Decontamination methods for respiratory protection mask model N95: a rapid review

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Research

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Abstract

Background: N95 respiratory protection masks are used by healthcare professionals to prevent contamination with infectious microorganisms transmitted by droplets or aerosols.

Methods: We conducted a rapid review of the literature analyzing the effectiveness of decontamination methods for mask reuse. The review was carried out in September 2020 using a simplification of the formal systematic review process, which simplified the stages of a complete systematic review, including the exclusion of an assessment of study methodology.

Results: A total of 563 articles were retrieved of which 48 laboratory-based studies were selected. Fifteen decontamination methods were included in the studies. Hydrogen peroxide was evaluated by 19 laboratory studies, ultraviolet germicidal irradiation by 21, ethylene oxide by 4, dry heat by 11, moist heat by 9, ethanol by 5, isopropanol solution by 2, microwave oven by 11, sodium hypochlorite by 10, autoclave by 7, electric rice cooker by 3, cleaning wipes by 1, bar soap and water 1, multi-Purpose High-Level Disinfection Cabinet by 1 and chlorine dioxide by 1. Five methods appear promising: hydrogen peroxide vapor, ultraviolet irradiation, dry heat, wet heat/pasteurization, and microwave ovens.

Conclusions: Positive results should be considered with caution as they represent a small number of studies, reflect ideal laboratory conditions, and may have limited applicability in realistic situations and for health systems.

Background

The world is facing a pandemic of coronavirus disease (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[1–5] Respiratory transmission routes of these viruses between humans are well established and based on transport via aerosols, droplets, secretions or through direct contact with nasal mucosa.[6]

The use of respiratory protection masks, particularly model N95, by health professionals in the care of infected patients is recommended in aerosol-producing procedures (tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, manual ventilation, before intubation, collections of nasotracheal secretions and bronchoscopies) and the recommendation is to discard it after close contact with a patient (single-use).[7–9]

During the current COVID-19 pandemic, governments have found it difficult to acquire adequate amounts of Personal Protection Equipment (PPE) including respiratory protection masks; this has been accompanied by a high level of infection of health professionals on the front lines of services.[10–14] The COVID-19 pandemic has not only exposed the need for health professionals to have access to the most effective PPE, it has exposed the inability of many health systems to meet this need. In this context and with the goal of enabling reuse of protective masks, research on alternatives for their decontamination has been carried out.

Why is this Review needed?

The recent epidemics and pandemics caused by respiratory viruses have been characterized by a shortage of N95 masks. In this scenario health care professionals seek alternatives, including the decontamination and reuse of PPE.[15] However, there is concern about disease transmission as there are no best practices for mask decontamination and reuse.[16] In critical circumstances, rapid analyses are recommended by WHO[17] to provide guidance for timely decision making. This quick review examines the knowledge base on the effectiveness and safety of decontamination methods for N95 masks for reuse as protection against COVID-19 and other respiratory viruses. A recent systematic review evaluated the efficacy and safety of N95 mask disinfection methods with emphasis on decontamination from SARS-CoV-2[18]. Nevertheless, it must be considered that we will continue to observe the emergence of new viruses and infections[19], and concerns about efficacy and safety of methods of decontamination of personal protective equipment for will remain until more scientific evidence emerges. Furthermore, recently the likelihood of a second wave of COVID-19 points to the recurrence of previous problems and the need for planning for stockpiling and handling of personal protective equipment.[20,21]

Methods

Search strategy and selection criteria

This rapid review follows the principles outlined by Haby et al[22], which simplify the stages of a complete systematic review, including the exclusion of an assessment of the risk of bias in the included studies and . According to these principles, we developed a specific protocol for this study (Supplementary material 1). Searches were conducted on Medline, Cochrane Library and EMBASE databases on September 25, 2020. Search terms were related to decontamination (e.g., “Sterilization”, “Disinfection” and “Decontamination”), reuse (e.g., “Equipment Reuse” and “Reuse”), device failure (“Equipment Failure”) and masks (e.g., “N95” and “filtering facepiece respirators”). Articles were included that evaluated methods for decontamination of N95 masks for reuse and whose outcome was the effectiveness, safety, maintenance of protection or filtering characteristics of the evaluated decontamination method. The language and date of publication of references was not an exclusion criterion.

