

PERSONAL PROTECTIVE EQUIPMENT FOR HEALTH CARE WORKERS IN THE PRESENT CORONA VIRUS PANDEMIC: THE INDIAN SCENARIO (MAY 2020)

and the correct path forward

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There is a lot of disinformation and lack of clarity on the use of PPE (Personal Protective Equipment) in health care workers.

Unfortunately, the sad situation is that we, the end users, have very little knowledge about the proper standards required of a PPE. This lack of knowledge could very well be lethal to our health. A more alarming fact is that the official agencies supposed to set standards for PPE's in India are grossly inadequate and not performing all the tests required to certify the quality of PPE's (More on this later). So, we cannot rely on present official certifying agencies to ensure that the PPE that we use is protecting us from the deadly-Coronavirus.

India, being the so called nation of "Jugaad", has lived up to its name and scores of companies have started manufacturing PPE's in large quantities seeing the huge potential for profit or with a genuine desire to help, but with half-baked knowledge. Unfortunately, we, the healthcare workers are the victims of such over enthusiastic efforts.

The sole purpose of this write-up is to make each end-user aware of the minimum requirements of a PPE and the tests it should ideally pass to be used to protect oneself against the "SARS-CoV-2" virus.

Let us start with the "**Fabric**". Theoretically any "Waterproof" fabric like PVC, rubber or plastic sheet can be used. Though they are impermeable to liquids and viruses, they cause severe discomfort to the user within minutes of wearing them. This is because these waterproof fabrics do not allow water vapor to escape, thus causing excessive sweating and increase in body temperature.

So, the ideal PPE should be made of what is called "**Waterproof breathable fabrics (WBFs)**". In simple terms, it should be completely resistant to liquid droplets, but should allow water vapor to escape from the inside to maintain bearable comfort levels for the user.

A WBF can be engineered by using:

- (1) Tightly woven fabrics (half-basket, plain, or twill weave) with a water-repellent (silicone or fluorochemical) finish.
- (2) Microporous (pore size <math><2-3\mu\text{m}</math>) membranes or coatings (polyurethane, polytetrafluoroethylene, acrylics, or polyamino-acid) on cotton non-woven fabrics.

(3) Hydrophilic membranes or coatings (such as polyurethane-based thermoplastic elastomer).

(4) Smart or intelligent polymers (shape memory polyurethane, or cotton fabric coated with N-tert-butylacrylamide-ran-acrylamide).

Along with these functionality requirements, it is also necessary that the fabric used in medical gowns should not promote the growth of any trapped infectious microorganisms; this specification can prevent the risk of secondary infections to healthcare personnel when reusing the gowns. To this purpose, antimicrobial finishes (e.g., silver/metal compound finish, quaternary ammonium compounds finish, N-halamines finish) are often applied to fabrics used to produce reusable medical gowns.

This layered fabric should pass stringent testing standards before being used for medical use PPE's.

Indian certifying agencies generally just test for “**Synthetic blood penetration test**” and the thickness of the fabric (GSM). No other parameter is tested.

According to International standards of reputed agencies like CDC, USFDA, European CDC and Chinese CDC the following parameters need to be tested on the fabric before being used for construction of medical PPE's:

1. **Tensile strength**
2. **Seam strength**
3. **Abrasion resistance**
4. **Virus resistance and Bacterial resistance**
5. **Puncture resistance**
6. **Liquid repellence**
7. **Water vapour transmission**
8. **Hydrostatic test**
9. **Mist test**

The Government of India does not seem to be keen on enforcing these minimum standards. That means as HCW's, our lives are at risk and no one seems to care. We again reiterate, since the relevant authorities are turning a blind eye to the quality of PPE's, it is our own responsibility to choose the correct PPE for our own protection.

In the last 2 months, after seeing scores of PPE's being offered in the Indian market, we have realised that most of the PPE's being manufactured here, with or without certification, are of poor quality, wrong design elements and most importantly inadequately protective against the threat of Coronavirus.

