HCFI Dr KK Aggarwal Research Fund

HCFI Round Table Expert Zoom Meeting on "COVID-19 in Children and Medical Masks"

28th August, 2021 (11 am-12 pm)

Key points of HCFI Expert Round Table

COVID-19 in children

- The true incidence of coronavirus disease 2019 (COVID-19) in children is not known. This is due to lack of widespread testing, prioritization of tests for adults, less severe illness and fewer hospitalizations in children.
- There should be a high index of suspicion for COVID-19 in children with fever.
- In the US, children below 18 years of age constituted 12% of all cases with less than 2% requiring hospitalization. In European countries, around 9% children were affected, of which 3.5% needed intensive care.
- In Nepal, children <20 years of age accounted for nearly 9% of total cases and in Bangladesh, this figure was 10%.
- As per the National Centre for Disease Control (NCDC) data, less than 12% of confirmed cases were children younger than 20 years and around 4% were children below 10 years of age.
- At CNBC, out of the total positive 9.5% cases, the positive pediatric cases were 3.9% and 0.4% required hospitalization.
- Classical COVID-19 symptoms are fever, sore throat, headache, myalgia, fatigue, coryza, poor feeding in an infant and loss of taste/smell in children older than 8 years. The atypical symptoms are diarrhea, vomiting, abdominal pain, rash, COVID toes.
- Infection may be asymptomatic when the child is diagnosed while screening other family members. The infection can be mild (SpO_2 >94%), moderate (SpO_2 90-93%) or severe (SpO_2 <90%).
- Children likely have similar viral loads in the nasopharynx, similar secondary infection rates and can also spread the infection to others.
- Risk factors for severe COVID-19 include obesity, diabetes, severe malnutrition, malignancy, immunosuppression.
- Remdesivir is not recommended in children. Computed tomography (CT) chest is indicated only if there is no improvement in respiratory status. Likewise, steroids are indicated only in severe and critically ill cases.
- Multisystem inflammatory syndrome in children (MIS-C) is also called pediatric inflammatory multisystem syndrome temporally associated with SARS-CoV-2 (PIMS-TS). It typically appears 4 to 6 weeks after the infection.
- It is important to be able to suspect and correctly diagnose MIS-C, know the list of investigations to be used judiciously, appropriate line of treatment and when to refer the child.
- Some children with MIS-C may later develop hyper-inflammatory disease with manifestations similar to Kawasaki disease or toxic shock syndrome.
- Patients with Kawasaki disease diagnosed during and after COVID-19 differed from those diagnosed before, clinically and biochemically, and therefore were classified as Kawasaki-like disease. They were older, had respiratory and gastrointestinal (GI) involvement, and signs of cardiovascular involvement. They had leukopenia with marked lymphopenia, thrombocytopenia, increased ferritin and had markers of myocarditis. The disease was more severe.
- Several studies have characterized MIS-C in the pediatric age group.
- Tier 1 tests include complete blood count (CBC) with differential counts, C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), reverse transcription polymerase chain reaction (RT-PCR) for SARS-CoV-2, dengue serology, peripheral smear (PS) for malaria, blood culture, electrolytes, liver function test (LFT) and kidney function test (KFT).
- Tier 2 tests include ferritin, lactate dehydrogenase (LDH), prothrombin time/activated partial thromboplastin time (PT/aPTT), fibrinogen, D-dimer, chest X-ray, echo, ECG, troponin-I, interleukin (IL)-6, B-type natriuretic peptide (BNP) and creatine kinase (CK).
- Tropical fevers, toxic shock syndrome and bacterial sepsis must be excluded before making a diagnosis of MIS-C.

