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Reprocessing of N95 masks: Experience from a resource-limited setting in India

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ARTICLE INFO

Article history:

Received 3 June 2020

Received in revised form 23 December 2020

Accepted 23 December 2020

Keywords:

N95 masks
Plasma sterilization
Filtering efficiency
Ethylene oxide
Pandemic
UV irradiation

ABSTRACT

Objectives: Due to the surge in demand for N95 masks during the Covid-19 pandemic, and considering the situation in countries grappling with acute shortages of N95 masks, this study investigated the possibilities of decontamination and reuse of masks.

Methods: Three N95 masks of different makes (A, B and C) were subjected to six decontamination methods: ultraviolet (UV) irradiation, isopropyl alcohol (IPA) dip, plasma sterilization (Sterrad[®]), ethylene oxide (ETO, 3M[®]), dry heat sterilization, and moist heat sterilization (autoclaving). The integrity of the N95 masks was assessed by measuring their particle filtering efficiency at particle sizes ranging 0.3–0.5 microns.

Results: All the masks decontaminated with ETO and plasma sterilization retained over 95% particle filtering efficiency. Masks decontaminated using IPA dip and autoclaving showed a drop, and UV irradiation showed variations in particle size efficiency degradation after decontamination.

Conclusions: Plasma sterilization is recommended for decontamination of N95 masks in low-resource settings. ETO is not recommended due to hazards associated with handling of ethylene oxide, although the filtering efficiency was retained. Since the UV irradiation method showed variations in results, evaluation of UV decontamination for N95 masks needs to be performed on a case-by-case basis.

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Introduction

COVID-19 is an unanticipated pandemic of unprecedented magnitude. The pandemic highlighted pitfalls in logistics and supply chain management of personal protective equipment (PPE) and N95 masks early in the outbreak in many countries and institutions. The World Health Organization (WHO) has developed guidelines for rational use of PPE, which indicate that healthcare workers exposed to aerosol-generating procedures while handling COVID-infected people need to use N95 respirator or filtering facepiece respirator (FFP2) face masks or equivalent (WHO, 2020). The need for mask usage by the general population was recently added by the Centers for Disease Control and Protection (CDC) but

it has been quite clear since early in the course of the pandemic (CDC, 2020; Heinzerling et al., 2020) that N95 masks are required during aerosol-generating procedures, splashes and sprays in intensive care units (ICUs) and emergency rooms.

Most hospitals in India were unprepared for the surge in demand for N95 masks early in the pandemic. This was probably the case in several low-income and middle-income countries. Most suppliers had also diverted all masks to China in February, as there was an exponential increase of cases in Wuhan and India still only had a handful of cases involving those who had travelled back from China, the Middle East or Europe. Ideally, N95 respirators and FFP2 masks are intended for single use. However, due to the short supply of PPEs, it was decided to start looking for alternatives to extend the use and reuse N95 masks. No guidelines were present in early March on extended use and there were anecdotal methodologies from Nebraska Medicine (2020) and Duke's University (Schwartz et al., 2020) on reprocessing masks. Extended use was defined as continuous use of the N95 mask when attending to more than one

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Table 1
Methodology used for treatment of masks.

Methodology	Time of exposure	Other characteristics
Ultraviolet (UV) radiation (254 nm)	10 min	The mask was suspended in a UV chamber of size 500 × 500 × 300 mm. The UV chamber was provided with 8 nos of UVC lights each of 18 W, covering all sides. The UV chamber was maintained at 35 °C. The time of exposure was 10 min.
Isopropyl alcohol (IPA) dip (70%)	1 min	The face masks were immersed in a tray of 70% IPA for 1 min and aerated under a laminar air flow for 15 min in a laminar flow cabinet.
Ethylene oxide (ETO)	12 h	12 h of aeration was performed
Moist heat sterilization (autoclave)	20 minutes	134 °C at 15 Pa pressure
Plasma sterilization (Sterrad NZ 100)	72 min long cycle used	Each cycle can decontaminate 10 mask pouches (Tyvek® Pouch with STERRAD Chemical Indicator). Upon completion of the cycle, the compatible N95 respirators were aerated in an opened pouch for 1 h, after which they were ready for use.
Dry heat sterilization (hot air oven)	1 h	At 160 °C for 1 h

patient in a ward for more than one shift (Centers for Disease Control and Prevention, 2021). Re-use of mask was defined as reprocessing the mask by various recommended techniques (sterilization or high-level disinfection) and extended use following reprocessing.

