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Mini Review

Personal Protective Equipment (PPE), their Standards, Donning-doffing Procedures and Challenges of Indian Drug Regulatory Authorities with the New Indian PPE Manufacturers; Personal Protective Equipment and Challenges

Dipak Kumar Mal[2], Biswajit Mukherjee[1]*

[1] Department of Pharmaceutical Technology, Jadavpur University, Kolkata 700032, India
[2] Department of Pharmacy, Cooch Behar Polytechnic, Keshab Road, Cooch Behar, Cooch Behar - 736101

*Address for correspondence: Department of Pharmaceutical Technology, Jadavpur University, Kolkata 700032, India.
Tel. +91-33-24572588, E-mail: **********

ABSTRACT

Health care professionals rely on personnel protective equipment (PPE) including gown, gloves, goggles, face mask/N-95 respirators, and face shields etc to fight against COVID-19. The components of PPE act as an obstacle that prevents movement between infectious viral or bacterial contaminants and wearer's mouth, nose or eyes and other parts of the body. All PPE is intended for use as medical device must follow the rules and regulations or standards for protection. The manufacturer has to show that they meet the prescribed criteria of competent authority in case of labelling, sterilisation criteria etc. the PPE must be biocompatible for at least 6-8 hrs. The wearer must follow the right procedure of donning and doffing of PPE. We here highlighted the various PPE with their standards, donning and doffing procedures, and challenges faced by Indian regulatory authority to maintain standards from the inland new manufacturers. Different research works are required to make the PPE fit and comfortable to accept for use for a long period.

Keywords: Personnel Protective Equipment, COVID-19, Donning, Doffing

1 Introduction

Personal Protective Equipment (PPE) used by health workers provides them protection against pandemic infections such as COVID- 19 during clinical care for patients [1]. PPE were also used by health staff during filovirus infection (Ebola and Marburg) in 2014 as per Rapid Advice Guideline of WHO [2]. PPE is used by doctors, nursing staff, health care workers in health care establishment such as hospitals, clinical laboratories, pathological testing units, microbiological laboratories etc. PPE acts as a protective barrier between host (skin, mouth, nose, or eyes (mucous membranes) of humans and infecting agents such as virus, bacteria etc. PPE has the capacity to block transmission of germs from body fluids, blood or secretion

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from respiratory tract. PPE also protects infected person from any new infection [3] from others (doctors, nursing staff, visitors, health care worker, other patients etc) upon following standard procedures and protocol prescribed by WHO. However, PPE must be of correct standard and used in a safe manner [4] specially while putting on and removing PPE [5]. Further, decontaminating the PPE by using disinfectant fluid is equally important.

Besides, the other infection controlling measures such as i) hand washing using alcohol containing and alcohol-based hand rub or hand sanitizers, ii) covering sneezes and coughs are also required. PPE and COVID-19 are popularly echoed and COVID-19[6] declared pandemic (a disease affecting or attacking the population of an extensive region, country, continent, and the globe) by WHO on 11 March 2020.

Here we want to describe various types of PPE specially highlighting their safety standards to provide a vivid idea about PPE [7] and how to use them safely based on their requirements. Further, we have focussed on some challenges faced by Indian drug regulatory authorities with the new manufacturers of PPE.

Components of PPE: Components of PPE for infection control are

1) Protective clothing/Gown or coveralls/full body suits
2) Gloves
3) Goggles/safety glasses
4) Facemasks and /Surgical mask or N-95 respirators
5) Shoe-covers
6) Face shield

2 Protective clothing/ Gown or coveralls/ full body suits:

2.1 Medical gowns

Gowns are personal protective equipment used in health care establishments. They are used to protect the wearer from the spread of contamination or infection while comes in contact with potentially infectious liquid, solid material, vulnerable patients [1] and transferring microorganisms.

Gowns are of different kinds such as surgical gowns, isolation gowns, surgical isolation gowns, nonsurgical gowns, procedural gowns, and operating room gowns [8].

