and adult population. A repository of published literature compiled by the Cochrane Gynaecology and Fertility group was reviewed for additional studies. Guidelines published by Pediatric and Obstetric Societies and bibliographies of relevant articles were also searched. Ninety new articles were found and have been included to update the evidence body.

Clinical Practice Questions for obstetricians and neonatologists

Following questions were short-listed:

**Pregnant women with travel history, clinical suspicion or confirmed case**

- What should be the care of pregnant women with a history of travel to a high-risk area or exposure to a confirmed/suspected case of COVID-19?
- Which pregnant women need testing for COVID-19?
- Where in a healthcare facility should a pregnant woman with suspected or confirmed COVID-19 deliver?
- What infection control measures should be undertaken in triage, labor, and delivery of pregnant women with suspected or confirmed COVID-19?
- What should be the method of labor induction and mode of delivery in pregnant women with suspected or confirmed COVID-19?
- What should be the specific care of pregnant women with confirmed COVID-19?

**Neonatal Care**

7. What precautions should the neonatal resuscitation team take when attending the delivery of a woman with suspected or confirmed COVID-19?
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 the 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?
12. In symptomatic neonates, what is the role of specific treatment in case of perinatal exposure and case of confirmed 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 the 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 a history of travel to a high-risk area or exposure to a confirmed/suspected case of COVID19?

PICO question
Among asymptomatic pregnant woman with a history of contact with COVID-19 infected person or history of travel to a district in a red zone or a containment area, which is better: isolation/quarantine as recommended for non-pregnant individuals versus specific isolation/quarantine practice (hospitalization/specially designated facility/longer or shorter isolation)?

Summary of Evidence
Of the 3323 articles on the Coronavirus infection, 80 addressed the issue in pregnant women. No clinical trials have compared specific care including isolation strategies in pregnant women. A total of 13 studies (12 case series/reports and 1 retrospective cohort study) reported outcomes in 113 women with pregnancy and Coronavirus infection. Due to the absence of a comparative group it is not possible to estimate the effect of COVID-19 infection in pregnancy. However, almost all pregnant women had a mild infection.

Values and preferences
No evidence is available about the preference of pregnant women, families, healthcare providers, or policymakers about the isolation of exposed women during the postnatal period. Due to the non-severe nature of the disease, women will likely prefer to remain at home during the quarantine period.

Resources required
Significant resources including the 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 exposure to a confirmed/suspected case of COVID-19 or travel to a district in red zone or a containment area during last 2 weeks 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. For home quarantine, the guidelines issued by ICMR/MoHFW should be adhered to.
Practice Question 2: Which pregnant women need testing for COVID-19?

(This practice question has been rewritten based on ICMR recommendations on testing in pregnant women)

Till recently, the criteria for laboratory testing were the same for pregnant women and the non-pregnant population i.e.

- All symptomatic individuals who have undertaken international travel in last 14 days
- All symptomatic contacts of laboratory-confirmed cases
- All symptomatic health care workers with ILI
- All patients with Severe Acute Respiratory Illness (fever AND cough and/or shortness of breath)
- 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 in hotspots/cluster (as per MoHFW) and in large migration gatherings/evacuation centers

Direct and high-risk contact is defined as those living in the same household, traveling together by any conveyance, working together in proximity (same room), or healthcare workers providing direct care.

Recently, ICMR has announced an additional criterion for pregnant women: pregnant women residing in clusters/containment area or large migration gatherings/evacuation centers from hotspot districts presenting in labor or likely to deliver (by induction of labor or elective cesarean section) in next 5 days should be tested even if asymptomatic.

RECOMMENDATION 2

- Testing for pregnant women should be done as per ICMR testing strategy.

- In addition, pregnant women residing in clusters/containment area or in large migration gatherings/evacuation centres from hotspot districts presenting in labor or likely to deliver (by induction of labor or elective cesarean section) in next 5 days should be tested even if asymptomatic.

