

N-95 mask and face shield head light: An ideal combo for ENT doctors during COVID 19 pandemic

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Ethics declarations

Abstract: The present pandemic of COVID-19 is caused by the virus SARS-CoV-2 and constitutes a public health emergency of global concern. This virus primarily spreads between people during close contact often via small droplets produced by coughing, sneezing, and talking. The droplets usually fall to the ground or onto surfaces rather than remaining in the air over long distances. The Symptoms of COVID-19 infection include fever, cough, and respiratory distress. Right now here none of the private healthcare establishments here have access to rapid diagnostic kits to ascertain whether a patient who comes for treatment is infected or not. Since ENT doctors work in close proximity to the patient's nasal, oral cavities, it is quite crucial for the doctor to undertake personnel protection and appropriate preventive and infection control measures to avoid the spread of the virus. Masks, Face shields are personal protective equipment devices that are used by medical, Para medical staff for protection of the facial area and associated mucous membranes during pandemic. In the wake of scarcity of Personal Protective Equipment (PPE) kits, face shields during the COVID 19 Pandemic, newer methods of devices has to be considered to overcome the present day scarcity. One such simple improvised device is face shield head lamp which is helpful for ENT doctors to examine patients without jeopardizing the safety of front line Health care worker. This article reviews and tries to give an overview to the ENT surgeons about this pandemic, how to prepare face shield head lamp, provide details about PPE kits, face shields, masks, the infection control and preventive measures that can be employed by them to prevent further spread and subsequent worsening of the current disease scenario based on the current research evidence.

Key words: Covid-19, face shield. PPE, ENT, safety

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I. Introduction

Corona virus disease 2019 (COVID-19) caused by severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) is an ongoing global health emergency. The epicenter of this ongoing outbreak is in the city of Wuhan in Hubei Province of central China and the Huanan seafood wholesale market was thought to be at least one of the places where SARS-CoV-2 from an unknown animal source might have crossed the species barrier to infect humans¹. On 30th January, 2020, WHO declared the outbreak a Public Health Emergency of International concern. On 11 March, WHO Director General characterized COVID-19 as a pandemic². SARS-CoV-2 is closely related to SARS-CoV, and is thought to have a zoonotic origin.³ SARS-CoV-2 genetically clusters with the genus *Betacoronavirus*, and is 96 per cent identical at the whole genome level to other bat coronavirus samples and 92 per cent identical to pangolin coronavirus. Coronaviridae is family of zoonotic virus which primarily targets the human respiratory system³. Coronaviruses are large enveloped, positive single stranded RNA viruses that can be divided into four genera, namely alpha, beta, delta and gamma. Since they are positive-sense single-stranded RNA viruses, they do not need to carry enzymes to initiate infection. The virus genome was found to be 75-80% identical to the SARS-CoV-1 which had caused the SARS epidemic⁵. This virus binds to their target cells through angiotensin converting enzyme 2 (ACE 2) which is expressed by epithelial cells of lung, intestine and blood vessels. World Health Organisation (WHO) has classified COVID-19 as a Beta-CoV of group 2B

The virus is primarily spreads between people during close contact, often via small droplets produced by coughing, sneezing, and talking. The droplets usually fall to the ground or onto surfaces rather than remaining in the air over long distances⁴. People may also become infected by touching a contaminated surface and then touching their face. On surfaces, the amount of virus declines over time until it is insufficient to remain infectious, but it may be detected for hours or days. It is most contagious during the first three days after the onset of symptoms, although spread may be possible before symptoms appear and in later stages of the disease.

Many nations are facing huge crisis in terms of finance, available resources and sufficient number of health workers. Treatment protocols are focused on recovery of diseased patients, prevention of spread of infection.

The guidelines have been adapted from the existing WHO & CDC recommendations. These guidelines are supplementary to the existing Hospital Infection control Manual of AIIMS.

