

## One Virus! But Different Masks in Different Countries for Protection Against it! How to Choose?

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**Abstract:** COVID -19 is causing plenty of deaths in India as well as globally and many of them are health care workers (HCWs). As per data given by IMA 744 MBBS doctors have been died due to Covid – 19 till 4 February 2021<sup>3</sup>. As this disease transmitted between person to person by respiratory droplets hence mask hygiene is very important effective preventive measure for HCWs. In market due to high demand, much different type of masks is available with different specifications. Some of them are from Indian origin and many of them are procured from foreign. Many of them are not effective to safeguard health care workers against COVID 19 infection<sup>2</sup>. Hence this paper will discuss different country specific standards of masks in relation to SARS COV-2 as well as home based disinfection method of masks. In market many masks are available and most of them are sub-standard and making falsely claim of N95. Most of them are not able to protect Health Care Workers from the infection of SARS COV-2. Hence in this paper will examine different countries specific standard of mask with respect to size of SARS COV-2. US standard N95 masks will give desire level of protection against SARS COV-2. **Conclusion:** NIOSH certified N95 or N99 or N100 mask should be given priority over other countries N95 equivalent masks. Chinese masks GB2626-2006 are least recommended among all other countries N95 equivalent masks<sup>6</sup>. [Saxena P Natl J Integr Res Med, 2021; 12(5): 73-79]

**Key Words:** COVID-19, N-95 Mask, Quality Indicators, Infection-prevention

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**Introduction:** WHO declare the global pandemic of COVID -19 on 11 March 2020. As on 15 March, Globally more than 120 million peoples have been infected and more than 2.5 million people have been died<sup>1</sup>. More than 11 million cases are also found in India and out of them 0.15 million have been died including many doctors and other health care staff. COVID -19 is caused by virus Severe Acute Respiratory Syndrome Coronavirus-2 (SARS COV-2) also known as novel coronavirus-19. This disease is primarily a respiratory disease and is transmitted between people via respiratory droplets that get generated when people cough, sneeze, or exhale. SARS COV-2 virus is highly infectious with reproduction number is around 2 to 3 or more.

Single patient can able to transmit the infection to 412 normal persons in a month. During treatment of COVID 19 patients many doctors and nurses have been infected and unfortunately some of them have been died. At present no definitive pharmaceutical treatment is available. Only prevention is ultimate resort. Some effective preventive measures are there like social

distancing, hand washing and mask hygiene. But it is not possible all the times for Health Care Workers to make social distancing with patients.

As this disease transmitted between person to person by respiratory droplets hence mask hygiene is very important effective preventive measure for HCWs. In market due to high demand, many different type of masks are available with different specifications. Some of them are from Indian origin and many of them are procured from foreign. Many of them are not effective to safeguard health care workers against COVID 19 infection<sup>2</sup>.

Prime Minister of India has already been announced that mask will be the part of the life for long time. Hence Health Care workers should be well versed regarding minor details of mask so that they can appropriately select the right mask.

As per data given by IMA 744 MBBS doctors have been died due to Covid – 19 till 4 February 2021<sup>3</sup>. Hence this research article is written to provide all basics and necessary information regarding

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masks so that HCWs can choose appropriate masks for themselves. Transmission of COVID-19 – There are three routes of transmission of COVID -19: Contact Transmission, Droplet Transmission, Air-borne Transmission.

**Contact Transmission:** Droplets from COVID 19 patients can be present on objects and surfaces around the person such as tables, doorknobs and handrails. People can become infected by touching these objects or surfaces, then touching their eyes, nose or mouth<sup>4</sup>.

**Droplet Transmission:** As per WHO, droplets are defined as size > 5 micron<sup>5</sup>. The spread of an infectious agent caused by the dissemination of droplets. Droplets are primarily generated from an infected (source) person during coughing, sneezing and talking. Transmission occurs when these droplets that contain microorganisms are propelled (usually < 1 m) through the air and deposited on the conjunctivae, mouth, nasal, throat or pharynx mucosa. Most of the volume (> 99%) comprises large droplets that travel short distances (< 1 m) and do not remain suspended in the air. Face shields can help decrease exposures to and Contamination from large particle aerosols, but they do not offer inhalation protection against small particle aerosols (< 5 micron).

