

Is it possible to decontaminate N95 masks in pandemic times? integrative literature review



É possível a descontaminação de máscaras N95 em tempos de pandemia? revisão integrativa da literatura

¿Es posible descontaminar las máscaras N95 en tiempos pandémicos? revisión integrativa de la literatura

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ABSTRACT

Objective: To evaluate the protocols on decontamination/reuse of N95 masks available in the literature in times of the Covid-19 pandemic.

Method: Integrative literature review, in the period from 2010 to 2020, on the databases MEDLINE/PubMed, Science Direct, Cochrane, SAGE journals, Web of Science, Scopus, Embase and Wiley, with the descriptors Masks AND Respiratory protective devices; Mask OR N95 AND Covid-19; N95 AND Respirators; Decontamination AND N95 AND Coronavirus; Facemask OR Pandemic.

Results: Twelve studies were included, of which 3 (30.0%) used ultraviolet germicidal irradiation and indicated mask deterioration between 2 and 10 cycles, 4 (40.0%) used hydrogen peroxide vapor, and seal loss varied from 5 to 20 cycles, 4 (33.3%) evaluated the structural integrity of the N95 mask through visual inspection and 6 (54.4%), its filtration efficiency.

Conclusion: Reuse strategies to overcome a shortage of devices in the face of the pandemic challenge the current concept for good practices in health-product processing.

Keywords: Masks. Respiratory protective devices. Decontamination. Coronavirus. Coronavirus infections. Pandemics.

RESUMO

Objetivo: Avaliar, na literatura, os protocolos disponíveis sobre descontaminação/reutilização das máscaras N95 em tempos de pandemia da Covid-19.

Método: Revisão integrativa, no período de 2010 a 2020 nas bases de dados MEDLINE/PubMed, Science Direct, Cochrane, SAGE journals, Web of Science, Scopus, Embase e Wiley, com os descritores Masks AND Respiratory protective devices; Mask OR N95 AND Covid-19; N95 AND Respirators; Decontamination AND N95 AND Coronavirus; Facemask OR Pandemic.

Resultados: Incluíram-se 12 estudos, dos quais 3 (30,0%) utilizaram irradiação germicida ultravioleta e indicaram deterioração da máscara entre 2 a 10 ciclos, 4 (40,0%) utilizaram o vapor de peróxido de hidrogênio e a perda da vedação variou de 5 a 20 ciclos, 4 (33,3%) avaliaram a integridade estrutural por meio de inspeção visual e 6 (54,4%), a eficiência da filtração da máscara N95.

Conclusão: Estratégias de reutilização para suprir a escassez de dispositivos diante da pandemia desafiam o conceito vigente para as boas práticas do processamento de produtos para saúde.

Palavras-chave: Máscaras. Dispositivos de proteção respiratória. Descontaminação. Coronavirus. Infecções por coronavirus. Pandemias.

RESUMEN

Objetivo: Evaluar, en la literatura, los protocolos disponibles sobre descontaminación / reutilización de máscaras N95 en tiempos de pandemia de Covid-19.

Método: Revisión integrativa, en el período 2010 a 2020 en las bases de datos MEDLINE / PubMed, Science Direct, Cochrane, SAGE, Web of Science, Scopus, Embase y Wiley, con los descriptores Masks AND Respiratory protective devices; Mask OR N95 AND Covid-19; N95 AND Respirators; Decontamination AND N95 AND Coronavirus; Facemask OR Pandemic.

Resultados: Se incluyeron doce artículos, de los cuales 3 (30,0%) usó irradación germicida ultravioleta e indicó deterioro de la máscara entre 2 y 10 ciclos, 4 (40,0%) utilizó vapor de peróxido de hidrógeno y la pérdida del sello varió de 5 a 20 ciclos, 4 (33,3%) evaluó la integridad estructural a través de la inspección visual y 6 (54,4%), la eficiencia de filtración de la máscara N95.

Conclusión: Las estrategias de reutilización para abordar la escasez de dispositivos frente a la pandemia desafían el concepto actual de buenas prácticas en el procesamiento de productos de salud.

Palabras clave: Máscaras. Dispositivos de protección respiratoria. Descontaminación. Coronavirus. Infecciones por coronavirus. Pandemias.

