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INNOVATIVE ALTERNATIVES OF PPE IN COVID-19 PANDEMIC - OUR EXPERIENCE

Dr Shivaam Kesarwaani[*1], Dr Somnath Saha[2]

[1] Post Graduate Trainee, Department of ENT, Head & Neck Surgery, Calcutta National Medical College & Hospital, Kolkata.
[2] Professor & Head, Department of ENT, Head & Neck Surgery, Calcutta National Medical College & Hospital, Kolkata.
*Correspondence:
Dr.Shivaam Kesarwaani
Email: shivaam.edutech@gmail.com

Introduction & Background:

In the current scenario of rapidly spreading pandemic infection due to the coronavirus, SARS-CoV2, otolaryngologists and surrounding staff are especially vulnerable to viral transmission directly through mucus, blood, and aerosolized particles when examining or operating. There is evolving evidence from China, Italy, and Iran that otolaryngologists are in the group with the highest risk of contracting the virus while performing upper airway procedures and examinations, if not using appropriate Personal Protective Equipment (PPE).

Until the supply of testing materials catches up with the accelerating demand for testing, there will be circumstances that the COVID-19 status of these patients is unknown.

Therefore, when a detailed examination or surgical procedure is necessary for urgent or emergency care and the -19 status of the patient cannot be confirmed, then the patient should be handled as if they are COVID-19 positive. This consideration should apply regardless of whether one is in an office, hospital, or operating room setting. Furthermore, the provider and surrounding staff must have the necessary PPE.

As the coronavirus disease 2019 (COVID-19) pandemic accelerates, global health care systems have become overwhelmed with potentially infectious patients seeking testing and care.

Preventing spread of infection to and from health care workers (HCWs) and patients relies on effective use of personal protective equipment (PPE)—gloves, face masks, air-purifying respirators, goggles, face shields and gowns. A critical shortage of all of these is projected and has already developed in Indian hospitals.

PPE, formerly ubiquitous and disposable in the hospital environment, is now a scarce and precious commodity in many locations when it is needed most to care for highly infectious patients. An increase in PPE supply in response to this new demand will require a large increase in PPE manufacturing, a process that will take time many health care systems do not have, given the rapid increase in ill COVID-19 patients.

It's a challenging problem, and we're working to solve it in several ways. When PPE supplies cannot be filled by a health care facility's normal suppliers and the state cannot find a vendor, the best option left to doctors across the globe is to innovate and come up with temporary alternative solutions to PPE using locally available materials, at least till the time proper and convention PPE is made readily available to them. This article discusses various such alternatives being used at our hospital & some other such innovations from across the globe.

MATERIALS & METHODS:

The team at Department of ENT, Calcutta National Medical College & Hospital,Kolkata during the month of March 2020, focused on innovating & researching about temporary alternatives to personal protective equipment (PPE), in response to the current trend of PPE scarcity around the world.

This article discusses various such alternatives used at our hospital & other such innovations from across the globe.

The team designed two types of easy to make head gear (fig.2&3), which can be used while doing aerosol generating procedures like emergency tracheostomy, sample collection etc.

A group of nurses were specially allotted for preparation, sterilization & proper disposal of the head gears in advance. Sterilisation before the usage was done by either ethyl alcohol (92%-95%) or 1% hypochlorite solution. After usage it was disposed of in yellow cloured plastic bags /containers.

Materials Used:

A) For Model "A" face shield head gear:
   1) OPG Plastic Sheets
   2) Thick ribbon thread (30 cm)
   3) Scissors
   4) Cellophane tape

B) For Model "B" head gear:
   1) Transparent plastic packet(50 cm(L) x 60 cm(B))
   2) Surgical Mask
   3) Scissors
   4) Cellophane tape.

DISCUSSION :

In its current guidance to optimize use of face masks during the pandemic, the Center for Disease Control and Prevention (CDC) identifies 3 levels of operational status: conventional, contingency, and crisis[1] During normal times, face masks are used in conventional ways to protect HCWs from splashes and sprays.

When health care systems become stressed and enter the contingency mode, CDC recommends conserving resources by selectively cancelling non-emergency procedures, deferring non-urgent outpatient encounters that might require face masks, removing face masks from public areas, and using face masks for extended periods, wherever feasible.

When health systems enter crisis mode, the CDC recommends cancellation of all elective and non-urgent procedures and outpatient appointments for which face masks are typically used, use of face masks beyond the manufacturer-designated shelf life during patient care activities, limited reuse, and prioritization of use for activities or procedures in which splashes, sprays, or aerosolization are likely[2].