Results

Search results and study selection process

The complete search strategies can be found in Table 1 of Supplementary material 2. Initial searches retrieved 552 articles (Medline: 381, Cochrane: 52 and EMBASE: 119). Manual searches detected 11 additional publications. Mendeley citation management software was used for automatic removal of duplicate articles, remaining 301 studies. Two reviewers (LFP and AIQC) independently screened the 301 studies using the Rayyan systematic review application to screen abstracts and titles.[23] Of these, 240

were excluded for not meeting the inclusion criteria. The full texts of 61 studies were screened by two reviewers (LFP and AIQC) and thirteen additional studies were excluded. Excluded full text studies and the reasons for exclusion are listed in Table 2 of Supplementary material 3. At the end, 48 studies were selected for the full review process (Figure 1).

Data extraction

Two reviewers (LFP and AIQC) independently used a pre-specified data extraction sheet form designed to obtain the specific data required for this review. The data extracted from the primary studies were: data related to the author, year, study objective, intervention, comparator, commercial mask model, target microorganism, results and conclusions of the study authors, limitations and detailed description of the decontamination process making its reproducibility in other scenarios possible.

Characterization of the included studies

The specifics of each study (cycles, temperatures, protocols, densities, exposure time, technology used and results) are described in Table 3 of Supplementary material 4 and the differences before and after decontamination are shown in Table 4 of Supplementary Material 5 for outcomes: filter aerosol penetration, filter airflow resistance and filtration efficiency. Results of the studies were summarized based on decontamination method and results for the two issues:[24]

1. Whether the device maintains its structural characteristics and provides an adequate level of protection after the decontamination method, without any risk of exposure for the health professional to exposure to inhalable chemical residues that may have remained after the method used. The penetration of 0.3 μm (aerodynamic mass mean diameter) of sodium chloride aerosols aerosol particles through a certified N95 respirator cannot exceed 5%.[25]
2. Whether the decontamination method used was effective in reducing or completely eliminating the infectious capacity of the target organism without any risk of exposure for the health professional to contamination.

Fifteen methods were assessed in the 48 papers: hydrogen peroxide, ultraviolet irradiation, ethylene oxide, dry heat, moist heat/pasteurization, ethanol, isopropanol solution, microwaving, sodium hypochlorite (NaClO), autoclaving, electric rice cooker, cleaning wipes, bar soap and water, Multi-Purpose High-Level Disinfection Cabinet (Altapure, Mequon, WI) and chlorine dioxide (ClO_2).[24,26–72]

1. Hydrogen peroxide

Hydrogen peroxide was evaluated in its liquid, plasma and gas/vapor forms by nineteen laboratory studies.[28,35–39,43,47,53–57,60,61,64,68,70,71] The effect of hydrogen peroxide on the filtering capacity varied according to the method used. Hydrogen peroxide plasma led to changes in the masks' metallic nasal clips[61] and degradation in their filtering performance.[37] Treatment with liquid hydrogen peroxide caused oxidation of the metal clips[37] but also inactivated the influenza H1N1 virus.[70] When used as steam,

hydrogen peroxide did not leave residual chemical products,[57] the integrity and filtering capacity of the mask were maintained,[28,37,73] and the method was effective in eliminating SARS-CoV-2[28] and spores of *Geobacillus stearothermophilus*.[57]

2. Ultraviolet germicidal irradiation (UVGI)

The effect of ultraviolet germicidal irradiation on N95 respirators masks was evaluated by 21 studies[24,28,30,33,37,42,45–48,50,51,53,56,58–63,65] and there was a difference between studies in relation to UVGI doses and application of time periods. In general, UVGI did not affect the integrity and ability of the masks to filter aerosols or adapt to the face, nor did it leave a smell, irritating/toxic residues, or create important changes in appearance even when multiple cycles were performed.[24,28,30,37,42,45,46,48,53,56,60–62] However, different commercial brands of N95 models resisted differently in terms of performance penetration after multiple cycles and doses applied.[46] The method was effective against the influenza virus H5N1,[24] SARS-CoV-2,[28] bacteriophages MS2,[30] and influenza virus H1N1.[33,50] At the same time, even after 20 min of irradiation with 365 nm UVA the relative survival of *Bacillus subtilis* spores remained above 20%.[45]

3. Ethylene oxide

Evaluated by four studies,[37,56,60,61] the effectiveness of ethylene oxide (EtO) depended on the type of sterilization equipment used, whether there was a hot cycle, and exposure to EtO. The process did not affect the filtration, resistance, odor or appearance of the masks. The main limitations of the method were the processing time and the presence of toxic residues and by-products. None of the studies reported the effectiveness of EtO treatments on microorganisms.