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■ INTRODUCTION

The respirator-type face masks, certified by the National Institute for Occupational Safety and Health (NIOSH), are one of the main personal protective equipment (PPE) recommended for use by health professionals in view of the risk of exposure to particles up to 0,3 microns in diameter transported by air and infectious aerosols, as well as their resistance against fluids⁽¹⁻²⁾. Although there are several types of respirator face masks available, the N95 or PFF2 (filtering facepiece), as denominated in Brazil⁽³⁾, receive a certificate of approval (CA) issued by the Ministry of Labor and Employment (MTE), after the performance of resistance and performance tests that follow the Respiratory Protection Equipment Standard of the Brazilian Association of Technical Standards (ABNT)⁽³⁾.

Recommendations from NIOSH and the World Health Organization (WHO) point to the disposal of N95 masks immediately after use⁽¹⁻²⁾. However, circumstances resulting from an emerging infectious disease, such as the new coronavirus pandemic, which requires exponential use due to the high demand for care of infected patients, tend to lead to a shortage of these respirators due to the available supply. This situation has been reported by several countries, characterizing a shortage of this device in health services⁽¹⁻²⁾. This fact was demonstrated during the H1N1 pandemic, in 2009, in a study by the Institute of Medicine, which suggested the need to purchase 90 million N95 masks for 42 days of patient care. However, the real rate of use was 51% higher than the historical baseline, resulting, at the time, in a lack of such equipment⁽⁴⁾.

The Food Drug and Administration (FDA)⁽⁵⁾ and Centers for Disease Control and Prevention (CDC)⁽⁶⁾ proposed the reuse of N95 masks strictly during the pandemic, a suggestion accepted by NIOSH⁽²⁾ in the context of the COVID-19 pandemic as an emergency strategy, considering the risk of shortages.

Despite its function of filtering airborne particles (mold, *Bacillus anthracis*, *Mycobacterium tuberculosis*, influenza virus, lipid and non-lipid viruses, coronavirus 2 severe acute respiratory syndrome virus (SARS-Cov-2), *Bacillus subtilis*, aerolized bacteria), these respirators do not eliminate the risk of contracting infection or disease due to the possibility of self-inoculation of particles that may remain in the outer layers of the equipment or its internal contamination, favored by repeated use and/or inappropriate removal of masks N95⁽⁴⁾.

The reuse of N95 masks, however, is controversial and complex regarding the safety of their processing for new use among healthcare professionals. Nonetheless, with this

possibility of allowing decontamination of these respirators on an emergency basis, some medical equipment companies are proposing to decontaminate the masks using their own protocols. It is necessary to establish whether this decontamination process will be able to guarantee the maintenance of the sealing, integrity and filtration characteristics of the N95 masks, satisfying the requirements for resistance to breathing and air penetration through the filter for a new use^(3,7). And, even if all this is achieved, how to determine the number of safe reuses to avoid contamination of health professionals?

This concern is justified by the increasing number of health professionals infected with the new coronavirus and death records due to this contamination⁽⁸⁻¹⁰⁾. And, for the N95 masks decontamination process, questions about the safety of reuse, respecting the different realities in Brazil, only reinforce the contradiction of a recommendation that does not provide for the cleaning of such masks prior to their decontamination and that puts into question everything current scientific knowledge, on the premise that it cannot be disinfected or sterilized without prior cleaning.

In view of this reality, questions, contradictions and uncertainties have been associated with the recommendation to reuse the N95 mask during the Covid-19 pandemic period in relation to the safety of its reuse by the health professional. Therefore, this study seeks to answer the following research question: *is it possible to decontaminate/reuse N95 masks, ensuring they maintain their safety, integrity, filtration and sealing efficiency for healthcare professionals?* To answer this question, the objective was to evaluate, in the literature, the available protocols on N95 mask decontamination/reuse in times of Covid-19 pandemic.