WHO guidelines Protecting yourself and others from the spread COVID-19

- Regularly and thoroughly clean your hands with an alcohol-based hand rub or wash them with soap and water.
- Social distancing: Maintain at least 1 meter (3 feet) distance between yourself and others. Avoid going to crowded places. Why? Where people come together in crowds, you are more likely to come into close contact with someone that has COVID-19 and it is more difficult to maintain physical distance of 1 metre (3 feet).
- Avoid touching eyes, nose and mouth. Why? Hands touch many surfaces and can pick up viruses. Once contaminated, hands can transfer the virus to your eyes, nose or mouth. From there, the virus can enter your body and infect you.
- Make sure you, and the people around you, follow good respiratory hygiene By following good respiratory hygiene, you protect the people around you from viruses such as cold, flu and COVID-19.
- Stay home and self-isolate even with minor symptoms such as cough, headache, mild fever, until you recover.

World Health Organization is rapidly undertaking all possible measures to control the disease, prevention of spread of infection, issued few guidelines for mask, PPE kit, shields usage and social distancing ⁷

Recommendations for wearing masks have been a subject of debate⁵. The WHO has recommended healthy people wear n-95 masks only if they are at high risk, such as those who are caring for a person with COVID-19. China and the United States, among other countries, have encouraged the use of face masks or cloth face coverings more generally by members of the public to limit the spread of the virus by asymptomatic individuals as a precautionary principle several national and local governments including India have made wearing masks mandatory ⁶.

II. Discussion

The very nature of ENT(ear nose and throat) doctor doesn't allow its practitioners to maintain the basic norms of social distancing. While a general medicine doctor can still maintain a safe distance and be able to check the patient and prescribe medicines while treating the patients. With the extreme shortage of the N95 masks and other disposable masks, our simple and economic option for preparing our own effective barrier face masks and face shields by use of locally available resources will help to tide over the crises of shortage.

Surgical masks recommended for those who may be infected, as wearing this type of mask can limit the volume and travel distance of expiratory droplets dispersed when talking, sneezing, and coughing Surgical mask or face mask is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. While a surgical mask may be effective in blocking splashes and large-particle droplets, a face mask, by design, does not filter or block very small particles in the air that may be transmitted by coughs, sneezes, or certain medical procedures. Surgical masks also do not provide complete protection from germs and other contaminants because of the loose fit between the surface of the face mask and your face

N95 Mask: is FDA approved the N95 mask requires a fine mesh of synthetic polymer fibers, also known as nonwoven polypropylene fabric, which is produced through a process called melt blowing that forms the inner filtration layer that filters out hazardous particles ⁸. During crisis situations where there is a shortage of N95 respirators, such as the COVID-19 pandemic. Centers for Disease Control and Prevention (CDC) has recommended strategies for optimizing their use in healthcare settings N-95 respirators can be used beyond their Manufacturer-designated shelf life, although components such as the straps and nose bridge material may degrade, making it particularly important that the wearer perform the expected seal check. N95 respirators can be reused a limited number of times after being removed, as long as they have not been used during aerosol-generating procedures, preliminary data suggests limiting to five uses per device. AIIMS guidelines for reusing N-95 mask The circular said, "It is imperative that in accordance with the evidence based on scientific literature, these 95 masks are to be disinfected by individual users, by keeping them in open after use or by other methods, and re-used at least 4 times each, whereby these 5 masks will suffice for about 20 days ¹⁴.

An FFP (filtering face piece) mask also called respiratory protection mask or simply respirator is a type of protective mask certified by the European Union that serves to protect against particulates such as dust

particles and various viruses in the air. There are three classes of these masks, namely FFP1, FFP2 and FFP3⁹
10.

FFP1 mask: FFP1 mask It is the least filtering mask of the three. Aerosol filtration percentage around: 80% ,leak rate: Maximum 22%.It is mainly used as a dust mask in particular dust from coal, silica, iron ore even cement.

