**Title**: Unmasking N95 for COVID-19 Healthcare Workers in India

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**Abstract**: Amidst the COVID-19 pandemic, the semantic relationship between N95 and respirator masks for COVID-19 prevention bear an uncanny resemblance to the Colgate-Toothpaste synonymy. Guidelines issued by Government of India have further added to the mix-up by using the term N95 respirator mask for what should have been known as Filtering Facepiece Respirator. Because of this users, including healthcare professionals, are skeptical of any other respirator mask without the N95 label. This makes healthcare professionals doubtful about other equivalent respirator masks and at the same time also raises a possibility of fake, uncertified and counterfeit masks dubiously labelled as “N95” finding way into the hospital supply.

**Main article with references**:

On 19 March 2020, the World Health Organization released the “Rational use of personal protective equipment (PPE) for coronavirus disease (COVID-19)” document summarizing WHO’s recommendations for the rational use of personal protective equipment (PPE) in health care and community settings, as well as during the handling of cargo (1). In line with the same recommendations, Directorate General of Health Services (Ministry of Health and Family Welfare, Government of India), released the “Novel Coronavirus Disease 2019 (COVID-19): Guidelines on rational use of Personal Protective Equipment” guidelines documentfor health care workers and others working in points of entries (POEs), quarantine centers, hospital, laboratory and primary health care / community settings (2). The document also lists all personal protective equipment including the ambiguous term “N95 respirator masks”.

The guideline document issued by the Government of India has incorrectly used the term N95 respirator mask for what should be known as Filtering Facepiece Respirator (FFR). This is a problem because N95 is a type of “Particulate” Filtering Facepiece Respirator (not resistant to oil). Here it is pertinent to make a distinction between an industrial (standard) N95 respirator and a Surgical (medical) N95 respirator that could be used by healthcare professionals while delivering medical care (3). A surgical N95 respirator is a single use device that is also tested for its ability to resist penetration by high pressure streams of liquid, for instance a splash of blood4. In the United States of America, where the term N95 has originated, a NIOSH approved standard N95 respirator is approved by FDA as Surgical (medical) N95 respirator for healthcare use only after it has cleared tests for resistance of medical face masks to penetration by synthetic blood. So in a way Surgical N95 masks are an intermediate product between standard N95 respirators and triple layer medical masks. The Government of India has overcome this issue of fluid resistance by including an ASTM F1862, ISO 22609, or equivalent standard for FFRs (2). Although this appears to be mandatory but considering the FFR shortage situation, healthcare workers who are not likely to suffer splashes of blood or fluid may wear the standard NIOSH certified N95 masks. All particulate FFRs used in healthcare without certification for fluid resistance (and only for particles) should carry with it a warning, at least to use face shields when there is likelihood of a blood/ fluid splash. FFRs with exhalation ports should not be used in situations where a sterile field must be maintained because it allows unfiltered exhaled air to escape (4).

N95 respirator is just one type of particulate FFR. There are many other equivalents, e.g., FFP2, KN95 etc. In addition to NIOSH certified N95 respirators, the Government of India has also prescribed a FFP2 mask with EN149:2001 standards (Quality compliant with standards for “medical N95 respirator”: a. NIOSH N95, EN 149FFP2, or equivalent). In the guideline document, the difference between a medical N95 respirator and standard N95 respirator is not categorically stated. Also whether to use the Bureau of Indian Standards IS 9473:2002 FFP class 2 S/SL for respiratory masks is surprisingly not included although it is an equivalent FFR (5).

