

## **Philippine COVID-19 Living Clinical Practice Guidelines**

Institute of Clinical Epidemiology, National Institutes of Health, UP Manila In cooperation with the Philippine Society for Microbiology and Infectious Diseases Funded by the DOH AHEAD Program through the PCHRD

### N95 Decontamination

## RECOMMENDATIONS

In situations where there is shortage of filtering facepiece respirators (FFR), we suggest the use of Hydrogen Peroxide Vapor (HPV), Ultraviolet Germicidal Irradiation (UVGI), moist heat and peracetic acid dry fogging system (PAF) as options for N95 mask decontamination as recommended by the manufacturer based on their ability to reduce SARS-COV-2 load and infectivity while still maintaining N95 mask integrity. *(Low quality of evidence; Conditional recommendation)* 

We recommend against the use of autoclave and alcohol as these methods alter filtering facepiece respirator's (N95) integrity and degrade filtration efficacy. (Very low quality of evidence; Strong recommendation)

### **Consensus Issues**

Reuse of N95 masks should be considered only in cases of shortages and not during times of normal supply. It is important to specify the maximum number of cycles by which the decontamination techniques can still preserve the functional and physical integrity of the N95 mask: (1) autoclave- up to 2 cycles; and (2) moist heat, HPV and PAF- up to10 cycles.

Regarding local availability, some noted that HPV is usually not afforded in resource-limited settings, making UVGI a more preferable option due to its lower cost. In practice, however, HPV is considered more effective in decontamination. Its mist can reach all the spaces once halo fogging is done, which is beneficial to N95 mask since it has many pores. In contrast, UVGI can only disinfect the area reached by the UV light. Although HPV is available in the country, its use will entail the need for a special decontamination room and a machine. Some noted that HPV is usually not affordable in resource-limited settings. The panel also stressed the importance of checking the condition of the N95 mask before decontamination and not just solely rely on the manufacturer's recommendation. Likewise, the proper procedure before decontamination should also be emphasized.

On the recommendation against the use of autoclave, it was clarified that although it can destroy the virus, the physical and functional integrity of the N95 mask are affected.

In terms of the other decontamination techniques, no study was found on the effectiveness of air dry alone, exposure to sunlight, soap and water, 0.5% chlorine solution, and for other disinfecting agents such as benzalkonium chloride.



# **EVIDENCE SUMMARY**

## What are effective decontamination techniques for N95 reuse?

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### **Key Findings**

Eight quasi-experimental studies reported the effects of six decontamination techniques (i.e., alcohol, autoclave, moist heat, HPV, PAF, UVGI) on SARS-CoV-2 laden N95 masks. There is low evidence on use of Hydrogen Peroxide Vapor (HPV), Ultraviolet Germicidal Irradiation (UVGI), moist heat and peracetic acid dry fogging system (PAF) as options for N95 mask decontamination. These decontamination methods resulted in  $\geq$ 4.79 log<sub>10</sub> reductions in SARS-CoV-2. Except for autoclave, they preserved the quality fit of N95 masks after 10 decontamination cycles. There is very low evidence against the use of autoclave and alcohol for N95 mask decontamination as these methods alter N95 integrity and degrade filtration efficacy.

#### Introduction

N95 masks are single-use devices that should be discarded after use to avoid self-inoculation & cross-contamination, especially after aerosol-generating procedure.[1,2] The Asia Pacific Center for Evidence-Based Healthcare and PSMID (Apr 3, 2020) has stated that based on available evidence prior to 2020, ultraviolet germicidal irradiation (UVGI), microwave-generated steam, warm moist heat, and HPV all effectively reduced viral or bacterial loads and maintained N95 mask integrity. [2,3] However, the effectiveness of these methods against SARS-CoV-2 remains unclear. [5]

### **Review Methods**

We comprehensively searched various electronic databases<sup>1</sup> until Feb 5, 2021, for any study type investigating the decontamination effects on N95 masks' sterilization efficiency, filtration efficiency, mask integrity, or incidence of infection. We used these keywords in searching for the relevant literature: 1. N95 masks OR respiratory devices; 2 infection control OR decontamination; 3. reuse OR extended use. We excluded studies that focused on decontamination of other mask types (e.g., gauze, cloth, spun-lace, elastomeric, powered-air-purifying, surgical masks) and other article types (e.g., abstracts, posters, review, articles, book chapters, letters, guidelines, points of view. We included only articles with full-text reports written in English.

<sup>&</sup>lt;sup>1</sup> MEDLINE through Pubmed, Cochrane CENTRAL Database, ChinaXiv.org, USA clinical trials, China chictr.org, WHO, COVID-19 Open Living Evidence Synthesis, Living Evidence on COVID-19, Australia covid19 evidene.net.au, WHO Therapeutics, and COVID-19 guidelines.