- MIS-C treatment involves immunomodulatory treatment (intravenous immunoglobulin [IVIg], steroids, IL-6 antagonists, IL-1 antagonists and tumor necrosis factor [TNF]-α inhibitors) and supportive treatment (oxygen, IV fluids, paracetamol, anticoagulants).
- MIS-C is diagnosed only in the presence of a hyperinflammatory state.
- Discharge criteria include 3 to 4 days of declining inflammatory markers, afebrile/without supplemental oxygen/inotropes for 48 hours, heart failure controlled on oral medication, findings stable on echocardiography (to be repeated 7-14 days and 4-6 weeks post-discharge).
- Overall prognosis is good and most patients usually recover.
- It has been shown that children have a significant fear of COVID-19, boredom and sleep disturbances.
- Families should be helped to recognize the signs of stress, such as sadness, unhealthy eating or sleeping habits, difficulty with attention and concentration. Some children may become silent, while some may express anger and be hyperactive.
- Maintain a normal routine and keep them active, talk to and listen to children, give them accurate information and encourage them to connect to friends and family through video calls.
- Keep up with routine immunizations and routine check-ups for comorbidities.
- Nutritional care of COVID-positive children is essential; enteral feeding is preferred; if child not accepting orally, then nasogastric feeding.
- Mothers should be encouraged to breastfeed while taking all infection prevention measures.
- Maintenance fluid requirement for a 25 kg child is around 1,600 mL.
- Clinical monitoring includes fever, respiratory rate, SpO_2, activity level, feed intake and urine output.
- Red flag signs include child becoming lethargic, not accepting feeds and vomiting, not passing urine, high respiratory rate, chest in drawing, SpO_2 <94%, cold palms and soles and bluish discoloration of body.
- Children with severe COVID-19 particularly require enhanced care and follow-up for likely complications such as infections – pneumonia, mucormycosis. Home SpO_2 monitoring with pulse oximeter for such children is advised.
- Family should be counseled to watch for signs of stress and anxiety and advised about warning signs (fever, fall in SpO_2, increased cough or dyspnea, headache, tooth pain, nasal blockage).
- All family members should practice infection prevention measures after discharge at home and work places.
- Masking is not recommended for children younger than 5 years.
- Schools should be reopened in a phased manner with adequate mitigating measures in place.
- Preparation for the third wave is very crucial. This includes identifying facilities for managing pediatric COVID cases, strengthening of pediatric tertiary care centers and establishment of pediatric beds and ICUs.

Excerpts from presentation by Dr Mamta Jajoo, Professor Pediatrics, Chacha Nehru Bal Chikitsalaya, Delhi

Medical masks

- India needs to mask up to avoid the third wave. The pandemic is still ongoing and is not close to being over. With the emergence of newer virulent strains, such as the Delta variant, it is very important to protect ourselves.
- Even with full vaccination, we must continue to wear a mask. Masks are the new normal.
- Compliance to masks in India is low, despite the deadly second wave. People do not wear masks properly as also shown in a recent study, wherein 67% of citizens failed to comply with proper masking. Crowds are common and social distancing is not adhered to.
- Masks are simple and mandatory barriers, which protect from respiratory droplets.
- Masks can be said to be the personal protective equipment (PPE) for the public during the ongoing pandemic.
- Universal masking is one of the most important prevention strategies recommended by the Health Ministry and the Centers for Disease Control and Prevention (CDC) to slow the spread of the virus.
- Common masks filter about 10% of exhaled aerosol droplets due to problems with the fit, whereas the N95 and KN95 masks filter more than 50% of the aerosols.
- A disposable surgical mask is fluid resistant and protects against larger particles (5 microns in

size), droplets and spray. The N95 mask, on the other hand, also blocks at least 95% of very small particles (0.3 microns). The size of the coronavirus is 0.3 micron.

- The Research For Resurgence Foundation (RFRF) strongly recommends use of masks of higher filtration capability for effective control of the Delta plus variant.
- A fabric mask or even surgical mask is not the right mask to filter out any or all forms of virus.
- The first layer (outer; dark blue or green) of a disposable surgical mask is the fluid-repellent layer and is to be worn outwards. The third layer (inner; white) is the absorbent layer and is to be worn inside. The second layer (melt blown material infused in a nonwoven fabric) is the filtering layer.
- A tight fitting N95 surgical mask achieves a close facial fit and guarantees minimal leakage from the edges of the mask on inhalation. The N95 respirator reduces exposure to small particles and large droplets.
- National Institute of Occupational Safety and Health (NIOSH), South India Textile and Research Association (SITRA) and Institute of Nuclear Medicine and Allied Sciences (INMAS) are the three agencies that have been authorized to test the efficacy of the masks and PPE kits. NIOSH/SITRA certification is mandatory for the masks.
- Factors important for optimal protection are good fit, high filtrating efficiency, high fluid resistance of the outermost layer, high thread count and good breathability. Washability without affecting the structure and efficiency are additional factors for good effectiveness.
- More than the number of layers, the filtering fabric makes the mask more efficient to prevent virus entry.
- Many masks are being sold that do not conform with the SITRA tests.
- The CDC and the Health Ministry recommend double masking to slow the spread of COVID-19. If the two masks fit well, they can produce an overall efficiency of more than 90% for particles sized 1 micron and larger.
- Coating of masks can filter virus and bacteria to nearly 100%. It also provides splash resistance to up to 140 mmHg. The coating is embedded in the cotton fabric pores.
- Biodegradable nanosilver coated masks are also available.