In the year 2004, the United State Food and Drug Administration (US-FDA) recognised the standards specified by American National Standards Institute/Association of the Advancement of Medical Instrumentation (ANSI/AAMI) PB70:2003. As per risk level new terminologies developed to describe gown are:

- Level 1: *Minimal risk* area, such as standard isolation, cover gown for visitors, or in a standard medical unit during basic care.
- Level 2: *Low risk* area such as suturing area, in the Intensive Care Unit (ICU), during blood draw, or a pathology lab.
- Level 3: *Moderate risk* area such as in the Emergency Room, or for trauma cases, during arterial blood draw, inserting an intravenous (IV) line.
- Level 4: *High risk* area such as when pathogen resistance is needed or infectious diseases are suspected (non-airborne), during long, fluid intense procedures, surgery etc.

2.2 Surgical Gowns

This type of gown is described by FDA as class II category medical device that requires a 510(k) premarket notification. It is a personal protective garment[9B] to be used by the health care personnel during surgical procedures to protect both the patient and wearer from the transfer microorganism, body fluids, and

particulate matter. While in critical zones, gown would be: front of the body from top of shoulders to knees and the arms from the wrist cuff to above the elbow. This type of surgical gowns can be used for any risk level (Levels 1-4). As per FDA all surgical gowns must be labelled as a surgical gown.

2.2.1 Critical Zones for Surgical Gowns (Source: US-FDA)

- The entire front of the gown (areas A, B, and C) is required to have a barrier performance of at least level 1.
- The critical zone compromises at least areas A and B.
- The back of the surgical gown (area D) may be non-protective.

2.3 Surgical Isolation Gowns

Surgical isolation gowns are designed for use in the area from medium to high risk zone of contamination and it has a larger critical zone than the conventional surgical gown. This type of gown is regulated by FDA as in the case of Class II medical device notifications. [2]

- The entire gown (areas A, B, and C), including seams but excluding cuff, hems, and bindings, is required to have a barrier performance of at least Level 1.
- Surgical isolation gowns are used when there is a medium to high risk of contamination and need for larger critical zones than traditional surgical gowns.

2.4 Non-Surgical Gowns

These are Class I devices (exempt from premarket review) intended to protect the wearer from the transfer of microorganisms and body fluids in low or minimal risk patient isolation situations. However, non-surgical gowns are not worn during surgical procedures, invasive procedures, or when there is a medium to high risk of contamination. Non-surgical gowns should also cover as much as the size of body appropriately and similar to that of surgical isolation gown [9].

2.5 Standards for Gowns

Gown must be labelled that it has been passed the test of standard for performance (**Table 1**) so that end user and procurers could determine what particular gown they require. FDA approved the standard of American Society for Testing and Materials (ASTM) F2407. Surgical gowns are tested forits tear resistance, seam strength, lint generation, evaporative resistance, and water vapor transmission.

Table -1 Standards tests as recommended by US-FDA

Sl no	Tests	Standard
1	Tensile Strength	ASTM D5034, ASTM D1682
2	Tear resistance	ASTM D5587(woven), ASTM D5587 (nonwoven), ASTM D1424
3	Lint Generation	(ISO 9073 Part 10)
4	Water vapor transmission (breathability)	ASTM F1868 Part B, ASTM D6701 (nonwoven), ASTM D737-75
5	Seam Strength	ASTM D751 (stretch woven or knit)

2.6 Sterility Information for Gowns

2.6.1 Labelled sterile information contains

Method of Sterilization to be applied.

- A description of the method that will be used to validate the sterilization cycle.
- Reference to a standard method (e.g., AAMI Radiation Standard) usually is sufficient for established sterilization methods with FDA-recognized standards.
- The sterility assurance level (SAL) for the device: A SAL of 10^{-6} is required for surgical drapes and surgical gowns which are to be used during surgical procedures.
- A description of the packaging's ability to maintain the device's sterility.
- If sterilization involves ethylene oxide (EtO), the maximum levels of residues of ethylene oxide, ethylene chlorohydrin, and ethylene glycol which remain on the device should be consistent with the draft Federal Register Notice on EtO limits.
- In the case of radiation sterilization, the radiation dose to be mentioned.