■ METHOD

Integrative review study with bibliographic survey, carried out between March and April 2020, using the PICO strategy, which represents an acronym for Patient, Intervention, Comparison or control and "Outcomes"⁽¹¹⁾. In the present review, "P" was established for health professionals, "I" for decontamination/reuse of N95 masks, "C" did not apply to the study and "O" for maintaining safety, integrity, filtration efficiency and sealing of N95 masks. Thus, the following guiding question was structured: *is it possible to decontaminate/reuse N95 masks ensuring the maintenance of their safety, integrity, filtration and sealing efficiency for healthcare professionals?* The following, databases were consulted: MEDLINE/PubMed (OVID interface, Epub Ahead of print), Science Direct, Cochrane, SAGE journals, Web of Science, Scopus, Embase and Wiley. They also included preprint servers, such as medRxiv and SciELO

preprint, due to the limitation of studies that answered the research question. The following descriptors, from Medical Subject Headings (MeSH), were used for the search strategy: Masks AND Respiratory protective devices; Mask OR N95 AND Covid-19; N95 AND Respirators; Decontamination AND N95 AND Coronavirus; Facemask OR Pandemic. Despite searches for equivalent descriptors in Portuguese in Health Sciences Descriptors (DeCS), such as: "Masks", "Respiratory protection devices", "Decontamination", "Coronavirus", "Coronavirus infections", and "Pandemics", no studies were found on the subject, and only international articles in the English language were included in this review.

The search period in the databases covered publications referring to the years 2010 to 2020, due to previous exploration on the theme and the finding that it was little investigated before the Covid-19 pandemic. Experimental studies published since 2010 have been identified, since, with the H1N1 pandemic, in 2009, similar questions were raised regarding the scarcity of N95 masks, the results of which have supported the suggestion of their reuse by American agencies at this time.

The inclusion criteria were complete original articles in English that addressed the decontamination and reuse of N95 masks and their validation based on tests carried out for integrity, functionality, filtration and sealing. Integrity concerns the structural and morphological characteristics of the masks, such as holes, fissures, breaks, melting of the material, increased roughness, hardness and porosity. Functionality refers to the functions of the device that are assessed through filtration, breathing resistance, particle penetration and adjustment or sealing tests. Filtration refers to the mask filter's ability to retain biological particles of any nature with absolute filter efficiency of 99.9992% for 0.3-micron particles⁽²⁻³⁾. Sealing refers to the ability to adjust the mask to the face of the professional, without them inhaling or exhaling particles and aerosols measured by means of a quantitative adjustment factor. Technical reports from the FDA and Stanford University, California, United States, were also included. Reports from Stanford University are justified, due to recent research carried out in health laboratories, associated with the validation of the N95 mask⁽¹²⁾. Systematic review articles, meta-analyzes and letters to the editor were excluded, due to the need to include articles with a methodological focus on the experimental validation tests for N95 masks in view

of the scarcity of scientific evidence proving the reuse of these devices.

Thus, the integrative review was built from the definition of the research question, establishment of inclusion and exclusion criteria with the search in the literature, definition of the information extracted from the studies, evaluation of the included studies, interpretation of the results and synthesis of the data⁽¹³⁾.

The following flowchart presents the selected articles and the sequence adopted until the inclusion of those considered relevant for analysis, according to the criteria proposed for the study (Figure 1).

Initially, the selection of articles was carried out in pairs by the researchers, with a critical evaluation of the articles, analyzing, in detail, the validation tests and criteria for recommending the decontamination and reuse of N95 masks. The studies were selected from abstracts and later read in full. The experimental tests for the functionality and integrity of the N95 mask and the number of associated decontamination cycles were compared between the studies at each reading.

After the first selection to meet the inclusion criteria, the analysis of the articles selected in full took place from an instrument of data collection and synthesis, aiming to extract, organize and summarize the information for the presentation of the results from the following aspects: year of publication, authors, intervention (sample, decontamination method, process validation), main results and recommendations/ conclusions.

■ RESULTS

In the survey conducted, 23 articles were eligible in the first stage, 13 of which were excluded because they did not meet the inclusion criteria. At the end of the analysis, 12 original articles were included, which carried out experimental studies illustrated in Charts 1 and 2. Regarding the database, we found four articles from MEDLINE/PubMed (years: 2015; 2017; 2018; 2020), one from SAGE journals (year: 2010), three from medRxiv (all from the year 2020), one from the Web of Science (year: 2020), one from Embase (year: 2020), a technical report from an FDA experimental study (year: 2016) and a technical report from the Anesthesia Informatics and Media Lab at Stanford University (year: 2020).