Asymptomatic pregnant women should be tested in the health facilities where they were expected to deliver, and all arrangements should be made to collect and transfer samples to testing facilities. Women should not be referred for lack of testing facility.
Practice Question 3: Where in a healthcare facility should a pregnant woman with suspected or confirmed COVID-19 deliver?

The Ministry of Health and Family Welfare has proposed that in a particular geographical area, dedicated facilities should be identified amongst the public healthcare establishments for COVID-19 suspected or confirmed individuals. These facilities are further stratified according to the infrastructure and level of care into COVID Care Centers (CCC), Dedicated COVID Health Centers (DCHC), and Dedicated COVID Hospitals (DCH). Maternity care services and other specialty services would be available at a DCHC and DCH.

Large hospitals with adequate space, infrastructure, and logistics can divide the hospital into non-COVID and COVID zones. There should be no or minimal crossover of patients, hospital personnel, and material between the zones. In an ideal set-up, there should be three demarcated zones – clean, potentially contaminated (for pregnant women with suspected infection), and contaminated (for pregnant women with proven infection) 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 facility to deal with outpatient, inpatient care, labor room, OT, and intensive care management. If possible, each patient should be kept in a separate room with an attached bathroom. If this is not feasible, an adequate distance between the beds should be maintained. Wherever possible, it may be beneficial for the entire contaminated zone (wards, labor rooms, operation theatres, and ICU) to have a negative pressure system to limit the spread of infection.

<table>
<thead>
<tr>
<th>Contaminated</th>
<th>Potentially contaminated</th>
<th>Clean</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 positive women</td>
<td>The test result is awaited (including asymptomatic pregnant women being tested as per current testing strategy)</td>
<td>No symptoms of SARI AND No contact with infected individual AND No travel history to red zone or containment area during the last 2 weeks</td>
</tr>
<tr>
<td></td>
<td>Symptoms of SARI</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Contact with an infected individual</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Travel in the last 14 days</td>
<td></td>
</tr>
</tbody>
</table>

Every pregnant woman should be triaged at entry and then allotted into one of the zones depending on the presentation. If in a health facility, all asymptomatic pregnant women are being tested as per the ICMR testing strategy, these women may be moved to the clean area if they test negative. However, suspect pregnant women with respiratory symptoms (fever AND cough and/or shortness of breath) should not be moved to a clean area even if one RT-PCR is negative.

Small stand-alone maternity hospitals/nursing homes may not have adequate resources to have separate zones and provide COVID care safely. All healthcare facilities in a defined geographic area should be classified and designated for a specific type of care based on the above factors and there should be well defined and well-publicized referral pathways.

Given the rapid spread of COVID-19 in many areas of the country but non-availability of universal testing, it will be prudent to use ‘standard precautions’ in all deliveries. If a case who delivers in a non-COVID facility turns out to be COVID-19 positive, actions should be
taken as per MOHFW’s ‘Guidelines to be followed on detection of suspect/confirmed COVID-19 case in a non-COVID Health Facility’ [29].

**RECOMMENDATION 3**

- COVID care facilities should be identified in the public and private sector. These would be large multispecialty hospitals with adequate space, infrastructure and logistics. Referral pathways from non-COVID facilities should be well established.

- In such COVID care facilities, three demarcated zones (clean, potentially contaminated and contaminated), each housing all the needed equipment and services (wards, labor rooms, operation theatres, neonatal resuscitation areas and mother and neonatal ICU) are required for management of non-COVID, suspected and confirmed COVID-19 mothers.

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.

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

- If a case who delivers in a non-COVID facility turns out to be Covid-19 positive, actions should be taken as per MOHFW’s ‘Guidelines to be followed on detection of suspect/confirmed COVID-19 case in a non-COVID Health Facility’.

Practice Question 4: What infection control measures should be undertaken in triage, labor, and delivery of pregnant women with suspected or confirmed COVID-19?

Healthcare workers should follow the correct use of appropriate personal protective equipment (PPE). In addition:

- 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 the physical 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.
• Regularly perform hand hygiene with soap and water or alcohol-based rubs.
• All patients should wear surgical masks.