4. Dry heat

The use of dry heat was evaluated for by eleven different experimental studies.[27,28,40–42,47,52,59–61,66] Temperatures between 70 and 85 °C did not affect the structural characteristics of the masks under various humidity conditions (≤100% RH).[28,42] The filtering efficiency remained acceptable (≥95%) up to 50 cycles at 85 °C and 30% of RH.[42] Dry heat at 70ºC was effective against the SARS-CoV-2 for 1–2 rounds of decontamination but should not be used for 3 rounds.[28]

5. Moist heat / pasteurization

Nine studies[24,26,27,33,37,42,48,49,62] evaluated the effect of moist heat between 60 and 100°C. The method did not alter mask fit, odor or comfort.[24,33,37,42,62] In one study[42] filtration efficiency has a significant drop after cycle 5.

Moist heat (65±5 °C for 3h) was also effective in eliminating H1N1[33] and H5N1[24] viruses.

6. Ethanol

Different methods of decontamination with ethanol were tested: spray,[28] immersion,[31,42,44] and pipette drips.[45] Results were divergent between methods. The filtration efficiency of masks was degraded to unacceptable levels when they were immersed in alcohol.[31,42,44] Mask filtration performance was not significantly reduced after single ethanol sprays which were also effective in eliminating SARS-CoV-2.[28] Subsequent rounds of spraying caused sharp drops in filtration performance.[28] Pipette drips were not effective in eliminating *Bacillus subtilis* spores.[45]

7. Isopropanol solution

The filtering capacity of N95 masks was changed and the particle penetration through the N95 mask exceed 5% after they had been submerged in isopropanol solution.[44,60] Effects on microorganisms were not evaluated.

8. Microwave oven

Eleven studies tested the use of microwave ovens in the disinfection of N95 masks.[24,29,30,33,37,48,52,60–62,67]. The type of commercial furnace, maximum temperature, and time protocols varied between the studies (Table 3, Supplementary material 4). When masks were placed directly on the rotating plate of the microwave without protection, two commercial models of the tested masks melted.[61] When the masks were placed in containers with water[24,33,37,62] or in steam bags specifically marketed for microwave ovens no residual odor was observed.[30] In addition, there were no structural changes affecting adjustment on the face, filtration capacity, or resistance to airflow and none of the metal components melted or combusted. Microwaving the masks was effective in eliminating H5N1[61] and H1N1 influenza viruses[62] and bacteriophage MS2.[30]

9. Sodium hypochlorite (NaClO)

Ten studies[29,37,42,44,45,53,56,60,61,63] evaluated the use of hypochlorite at different concentrations and application methods (Table 3, Supplementary material 4). The maintenance of mask integrity and filtering capacity varied between studies. One study found that one round of disinfection drastically degraded filtration efficiency to unacceptable levels.[42] A second found that application of sodium hypochlorite discolored the metallic components of the masks and left a characteristic smell of bleach.[61] Finally, one treatment caused the release of low levels of hydrochloric gas.[56] On the other hand, two studies[37,44] reported that the method did not affect the filtration or airflow resistance performance of the masks. Only one of the studies tested sodium hypochlorite as a disinfectant, reporting that it was effective in eliminating *Bacillus subtilis* spores.[45]

10. Autoclave

As it is an equipment present in all hospital environments, the autoclave was evaluated by 7 studies with the perspective of being an accessible method.[31,32,44,45,60,69,72] Autoclave disinfection was effective in

eliminating *Bacillus subtilis* spores,[45] however, had little altered the structural integrity of the masks.[44]

11. Electric rice cooker

Despite showing 99–100% biocide efficacy against *Bacillus subtilis*[45] spores after using dry heat for 3minutes (149–164 °C, without adding water) and the treatment (for 13-15 minutes, including 8-10 minutes of heating and 5 minutes of steam) also resulted in a greater than 5 log10 reduction in bacteriophage MS2 and methicillin-resistant S aureus.[40] However, the method visibly changes the mask's integrity.[44]

12. Cleaning wipes

The effectiveness of commercial wipes containing 0.9% hypochlorite, benzalkonium chloride or no active antimicrobial ingredients was evaluated in masks contaminated with *Staphylococcus aureus* and mucin.[34] The three mask models withstood handling and abrasion during the disinfection process. All were successfully disinfected against atypically high microbe levels by wipes containing antimicrobial agents but the inert wipes did not produce adequate disinfection.