Certification is an important consideration here because this is the only way by which healthcare organizations can assure the quality of a respirator/ mask. N95 types of particulate respirators are certified by NIOSH and also by FDA if ASTM certified. All NIOSH certified FFRs bear a NIOSH testing and certification approval number on individual respirators or packaging, e.g., TC-84A-XXXX. This approval number may be verified on the NIOSH website. In addition, a comprehensive list of FDA approved surgical N95 respirator models may be accessed at <https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource3surgicaln95.html>. EN 149:2001 FFP2 is an equivalent European standard for FFRs and individual certificates/packaging/respirators may be checked for verification or on the rapid alert system for dangerous non-food products (<https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm>). Bureau of Indian Standards (BIS) certified masks will bear the standard mark “ISI” on all FFRS with CM/L number. A list of licensed vendors of BIS masks may be searched at <https://www.manakonline.in/MANAK/login> for further verification. KN95 masks were recently approved by Food and Drug Administration, USA as a non-NIOSH certified NIOSH equivalent FFR. These FFRs will bear the Code of China standard number GB 2626-2019 issued on 31 December 2019. The other equivalent FFR types & certifications are P2 Australia New Zealand AS/NZA 1716:2012, Korea 1st class Korea KMOEL-2017-64 and DS Japan JMHLW-Notification 214, 2018. To allay fear & panic amongst workers, healthcare organizations in India must include equivalent certifications in their COVID-19 policy documents. It is important to know that certifications are not valid after expiry of products. Government of India has fixed a period of 5 years for expiry following date of manufacture.

As India faces massive shortage of FFRs amid this COVID-19 pandemic, many counterfeits and uncertified respirators are finding their way into the healthcare system (6). Counterfeits and uncertified respirators are two distinct entities. Counterfeits are a fraudulent imitation of a genuine product. They may be recognized by having a high index of suspicion, verifying manufacturers & trademarks from certifying agencies and purchasing from authorized retailers. Uncertified respirators present a different problem. Although manufacturers do test FFRs in their laboratories for quality, it is possible that certification may be delayed due to procedural reasons or bureaucracy. Though not quality assured, this automatically does not translate into the fact that FFRs are of a poor quality. In times of shortage, a supply of uncertified FFRs may present serious dilemmas for healthcare professionals. A classic example are respirators with N95 labels but without any certification marks doing rounds in hospitals across India. Another example of possible counterfeit FFRs is when 2 or more certifications/ standards are printed on the same respirator mask, e.g., both NIOSH and EN149. A list of authorized dealers with their nodal officers appointed by the government of India may be accessed here <http://texmin.nic.in/advertisement/nodal-officers-ministry-textiles-regulate-production-quality-distribution-supply-masks>.

There are speculations about the effectiveness of N95 FFRs over triple layer medical masks. A randomized control trialpublished in JAMA on 03 September 2019 has concluded that “among outpatient health care personnel, N95 respirators vs medical masks as worn by participants in this trial resulted in no significant difference in the incidence of laboratory-confirmed influenza” (7). Trials like this on one hand though reduces fear amongst healthcare workers, but on the other hand may serve to trivialize the extent of the problem if results are accepted at face value. Both medical masks or FFRs are barriers against droplets and bioaerosols but FFRs have an additional property of sealing the user’s face around nose & mouth. In principle, medical masks are worn to prevent transmission of infection from healthcare professionals to patients and FFRs are to prevent the occupational hazard of getting infected from patients. Although there is not enough evidence to support air borne transmission of COVID-19, “WHO continues to recommend airborne precautions for circumstances and settings in which aerosol generating procedures and support treatment are performed, according to risk assessment.” (8)

FFRs are an important component of personal protective equipment and one should stick to certified respirators, both for particles (including bioaerosols) and fluid resistance. The decision to use laboratory-tested but uncertified FFRs in times of shortage/crisis is a difficult one but requires judicious balancing of risks and benefits by healthcare authorities. Use of triple layer medical masks could be an acceptable option in times of shortage (9, 10). For fomite transmission hand hygiene is sine qua non. Healthcare organizations must formulate their own risk assessment protocols based on guidelines/recommendations issued by WHO or the Government of India for judicious use of FFRs. As COVID-19 viral load to healthcare professionals, it is the responsibility of healthcare organizations to protect their workers from fake, counterfeit and, if possible, uncertified masks. The authorities in charge of procuring masks for their organizations must adhere to standards at all costs for ensuring safety of all healthcare professionals. Healthcare workers should not be viewed as “immune” to COVID-19.

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