Materials and methods

The decontamination of masks was studied using six methods that have been suggested by the CDC for decontamination and reuse of FFP masks before formulating the standard operating procedure for extended use and reuse. Six N95 masks each from three different makes/model numbers (A, B and C) were subjected to six decontamination methods: ultraviolet (UV) radiation exposure, isopropyl alcohol (IPA) dip, ethylene oxide (ETO, 3M®), autoclave, plasma sterilization, and dry heat sterilization. The processing details are shown in Table 1. All experimental runs were in triplicate. The particle filtering efficiency of the mask for particles in the size range of 0.3–0.5 microns was measured before and after the mask decontamination procedure to study for any degradation in the filtering efficiency.

Filtering efficiency of the mask

Each mask was folded and clipped around its periphery and made into a chamber (like a bulb), leaving a small opening for entry of the sampling tube of the particle concentration measuring instrument. A METONE airborne particle counter with a measuring range of 0.3–10 microns and flow rate of 28.3 L/min (1 cfm) was used for particle concentration measurement. This is a particle counter that is used for particle concentration measurements used for clean room classification in accordance with ISO 14644 standard. An airtight seal was made around the sample suction

tube to avoid ambient air from bypassing the mask and getting into the particle counter. The inbuilt vacuum pump of the particle counter was used to draw air through the mask (from the ambient air) at 28.3 L/min (1 cfm). The sampling time for each reading was 1 min. A 1-min flushing (purge) time was allowed to obtain stable and correct readings. The ambient air particle concentration in the test lab environment was considered as the Upstream (USC) concentration value, which was the average of three individual readings. The particle concentration inside the mask was considered as the Downstream concentration (DSC) value, which was the average of three individual readings. For calculation of filtering efficiency, particles in the size range 0.3–0.5 microns were considered. Percentage filtering efficiency of the mask was calculated as $E_f = [1 - (DSC / USC) * 100]$.

Degradation of mask performance

The degradation in the particle filtering efficiency of the masks after the decontamination process was studied by measuring the particle filtering efficiency before decontamination (E_{bd}) and the particle filtering efficiency after decontamination (E_{ad}) and calculating the degradation percentage. Percentage filtering efficiency degradation of the mask was calculated as $D_{fe} = [(E_{bd} - E_{ad}) / E_{bd}] * 100$.

All results were statistically analyzed to calculate the process mean and standard deviation (SD).

Results

All methodologies were run with the respective quality controls. Filtering efficiency of the masks was studied for particle challenge falling between the size range 0.3–0.5 microns. The results are shown in Table 2. Physical deformity was noticed in

Table 2
Particle filtering efficiency of N95 mask before and after different decontamination procedures.

Disinfection Method	Average particle filtering efficiency before decontamination process (E_{bd}) (%)			Average particle filtering efficiency after decontamination process (E_{ad}) (%)			Particle filtering efficiency degradation (D_{fe}) (%)			Particle filtering efficiency degradation	
	Mask A	Mask B	Mask C	Mask A	Mask B	Mask C	Mask A	Mask B	Mask C	Process mean (%)	Process standard deviation
UV radiation	99.52	96.14	98.77	81.71	91.11	95.92	17.90	5.23	2.89	8.67	8.07
IPA dip	99.42	96.59	98.65	84.34	85.9	88.49	15.17	11.07	10.30	12.18	2.62
ETO sterilization	99.47	96.83	97.94	99.37	95.88	97.41	0.10	0.98	0.54	0.54	0.44
Moist heat sterilization (autoclave)	99.58	95.61	99.03	92.34	90.33	89.17	7.27	5.52	9.96	7.58	2.23
Plasma sterilization	99.39	97.12	98.22	96.20	94.91	96.35	3.21	2.28	1.90	2.46	0.67
Dry heat sterilization (hot air oven)	99.29	95.34	98.58	71.64	NR	NR	27.85	NR	NR	NR	NR