13. Bar soap and water

Average penetration had markedly increased for N95 respirators after being submerged and the authors hypothesized the soap could have removed the charge on the fibers similar to the effect observed with isopropanol solution exposure.[60]

14. Multi-Purpose High-Level Disinfection Cabinet (Altapure, Mequon, WI)

The treatment was effective against microorganisms and the researchers reported no visible changes in the masks. However, the efficiency of the filtration has not been confirmed.[59]

15. Chlorine dioxide (ClO_2).

The method significantly changed the filtering efficiency of the tested masks.[68]

Discussion

Fifteen decontamination methods were identified in the 48 studies[24,26–72] included in this review. All reports were based on laboratory tests, with ten addressing the infectious capacity of microorganisms and fifteen studying the structural integrity of the masks after the decontamination process.

The studies included in this review used different methodologies. This makes it difficult to summarize the results. This review reveals the inadequacy of the evidence supporting the use of N95 mask decontamination methods. In particular, if the elimination of an organism's infectious capacity has not been proven then a mask that retained its structural integrity is still a potential vehicle of transmission.

This concern is reinforced by a recent study showing that pathogens may be present on the external surface of about 10% of used masks, and that the risk of infecting the user increases with prolonged use.[74] The number of viral particles and their survival time are key determining factors when consideration of reuse becomes necessary.[75]

So far the evidence does not indicate a method that is consistently safe and effective to decontaminate N95 respiratory protection masks. Several of the published results are promising, in particular, hydrogen peroxide vapor, germicidal ultraviolet irradiation, dry heat ≤85 °C, moist heat/pasteurization, and microwaving because in the outcomes (filter aerosol penetration, airflow resistance and filtration efficiency) they maintained integrity the integrity of the masks. However, the studies used different decontamination methods, doses and procedures and the most valuable for decision making is to evaluate after which methods the filtration efficiency remained unchanged or within the established thresholds.[25]

In particular, hydrogen peroxide vapor and ultraviolet germicidal irradiation require specific equipment and environments; cost will be a major consideration. Dry heat, wet heat/pasteurization, and microwave ovens also showed positive results in terms of effectiveness and safety and are more accessible methods in scenarios of scarce financial resources. Studies are needed that assess the feasibility of these methods, especially by health systems in developing countries.

The disinfection protocols that used hydrogen peroxide (solution and plasma), ethylene oxide, ethanol, sodium hypochlorite, autoclaves, electric rice cooker, and isopropanol solution interfered with the integrity of the masks within the test conditions used in the studies. Commercial cleaning wipes were effective antimicrobial agents and did not degrade the masks but were only evaluated by a single study and for two microorganisms.

In the case of serious emerging infections such as COVID-19 the principle of universal precaution must be considered, that is, a balance must be made between the benefits and risks of the possible decontamination methods, in order to ensure maximum safety and real protection for the user, especially in the case of two health professionals on the front line.[15,76]

The present study has limitations as, for example, only three databases were searched, given that it was carried out as a quick response in the midst of the COVID-19 pandemic and we adopted a series of methodological simplifications that may affect the findings and our interpretations. Eliminating the evaluation of the studies' methodological qualities was among the simplifications and calls for caution in interpreting the results presented. The strengths of this review, however, are the number of identified methods, the multiple approaches used to search for relevant studies, and the participation of a team of multi-disciplinary specialists in all stages of the project.

Conclusion

Health care workers on the front lines of pandemics must be guaranteed access to effective PPE. There is currently insufficient evidence to recommend any method as being safe and effective for the decontamination and reuse of respiratory protection masks. There are several promising methods worth further study such as hydrogen peroxide vapor, germicidal ultraviolet irradiation, dry heat at temperatures ≤85°C, wet heat / pasteurization and the microwave oven. However, it is important to emphasize that all need further evaluation and validation in real-life scenarios and with consideration of economic issues of implementation.