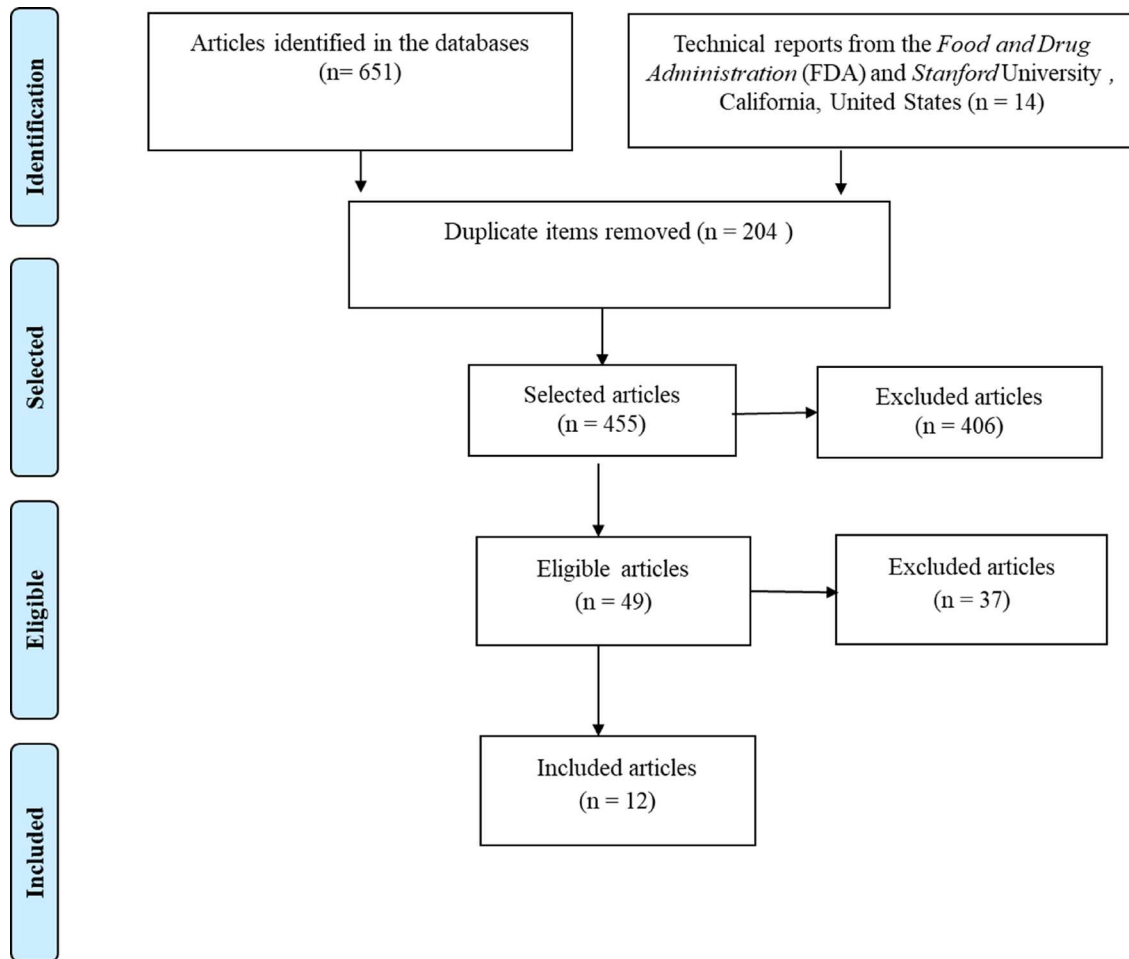


Figure 1 – Flowchart of the articles selected in the study
 Source: Adapted from Prisma⁽¹⁴⁾.

Author/ year	Study design	Decontamination methods	Results
Lindsley et al. ⁽¹⁵⁾ 2015	Experimental study: - Particle penetration test. Flow resistance test. -Respirator tissue layer traction test. -Elastic strap stretch test.	Ultraviolet germicidal irradiation. Number of cycles tested: five cycles.	-90% of the material degraded after the second cycle in doses of 120-470 joules per square centimeter. -Braking force decreased and varied between models: up to 90%. -Resistance to flow increased. -Small increase (up to 1.25%) in particle penetration.