10 points to consider for an ideal PPE for use in Health care setting:

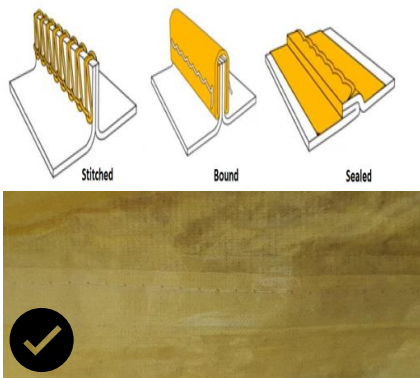
1. Single piece coverall is better than a 2-piece Jacket and Pants



2. Medical (surgical) gowns with open or closed back are not adequate while managing Covid patients, there are lots of areas through which contamination can occur



3. The **Seam stitching** should be sealed with a special heat-sealing tape (Most of our PPE's are either not sealed at the seams or sealed with low quality locally sourced tape). **Needle holes and inter stitch areas are prone to virus and liquid entry if not properly sealed.**



Dupont PPE with Hot Air Sealed Seam
(Is essential in reusable coveralls)



Seam sealing with special tapes can also be reused though reusability varies on adhesive properties of the tape.

No.	Description
1	Neck Gown - Single Sided
2	Neck Gown
3	Breast & Waist Guard Gowning
4	Neck Gown - Double Sided
5	Cap - Back - Neck - Back - Neck - Back
6	Cap - Neck - Back - Neck - Back - Neck - Back
7	Neck Gown - Double
8	Neck Gown - Double - Double
9	Seam Sealing - Critical Point - Back - Front - Side
10	Cap - Back
11	Cap - Front
12	Cap - Side
13	Cap - Back - Front
14	Cap - Back - Front - Side
15	Cap - Back - Front - Side - Back



Indian PPE with no seam protection



Indian PPE with manually applied local tape are acceptable for disposable PPE's

4. The PPE should cover maximum body area and not expose any area during natural movements



5. A fully protective PPE should be closed with a full-length Zip line which is then covered with a wide flap keeping the zip area non contaminated while doffing



6. The Face, wrist and Ankle openings should have a good quality elastic to snugly fit and not allow liquid spills to enter inside.

7. The collar area or neck area should ideally overlap the respirator or mask being worn. An integrated hood as seen here covering the head, forehead, ears and chin is preferable.



8. A separate head piece with a transparent front is generally very uncomfortable if used without an independent air supply and scavenging system.

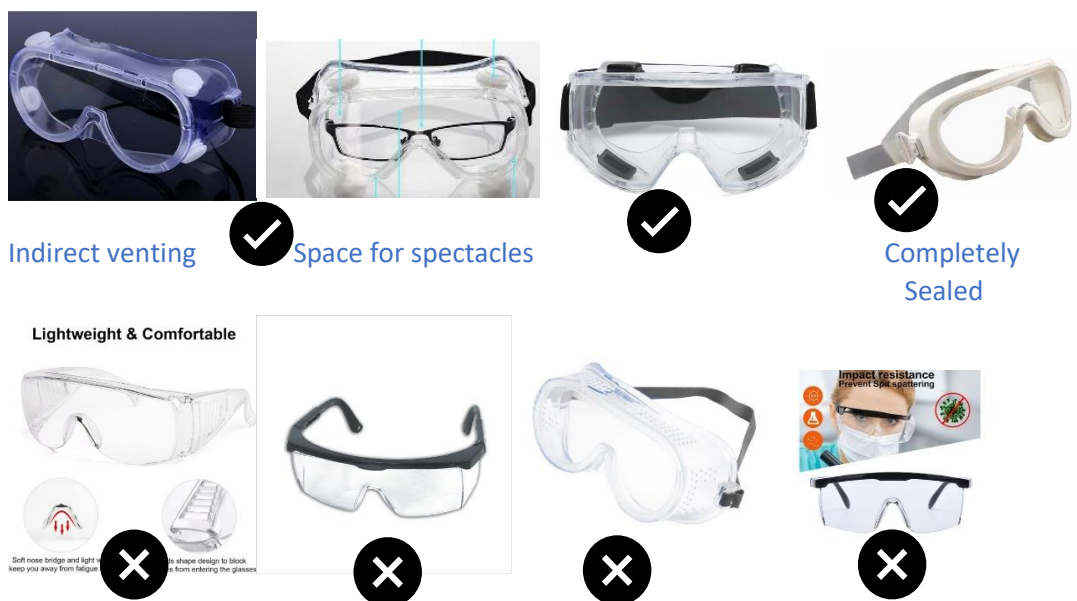


9. Face protection:

- A. N95 / KN95 / FFP 2 or better respirator with a self-assessed fit test. If you keep a beard, it is recommended that you either shave it off before using any of the usual N95 masks or alternatively, use a N99 or N100 full or half face respirator.