FFP2 mask :FFP2 masks with exhalation valve Aerosol filtration percentage: 94%,internal leak rate: Maximum 8% This mask can also serve as protection against influenza viruses such as avian influenza or severe acute respiratory syndrome associated with the corona virus (SARS), as well as against the bacteria of pneumonic plague and tuberculosis. It is similar to the N95 mask FFP3 mask : FFP3 mask with exhalation valve Aerosol filtration percentage: 99%.Internal leak rate: Maximum 2%The FFP3 mask is the most filtering of the FFP masks. It protects against very fine particles such as asbestos and ceramic. It does not protect against gases

Cloth masks ;There are several studies for several commonly used fabrics including cotton, silk, chiffon, , various synthetics, and their combinations as material of choice for face mask. Although the filtration efficiencies for various fabrics when a single layer was used ranged from 5 to 80% for particle sizes of <300 nm, the efficiencies improved when multiple layers were used and when using a specific combination of different fabrics. Filtration efficiencies of the hybrids (such as cotton–silk, cotton–chiffon,) was >80% (for particles <300 nm) and >90% (for particles >300 nm). Studies have shown that the enhanced performance of the hybrids is likely due to the combined effect of mechanical and electrostatic-based filtration. Cotton, the most widely used material for cloth masks performs better at higher weave densities (*i.e.*, thread count) and can make a significant difference in filtration efficiencies. Other studies also imply that gaps (as caused by an improper fit of the mask) can result in over a 60% decrease in the filtration efficiency, implying the need for future cloth mask design studies to take into account issues of fit and leakage, while allowing the exhaled air to vent efficiently. Overall, we find that combinations of various commonly available fabrics used in cloth masks can potentially provide significant protection against the transmission of aerosol particles. Combining layers to form hybrid masks, leveraging mechanical and electrostatic filtering may be an effective approach. This could include high thread count cotton combined with two layers of natural silk or chiffon, for instance. A quilt consisting of two layers of cotton sandwiching a cotton–polyester batting also worked well. In all of these cases, the filtration efficiency was >80% for <300 nm sized particles¹³.

PPE Kits : According to the Ministry of Health and Family Welfare Directorate General of Health Services guidelines for PPE kits are : • should contain 6 items: Goggles, Face-shield, head cover , Mask, Gloves ,Coverall/gowns (with or without aprons • Impermeable to blood and body fluids • Single use • Avoid culturally unacceptable colors e.g. black • Light colors are preferable to better detect possible contamination • Thumb/finger loops to anchor sleeves in place • Quality compliant with following standards Meets or exceeds ISO 16603 class 3 exposure pressure, or equivalent .Most important item in PPE kit is gown which is made of Woven or nonwoven fabric . Knitting technology is used generally for most of the reusable gowns, gowns cuffs, for nonwoven fabrics gowns meltblown and spunbond technologies is used. Disposable gowns are designed to be discarded after a single use and are typically made of nonwoven materials alone or in combination with materials that offer increased protection from liquid penetration, such as plastic films. The basic raw materials typically used for disposable surgical gowns are various forms of synthetic fibers (e.g. polypropylene, polyester, polyethylene)on the other hand reusable gowns are typically made of 100% cotton, 100% polyester, or polyester/cotton blends. These fabrics are tightly woven plain weave fabrics that are chemically finished and may be pressed through rollers to enhance the liquid barrier properties. Reusable garments generally can be used for 50 or more washing and drying cycles. Studies have shown that The random orientation of the fibers in the nonwoven fabrics successfully reduces liquid transmission by (i) providing filtering media (ii) reducing the capillary formation and offers more protection compared to fabric woven reusable gown. Design and performance characteristics vary as a result of trade-offs in cost, comfort and the amount of barrier protection provided^{16 17}. Currently, there are four labs in the country which have the Synthetic Blood Penetration Resistance Test facilities. These are also the labs that approve tests and certification for PPE required for COVID-19. The four labs include South India Textiles Research Association located in Coimbatore, DRDE in Gwalior, Heavy Vehicles Factory in Avadi and Small Arms Factory in Kanpur.