Chart 1 – Studies analyzed on the decontamination of N95 masks in the period 2010-2020

Author/ year	Study design	Decontamination methods	Results
Battelle ⁽¹⁶⁾ 2016	Experimental study: -Aerosol filtration performance tests. -Inhalation resistance test. -N95 mask sealing test. -Visual and tactile Integrity test.	Hydrogen peroxide vapor. Number of cycles tested: fifty cycles.	-Visual inspection. Fragmentation of the elastic strips after thirty cycles. -Sealing test - endured twenty cycles. -Efficiency of aerosol filtration and inhalation resistance endured fifty cycles.
Lin et al. ⁽¹⁷⁾ 2017	Experimental study: - Particle penetration test. - Filtration test.	Dry heat, moist heat autoclave, low temperature decontamination using ethanol, isopropanol and bleach. Number of cycles tested: six cycles.	-Particle penetration greater than 27.9 nanometers increased by 5% and, for particles from 14.1 to 594 nanometers, increased by 8.6% after six cycles. -Liquid chemical methods destroyed the N95 mask filter after six cycles; -The N95 mask filter has melted in dry heat with temperatures higher than 100 °C.
Mills et al. ⁽¹⁸⁾ 2018	Experimental study: -Test evaluated the decreased logarithmic concentration of the virus (10^5 viruses by filtering the face mask).	Germicidal ultraviolet irradiation. Number of cycles tested: one cycle.	-Reduction of viral load in 12 models of masks after dose of one joule per square centimeter. -Three models did not present significant decrease in the viral load tested.
Kenney et al. ⁽¹⁹⁾ 2020	Experimental Study: -Contamination of N95 masks by aerolized virus. -Visual and tactile Integrity test.	Hydrogen peroxide vapor. Number of cycles tested: five cycles.	-Visual inspection did not reveal any visible deformities. -Reduction of infectious virus load below the detection limit (reduced about 10% of the infectious dose applied in tissue culture).
Price and Chu ⁽¹²⁾ 2020	Experimental study: Contamination of N95 masks with <i>Escherichia coli</i> .	Dry heat. Number of cycles tested: twenty cycles.	-Maintenance of filtration performance in up to twenty cycles. -The method was efficient in decreasing 99% of <i>Escherichia Coli</i> .
Oral et al. ⁽²⁰⁾ 2020	Experimental study: -Filtration test. -Sealing test. -Contamination of N95 masks by SARS-Cov-2 (<i>National Emerging Infectious Diseases Laboratories/Level 4</i>).	Hydrogen peroxide vapor. Number of cycles tested: one cycle.	-Filtration and sealing not compromised. -Reduction of the infectious virus load to below the detection limit.

Chart 1 – Cont.

Author/ year	Study design	Decontamination methods	Results
Liao et al. ⁽²¹⁾ 2020	Experimental study: - Filtration test.	Germicidal ultraviolet irradiation. Number of cycles tested: ten cycles. Ethanol and 2% chlorine-based solution. Number of cycles tested: one cycle. Dry heat. Number of cycles tested: twenty cycles.	-Ultraviolet irradiation by germicide: filtration efficiency has not been compromised. Signs of deterioration after ten cycles. -Ethanol and 2% chlorine-based solution: filtration degradation and impairment. -Dry heat: efficiency greater than 95% in filtration.
Kumar et al. ⁽²²⁾ 2020	Experimental study: -External contamination of the mask with the vesicular stomatitis virus or with Sars-CoV-2 (<i>National Microbiology Laboratory, Public Health Agency of Canada, Winnipeg, Canada</i>). -Sealing test.	Hydrogen peroxide vapor. Number of cycles tested: ten cycles. Steam autoclave. Number of cycles tested: ten cycles. Ethylene oxide. Number of cycles tested: three cycles.	-Hydrogen peroxide vapor: loss of the functionality of the N95 mask in five cycles. There was no recovery of viral load after ten cycles. -Steam autoclave: loss of N95 mask adjustment in the first cycle. -Ethylene oxide: maintenance of the N95 mask adjustment in the three cycles. There was no recovery of viral load after ten cycles.
Pascoe et al. ⁽²³⁾ 2020	Experimental study: -Contamination of N95 masks with <i>Staphylococcus aureus</i> . -Filtration test. -Visual and tactile integrity.	Dry heat and steam generated by a microwave oven. Number of cycles tested: three cycles.	-Dry heat and steam generated by a microwave oven: the methods were efficient in decreasing 99% of <i>Staphylococcus aureus</i> ; -Dry heat and steam generated by microwave oven: loss of 50% in filtration efficiency. -Vapor generated by a microwave oven: loss of the integrity of the N95 mask after a cycle (deterioration of the metal clip and presence of holes), The elastic straps were not compromised.
Xiang et al. ⁽²⁴⁾ 2020	Experimental study: -Contamination of N95 masks with six strains of pathogenic bacteria, one of fungus and one of the H1N1 virus. -Filtration test. -Sealing test.	Dry heat. Number of cycles tested: one cycle.	-Elimination of strains and inactivation of the H1N1 virus. -Efficiency greater than 95% in filtration. -Maintenance of the N95 mask adjustment.