**Air-Borne Transmission<sup>6</sup>:** Aerosols (< 5 micron) are so small that buoyant forces overcome gravity, allowing them to suspended in the air for long periods, or they evaporate before they hit the floor, leaving the solid particulate (“droplet nuclei”) free to float very long distances(>1 metre) , causing what we often refer to as “airborne” transmission<sup>1</sup>. Recent study has shown that in closed conditions SARS COV-2 is

also transmissible through air<sup>2</sup>. Hence N95 respirator is needed to prevent the inhalation of SARS COV-2.

**Objective:** To discuss country specific standards of surgical mask. To discuss country specific standards of Respirator. To discuss home based disinfection method for Respirator. To discuss identification of original & counterfeit N95 Respirator.

In market many masks are available and most of them are sub-standard and making falsely claim of N95 most of them are not able to protect Health Care Workers from the infection of SARS COV-2. Hence in these paper different countries specific standard will be analysed with respect to size of SARS COV 2.

**Surgical Masks:** The surgical mask is made up of three layers. The innermost layer is made up of an absorbent material that absorbs moisture from the wearer’s breath, the middle layer is made up of a melt-blown material that acts as a filter, and the outer layer is made up of material that repels liquid. The pleats are intended to increase the surface area so that the nose and the chin can also be adequately covered. It is held in place by strings either looping around the ears or tied behind. There are varying levels of quality for surgical masks and the extent of protection depends on the specification of manufacture. Surgical masks need to conform to the following quality standards: bacterial filtration efficiency >95% for 3 micron size and particulate filtration efficiency >95% for 0.1micron particle size<sup>7</sup>. In the USA, the FDA sets standards and certifies the surgical masks. Many countries have different specifications for surgical mask as given in table.

**Table 1: Country-Wise Specifications For Surgical Masks<sup>7-10</sup>**

No.	Country	Standard	BFE	PFE(%)
1	India <sup>7</sup>	IS 16289	3.0 ± 0.3 µm > 95%	0.1µm > 95%
2	United States <sup>8</sup>	ASTM F2100	3.0 ± 0.3 µm > 95%	0.1µm > 95%
3	China <sup>9</sup>	YY 0469	3.0 ± 0.3 µm > 95%	0.3µm > 30 %(11)
4	European Union <sup>10</sup>	EN14683	3.0 ± 0.3 µm > 95%	Not Required

**Bacterial Filtration Efficiency (BFE):**Bacterial Filtration Efficiency or BFE is a measurement of a respirator material's resistance to penetration of bacteria. Results are reported as percent efficiency and correlate with the ability of the fabric to resist bacterial penetration<sup>11</sup>. The test is

conducted using Staphylococcus aureus as the challenge organism with a mean particle size (MPS) of 3.0 ± 0.3 µm<sup>12</sup>.

**Particulate Filtration Efficiency (PFE):** The Particle Filtration Efficiency (PFE) test evaluates the

nonviable particle retention or filtration efficiency of filter media and other filtration devices at sub-micron levels<sup>13</sup>. It is done by sodium chloride aerosols size 0.1 micron<sup>14</sup>. It is seen that 20%-85% of viruses 0.1 microns in diameter can penetrate these masks. Protective value is just 35%<sup>15</sup>. Therefore they are not the best way to prevent the inhalation of viruses. If the wearer already has contracted a virus, a surgical mask can help prevent the transmission of the virus to others. SM may not be able to provide substantial protection against aerosol particles at least up to ~0.5 micron<sup>16</sup>. Hence Surgical masks are not very effective against prevention of SARS COV-2, as SARS COV-2 virus is much smaller in size i.e. 0.06 to 0.140 micron<sup>17</sup>.

**Respirator:** A respirator is a type of personal protective equipment. It prevents the wearer from inhaling aerosols (dust, smoke, mist) as well as vapours or gases (disinfectants, anaesthetic gases) that are health hazardous. It also protects the wearer from airborne infectious agents i.e. against contamination by a virus such as coronavirus, SARS, H1N1, etc. It has two specific characteristics, viz: (1) an air filtering system that prevents the passage of noxious substances and micro-organisms from entering inside the respiratory tract, and (2) a tight fit, so that air does not leak from the sides into the nose and mouth.