The term “universal precautions” refers to the measures taken to prevent the transmission of blood-borne infections to healthcare workers. This was later called “standard precautions” to cover the risk of transmission through contact with body fluids. In settings where the pregnant woman is confirmed to have COVID-19 infection and presents in labor or is undergoing a surgical procedure, there is a need to follow these and some enhanced measures using PPE to prevent acquiring infection through respiratory droplets. The PPE should include masks such as the N95 respirator mask (fitted to size) and face protection by a face shield or at least goggles and other measures. If it is an emergency 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 or are from containment areas.

<table>
<thead>
<tr>
<th>Protection level</th>
<th>Scope of application</th>
<th>Protective equipment</th>
</tr>
</thead>
</table>
| Level 1          | Pre-examination triage, general outpatient department | Disposable surgical cap  
Disposable surgical mask  
Work uniform  
Disposable latex gloves and/or disposable isolation clothing |
| Level 2          | 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 | Disposable surgical cap  
Medical protective mask (N95)  
Work uniform  
Disposable medical protective uniform  
Disposable latex gloves  
Goggles |
| Level 3          | Intubation, resuscitation of suspected/confirmed patients where there is a risk of spray or splash of respiratory secretions or body fluids or blood  
Surgery, procedures, delivery of suspected/confirmed patients  
Autopsy of suspected/confirmed patients | 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 |
The procedure of wearing (donning) and removing (doffing) of the PPE should be strictly followed.

**RECOMMENDATION 4**

- When providing healthcare to women in labor with suspected or confirmed COVID-19, follow the 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 N95 and face protection by a face shield or at least goggles.
- Reception and triage should be in the same room that is 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 suspected or confirmed COVID-19?**

**PICO question**

For pregnant women with confirmed COVID-19, what labor induction method and mode of delivery are recommended? Does it differ from non-infected pregnant women? (e.g. early induction or operative delivery)?

**Summary of Evidence**

A literature search revealed 3323 articles on Coronavirus infection, 80 addressed the issue in pregnant women. Besides, 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 13 studies (12 case series/reports and 1 retrospective cohort study) reported outcomes in 113 women with pregnancy and Coronavirus infection. The majority of women in these studies were delivered by cesarean section. However, in the only case-control study, all controls also delivered by the cesarean section. The incidence of cesarean 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 cesarean section. Literature indicates the possibility of a higher incidence of fetal distress in infected pregnant women. However, due to the 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. A pregnant woman who has significant respiratory compromise represents a difficult decision-making situation. Delivery by cesarean section would reduce the maternal respiratory and metabolic load. However, this has to be balanced against the risks of operative intervention and anesthesia in this state.

**Values and preferences**

No evidence is available about the preference of pregnant women, families, healthcare providers, or policymakers about the induction of labor or 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. Adequate resources including space, equipment, supplies, and trained healthcare providers are required for delivery, cesarean 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 labor or cesarean section.

- Continuous electronic fetal monitoring should be preferred 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 as indicated for a high-risk delivery but may be difficult with full PPE.

- 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 confirmed COVID-19?**

**PICO question**

Among pregnant women with confirmed COVID-19, 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 (200 mg thrice a day with meals) and Azithromycin (500 mg once a day) for 10 days have been shown to give virologic 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 criterion. 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. Subsequent experience has not shown any significant benefit and there are concerns about cardiovascular harm.

**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 randomized trials.

**Current guidelines by the Government of India do not recommend the use of hydroxychloroquine, chloroquine, or antivirals in pregnant women.**

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

**Values and preferences**

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

**Resources required**

The availability of specific antivirals in India is not easy. On the other hand, hydroxychloroquine and azithromycin are easily available and cheap. In the absence of specific literature, resources needed for the 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 confirmed COVID-19 should be managed with supportive care recommended for non-pregnant adults. Current guidelines by the Government of India do not recommend use of hydroxychloroquine, chloroquine or antiviral drugs in pregnant women.