many of the face masks subjected to the dry heat sterilization procedure; hence, the results were not provided in full. Irradiation by UV showed a wide variation in results (81.71% for mask A, 91.11 for mask B and 95.92% for mask C), which could have been due a wide variety of factors attributed to the individual makes/models. The process SD (Table 2) was highest for UV treatment (8.07) followed by IPA dip (2.62) and autoclaving (2.23). The lowest SD was with ETO treatment (0.44) and plasma sterilization was close to this (0.67). It is recommended that evaluation of UV as an irradiation method for N95 masks needs to be performed on a case-by-case basis. The IPA dip and autoclaving methods showed a significant decrease in particle filtering efficiency after the decontamination procedure and therefore these methods as not recommended as suitable for decontaminating N95 masks. Although the filtering efficiency of N95 masks after ETO treatment was the highest, with lowest degradation, there were concerns about its use due to risks for staff and handlers; hence, the method was not considered further. N95 masks subjected to plasma sterilization yielded filtering efficiency of 96.20% for mask A, 94.91% for mask B and 96.35% for mask C (Table 2), with the second lowest degradation in comparison with the other decontamination methods; hence, this was considered a good option for developing a protocol for N95 mask reuse.

Based on the results, a protocol for extended use and reuse was created and circulated. Each user was given an N95 mask along with a plasma sterilizer cover. Each user was given instructions for extended use and reuse. Extended use referred to wearing the same N95 mask for repeated encounters with patients without removing the PPE in between encounters for up to 5 days. Each person had to wear correctly fitting masks, as a FIT test was not performed before going into the patient care area. The user was advised to never touch the front of the mask. Extended use of the mask was not recommended following an aerosol-generating procedure in a known Covid-19-positive patient. The masks were to be removed after hand washing by holding the ear loops. The front of the mask was presumed to be contaminated so the user was advised to remove it slowly and carefully.

Reuse of N95 masks

The authors working in various institutions developed protocols based on plasma sterilization being a method for reprocessing of masks. Five masks with five breathable paper bags and five plasma sterilization bags were issued. Each bag and mask had the date and name, and location to be completed (i.e. mask 1 on day 1, mask 2 on day 2, and so on). Following a shift, mask 1 on day 1 would be appropriately removed and stored in bag 1, dried and reused on day 6 after reprocessing. Each mask was handled as contaminated following the first use. Reprocessing was performed with one cycle of plasma sterilization only. All sterilization was performed in a Sterrad NX 100 Plasma sterilizer with a 52-minute cycle as per the Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (Covid-19) Public Health Emergency (Revised) (FDA, 2020). Biological indicators were used with every run. This is an extension of the protocol recommended by the All India Institute of Medical Sciences (AIIMS, 2020).

An N95 mask was discarded if it was:

- 1 Damaged/moistened.
- 2 Used in an aerosol-generating procedure in a known Covid-19-positive patient.
- 3 Used for >12 h straight or if the wearer had difficulty in breathing.

Discussion

At the beginning of the COVID-19 pandemic, with little knowledge about the mode of transmission of SARS-CoV-2, every healthcare set-up was needing N95 masks. The CDC recommendation of extended use and limited use of N95 masks suggests minimizing N95 mask users, using alternatives, implementing extended use and/or limited reuse of N95 masks, while prioritizing the use based on risk assessment (CDC Niosh., 2021).