**Table 2: Classes Of Disposable Particulate Respirators According To European Standard EN 149: 2001<sup>18</sup>**

No.	Type Of Masks	% Of $\geq 0.3 \mu\text{m}$ Particles Filtered (%)	Inside Leakage (%)	Effective Against COVID-19
1	FFP 1	80	22	No
2	FFP 2	94	8	Yes
3	FFP 3	99	2	Yes

**Table 3: Filtration Efficiency Of Different NIOSH Certified Masks<sup>19</sup>**

No.	Type Of Masks	% Of $\geq 0.3 \mu\text{m}$ Particles Filtered (%)	Inside Leakage (%)	Effective Against COVID-19
1	N95	95	--	Yes
2	N99	99	--	Yes
3	N100	99.97	--	Yes

**Table 4: Properties Of N95 Equivalent Respirators For Different Countries**

No.	Country	Country Specific Standard Name	Particle Filtration Efficiency MMAD NaCl Aerosols	Count Median Diameter CMD NaCl Aerosols	MPPS NaCl Aerosols
1	India <sup>20</sup>	IS 9473-2002	600 Nanometre	20-2000 Nanometre	500 Nanometre
2	United States <sup>21</sup>	NIOSH Title 42 CFR Part 84	300 Nanometre	75 $\pm$ 20 Nanometre	30-40 Nanometre 3-6
3	China <sup>22</sup>	GB2626-2006 GB 19083-2010	300 Nano mtr	75 $\pm$ 20 Nanometre	30-40 Nanometre
4	European Union <sup>21</sup>	FFP2 EN 149:2001+A1:2009	600 Nanometre <sup>25</sup>	20-2000 Nanometre	500 Nanometre
5	Australia/ Newzeland <sup>23</sup>	P2 (AS/NZ 1716:2012)	300 - 600 Nanometre <sup>y</sup>	20-2000 Nanometre	500 Nanometre
6	Korea 1 <sup>st</sup> Class <sup>23</sup>	KMOEL-2017-64	600 Nanometre	20-2000 nanometre	500 Nanometre
7	Japan <sup>24</sup>	DS(Japan JMHLW-Notification 214,2018)	300 Nanometre	60 to 100 nanometre	30-40 Nanometre
8	Mexico <sup>23</sup>	NOM-116-2009	300 Nanometre	75 $\pm$ 20 Nanometre	30-40 Nanometre
9	Brazil <sup>23</sup>	PFF2 (ABNT/NBR 13698:2011)	400-600 nanometre	20-2000 Nanometre	500 Nanometre

**Discussion:** There are few important parameters to check filter efficiency –Particle filtration efficiency, Mass Median Aerodynamic Diameter,

Count Median Diameter and Most Penetrating Particle Size. Particle Filtration efficiency<sup>26</sup> is usually stated as percentage of particles of certain size that would be stopped or retained by filter media. Mass median aerodynamic diameter(MMAD)<sup>27</sup> is defined as the diameter at which 50% of the particles of an aerosol by mass are larger and 50% are smaller.

Count median diameter (CMD)<sup>27</sup> is defined as diameter at which half of the particles (by count or number) of a given aerosol have the diameter smaller and other half is larger. Most penetrating particle size (MPPS)<sup>28</sup> is the size of the particles that are the most able to pass the filter and none of the filtration mechanisms are as effective.

National Institute of Occupational and Safety Health (NIOSH) challenge aerosol is often referred to as “0.3  $\mu\text{m}$  in size”, which technically means the mass median aerodynamic diameter and was selected, based upon most penetrating particle size (MPPS) i.e 0.3  $\mu\text{m}$ . The aerosol utilized by NIOSH to evaluate respirators for use against solid particles is sodium chloride (NaCl).

This test aerosol has a mass median aerodynamic diameter of 347 nm and which is equivalent to  $75 \pm 20$  nm count median diameter (CMD). It is important to note that for electret filters the aerosol filtration in the ultrafine size (< 0.1 micron) range is governed by the physical particle diameter i.e. count median diameter rather than the mass median aerodynamic diameter. Hence NaCl particle with a physical diameter or count median diameter of 65 nm equates to a MMAD of 300 nm Table 429. Even MPPS (Most penetrating particle size) for electret filter is 30-40 nano-meter as compared to 500 nano-meter for mechanical filter<sup>16</sup>.