- Currently recommended national management includes oxygen therapy/respiratory support for treatment of hypoxemic respiratory failure, fluid therapy, antibiotics and management of shock.

The choice of specific antiviral therapy and immunomodulatory agent is likely to change with rapidly emerging evidence and updated national guidance (available at the website of Ministry of Health and Family Welfare) should be consulted.

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

**Rationale:** Around 10% of neonates are anticipated to require resuscitation including oronasal 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 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) and Society of Obstetricians and Gynecologists of Canada recommend delayed cord clamping unless there are other contraindications while American College of Obstetrics and Gynecologists (ACOG) and Chinese guidelines recommend immediate cord clamping.

In the radiant warmer designated for resuscitation, the neonatal team should 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 can result in the generation of aerosols. If a T-Piece resuscitator is used, a disposable circuit should be used. High-efficiency particulate air (HEPA) filters can be attached at the patient outlet of the positive pressure ventilation device to decrease environmental contamination from exhaled air. Indications for intubation are 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 and dispose of them as per disposal policy and perform hand hygiene. Transfer of the neonate to the designated area can be performed by another healthcare worker wearing appropriate PPE. However, if there is a shortage of personnel, the resuscitation team member can doff partially and wear a fresh outer gown and gloves to transport the neonate. If the neonate is on respiratory support, transport personnel should wear an N95 mask.

**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 should 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.

- Delayed cord clamping and skin to skin contact can be practiced.

- 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 or a T-piece resuscitator with disposable tubing may be used.

- Avoid routine oral or nasal suction unless indicated to clear the airway.

- Endotracheal administration of medications should be avoided.

- Indications for intubation shall not change because of maternal COVID-19 status. Plexiglass boxes with access portholes can be used to minimize aerosol spread during intubation and suction.

- 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.

- Bathing is not recommended in view of risk of hypothermia and hospital acquired infections.
Practice question 8: What should be the feeding policy for stable neonates born to COVID-19 mothers?

*PICO question*

For well neonates exposed to COVID-19 infection from mothers/other relatives/healthcare providers and requiring routine essential newborn care, does feeding expressed breastmilk, donor milk, or formula milk reduces 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 COVID-19/SARS-CoV-2 infection in neonates or pregnant women or breastfeeding. 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.

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.

*Milk donation*: Based on the available data on other coronaviruses, it is likely that the process of pasteurization can destroy SARS CoV-2 is present in breastmilk. However, the European, as well as the Human Milk Banking Association of North America, recommend that mothers with active COVID-19 infection should not donate milk.

*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 have 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.

Rooming-in will also require resources - preferably single rooms with enough space for keeping the baby cot 2 m away from mother or in a ward with recommended physical separation between mothers and babies. Services of nurses trained in essential newborn care and lactation support along with laboratory support for management of jaundice will need to be organized in the dedicated COVID health centers and hospitals. A healthy family member, if available, can be trained to provide support to mother and baby, under the supervision of nurses. Round-the-clock coverage by pediatricians will also need to be arranged.

If expressed breast milk is used because of prematurity or sickness in baby or mother, nursing support will be required to help and support milk expression. Resources will be required for safe collection and transport several times a day, without contamination.
A. **Stable neonates exposed to COVID-19 infection from mothers or other relatives should be roomed-in with their mothers and be exclusively breastfed.** For supporting lactation, nurses trained in essential newborn care and lactation management should be provided. A healthy willing family member who is not positive for COVID-19, is not under direct contact with suspected or confirmed COVID-19 and is asymptomatic may be allowed in the room to provide support for breastfeeding and helping in taking care of the neonate.

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 a trained family member who has not been in contact with the mother or other suspected/proven case.

*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 for safe breastfeeding**

- 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.