### Results

Characteristics of included studies

Eight quasi-experimental studies reported on the effects of six decontamination methods on SARS-CoV-2- inoculated N95 masks. Seven laboratory-based studies [4-10] and one hospitalbased study [11] were included, all published in the year 2020. The effects of alcohol (n=2 studies) [4,5], autoclave (n=2 studies) [6,11], heat (n=1 study) [7], HPV (n=3 studies) [4,6,8], PAF (n=1 study) [6], UVGI (n=3 studies) [4,9,10] for SARS-COV 2 inactivation and on mask integrity were investigated. One study assessed only the effect on physical integrity of the mask, one study on the ability to decontaminate alone, while six analyzed both. Various commercially available N95 models, both medical and industrial grade were tested. No study investigated effect of decontamination on incidence of COVID- 19 infection. Studies by Smith et al. (2020) [5], Kumar et al. (2020) [6], and Fischer et al. (2020) [4] examined effects of several decontamination procedures.

#### Methodological quality

SARS-CoV-2 containing liquid media was applied directly to the N-95 masks [6-12]. The masks were not randomly allocated to decontamination groups [4-11]. Although assessors were not blinded to the decontamination method used, objective measures were used to determine virucidal activity and mask integrity [4-11]. Kumar et al. (2020) did not report the effect size on N95 functional intergrity, after a series of decontamination cycles [6]. These limited number of studies reported decontamination effects on a few new or unused N95 models artificially contaminated:

- a. 2 alcohol studies on 4 masks
- b. 2 autoclave on 6 masks
- c. 1 moist heat study on 4 masks
- d. 3 HPV studies on 6 masks
- e. 1 PAF study on 6 masks
- f. 3 UVGI studies on masks

#### Outcomes

Effectiveness outcomes based on the ability to remove infectious potential of SARS-COV2 were established based on real time reverse transcriptase polymerase chain reaction (RT-PCR) viral detection and viability in culture. Mask integrity was determined based on the ability to preserve filtration efficiency using quantitative FIT testing and visual and tactile analysis of facemask structure after one or several cycles of decontamination. No study reported on incidence or transmission of COVID-19 infection.



#### Alcohol

70% ethanol was sprayed on the mask exterior and interior. For overnight application, masks were saturated with 70% ethanol, placed in a sealed plastic bag overnight, removed in the morning and allowed to airdry for ~8 hours before the FIT test.

Ethanol treatment demonstrated sufficient virucidal activity in the studies. A single treatment however led to a drop in functional and physical integrity even when the mask felt dry to touch. The impact on integrity appeared to be time-bound. Some masks dried overnight showed detached nose guards. [5]

#### Autoclave

One autoclave cycle effectively reduced the SARS-CoV-2 virus on N95 masks and maintained its structural and functional integrity. [12] More than one autoclave cycle resulted in the failed quantitative fit test using Portacount of the rigid and molded an N95 subset (i.e., 3M 1860 and 8210). [6] In a study conducted in a hospital setting, undisclosed number of staff reported no change with ability to breathe while wearing N95 masks that had been autoclaved once, although there were comments on a slight change in respirator odor, less elasticity in the straps, and a 'softer' texture to the mask material. [11]

#### Heat

A single 70°C heat for 5 minutes inactivated the SARS-CoV-2 in all N95 masks. [13] The same effect was noted with a longer duration of heating (60 minutes) at 70°C. Besides, 60 minute-heating decontaminated the N95 masks with virus-laden blood and saliva. [7] The effects of heat on SARS-CoV-2 virus-infected N95 straps have not been investigated. [7] Moist heat (50–85% RH) disinfected SARS-CoV-2 or similar viruses at a shorter exposure time than dry heat. [14] The polypropylene microfibres of N95 masks degrades above 130°C, suggesting that N95 masks may withstand repetitive exposure to 70°C. [15] Ten thermal cycles of 60 min at 70 °C with either 0% or 50% relative humidity did not degrade the mask's structural integrity. Masks maintained fibre diameters similar to untreated masks and continued to meet standards for fit (185.4–203.6; n = 23) (p < 0.001), filtration efficiency (95.1–97.5; n = 12) (p = 0.003) and breathing resistance (62.9–95.5; n = 12) (p < 0.001). [7] In contrast, more than 2 rounds of decontamination resulted in decrease in filtration performance among heat treated masks. [6]