2.7 2.7. Biocompatibility Information for Gowns

Contact hour with the surgical gowns would be less than equal to 24 hours and it must be evaluated the cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10), and irritation or intracutaneous reactivity (ISO 10993-10). The said biocompatibility evaluation test is recommended by US-FDA.

3 Gloves

Medical gloves are one of the personal protective equipment used to protect wearer and /or the patient from the spread of infection. Medical gloves are disposable. Gloves are of different kinds such as examination gloves, surgical gloves, and medical gloves for handling chemotherapy agents (chemotherapy gloves). These are class I reserved medical devices which require a 510(k) premarket notification. These are regulated by US FDA. For medical applications, it is made up of any Poly (Vinyl Chloride) polymer compound. Glove applied with US Pharmacopoeia (**Table 2**) recommended absorbable dusting powder as lubricant. Other safe and effective lubricants may also be applied. The inside and outside surface of the poly (vinyl chloride) examination gloves shall be free of talc.

Its Physical requirements are:

i) Tensile strength, MPa (minimum): 11

ii) Ultimate Elongation, %, (Minimum): 300 [10]

They are also available in various sizes with tolerances (**Table 3**).

Table 2: Performance requirements as per US Pharmacopoeia:

Characteristic	**Related defects**
Sterility	falls sterility
Freedom from holes	Holes
Dimensions	width, length, and thickness
Physical requirements	before aging, after accelerated aging
Powder Free	Exceeds Maximum Limit
Residue Powder Amount	Exceeds Recommended Maximum Limit

Table 3: Dimensions and tolerances (source: ASTM)

Designation	Size							Tolerance
	6	6.5	7	7.5	8	8.5	9	
Width by size; mm	76	83	89	95	102	108	114	6
Width by small, medium, large & Extra-large, mm	Small		medium		large		x-large	5
	85		95		105		115	
Length, mm	230 for all size							Min.
Thickness, mm	For all sizes							
Finger	0.08							Min.
Palm	0.08							Min.

3.1 What to remember before using medical gloves

- Fresh washing of hand requires before putting on sterile gloves.
- Make sure that it is of suitable size to fit properly and comfortably during all patient care activities.
- Check that whether the natural rubber latex type of glove is free from allergy and if allergic replace with polyvinyl chloride (PVC), nitrile, or polyurethane type of glove.
- Careful consideration requires to avoid puncture fromsharp objects tomedical gloves.
- Always change your gloves if they rip or tear.
- On removal of gloves, wash your hands thoroughly with soap and water or alcohol-based hand rub.
- Medical gloves are disposable and never reusable.
- Never wash or disinfect medical gloves.
- Medical gloves are not exchangeable with other users.

4 Goggles/safety glasses

Goggles/ safety glasses form a protective [11] seal around the eyes, preventing solid or liquids or droplets containing microbes from entering under or around the goggles. Safety goggles [12] protect the eyes, eye sockets, and the facial area immediately surrounding the eyes from a variety of contaminants, microbes etc as a barrier. Especially this is important when working with or around liquids like body secretions that may splash, spray, or mist. Prescription lenses may be mounted behind protective lenses for correcting required vision.

4.1 Clear lenses

- Are available with removable lenses.
- May incorporate prescription lenses.
- Do not provide special protection against optical radiation.

Safety goggle [13] frames must be properly fitted to the health worker's face to form a protective seal around the eyes. Goggles should be fitted well otherwise necessary protection could not be attained.

4.2 Eyecup Safety Goggles

- Cover the eye sockets completely.
- Are available with direct or indirect ventilation.
- May be rigid or flexible.