When face masks are altogether unavailable, the CDC recommends using of face shields without masks, taking clinicians at high risk for COVID-19 complications out of clinical service, staffing services with convalescent HCWs presumably immune to SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), and use of homemade masks, perhaps from bandanas or scarves if necessary. Most of the countries globally are rapidly entering crisis mode.

WHO[3] says current global stockpile is insufficient, particularly for medical masks masks and respirators; the supply of gowns and goggles is soon expected to become insufficient as well. Surging global demand – driven not only by the increasing number of COVID-19 cases but also by misinformation, panic buying, and stockpiling – will result in further shortage of PPE globally.

The American College of Surgeons (ACS) released a Statement on PPE Shortage during the COVID-19 Pandemic[4] in which they recognized that many healthcare facilities are facing shortage of personal protective equipment (PPE), including face masks, gowns, and respirators. The ACS believes it is essential that surgeons, nurses, anesthesiologists, and other health care personnel be able to speak freely, without fear of retribution, as they seek to find a solution to accessing PPE. We advise surgeons to speak with their institutional leadership on these matters and to be able to direct any concerns to the ACS, with the goal of protecting themselves and their colleagues.

Suggested minimal PPE set :

The suggested minimal PPE set protects from contact, droplet and airborne transmission[5] The composition of the set is described in Table 1.

Table 1: Composition of Minimal PPE set

	Protection	Suggested PPE
1	Respiratory protection	FFP2 or FFP3 respirator (valved or non valved version) *
2	Eye protection	Goggles (or face shield)
3	Body protection	Long-sleeved water-resistant gown
4	Hand protection	Gloves

*(In case of shortage of respirators, the use of face masks (surgical or procedural masks) is recommended. When this type of PPE is used, the limitations and risks connected to its use should be assessed on a case-by-case basis.)

Respiratory protection:

The respirator protects from the inhalation of droplets and particles. Because different types of respirators fit differently between users, the respirator requires a fitting test.

The use of class 2 or 3 filtering face-piece (FFP) respirators - FFP 2 or FFP 3, when assessing a suspected or

managing a confirmed case. An FFP3 respirator should always be used when performing aerosol-generating procedures.

Face masks (surgical masks) mainly protect from exhaled droplets[5]; their use is recommended in case of shortage of respirators and on a case-by-case assessment. Surgical masks do not require fit testing.

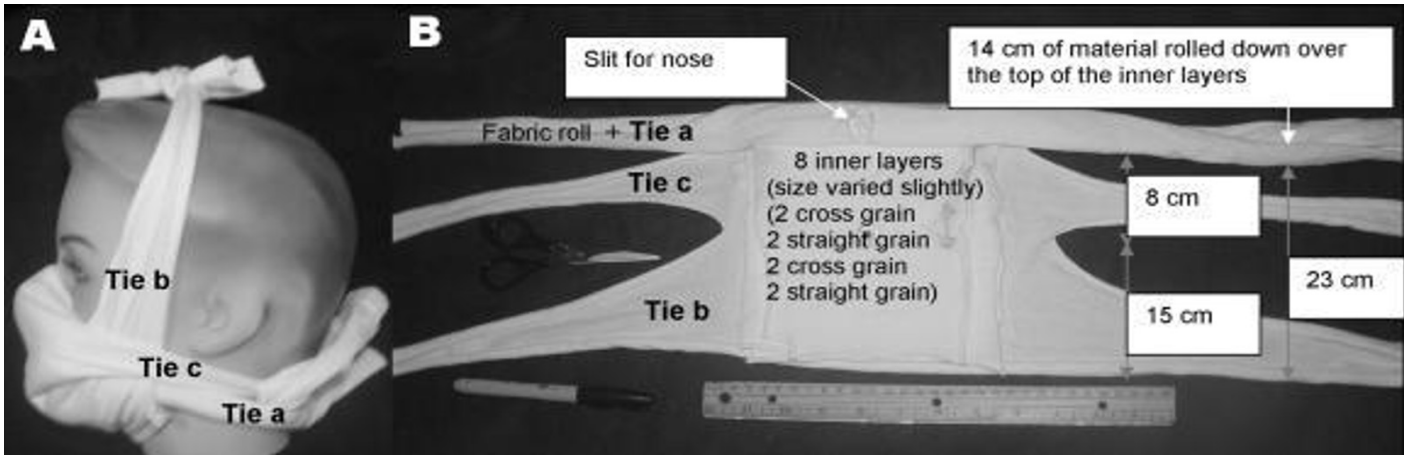

Figure 1 : Prototype mask. A) Side view, B) Face side. This mask consisted of 1 outer layer (≈37 cm × 72 cm) rolled and cut as in panel B with 8 inner layers (<18 cm2) placed inside (against the face).