A pilot study utilizing 2 industrial laundry dryers maintained mask integrity even after 3 dry heat cycles at 80  $\circ$ C for 65 min. In this study, the masks were sealed in Ziplocs bags and placed in the cardboard boxes positioned at the rear half of the dryer, The idea is to keep the masks protected from the extreme temperatures on the cylinder itself, and to stabilize the temperature both by using the region in the tumbler with lower temperature gradients and by using the more uniform equilibrium in the cardboard box. Laundry drivers are not designed for medical decontamination purposes. [17]



#### HPV

HPV and HP plasma led to immediate and rapid inactivation of SARS-CoV-2 on N95 mask upon treatment exposure. [6,10] Complete inactivation of SARS-COV2 was demonstrated with extended HPV cycle time of 5 hours. [8] In contrast, HP did not completely eliminate infectious SARS-CoV-2 RNA in all masks but the two healthcare grade masks did show an approximately five log10 reduction in SARS- CoV-2 RNA relative to the positive control. Such a log10 reduction in infectivity would exceed the '99.97%' germicidal efficacy quoted by some hand sanitizers and exceeds the three log10 reduction estimated to fully decontaminate a mask in an influenza model. [7]

N95 masks showed acceptable filtration performance even after multiple (i.e.,10) HPV cycles. [8]

#### PAF

A single PAF cycle deactivated the SARS-CoV-2 virus on N95 masks. [6]

#### UVGI

In a laboratory setting, 5 minutes of PX-UV resulted in a >4.79 log10 rapid reduction in SARS-CoV-2 viral load on N95 masks. [9] A 5-minute PX-UV did not alter the physical or functional integrity of N95 masks (9). N95 masks maintained their filtration performance up to three UV cycles. [4] Appendix 2 reports the effects of the six decontamination methods used in this review.

### **Recommendations from Other Groups**

The CDC (April 2020) has stated that N95 mask decontamination for reuse is only a contingency strategy to conserve supplies during the COVID-19 pandemic. UVGI, HPV, and moist heat has shown most promise in decontaminating N95 masks. Decontamination method should be evaluated for each FFR model.

The European Center for Disease Control and Prevention (June 2020) has listed UVGI, ethylene oxide, HPV, and dry and moist heat as N95 decontamination procedures that have favorable effectiveness and safety profile. However, these are considered only as a last resort if PPE shortages occurs. [18]

### **Ongoing Studies**

There were 8 ongoing pre-print studies investigating the decontamination effects of UVGI, HPV, heat, methylene blue and light on SARS-CoV-2-laden N95 masks.



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| Study, year               | Virus/Bacteria   | Intervention           | Outcome  |
|---------------------------|--|------------------------|--|
| Fischer, 2020             | SARS-CoV-2   | Alcohol<br>HPV<br>UVGI | Virus titer (TCID <sub>50</sub><br>/mLmedia)<br>Mask integrity (fit<br>factor)<br>Kill rate (per virus per<br>min)   |
| Smith, 2020               | SARS-CoV-2   | Alcohol<br>HPV         | FIT score  |
| Kumar, 2020               | SARS-CoV-2<br>Vesicular stomatitis<br>virus Indiana serotype         | Autoclave<br>PAF       | Sterilization efficacy<br>Quantitative fit test  |
| Czubryt, 2020             | SARS-CoV-2   | Autoclave              | Fit test<br>Pre- and post-<br>sterilization reject   |
| Daeschler, 2020           | SARS-CoV-2<br>Escherichia coli                                       | Heat                   | SARS-Cov-2<br>inactivation<br>Bacterial inactivation<br>Microstructural<br>analysis of the N95<br>filter layer<br>Quantitative N95<br>respirator fit testing<br>Filtration efficiency<br>and breathing<br>resistance testing |
| Ibáñez-Cervantes,<br>2020 | SARS-CoV-2<br>Staphylococcus<br>aureus<br>Acinetobacter<br>baumannii | HPV                    | Sterilization efficiency   |
| Simmons, 2020             | SARS-CoV-2   | UVGI                   | Sterilization efficiency   |
| Ozog, 2020                | SARS-CoV-2   | UVGI                   | Sterilization efficiency   |