4.3 Cover Safety Goggles

- May be worn over corrective spectacles without disturbing the adjustment of the spectacles.
- Are available in direct, indirect, or non-ventilated types.
- May be rigid or flexible

4.4 Ventilation

Ventilated goggles allow air circulation while providing protection against airborne particles, dust, liquids, or light

5 Facemasks and /Surgical Mask or N-95 respirators

Centre for Disease control and Prevention (CDC) recommend wearing cloth face coverings in public places where other social distancing measures are difficult to maintain (e.g., grocery stores, market, shopping mall and Pharmacies), **especially** in areas of significant community-based transmission. CDC also advises to use improvised face coverings made of simple cloth to slow the spread of the virus and help people who may have the virus and do not know it from transmitting it to others. Cloth face coverings [14] could be made from low cost cloth at home. It can be used as an additional, voluntary public health measure. Cloth face coverings should not be applied on young children under age 2 years. The cloth face coverings are not substitute for surgical masks or N-95 respirators. [15]

5.1 Surgical Mask

A mask which is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and even potential contaminants in the immediate environment. Surgical masks are regulated by USFDA under 21 CFR 878.4040. Surgical masks are not to be shared and It is labelled as surgical, isolation, dental, or medical procedure masks. They may come with or without a face shield. [8]
Surgical mask is of different kind in terms of thickness, different ability to protect oneself from contact with liquids. If fitted properly, a surgical mask is meant to help block large-particle droplets, splashes, sprays, or splatter that may contain germs (viruses and bacteria), keeping it from reaching mouth and nose. Surgical masks may also help reduce exposure of one's saliva and respiratory secretions to others. Surgical masks also do not provide absolute protection from germs and other contaminants because of the loose fit between the surface of the face mask [16]and face of user. Surgical masks are disposable [17] in nature and for one-time use. It is also advisable to wash hands after handling the used mask. Used mask should be discard safely placing it in a plastic bag and putting it in the trash.

5.2 N-95 respirators

A device designed to achieve a very close facial fit and very efficient filtration of airborne particles acting as a respiratory protector. Why it is called N-95? Because the N-95 respirator blocks at least 95 percent of very small particles having 0.3 micron in size. However complete elimination of the risk of illness or death cannot be achieved [R: USFDA]. FDA regulated these N-95 respirators with a labelled mark as "single-use," disposable devices. These are also discarded safely as like as that of surgical musk. N-95 respirators

[18] are designed for people with no facial hair and not for children. N-95 respirator regulated by the FDA, under 21 CFR 878.4040, and CDC National Institute for Occupational Safety and Health (NIOSH) under 42 CFR Part 84. Characteristics of N-95 respirator as identified by European Council

1. Shape that will not collapse easily
2. High filtration efficiency
3. Good breathability, with expiratory valve
4. Quality compliantwithstandardsformedicalN95respirator: a. NIOSH N95, EN 149FFP2, or equivalent
5. Fluid resistance: minimum 80 mmHg pressure based on ASTM F1862, ISO 22609, or equivalent.

6 Shoe cover

As prescribed by European Council [19], shoe covers should have the following characteristics.

1. Made up of the same fabric as of coverall
2. Should cover the entire shoe and reach above ankles

7 Face Shield

Specified by European Council [20]

1. Made of clear plastic and provides good visibility to both the wearer and the patient
2. Adjustable band to attach firmly around the head and fit snuggly against the forehead
3. Fog resistant (preferable)
4. Completely covers the sides and length of the face
5. May be re-usable (made of material which can be cleaned and disinfected) or disposable
6. Quality compliant with the below standards, or equivalent:
   a. EU standard directive 86/686/EEC, EN 166/2002 **b**. ANSI/SEA Z87.1-2010

European Council has recommended that all PPE items for supply need to be accompanied with certificate of analysis from national/ international organizations/labs indicating conformity to standards. Further, the council has also recommended that all items of PPE should be used within 5 years after manufacturing i.e. expiry period is 5 years from the date of manufacturing [19].

8 SEQUENCE FOR DONNING (PUTTING ON) PERSONAL PROTECTIVE EQUIPMENT (PPE):[15]

Step 1. Check for appropriate size of PPE

Step 2. Perform hand Hygiene using alcohol-based hand rub or hand sanitizer

Step 3. Wear inner shoe-cover and outer shoe-cover

Step 4. Perform hand Hygiene using alcohol-based hand rub or hand sanitizer

Step 5. Wear the gloves-

a) Apply first layer of gloves (check for tears)

b) Cut hole in lab coat for thumb

c) Pull lab coat over hand putting thumb through hole

d) Apply second layer of gloves (extend to cover wrist)

Step 6. Wear gown - Fully cover torso from neck to knees, arms to end of wrists, and wrap around the back. Fasten in back of neck and waist.