C. **Mothers are not eligible to donate milk in any of the following COVID-19 related situations in addition to standard criteria [30]**

- COVID-19 positive till she is declared free of infection.
- History of having stayed or transited in a containment zone during the previous 14 days.
- History of close contact with a confirmed or probable case of COVID-19 in previous 14 days.
- Suffering from symptoms like cough, fever, sore throat, running nose till found to be COVID-19 negative on nasopharyngeal sample RT-PCR.
- Person who worked in or attended a health care facility in which a case of COVID-19 infection has been confirmed.
Practice question 9: Is it necessary to separate the mother and baby if the mother is suspected or confirmed to be COVID-19 positive?

PICO questions

a. 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?
b. 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 neonates with mothers. Of 17 cases of neonatal infection (see the review of literature) reviewed, isolation from mother was practiced in all but 2 neonates.[14] Maternal infection was confirmed in the postnatal period in mothers of these 2 neonates. Breastfeeding was given without mothers wearing a mask. RT-PCR was positive on day 1 and day 3 respectively in these two neonates. In the remaining 15 cases, isolation from mother was practiced and neonates were suspected to be infected due to vertical transmission. In another case, neonate acquired infection on day 17 from two infected adults (including mother) in the household.[18] An estimation of the risk of transmission of the Coronavirus has shown basic reproduction number (R0) of 2.24 to 3.58 indicating a high risk of infection in 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 the preference of mothers, families, healthcare providers, or policymakers about the separation of mother and baby in case of COVID-19 infection. There is expected to be variation in the preferences as the disease is known to be milder in neonates and children. The variation is also evident in existing guidelines which prescribe 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.
Practice Question 10: Should symptomatic neonates needing intensive or special care be nursed in common room NICU/SNCU or isolation facility?

As discussed in the summary of the literature, vertical transmission from mother to fetus is not common. However, the guideline group feels that the evidence is limited and precautions need to be taken to prevent the potential transmission of infection from neonates born to suspected/infected mothers to other neonates.

RECOMMENDATION 9

- 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.

- Direct breastfeeding can be given. Mother should wash hands frequently including before breastfeeding and wear mask. If needed due to neonatal or maternal condition, expressed breast milk may also be fed.

If safe, early discharge to home followed by telephonic follow-up or home visit by a designated healthcare worker may be considered.
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 having preferably single closed rooms.

- This area should be separate from the usual NICU/SNCU with a transitional area in-between.

- In case 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 it is 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 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 can also be created by 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 infection, the newborn should be immediately shifted to the closest state designated COVID hospital where such facilities are available. Complete safety, 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?

- 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 a propensity for aerosol generation. CPAP may also generate aerosols but on the other hand, has numerous well-proven advantages over intubation especially in preterm neonates. Hence, CPAP may be used with the lowest possible flows, and neonates should be intubated only as per usual indication.
- Viral filters are recommended to prevent cross-contamination of pathogens between different patients.

**Endotracheal intubation**

- For COVID-19 patients requiring endotracheal intubation, intubation should be performed by the healthcare worker who is most experienced with airway management to minimize the number of attempts and risk of transmission.
- For non-emergent intubations, pre-medication should be used to decrease the probability of aerosol generation.
- If intubating, cuffed endotracheal tubes may offer an advantage.
- In-line suction devices should be preferred.
- To protect the healthcare providers during intubation, the use of a plexiglass box with access portholes can be considered to minimize aerosol spread. The box may, however, restrict the hand movement and requires training before use in the treatment of patients. Operators should be ready to abandon the use of the box should airway management prove difficult.
RECOMMENDATION 11

- Respiratory support for neonates with suspected/confirmed COVID-19 is guided by principles of lung protective strategy including use of non-invasive ventilation.

- CPAP should be preferred over NIPPV and High Flow Nasal cannulas.

- Intubation should be only for usual indications.

- If intubation is needed:
  - Consider use of pre-medication for non-emergent intubation.
  - Intubation should be performed by the healthcare worker who is most experienced with airway management.
  - Consider use of aerosol box during intubation and suction.
  - Consider using in-line suction device.
  - Attach a HEPA filter in the path of exhaled gas when using a mechanical ventilator or positive pressure ventilation device.