- B. Eye protection with Goggles that completely seal with soft silicone or rubber edges and anti-fogging mechanism are ideal. Plastic spectacles should not be used. A face shield may be used as an alternative, but it does not offer protection against aerosols. Use of both Goggles and face shield is most protective and recommended during high risk and aerosol generating procedures.



Eye wear not sealed completely or with direct holes at the sides do not protect against viral transmission.

Most Indian PPE Kits come with cheap and inadequate pair of eye protective spectacles. Any eyewear with open vents to prevent fogging does not adequately protect against coronavirus transmission.

- C. Head cover, (disposable) to be worn inside the hood is required for long hair management and as an extra layer of protection.



10. Accompanying gear:

A. Twin gloves, with the inner gloves overlapping the PPE sleeve at least till mid forearm.

Inner gloves

- a glove of intermediate thickness works well as an inner layer
- consider gloves with extended cuffs as they cover a larger section of the overall sleeves

Different combinations of inner and outer gloves



Inner gloves + outer nursing gloves:
For patient care

Inner gloves + outer surgical gloves
(sterile if required):
For medical interventions

- ideally, the inner pair of gloves should have a longer sleeve than the outer pair of gloves. This makes it easier to change gloves.

Unfortunately, we have not been getting the long gloves required for inner wear easily. There is a risk of skin exposure at the wrist when using the regular gloves. Ducting is a way out

B. Foot protection, with a full-length boot cover that overlaps completely with the PPE overall ankle ends. Use rubber Gum boots for additional protection especially in areas prone to spills or while handling dead bodies. Coveralls with integrated foot coverings are also equally protective and can be worn with Clogs.



C. Duct tape should be used additionally in high risk areas as extra protection to seal all overlaps and ends and should be available in all donning areas.



D. Biomedical waste bag to dispose of PPE after use should be available



Since in the near future, I do not envision a proper and safe licencing standard for medical use PPE's in our country, we will have to assess the PPE's on our own with the above knowledge and try to use the ones which tick most of the right boxes.

A good quality imported PPE kit from manufactures such as 3M, Dupont, Honeywell etc. will cost at least 8 to 15 times of the local ones but will offer the best protection. We have been working with many local manufacturers and educating them about the right fabrics, coatings and lamination processes etc. The local manufacturers are trying to improve their product, but we are still a long way from achieving good standards. There must be a strong political will and genuine concern about the safety of our frontline workers to make any substantial difference. Posters, Banners, clapping, statements applauding the Health care workers are morale boosters, but the real need of the hour is to give them proper safety equipment.

With the potential number of PPE's required considering our population and the way this present pandemic is spreading, there is no viable way that our healthcare system can bear the load both quantitatively and financially.

The best solution is to manufacture **reusable** PPE's which can be easily decontaminated with locally available and cheap chemical agents like 1% bleach or detergent solution and can be reused for at least 30 cycles. This is an achievable goal and will drastically reduce the financial burden on the hospitals, patients and the Government.

Checklist to choose the Right PPE



MATERIAL (any of these)

- Laminated (PE film coated on one side) non woven fabric. [disposable]
- Laminated (PE film coated on both sides) non woven fabric. [reusable]
- Layered Polymer or thermoplastic (smooth shiny sturdy feel like a windcheater fabric) with hydrophilic coating [reusable]
- Polyester fabric (cloth like feeling) with antimicrobial coating and/or hydrophobic coating [reusable]



SEAM MANAGEMENT

- Hot Air Sealed with transparent tape [Reusable]
- Seams sealed with special seam sealing tapes [may be reusable for some cycles]
- Seams sealed with locally sourced PVC tapes [disposable]
- **Do not choose PPE which has unsealed seams.**



COVERALL DESIGN

- Prefably single piece coverall with hood
- Design covers maximum part of body with comfort during movements
- Closure with a front zip that extends to and overlaps the chin and lower portion of N95 respirator
- A broad flap that covers the zip line completely so that the zip area remains uncontaminated during use
- Either integrated foot covering or seperate long Booties made of the same material



ACCESSORIES

- N95 or higher grade Respirator
- Eye Goggles with complete seal and either no vents or indirect venting
- Face Shield
- Disposable Head cap
- Long and short gloves for double gloving
- Gumboots or clogs
- Biomedical waste bag
- Duct tape for sealing.