Many successful techniques for decontaminating N95 masks – such as UV-C, Gamma irradiation, hydrogen peroxide vapors, and peracetic acid – have been studied over time; however, the COVID-19 pandemic has brought to light huge gaps in pandemic preparedness by healthcare facilities all over the world (Heimbuch et al., 2011; Feldmann et al., 2019; John et al., 2020).

This study aimed to find the best method with which to extend the use and attempt to decontaminate and reuse N95 masks to deal with the sudden increase in the demand for masks. All methods were based on previous experience with these techniques. The importance was the safety of the user in terms of the protection offered by the mask. Although the impact of the pandemic has been relatively delayed in India, with fewer deaths, prudent use of medical supplies is an urgent need, considering the behavior of the pandemic so far of overwhelming healthcare facilities, as has been seen in Europe and the USA with exponential increases in cases. The stigma associated with the disease has also seen a steep increase in the demand for PPE such as N95 masks.

Kobayashi et al. (2020) showed in a detailed review of policies from 27 countries on the extended use and reuse of N95 masks that five countries allowed extended use: Canada, France, Mexico, New Zealand and Sweden; and two countries allowed reuse of masks: Germany and Netherlands; and three countries/regions allowed both reuse and extended use: Brazil, European region and the USA. The recommended methods included dry heat at 65–70 °C, exposure to hydrogen peroxide vapors, UV light irradiation and moist heat. However, the current study showed that the integrity of the filters was best maintained by ETO and plasma sterilization (using H₂O₂ vapors). The exposure to heat in a hot air oven, as per current testing, was probably for too long at a very high temperature, which destroyed the integrity of the mask, immaterial of the make and model. Extended use according to current policy ranged from 12 to 40 h depending on the usage. Schwartz et al. (2020) showed that exposure to hydrogen peroxide vapor was a proven method of decontamination for reuse of N95 masks and called for an increased need to improvise and adapt, given the situation of a global pandemic. They also called for each facility to validate its own technique when Bioquell Z-2 and Bioquell ProteQ systems were used; hence, policies had to be devised, improvised and formulated given the current situation.

Autoclaving the masks did not perform well with all three makes/models used in this experiment, unlike the studies from the Netherlands by de Man et al. (2020) (which accepted autoclaving as a simple method for decontaminating N95 masks). However, it is useful to note that the experiments by de Man et al. were specific to a particular make and model of the mask and it is felt that those results cannot be generalized. Another study by Ma et al. (2020) autoclaved masks for 5 min and found it to be a useful technique to ensure decontamination. A study by Viscusi et al. (2009), which included five decontamination techniques for N95 masks, found the results to be make/model specific. However, their results showed that UV, H₂O₂ vapor exposure and ETO were the most promising techniques for decontamination. They raised concerns over ETO and H₂O₂ vapor exposure due to throughput capabilities. In the current study, the UV results were make and model specific, but plasma and ETO sterilization seemed to be stable methods across the make/models that were tested.

To conclude, experiments are needed to check the filtering efficiency of N95 masks after decontamination before formulating policies for reuse and extended use. Since healthcare workers' safety is paramount and given the large number of healthcare workers affected worldwide, this study recommends extended use and guardedly recommends reuse of N95 masks. Based on the results, plasma sterilization is a preferred option for decontaminating N95 masks during non-availability of supplies.

Funding

This work did not receive funding from any source, public or private.

Conflict of interest

None to declare.

Ethical approval

Not applicable since this was a laboratory study not involving any clinical samples or human and animal subjects.

Acknowledgements

The authors are thankful to the Management Board of Madras Medical Mission for permission to use facilities for carrying out this work.