- Healthcare providers should practice contact and droplet isolation and wear N95 mask while providing care in the area where neonates with suspected/confirmed COVID-19 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.

Recently the US Food and Drug Administration approved the use of convalescent plasma to treat people with severe or life-threatening COVID-19 infection. The plasma must be collected from recovered patients who can donate blood, have had no symptoms for 14 days, and have had negative results on COVID-19 tests. Severe disease was defined as dyspnoea, respiratory frequency ≥30 breaths per minute, blood oxygen saturation ≤93%, a ratio of the arterial partial pressure of oxygen to fraction of inspired oxygen (PaO2/FiO2) <300, or lung infiltrates >50% within 24 to 48 hours. Convalescent plasma is still considered an investigational new drug. There is currently no evidence to recommend its use in children or infants.
RECOMMENDATION 12

Specific anti-COVID-19 treatment with antivirals or chloroquine or 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, intravenous gamma globulin and convalescent plasma 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, what are the advantages of 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 the 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 the Environmental Protection Agency for disinfection. These products include ethyl alcohol, hydrogen peroxide, or sodium hypochlorite. The role of fumigation is not supported by existing literature or guidelines.
Values and preferences

No evidence is available about the preference of nurses, sanitation workers, healthcare providers, or policymakers about the 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 an 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 [31]:

- 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. For ensuring the efficacy of disinfection with H₂O₂ use the contact period recommended by manufacturer. Usually a contact period of 1 hour is required.
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. [32]

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.”
- 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 the protection of healthcare workers 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 prevents 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 the 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**

<table>
<thead>
<tr>
<th>Protection</th>
<th>Suggested PPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory protection</td>
<td>Triple layered surgical mask</td>
</tr>
<tr>
<td></td>
<td>N95 facemasks when performing an aerosol-generating procedure or in an area where neonates are being provided respiratory support by CPAP device/ventilator</td>
</tr>
<tr>
<td>Eye protection</td>
<td>Goggles or face shield</td>
</tr>
<tr>
<td>Body protection</td>
<td>Long-sleeved water-resistant gown including head and shoe cover.</td>
</tr>
<tr>
<td></td>
<td>A single piece head to toe water resistant body cover will be ideal for attending resuscitation in delivery room or OT</td>
</tr>
<tr>
<td>Hand protection</td>
<td>Well-fitting Gloves</td>
</tr>
</tbody>
</table>

**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 to avoid self-contamination because the PPE could by now be contaminated.

- The gloves are removed first because they are considered a heavily contaminated item. The use of alcohol-based hand disinfectants should be considered before removing the gloves. Dispose of the gloves in a biohazard bin.
- 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 the gown to be performed by grabbing the backside 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.
After the gown, the goggles should be removed and either disposed of if they are single-use or placed in a bag or container for disinfection. To remove the goggles, a finger should be placed under the textile elastic strap in the back of the head and the goggles are 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 the manufacturer’s recommendations.

The respirator/mask should be removed next. To remove the respirator/mask, a finger or thumb should be placed under the straps in the back and the respirator pulled off. The respirator (or the surgical mask) should be disposed of after removal (follow the policy of reuse of the N95 mask if recommended by your hospital). It is important to avoid touching the respirator/mask with the gloves (except for the straps) during its removal.

The last PPE items that should be removed are the new set of gloves that were worn after disposal of the contaminated gloves. The use of an alcohol-based solution should be considered before removing the gloves. Dispose of the gloves in a biohazard bin.

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 the Ministry of Health and Family Welfare (MOHFW), dated 21/3/2020, all biomedical waste should be disposed of following the national guidelines, 2016. [33]

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 following safe routine procedures and rules.
These guidelines should be followed even for healthy/asymptomatic neonates born to mothers with suspected/confirmed COVID-19 infection.