Excerpts from a presentation by Prof (Dr) Ashok Gupta, Recipient of Padma Shri, Bombay Hospital Institute of Medical Sciences, Mumbai

Participants: Dr Ashok Gupta, Dr Suneela Garg, Dr Anita Chakravarti, Dr Arun Jamkar, Dr Mamta Jajoo, Prof Bejon Misra, Dr DR Rai, Dr Jayakrishna Alapet, Dr KK Kalra, Dr Anil Kumar, Dr B Kapoor, Mrs Upasana Arora, Ms Ira Gupta, Ms Balbir Verma, Ms Priyanka Bapna, Mr Rajesh Chopra, Mr Saurabh Aggarwal, Dr S Sharma

HCFI Round Table Expert Zoom Meeting on "Medical Masks: Coating of Masks, Double Masking – Part 2"

4th September, 2021 (11 am-12 pm)

Key points of HCFI Expert Round Table

- Many people buy N95 masks to reduce their risk of getting COVID-19. But, health regulatory authorities recommend that the use of N95 masks be limited to healthcare workers.
- There are several counterfeit brands sold in the market, particularly in the developing countries. This raises safety concerns.
- Only patented technologies which have international certification and are based on peer reviewed evidence should be used.
- Nonwoven masks are manufactured using plastic variants such as polypropylene to provide protection against infections.
- Asia Pacific has emerged as the largest market for disposable face masks in 2019. India and China are among the largest manufacturers of disposable face masks. Hence, adherence to quality of masks is essential.
- Face masks are a ticking bomb; every minute, 3 million masks are thrown out and act as a source for other infections and toxicants in the environment.
- Certifications or patents are not enough to determine credibility. Stricter regulations on product testing for claims of manufacturers are essentail to ensure the effectiveness of the product advertised.
- Washable and reusable masks are favored. Face masks in esthetically appealing designs and prints to attract the consumer are available in the market.
- Silver has antimicrobial properties, which have been well-documented. The potential antiviral mechanisms of silver nanoparticles are binding

interaction with viral envelope proteins and inhibiting the virus from binding to the host's cell membrane. Size of nanoparticles has been thought to influence their antiviral efficiency.

- It is necessary to implement well-defined evaluation parameters and quality control protocols to improve product quality and consumer trust.
- Reusable face masks can be laundered for reuse (maximum 50 cycles).
- American Society for Testing and Materials (ASTM) Level 1 masks are for procedures in which there is low risk of fluid exposure (no fluid, splashes or sprays expected).
- ASTM Level 2 is for procedures in which there is moderate risk of fluid exposure (aerosols, splashes or sprays).
- ASTM Level 3 is for procedures in which there is heavy exposure to fluid (aerosols, splashes or sprays).
- Consumer Product Safety Commission (CPSC) under the Consumer Product Safety Act is charged with protecting the public from unreasonable risks of injury or death associated with the use of different types of consumer products under its jurisdiction.
- A face mask should have at least three layers: Inner absorbent layer made of a coated/absorbent cotton, middle filter layer made up of nonwoven material and outer fluid repellent layer.
- International Organization for Standardization (ISO), ASTM, NIOSH, SITRA, INMAS provide certifications to ensure the validity of claims of the manufacturer.
- Two innovations by IIT scientists have created a coating for masks that kill viruses within minutes: Nano coating system and a cloth mask coated with a biodegradable, biocompatible and nonirritant system.
- Antibacterial properties of silver are known for a long time. Use of silver in larger concentrations is harmful.
- Apart from the size, concentration of silver used, and the mask layer on which it is coated, a direct contact with hands also matters. A nanoparticle is <100 nm.
- Silver nanoparticles can have adverse effects on health in both animals and humans via dermal, respiratory and oral routes. Some airborne particles are released from nanoparticle impregnated products, even when nanoparticles are embedded inside the fibers.
- NIOSH has suggested an exposure limit of 0.9 $\mu g/m^3$ over 8 hours for respirable silver particles that are <100 nm in size.
- Environmental Protection Agency (EPA) prohibits manufacturers from advertising antimicrobial claims without proper registration of the product as a pesticide.
- Antiviral or antibacterial claims on products are also not allowed in accordance with Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).
- IIT Mumbai has developed a coating technology called Duraprot (durable + protection), which has been patented. Every nanotechnology that is developed is first evaluated for toxicity. The silver coating technology was also evaluated for any toxic or mucosal irritant effect.
- The coating material is a nanoemulsion of several bio-based materials. All ingredients are Food and Drug Administration (FDA) Generally Recognized As Safe (GRAS) approved materials, they are natural or naturally derived. The material is biodegradable, biocompatible and nonirritant.
- It is cross-linked to the fibers of the mask and retains its efficacy for until 20 wash cycles. It can be coated on cotton, polyester, viscose and rayon. It is easy to make and easy to coat.
- It has charge-based attraction and killing mechanism. Its anti-SARS-CoV-2 activity has been demonstrated by RT-PCR method. The swab (viral transport medium) was coated with the nanoemulsion.
- Any product which has health implications is supposed to be regulated, i.e., product standards have to be specified by law.
- Medical devices were earlier regulated as drugs by the Central Drugs Standard Control Organisation (CDSCO). All masks used for medical purposes are medical devices. Until February 2020, the Government had regulated or notified 37 categories of medical devices as drugs. In February 2020, CDSCO notified the definition of medical device. Any product, including masks, which falls under the definition, would deem to be regulated by the rules.
- From April 2020, all manufacturers of non-notified medical products/devices were given an option