References

- AIIMS (All India Institute of Medical Sciences). Standard Operating Procedure (SOP) for extended use of N95 mask for personal safety of Health Care Workers (HCW) at AIIMS. 2020. www.aiims.edu/en/notices.html?id=10444.
- CDC (Centers for Disease Control). Strategies for optimizing the supply of N95 respirators. 2020. www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html.
- Centers for Disease Control and Prevention (CDC). Recommended guidance for extended use and limited reuse of N95 filtering facepiece respirators in healthcare settings. <https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>.
- de Man P, van Straten B, van den Dobbelen J, van der Eijk A, Horeman AT, Koeleman H. Sterilization of disposable face masks by means of standardized dry and steam sterilization processes; an alternative in the fight against mask shortages due to COVID-19. *J Hosp Infect* 2020;. doi:<http://dx.doi.org/10.1016/j.jhin.2020.04.00>.
- FDA (Food and Drug Administration). Enforcement policy for face masks and respirators during the coronavirus disease (COVID-19) public health emergency. 2020. www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health.
- Feldmann F, Shupert WL, Haddock E, Twardoski B, Feldmann H. Gamma irradiation as an effective method for inactivation of emerging viral pathogens. *Am J Trop Med Hyg* 2019;10:1275–7. doi:<http://dx.doi.org/10.4269/ajtmh.18-0937>.
- Heimbuch BK, Wallace WH, Kinney K, Lumley AE, Wu CY, Woo MH, et al. A pandemic influenza preparedness study: use of energetic methods to decontaminate filtering facepiece respirators contaminated with H1N1 aerosols and droplets. *Am J Infect Control* 2011;39(1). doi:<http://dx.doi.org/10.1016/j.ajic.2010.07.004> e1–9.
- Heinzerling A, Stuckey MJ, Scheuer T, Xu K, Perkins KM, Resseger H, et al. Transmission of COVID-19 to health care personnel during exposures to a hospitalized patient – Solano County, California, February 2020. *MMWR Morb Mortal Wkly Rep* 2020;69(15):472–6.
- John A, Raju S, Cadnum J, Kipum L, McClellan P, Akkus O, et al. Scalable in-hospital decontamination of N95 filtering facepiece respirator with a peracetic acid room disinfection system. *Infect Control Hosp Epidemiol* 2020;. doi:<http://dx.doi.org/10.1017/ice.2020.1257>.
- Kobayashi LM, Marins BR, Costa PCDS, Perrazo H, Castro R. Extended use or reuse of N95 respirators during COVID-19 pandemic: an overview of national regulatory authorities' recommendations. *Infect Control Hosp Epidemiol* 2020;. doi:<http://dx.doi.org/10.1017/ice.2020.173>.
- Ma Q-X, Shan H, Zhang CM, Zhang HL, Li GM, Yang RM, et al. Decontamination of face masks with steam for mask reuse in fighting the pandemic COVID-19: experimental supports. *J Med Virol*. 2020;92:1971–4.
- Nebraska Medicine. Extended use and reuse of facemasks, respirators and protective eyewear for healthcare personnel. 2020. <https://www.nebras-kamed.com/sites/default/files/documents/covid-19/COVID-Extended-Use-Re-use-of-PPE-and-N95.pdf?date03212020>.
- Schwartz A, Stiegel M, Greeson N, Vogel A, Thomann W, Brown M, et al. Decontamination and reuse of N95 respirators with hydrogen peroxide vapour to address worldwide Personal Protective Equipment shortages during the SARS-CoV-2 (COVID-19) pandemic. *Applied Biosaf* 2020;. doi:<http://dx.doi.org/10.1177/1535676020919932>.
- Viscusi DJ, Michael SB, Benjamin CE, Ronald ES. Evaluation of five decontamination methods for filtering facepiece respirators. *Ann Occup Hyg* 2009;53(8):815–27.
- WHO. Rational use of Personal Protective Equipment (PPE) for Coronavirus disease (COVID19). 2020. <https://apps.who.int/iris/bitstream/handle/10665/331498/WHO-2019-nCoV-IPCPE-use-2020.2-eng.pdf?sequence=1&isAllowed=y>.