**RECOMMENDATION 15**

Follow routine biomedical waste disposal handling, segregation, transport and final disposal guidelines as prescribed by the Government of India. [33]

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

**Testing guidelines**

**Which neonates and when?**

1. **History of exposure to COVID-19 positive adult (irrespective of symptoms):**
   - Mother had COVID-19 infection within 14 days before birth, or
   - History of contact with COVID-19 positive persons (including mother, family members in the same household or direct healthcare provider) in the postnatal period

   **Timing of test:** At birth (if mother had COVID-19) or at detection of the history of contact with COVID-19 positive person (postnatal exposure). If a sample is not obtained at birth due to logistic reasons, it should be obtained as soon as possible. Rooming-in should not be postponed if testing is delayed.

   If the first test is negative, a repeat test should be done after 5-14 days of birth/exposure. However, the test should be done immediately, if new symptoms (respiratory distress, lethargy, seizures, apnea, refusal to feed, diarrhea) appear.

2. **Irrespective of history of exposure:**
   - Presenting with pneumonia or SARI that requires hospitalization, with onset at more than 48-72 h of age, unless there is another underlying illness that completely explains the respiratory signs and symptoms.

   **Features that suggest acute respiratory illness in a neonate are respiratory distress, with or without cough, with or without fever.**

   If a neonate’s test comes positive, repeat RT-PCR is not required to be done if the neonate is asymptomatic or has mild to moderate disease. In severe cases, a single negative RT-PCR should be demonstrated after the resolution of symptoms [34].
What sample? [35]

- Not mechanically ventilated
  - Two swabs: Nasopharyngeal and throat swabs placed in one viral transport medium (VTM) tube. Obtain specimens from both nostrils using the same swab.
  - If only one swab is available, the same can be used to sample first the throat and then the nasopharynx.

- Mechanically ventilated
  - Tracheal aspirate should be sent in a sterile screw-capped container and in addition, a nasopharyngeal swab should be sent in VTM.

Clinicians may consider additional rectal swab testing if available at their center, particularly for sick infants requiring prolonged hospital care.

How to collect?

- Upper nasopharyngeal swab
  - 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. The swab should reach depth equal to the distance from nostrils to the 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 routine testing (based on current advisory recommendations)

What PPE is needed for sample collection?

Clinicians should wear appropriate personal protective equipment during sampling.

- Nasopharyngeal swab
  - Disposable single-use glove
  - Disposable Plastic Apron
  - N95 mask
  - Eye Protection (surgical mask with integrated visor or full-face shield or visor or goggles/safety spectacles)
For any sampling from the lower respiratory tract in intubated neonates, a full set of PPE is a MUST
- Disposable single-use glove
- Long-sleeved disposable gown
- N95 mask or another respirator mask
- Eye Protection

Labeling 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 it is rendered non-infectious by the laboratory.

How to store?

Samples should be collected in viral transport media procured from the 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 to 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 and Guidance for sample Collection, Packaging, and Transportation for Novel Coronavirus.[33]

Where to send?

Authorized laboratories (See MOHFW website for latest list)

What test?

Reverse Transcriptase PCR is a rapid test for detecting COVID-19.

The cord blood sample should also be tested for IgM and IgG antibodies against COVID-19 infection.
RECOMMENDATION 16

Testing strategy for neonates

1. History of exposure to COVID-19 positive adult (irrespective of symptoms):
   - Mother had COVID-19 infection within 14 days before birth, or
   - History of contact with COVID-19 positive persons (including mother, family members in the same household or direct healthcare provider) in the postnatal period

Timing of test: At birth (if mother had COVID-19) or at detection of the history of contact with COVID-19 positive person (postnatal exposure). If a sample is not obtained at birth due to logistic reasons, it should be obtained as soon as possible. Rooming-in should not be postponed if testing is delayed.

If the first test is negative, a repeat test should be done after 5-14 days of birth/exposure. However, the test should be done immediately, if new symptoms (respiratory distress, lethargy, seizures, apnea, refusal to feed, diarrhea) appear.