# Appendix 1. Characteristics of Included Studies



## Appendix 2. The effects of decontamination methods on N95 masks

| Chudu                                | Method     | Studies; #<br>N95<br>model | Outcomes   |  |                                      | 1                     |
|--------------------------------------|------------|----------------------------|--|--|--------------------------------------|-----------------------|
| Study                                |            |                            | SARS-CoV-2<br>Inactivation                               | Physical integrity   | Functional integrity                 | Level of<br>evidence  |
| Fischer, 2020 (4)                    | Alcohol    | 2:4                        | rapid inactivation                                       | Loss after 2 <sup>nd</sup> round                             | ↓ filtration efficiency              | Very low <sup>1</sup> |
| Smith, 2020 (5)                      |            |                            | undetectable   | detached nose guards,<br>affected integrity (time-<br>bound) | impaired filtration (time-<br>bound) |                       |
| Kumar, 2020 (6)                      | Autoclave  | 2:6                        | 5.2-6.3 log <sub>10</sub><br>reduction                   | NR   | ↓ quality fit after 10<br>cycles     | Very low <sup>1</sup> |
| Czubryt, 2020 (11)                   |            |                            | NR   | less elastic straps,<br>softer mask, with odor               | ↓ fit test after 2 cycles            |                       |
| <b>Daeschler,</b><br><b>2020</b> (7) | Moist heat | 1:4                        | undetectable   | comfortable masks  | Passed after 10 cycles               | Very low <sup>1</sup> |
| Ibáñez-<br>Cervantes, 2020<br>(8)    | HPV        | 3:6                        | undetectable   | NR   | NR                                   | Low <sup>2</sup>      |
| Fischer, 2020 (4)                    |            |                            | extremely rapid  |  | Intact                               |                       |
| Kumar, 2020 (6)                      |            |                            | 5.2-6.3 log <sub>10</sub> reduction                      |  | passed quality fit after 10 cycles   |                       |
| Kumar, 2020 (6)                      | PAF        | 1:6                        | 5.2-6.3 log <sub>10</sub><br>reduction                   | NR   | passed quality fit after 10 cycles   | Very low <sup>1</sup> |
| Simmons, 2020(9)                     | UVGI       | 3:6                        | >4.79 log <sub>10</sub><br>reductions after 5<br>minutes | NR   | NR                                   | Low <sup>2</sup>      |
| Fischer, 2020 (4)                    |            |                            | slow deactivation  |  | Intact                               |                       |
| <b>Ozog, 2020</b> (10)               |            |                            | effective<br>decontamination                             |  | NR                                   |                       |

 $1 \le 2$  studies, high risk of bias

<sup>2</sup> 3 studies, high risk of bias

Legends: HPV, Hydrogen plasma vapor; NR, not reported; PAF, Peracetic acid dry fogging system; SARS-CoV-2, Severe acute respiratory syndrome coronavirus 2; UVGI, ultraviolet germicidal irradiation



# Appendix 3. Characteristics of Ongoing Studies

| Study                 | Virus/Bacteria   | Intervention                              | Comparator                         | Outcome   |
|-----------------------|--|---|------------------------------------|---|
| Campos et al          | SARS-CoV-2<br>Human coronavirus<br>NL63 (HCoV-<br>NL63)<br>Chikungunya<br>virus, Vaccine<br>strain 181/25<br>(CHIKV-181)   | Heat                                      | NA                                 | Filtration efficiency<br>Pressure drop<br>Sterilization efficiency  |
| Derr et al            | Phi6 bacteriophage<br>HSV-1<br>CVB3<br>SARS-CoV-2  | Aerosolized<br>hydrogen<br>peroxide       | NA                                 | Filtration efficiency test<br>Sterilization efficiency<br>Fit test  |
| Geldert et al         | SARS-CoV-2   | UVGI                                      | NA                                 | Sterilization efficiency<br>UV-C dose<br>Dose-response for SARS-<br>CoV-2 viral inactivation by<br>UV-C<br>Validating an optical model<br>of a UV-C decontamination<br>system<br>Intra-N95 variation in UV-C<br>dose and SARS-CoV-2<br>inactivation |
| Golovkine et al       | SARS-CoV-2   | UVGI                                      | NA                                 | Sterilization efficiency<br>UV-C dose measurements  |
| Lendvay et al         | SARS-CoV-2 (a<br>Betacoronavirus)<br>Nurine hepatitis<br>virus (MHV) (a<br>Betacoronavirus)<br>Porcine respiratory<br>coronavirus<br>(PRCV) (an<br>Alphacoronavirus) | Methylene Blue<br>and Light               | Hydrogen<br>peroxide<br>plus ozone | Sterilization efficiency<br>Respirator and mask<br>integrity  |
| Lensky et al          | SARS-CoV-2   | Heat using<br>commercial<br>laundry dryer | NA                                 | Sterilization efficiency<br>Mask integrity<br>Filtration efficiency<br>Manikin fit factor<br>Strap integrity  |
| Rathnasinghe<br>et al | SARS-CoV-2   | UVGI                                      | NA                                 | Sterilization efficiency  |



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|             |            |                        |    | Validation of the irradiation<br>protocol<br>Establishment of the<br>germicidal UVC exposure<br>protocol |
|-------------|------------|------------------------|----|--|
| Smith et al | SARS-CoV-2 | HPV<br>UVGI<br>Ethanol | NA | Sterilization efficiency<br>FIT test   |