There are multiple guidelines on how much level of protection is required in different healthcare settings. Almost all these guidelines advocate the use of N95 and gloves as being adequate for most clinical scenarios and advocate full PPE protection only for critical care areas and procedural settings. These guidelines are even more lax in the so called Non-Covid hospitals.

It is our opinion that these guidelines are blatant generalizations and grossly inadequate in a pandemic situation like present, each and every healthcare worker should be working with full PPE protection in all areas of the Hospital to protect optimally against getting infected, be it a Covid hospital or a Non-Covid hospital.

We have come to this conclusion because of the following observations:

- a) Multiple studies have proven effectiveness of PPE's against the present Virus.
- b) In a hospital, if we analyse the distribution of HCW's who get infected, most of them are in people who work in non-covid areas with inadequate PPE's as against people who are constantly seeing Covid19 patients but with adequate PPE's.
- c) In a still unpublished report from a UK hospital where every HCW works with full PPE as a policy, irrespective of his or her job description, there was zero transmission of Coronavirus to all its employees from covid19 patients.
- d) The ever-increasing plethora of clinical syndromes attributed to coronavirus from the initially described respiratory symptoms, to strokes, MI's, Kidney injuries, Vasculitis like in Kawasaki disease, Toxic shock like syndrome, multitude of skin lesions etc. it would be impossible to properly triage, suspect or diagnose each and every patient being seen in the OPD or admitted and exposure to us is inevitable.
- e) More and more reports of asymptomatic carriers and super shredders is another area of concern, making any random person who comes as an attendant a potential risk to us.
- f) The present state of confusion in the available Covid tests, RT-PCR regarding its poor sensitivity, the doubts regarding antibody tests to denote protectiveness, and possibility of reinfections and multiple reports of faulty kits, all make treating these patients a bit of a gamble.
- g) The studies conducted regarding viability of the virus on various surfaces, shows that it is quite a robust virus and can withstand adverse environment.
- h) The high level of mutations being described from various places denotes that the virus will be more contagious and more virulent.

Due to these reasons, we personally recommend that each and every Health care worker, should work with a full supplement of PPE's right from the Entry gate till the Exit gate in any healthcare facility. Shower facilities, Donning and Doffing cabins, PPE storage cabins, Availability of the correct PPE's, facilities to decontaminate them if we decide to use reusable ones and recommended Bio medical waste management facilities will have to be created.

Every single HCW will have to train in correct Donning and Doffing technique and continue using hand hygiene in between patients to prevent cross infections.

We also recommend that all Medical Practitioners and their staff should also don complete set of PPE's in their OPD chambers. Other measures like staggering of appointments, cleaning the Examination bed surface and other areas by using surface cleaning in between patients is needed.

It seems this virus is there to stay with us for a few months at least and the way we practice medicine has changed. The earlier we embrace this change; easier it will be for all of us.

Every one of us will have to take an individual decision about how much comfortable we are with the PPE components that we are using or are being provided by our institution. Certain items like Eye Goggles, face shields, N95 masks (with proper implementation of guidelines for reuse) etc. can last us several weeks, provided we take efforts to surface clean all of these immediately after use and Keep the N95 masks sealed in a paper bag.

We urge the authorities to urgently consider reusable PPE coveralls instead of disposable ones. This will result in huge savings for the concerned institutions as well as address the issue of safe disposal of PPE kits in the environment. The sheer number of disposable PPE's requiring waste disposal facilities will create a massive environmental impact, which will be mitigated to a large extent if reusable PPE's are used. On the other hand people will have to be trained for safe decontamination of used PPE's and every institution will have to create adequate facilities for local decontamination of the PPE's.

The fact remains that even the best PPE cannot be 100% protective. Accidents can happen during use. You can get infected if improper Doffing technique is used. Still, it is extremely important that we take an informed decision about our own safety and demand proper equipment to minimize the risk of infection.

We have lost enough Doctors, nurses, sanitary workers in this fight against Covid19. Let us not lose any more of our brothers and sisters because of avoidable factors.