List Of Abbreviations

COVID-19 coronavirus disease

EtO ethylene oxide

SARS-CoV-2 severe acute respiratory syndrome coronavirus 2

PPE Personal Protection Equipment

Influenza A virus subtype H5N1

Influenza virus A subtype H1N1

NaClO sodium hypochlorite

UVGI Ultraviolet germicidal irradiation

UVA Ultraviolet A

MS2 bacteriophage

WHO World Health Organization

Declarations

Ethical Approval and Consent to participate Not applicable

Consent for publication Not applicable

Availability of supporting data All data are included in the manuscript

Competing interests The authors declare that they have no competing interests

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Authors' contributions

All authors read and approved the final manuscript

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Figures

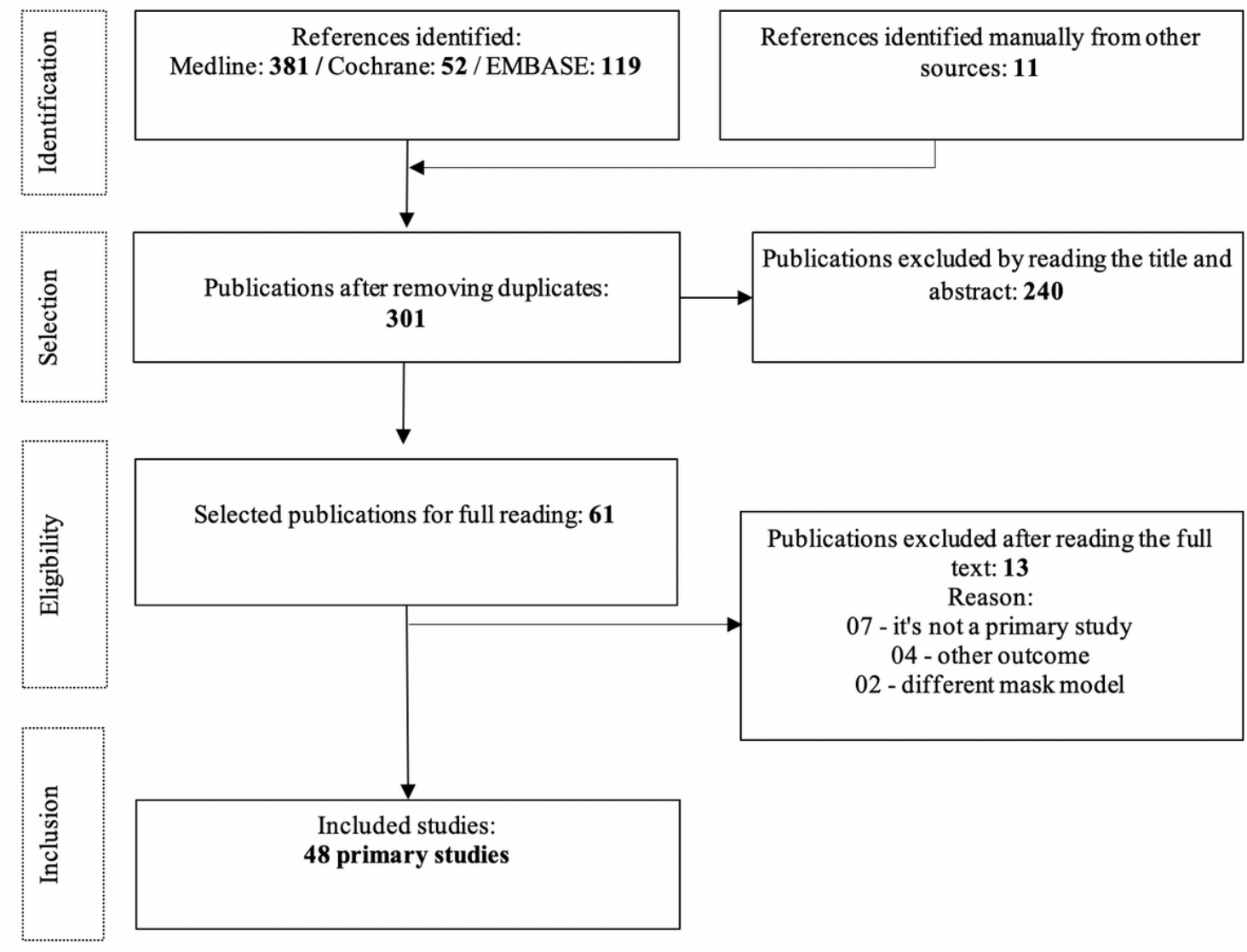

Figure 1

Flowchart of the study selection process

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