Face shields :A face shield, an item of PPE aims to protect the wearer's entire face from aerosols of infectious materials. In market various face shield are available but non are compactable with head lamp this made us to prepare our own device.

How to incorporate face shield into the head lamp to make face shield head lamp

Tools needed: Scissors, paper marker, scale.

Materials needed: Visor(face shield any type of clear plastic film) PET sheet of size 12"x10" is an ideal (200-300 microns thickness), Velcro strip, adhesive gum, Head lamp There are two types of plastic sheet available in market for face shield :PET sheets ,OHP sheet.PET (polyethylene terephthalate) sheet of thickness 200-300 micron is best for repeat use face shield. Compared to OHP sheet (Cellulose acetate), PET sheet is more thick withstands more force, more heat resistant.

How to make full adult-sized face shield, steps: (pictures 1-5)

1. Attach one Velcro strip to inner aspect of head light (One strip with hard plastic hooks on it) with adhesive glue or double side gum tape.

2. Attach the other Velcro strip to upper side of shield(one with the hairy-style "loop" material) with adhesive glue ,with marker mark central point.

3. Incorporate face shield into head lamp and Press the Velcro strips together to connect the two objects.

4. Pull the strips apart to separate the two objects.

Advantages of face shield head light: Extremely cheap ,easy to prepare, Comfortable to use, Protects a larger portion of the face Can be sterilized easily Protects against aerosols over a wider facial area. Minimal fogging, No impact on vocalization, No impact on breathing resistance ¹⁵ .

Methods of sterilization of face shields; 1% Sodium Hypochlorite solution for minimum of 20 min or 2 % Glutaraldehyde (cidex) for 10 min, best way of sterilization is UV or ETO. According to the AIIMS guidelines, coveralls and N95 masks can be decontaminated using doubling dilution of 11 % hydrogen peroxide vapor in a sealed room while face shields and goggles can be decontaminated using 1 per cent sodium hypochlorite solution and 70 per cent alcohol and 1% solution Sodium Hypochlorite for disinfection of common spaces (clinics, hospital lobby, etc) ¹⁴. Table 1

There have been no studies on incorporating face shield into head lamp. Our device have shown be promising results for routine ENT examination of patient during pandemic .Nevertheless, greater scientific studies are needed to establish this as simple effective simple device for examination ear, nose and throat.

III. Conclusion

The COVID 19 Pandemic has caused a huge devastation and destruction globally .This has resulted in paradigm shift in the social economic structure ,caused lot of uncomforness and anxiety among the health care providers and made to consider everyone around us a asymptomatic carriers of covid virus .The major challenge and the present need of the hour for an ENT Surgeon is to maintain social distance while examining the patients and this forced and posed to innovate a think tank to create new devices and with the scarcity of the N95, masks ,face shields and other disposable PPE kits simple locally available economic option devices are to be considered. Face shield head lamp is simple, easy to make, made of easily available materials, reusable and effective barrier examination device for ENT surgeons when used in combination with N-95 mask.

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Table :1 Guidelines for Preparation of 1% sodium hypochlorite solution

Product	Available chlorine	1percent
Sodium hypochlorite – liquid bleach	3.5%	1 part bleach to 2.5 parts water
Sodium hypochlorite – liquid	5%	1 part bleach to 4 parts water
Bleaching powder	70%	7g to 1 litre water

PICTURE 1



Velcro strip, adhesive gum, scissors, sheet, Head lamp,

PICTURE 2



Velcro strip (soft material) affixed to upper end of sheet,

PICTURE 3



Velcro strip (hard material) affixed to inner aspect of Head lamp

PICTURE 4



Face shield with Velcro strip, incorporating into Head lamp

PICTURE 5



Face shield, head lamp N-95 mask