Virginia M in a letter(6) described a simple, locally made, washable mask, which may be a solution if commercial masks are not available. A Hanes Heavyweight 100% preshrunk cotton T-shirt (made in Honduras) was boiled for 10 minutes and air-dried to maximize shrinkage and sterilize the material in a manner available in developing countries. A scissor, marker, and ruler were used to cut out 1 outer layer (≈37 × 72 cm) and 8 inner layers The mask was assembled and fitted as shown in Figure 1 . A fit factor is the number generated during quantitative fit testing by simulating workplace activities (a series of exercises, each 1 minute in duration).

The Portacount Plus Respirator Fit Tester with N95-Companion used for the test is an ambient aerosol instrument that measures aerosol concentration outside and inside the prototype mask. The challenge agent used is the ambient microscopic dust and other aerosols that are present in the air. A commercially available N95 respirator requires a fit factor of 100 to be considered adequate in the workplace. The prototype mask achieved a fit factor of 67 for 1 author with a Los Alamos National Laboratory (LANL) panel face size of 4, a common size. Although insufficient for the workplace, this mask offered substantial protection from the challenge aerosol and showed good fit with minimal leakage. While testers wore the mask for an hour without difficulty, we cannot comment on its utility during strenuous work or adverse environmental conditions.

2) Eye protection : Goggles, or face shields (Figure 2), should be used to prevent virus exposure of the eye mucosa. Important: goggles need to fit the user's facial features and have to be compatible with the respirator. Face shields are personal protective equipment devices that are used by many workers (e.g., medical, dental, veterinary) for protection of the facial area and associated mucous membranes (eyes, nose, mouth) from splashes, sprays, and spatter of body fluids. Face shields are generally not used alone, but in conjunction with other protective equipment and are therefore classified as adjunctive personal protective equipment.

We, at our centre, Calcutta National Medical College designed a simple, easy to make, yet effective disposable head gear, 10 of which can be made under 0.5$. Fig (2a,b,c) shows the model "A" face shield head gear prototype used.

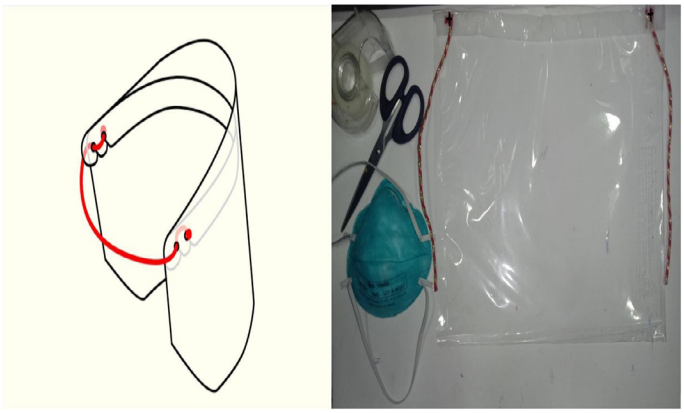

Figure 2: a) Prototype Design b) Material used in making face shield.

Figure 2c: Showing face shield application over N95 mask .

Advantages and disadvantages of face shields compared with other forms of face/eye protection that were noted by us are enumerated below (i.e., protective facemasks [filtering facepiece respirators, medical/surgical masks], goggles, safety glasses)in Table 2 [7,8,9].

TABLE 2:

Advantages and disadvantages of face shields compared with other forms of face/eye protection

S.no.	Advantages	Disadvantages
1	● more comfortable	● fogging
2	● protect a larger portion of the face	● bulkier than goggles and safety glasses
3	● easy to don and doff	● optically imperfect
4	● less fogging than goggles	● some models may not fit properly over some respirators (e.g., duckbill filtering facepiece respirators)
5	● can be worn concurrent to other face/eye PPE	● peripheral fit poorer than protective facemasks
6	● no impact on breathing resistance	● glare
7	● no fit testing required	

There is evolving evidence that otolaryngologists are among the highest risk groups when performing upper airway surgeries and examinations. Emergency procedures like tracheostomy, cut throat injuries etc. are some unavoidable short duration exposures, but carry a high risk of transmission of COVID-19 for on duty resident surgeons. We devised a better face shield which will provide a 360 degree protection from any aerosol exposure during the operative procedure . This can be worn over N95 respirators after sterilization with 1% hypochlorite or surgical spirit & discarded after single use. As these procedures last for a shorter duration , the little discomfort caused by wearing is tolerable in view of the protection it provides.