Hence N95 masks give maximum protection against ultrafine particles (<100 nm or 0.1  $\mu\text{m}$ ). As size of SARS COV-2 belongs to ultrafine range, hence electret filter are more effective against SARS COV-2 as compare to mechanical filters, because MPPS for electret filter is 30-40 nanometres and MPPS for mechanical filter is 500 nanometres. Several studies<sup>16,29</sup> have reported that the MPPS for an N95 FFR “electret” filter is <100 nm while a “mechanical” filter has an MPPS

of approximately 300 nm. Chinese GB 26 2006 masks efficiency ranges between 53% to 85 % not 95% and least efficacious among all N95 equivalent masks<sup>30</sup>.

Identification Of Original N95 Masks<sup>31</sup>: There are certain markings on every N95 masks to be identified as “original”. As per NIOSH guidelines following markings on N95 respirator are mandatory:

- NIOSH Logo or Name in
- TC Number
- Filter Designation ; N95 OR N99 OR N100
- Manufactures Name or Logo
- Lot Number
- Model Number

One can check TC number on NIOSH website [wwwn.cdc.gov](http://wwwn.cdc.gov) to be assured originality of N95 mask.

Identification of Counterfeit N95 Masks<sup>32</sup>: Here are certain features of counterfeit N95 masks:

- When Entering the TC Number in CDC website -No Result is shown
- Markings are absent only N95 is written
- NIOSH name or Logo is not printed
- TC Number is not printed on mask
- Ear Loop masks are not NIOSH certified

Identification Of Counterfeit KN95 Masks<sup>33</sup>: Here are certain features of counterfeit KN95 masks:

- Loose Ear-loops
- FDA Logo on Box or ON Mask
- FDA Certified mask (correct is FDA Clearance)
- Only KN95 is printed

Home Made Disinfection Of N95 Masks: Katelyn E. Zulauf and Alex B. et al Green described home-made N95 mask disinfection method. N95 Mask can be effectively decontaminated by using widely available 1100 watt microwave, mesh, rubber band and glass container. A 17 CM x 17 CM x 7.5 CM glass containers filled with 60 ml of distilled water, covered with mesh and secured with a rubber band. N95 respirator will be placed on mesh with conical point facing upward. Then glass container will be placed inside microwave.

After 3 minute treatment N95 mask will be sterilize. This method is validated for use of 20 times on a single respirator without detrimental effect on respirator integrity or fit<sup>34</sup>.

2. Doshi S et al described home-made N95 mask disinfection method using principle of moist heat.

In his method; A N95 respirator was placed in a 1.65L Pyrex container. A small strip of a paper towel (~5cm x 5cm before folding) was folded, doused in water under a tap, squeezed to remove excess water until it no longer dripped passively and then placed in the Pyrex mask container.

The container was closed with a tight lid. 2L of water was brought to a full rolling boil inside a separate, 5.7L vessel, and the vessel was then removed from heat. The sealed respirator container was immediately placed in the large vessel containing the boiled water.

The large vessel was covered with a non-airtight lid and allowed to sit with the closed respirator container inside for at least 45 minutes. The container was first removed from the large vessel and then opened. It is simple but reliable method provides a low cost, electricity free method for N95 decontamination<sup>35</sup>.

It is important to clarify that a Moist heat (>50% humidity, 65-80C temperature) was applied to N95 respirators for over 30 minutes by placing sealed containers with N95 respirators into water that had been brought to a rolling boil and removed from heat, and then allowing the containers to sit for over 45 minutes.

After rising to their threshold points, temperature and humidity remained above 65C and 50% for a treatment time of at least 30 minutes. Filtration efficiency of 0.3-4.99um particles remained above 97% after 5 treatment cycles across all particle size sub-ranges.

**Conclusion:** NIOSH certified N95 or N99 or N100 mask should be given priority over other countries N95 equivalent masks. But every N95 marked mask is not NIOSH certified i.e. counterfeit mask, so all the markings on N95 printed mask should be checked before using the mask. But still other countries N95 equivalent masks should be given priority over medical masks, procedure masks, DIY masks or homemade masks and can be identified by country specific standards printed on mask.

Chinese masks GB2626-2006 are least recommended among all other countries N95 equivalent masks<sup>36</sup>.

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