2 Irrespective of history of exposure:
   - Presenting with pneumonia or SARI that requires hospitalization, with onset at more than 48-72 h of age, unless there is another underlying illness that completely explains the respiratory signs and symptoms.

Features that suggest acute respiratory illness in a neonate are respiratory distress, with or without cough, with or without fever.

If a neonate's test comes positive, repeat RT-PCR is not required to be done if the neonate is asymptomatic or has mild to moderate disease. In severe cases, a single negative RT-PCR should be demonstrated after the resolution of symptoms [34].
Practice Question 17: What should be the visitation policy and preventive measures for visitors during the COVID-19 outbreak?

**RECOMMENDATION 17**

- Families of suspected and confirmed COVID-19 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 routine childbirth/neonatal care areas should be screened for symptoms of COVID-19.

- Persons with suspected or confirmed COVID-19 should not be allowed entry in the childbirth/neonatal care area.

- For neonates roomed in with mother having suspect/confirmed COVID-19, one healthy family member following contact and droplet precautions may be allowed to stay with her to assist in baby care activities.

- Visitation policy for COVID-19 mother to see her neonate admitted in NICU. Mother may be allowed to visit if she fulfills all of these:
  - Resolution of fever without the use of antipyretics for at least 72 hours AND
  - Improvement (but not full resolution) in respiratory symptoms AND
  - Negative results of a molecular assay for detection of SARS-CoV-2 in case of severe disease.
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 COVID-19 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 COVID-19 infection or with confirmed 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 of the exposed neonates from the health facility to ensure isolation for 14 days. 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

Suspect neonates

- Stable neonates exposed to COVID-19 and being roomed-in with their mothers may be discharged at the same time as mothers.
- Stable neonates exposed to COVID-19, in whom rooming-in is not possible because of the sickness in the mother and are being cared by a nurse or a trained family member may be discharged from the facility by 24-48 hours of age.

(Weak recommendations, based on consensus among experts, incubation period of SARS-CoV-2 infection in adults and older children and the absence of evidence for any beneficial effect or harm with early discharge following exposure to COVID-19)

COVID-19 positive neonates [34]

- Asymptomatic neonates or those with mild to moderate clinical course whose symptoms and need of oxygen abate within 3 days can be discharged from the hospital after 10 days without repeating RT-PCR test.
- In severe cases, a single negative RT-PCR should be demonstrated after resolution of symptoms, prior to discharge.

Remarks

- Early discharge to home may be followed by a telephonic follow-up or home visit by a designated healthcare worker.
- 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.
• If the discharged neonate is positive for COVID-19, uninfected individuals >60 years of age (e.g. grandparents) and those with comorbid conditions should not be assigned to provide care if possible.

Practice Question 19: What should be the occupational health policy specific to the COVID-19 pandemic?
• Healthcare workers directly involved in the care of COVID-19 patients are eligible for Hydroxychloroquine (HCQ) prophylaxis as per the latest ICMR guideline released on 22 March 2020. Eligible healthcare workers should contact their hospital teams for a prescription.
• Health care workers should be asked to avoid travel outside the city unless necessary.
• Health care workers who have traveled to a district in a red zone or a containment area 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 or another state should be asked to maintain social distancing from them.
• Health care workers who have a 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 a 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 professionals working in any childbirth or neonatal area should report to their supervisor if they have respiratory or other symptoms suggestive of COVID-19. 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 professionals directly involved in the care of patients with suspect/confirmed COVID-19 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 future.
Practice Question 20: What should be the immunization policy with respect to neonates born to women with suspected or confirmed COVID-19?

No clinical trials or specific information is available about vaccination of these neonates. Indian Academy of Pediatrics Committee on Vaccines & Immunization recommends continuing all immunizations during the pandemic. [36]

RECOMMENDATION 20

- Follow routine immunization policy in healthy neonates born to mothers with suspected/confirmed COVID-19.

- In neonates with suspected/confirmed infection, vaccination should be completed before discharge from the hospital as per existing policy.
References