Its use can be widened to other high risk procedures like oropharyngeal (throat) swab sample collection, emergency intubations & many more.

The fig3(a,b) shows the model "B" head gear prototype worn by resident surgeon.

Figure 3: a) Showing 360 degree protective head gear , b) Head gear used by resident surgeon (to be worn over N95 mask & PPE gown)

A 12 cm x 8 cm rectangular opening is created at the bottom of the face shield, near the supraclavicular region. Surgical mask is taped over the opening from inside. It will serve as a route for air entry, and will also prevent entry of any aerosol generated during the procedure. This model provides a better protection in procedures associated with high amounts of aerosol generation & thus belonging to the high risk category. The gear is for one time used & are disposed of according to the biomedical waste management plan in yellow bags & containers.

Upon researching how the problem of scarcity in PPE is being tackled in different parts of the world, we found many similar projects being practiced. In American Architects and Universities Leverage Open-Source Design[10] , using a file created by Erik Cederberg (of Swedish manufacturer 3DVerkstan), a host of American architecture studios (BIG, Brooks + Scarpa, Höweler + Yoon, Jenny Sabin, Edg, Weiss/Manfredi, Kohn Pedersen Fox and Handel Architects,) alongside the faculty in the Architecture, Art and Planning Department of Cornell University have begun leveraging their facilities, mass producing personal protective equipment to help combat the nation-wide shortage. A majority of their output has already been donated to Weill Cornell Medical Centre.

Kitchener-based Inksmith is helping in reducing the scarcity. Though focusing primarily on STEAM (science, technology, engineering, arts and math) learning through such methods as 3D printing[10].

Inksmith has pivoted to mass producing Health Canada –certified face shields

Originally able to manufacture only a handful at a time, the Kitchener-based company now estimates their capacity at 8,000 per day.

In the U.K, Batch.works, a design company that 3D prints fetching housewares[10], is now dedicating its factory to producing face shields. Batch.works hopes to soon send out 1,000 units a day through a partnership with local delivery company Pedal Me. Scuba diving masks being used as head gear with special filter attachment at the air inlet at top.The scuba diving masks and snorkeling goggles are available on Amazon and produced by companies such as sports giant Decathlon, while Acosta's team has made their design freely available, and is encouraging those with 3D printers to create the attachments and give them to hospitals which are lacking protective equipment.

The masks, however, have yet to be quality tested in a lab.

The project has gained traction with volunteers based in countries such as Colombia, Chile, the USA, UK, Australia, Germany, Canada, according to Acosta, printing the devices or solving logistical issues.

There is currently no universal standard for face/eye protection from biological hazards[11] . Therefore, the recommendations for the proper use of face shields vary widely, indicating the need for a consensus on the use of certain face/eye protection for specific medical procedures[12] .

OSHA's Bloodborne Pathogens standard (1910:1030 subpart (d)(3)(i)) states: "Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated."[13] .

Conclusion:

With over 100 countries worldwide now dealing with the impacts of COVID-19, significant pressure has been placed on critical medical supplies (masks, gear, ventilators etc), healthcare facilities and hospital staff. In response, a host of international designers, manufacturers, makers and producers have leveraged their collective resources to offer innovative solutions that alleviate the strains on medical equipment as well as to ensure front line workers stay safe. Our attempt was to put forward the world a way to fight the scarcity & discuss some of the most striking initiatives being taken in this direction. Popular news outlets report unconventional solutions for PPE at local hospitals, such as plastic garbage bags for gowns and plastic water bottle cutouts for eye protection[14].

Plans for resupply through the repurposing of industrial capacity and other means are welcome but seem unlikely to solve the shortage quickly enough as supply chains become more dysfunctional in the pandemic. The increase in people with respiratory symptoms visiting clinics and needing care is straining our healthcare system's supply of PPE in many areas. At this hour, these innovations provide much needed respite to healthcare workers and are in fact the need of the hour, until adequate PPE is available to the hospitals.

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