to register voluntarily along with ISO 13485 certification, which is for quality management. This period of voluntary registration ends on September 30. After this registration becomes compulsory. All products used during COVID – masks, PPE, oxygen concentrator, pulse oximeter, ventilators - are therefore unregulated as on today (as on the day of the meeting). However, product certification does not require product compliance yet.

- For Class A and B products, the CDSCO has given 1 year's time to comply with the legal requirements for the product.
- The standards prescribed are the Bureau of Indian Standards' (BIS) standards. From August 2022, compliance to BIS standards would be mandatory in order to sell a product in the market.
- The Health Ministry guidelines for PPE kits still talk of foreign standards and not BIS standards. The Textile Ministry; however, is advising every manufacturer to get certification from BIS.
- The only assurance for quality is the ISI mark. Look at ISI mark when buying masks.
- At the request of the government, BIS put a condition for the manufacturers that products would be sold to the government first. So, masks with ISI mark may not be available in the open market.
- As of today, there is no legal compliance expected from mask manufacturers; legal compliance (to some extent) starts from 1st October; product compliance gets effective from August 2022.
- Two Indian standards are available for masks: IS 16829:2014 for surgical face mask and IS 9473:2002 for N95 masks in line with the ASTM and BIS standards.
- These standards require the bacteria filtration efficiency, particle filtration efficiency, splash resistance and breathability.
- At present, 56 licenses have been granted from IS 16829. This list is available publicly on BIS website and is updated in real time.
- Coating of masks (with silver nanoemulsion) is not specified as a requirement, but may be given as optional requirement.
- The resistance to inward leakage of surgical masks is poor. Therefore, all frontline workers use N95 and FFP2 masks.
- N95 mask is a 5-layer mask; it has very good resistance to inward leakage.
- The fit of surgical mask and N95 vary greatly.
- BIS is converting respirators to medical respirators. Apart from filtration efficiency and inward leakage, requirement of bacteria filtration efficiency and splash resistance is also being specified.
- There should be a standard for the barrier masks for use by the general public, which provide only breathability and particle filtration efficiency, apart from design and reusability requirements.
- ASTM, AFNOR, Ireland have already brought standards for barrier masks. BIS is working on standards for the barrier mask and will soon bring out a mask for the general public with a caveat that these masks are not suitable for the medical professional.
- A strong redressal mechanism is available online.
- 261 licenses for N95 masks have been granted as on today.
- N99 and FFP3 masks are also now being provided.
- As of today, there are no regulations. In future, CDSCO will be the regulatory authority. States have drug inspectors, etc. If there is any misuse of BIS marks (fake ISI marks), BIS has the power to raid such premises and search. It can also act if somebody who holds a BIS license gives substandard quality.
- Breathability is a prime requirement of masks – it is 29.4 Pascals, which is equivalent to 3 mm of water column.

Participants: Dr Ashok Gupta; Dr Suneela Garg; Dr DR Rai; Mr JK Gupta, BIS; Mr Anil Jauhri, Ex-CEO - NABCB, QCI; Prof Naveeen K Navani, IIT Roorkee; Mr Kapil Punjabi, IIT Mumbai; Dr Anita Chakravarti; Dr Arun Jamkar; Dr KK Kalra; Dr Anil Kumar; Ms Ira Gupta; Ms Priyanka Bapna; Dr S Sharma.