Step 7. Wear N-95 respirator-

- Secure ties or elastic bands at middle of head and neck
- Fit flexible band to nose bridge
- Fit snug to face and below chin
- Fit-check respirator

Step 8. Wear goggles or face shield - Place over face and eyes and adjust to fit

Step 9. Wear hood of upper part of the body

Step 10. Check for fitness control or mobility.

9 SEQUENCE FOR REMOVAL OR DOFFING PERSONAL PROTECTIVE EQUIPMENT (PPE): [15]

Step 1. Perform hand Hygiene using alcohol-based hand rub or hand sanitizer

Step 2. Remove inner and outer shoe-cover

Step 3. Disinfect the outer gloves. a) Using a gloved hand, grasp the palm area of the other gloved hand. b) and peel off first glove. c) Hold removed glove in gloved hand d) Slide fingers of ungloves hand under remaining glove at wrist and peel off second glove over first glove e) Discard gloves in a waste container

Step 4. Remove hood cover of the upper part of the body, goggles and or face shield.

Step 5. Remove the gown

Step 6. Perform hand Hygiene using alcohol-based hand rub or hand sanitizer

Step 7. Disinfect inner gloves

Step 8. Remove inner glove and discard

Step 9. Perform hand Hygiene using alcohol-based hand rub or hand sanitizer

Step 10. Wear new glove to remove N-95 respirator

Step 11. Perform hand Hygiene using alcohol-based hand rub or hand sanitizer

Step 12. Remove gloves and perform hand hygiene.

Step 13. Remove shoe and disinfect with hypochlorite solution

10 Challenges faced by Indian drug regulatory authorities with the manufacturers of PPE in post COVID- 19 situations

In post-COVID-19 situations, there are numbers of Indian manufacturers started producing PPE items as they have a high demand. It is good to see that so many manufacturers came up quickly to produce PPE to help Indian health sectors. But the standards of the products are always difficult to judge. We have experienced that majority of the cases; labels of the products are also improper. Standards of the products, their comfortableness to wear, efficiencies, method of sterilisation, duration of use, if reusable how to use it after its every usage should be specially mentioned than the other information usually given. However, there should be a stringent specification of standards guided by drugs law and controlled by Indian drug regulatory authorities to maintain the standards of the produced items. Moreover, they should be properly labelled. Indian drug regulatory authorities must develop quickly the checking-facilities, checking guidance and their own set-up of PPE-product checking laboratories to authenticate the PPE products.

11 Conclusion

PPE is a very useful tool to control infectious, epidemic or pandemic diseases. In USA, FDA developed guidelines for standards and specifications of PPE in collaboration with ASTM, OSHA, ISO, CDC and other international organisations. European council framed a guideline for preparation and application of PPE components. However, a universal standardisation and specification guideline is required. In India, a suitable body may be constituted to develop and promote components of PPE with respect to the global scientific standards and guidelines. PPE gown must be opaque and comfortable to wear. A proper legislative approach on PPE may be developed to fight against COVID-19. To prevent the loss of human resources, the standards and specifications are to be fixed and to be regulated by the competent authority. The comfort of using them for a prolonged period is a great challenge with the current PPE. Hence, research should be on for developing materials to design PPE that would be comfortable to wear and would

not indulge even any nanosize particles to adhere on the surface. Independent India inherited a weak back-bone of drug industry, underdeveloped infrastructural facilities, lack of efficient manpower and a stagnant economy. In post-independence scenario, the successive governments aimed at fast economic activity by establishing core and basic drug industries in public sector. Eventually there have been formulation industries in a significant way. However, drug law is still age-old and predominant changes are necessary in many parts. Further drug regulatory authorities should have a sharp eye on any new products even in emergency situation. In the event of COVID-19 pandemic Indian industry should produce PPE of uniform standards with the specifications as prescribed by Indian drug regulatory authorities (IDRA) (both the central and state governments). Moreover, IDRA should develop a quick facility to test the standards of the products too.

12 Declarations

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12.2 Competing Interests

Authors report no conflict of interest.

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