Chart 1 – Cont.
Source: Research data, 2020.

According to Chart 1, it was found that, regarding the validation of decontamination for reuse, 8 (72.7%)^(12,15-17,20-24) of the studies were based on the N95 mask functionality tests. Functionality tests included sealing, filtration, particle penetration and resistance to flow, and inhalation tests. None of these studies, however, evaluated the microstructure of N95 masks. Three (27.3%)^(16,19,23) evaluated the structural integrity through visual and tactile inspection, 1 (11.1%)⁽¹⁵⁾, the integrity/degradation of the material through the tensile test, 6 (54.4%)^(12,16-17,21,23-24), the filtration efficiency and performance of the N95 mask and 4 (36.4%)^(16,20,22,24), the adjustment and the N95 mask seal. The main changes resulting from eight methods of decontamination of N95

masks, analyzed by Bergman et al., 2010⁽²⁵⁾, are presented in Chart 2, with emphasis on relevant aspects to be considered in the evaluation of such equipment regarding its reuse. This study⁽²⁵⁾, published in 2010, was the first to perform different validation tests with N95 masks after three decontamination cycles, and the only one that compared the experimental conditions and specified parameters for each autoclave used for each type of intervention. The study associated the parameters of each decontamination method with specific changes in functionality and integrity⁽²⁵⁾. The study design was based on the N95 mask filtration test and the particle penetration test⁽²⁶⁾. Integrity was assessed through visual inspection⁽²⁵⁾.

Decontamination method	Results after three tested cycles
Hydrogen peroxide gas plasma (STERRAD®100S); Specifications. 59% hydrogen peroxide, short cycle for 55 minutes, temperature between 45 °C and 55 °C.	-Increased particle penetration level in more than 5%. -Little or no effect on filtration efficiency. -No changes in the physical integrity of the N95 mask were observed.
Hydrogen peroxide vapor (RBDS™, BIOQUELL UK Ltd, Andover, UK). Specifications 30% hydrogen peroxide. 15 minutes of stay and 125 minutes for the total cycle. Aeration for 24 hours.	-Little or no effect on filtration efficiency. -No changes in the physical integrity of the N95 mask were observed.
Germicidal ultraviolet irradiation (UV Bench Lamp (UV-C, 254 nanometers,40 W), Model XX-40S (UVP, LLC, Upland, CA). Specifications 45 minutes of exposure to an intensity of 1.8 microwatt per square centimeter. Only the outside of the mask was exposed.	-Little or no effect on filtration efficiency. -Increased particle penetration for particles smaller than 2.12%; -No changes in the physical integrity of the N95 mask were observed.
Ethylene oxide. Amsco® Eagle® 3017, 100% ethylene oxide, Sterilizer/Aerator (STERIS Corporation, Mentor, OH); Specifications: one hour of exposure (736 milligrams per liter), followed by 12 hours of aeration.	-Increased particle penetration for particles smaller than 2.12%; -No changes were observed in the physical integrity of the N95 mask. -Little or no effect on filtration efficiency.
Liquid hydrogen peroxide. Specifications 30% hydrogen peroxide. 30 minutes of immersion in 6% hydrogen peroxide solution.	-Oxidation of the clamps in varying degrees.

Chart 2 – Main changes resulting from the various decontamination methods of the N95 masks. Results adapted from the study by Bergman et al. ⁽²⁵⁾

Decontamination method	Results after three tested cycles
Wet heating. (80% relative humidity in a Caron 6010 [®] <i>laboratory incubator model</i> (Marietta, OH)). Specifications: 30 minutes incubation at 60 ^o C.	-Separation of the N95 mask foam. -Melting of elastic straps.
Bleach. Specifications. 30 minutes of submersion in 0.6% sodium hypochlorite solution.	-Slightly stained nasal foam. -Clamps with oxidation of several levels. -Inner nasal cushion discolored or dissolved.
Steam generated by microwaves; (2,450-Megahertz, model R-305KS (<i>Sharp Electronics Corporation</i> , Mahwah, NJ). Specifications: exposure time of two minutes, at 10 Watts, with 1100 Watts being the maximum power of the equipment.	-Separation of the nasal foam. -Melting of elastic straps.

Chart 2 – Cont.
 Source: Research data, 2020.

DISCUSSION

The results of the present study showed that the decontamination methods and parameters used contributed to the indication of different numbers of decontamination cycles^(15–24). However, a maximum number of safe reuses has not been determined, only a number of cycles in which functional losses of the N95 mask and degradation are made visible to the naked eye during the different cycles^(15–22).

It is necessary to rethink the high viral transmissibility in the context of Covid-19, considering how insecure this standardization can be. And, as highlighted in the National Nurses United opinion⁽⁸⁾, for new US federal guidelines, which encourage hospitals and other healthcare systems to allow for multiple reuses and/or decontamination of N95 masks, there is no validated scientific evidence that the reuse process will protect a healthcare professional from being infected, in addition to that they violate respiratory protection rules⁽⁶⁾.

Decontamination can impact the functionality and integrity of the materials of N95 masks in order to reduce their ability to protect the healthcare professional due to the loss of their adjustment function, or by the increased penetration of particles, thus interfering in their main efficiency function, which reduces the protection to the professional.

The N95 mask, when subjected to physical and chemical processes, can degrade and oxidize, showing visible signs of breakage, deformations and cracks, which can only be

evaluated microscopically. Thus, the visual inspection of this equipment alone does not allow it to be safely reused, especially regarding the maintenance of structural integrity, filtration capacity and effective maintenance of the N95 mask seal.

In the present review, none of the experimental studies tested the microstructural integrity of the devices, which would include a detailed analysis of the layers of fabrics and materials that make up the N95 masks. This analysis can be performed using equipment that allows a microscopic visualization of possible morphological deteriorations not visible to the naked eye, such as, for example, Scanning Electron Microscopy, which allows the degree of corrosion, porosity and wear of the material to be assessed^(2,3,7).

Four (33.3%) studies only performed visual inspections to assess the integrity of N95 masks^(16,19,23,25), which may have compromised the evaluation of possible micro-punctures and micro-cracks in the fabric, contributing to the adhesion of biofilms and consequent self-contamination of professionals in the reuse of devices.

Studies that evaluated the integrity in a visual and tactile way can determine a number of cycles, however, they cannot guarantee the safety of reuse or, above all, determine a number of maximum reuses for N95 masks^(16,19,23,25).

The reuse of N95 masks goes far beyond its compatibility with tested decontamination methods. Physical, chemical and oxidative degradation processes can manifest slowly,

while, during visual and tactile inspection, changes such as deformation of parts of the device, breaks and the presence of holes already indicate the final process of material deterioration^(10-13,23).

Some of the decontamination methods tested, such as steam generated by microwaves, moist heating and bleaching, caused immediate changes and damage, such as melting of the respirator, degradation and significant loss of the components and layers of the N95 mask, which made it impossible to indicate different numbers of reuses^(15-23,25). Processes such as ethylene oxide, starting from three cycles, also visibly showed the degradation of this equipment, such as the loss of its sealing property⁽²²⁾.

The dry heat method, however, was considered safe after a decontamination cycle of the N95 mask, for maintaining its filtration characteristics against the tested bacteria and virus strains, in addition to its functionality and integrity⁽²⁴⁾. Furthermore, some authors found that dry heat decontamination did not impair the functionality of N95 masks tested in up to 20 cycles^(12,21).

On the other hand, different types of manufacturers and experimental tests may make it impossible to adequately indicate possible numbers of reuse. Filtration efficiency, for example, after using dry heat, can decrease up to 50% of its capacity depending on the device manufacturer⁽²³⁾. And, even if the maintenance of the macroscopic integrity of the N95 mask is proven, it is unknown whether there is a microscopic deterioration that could influence the functionality of the device⁽²³⁾.

The importance of the integrity analysis and the filtration functionality are unquestionable, as the study by Hwang et al., 2020⁽²⁶⁾, which simulated the use of the N95 mask in procedures that generated aerosols or that required great body movement by professionals, such as chest compression⁽²⁶⁾. The study showed that, after validation tests, the N95 mask adjustment factor and the results of the permeability test and filtration performance decreased after each procedure⁽²⁶⁻²⁷⁾.

In other words, it is necessary to consider that N95 masks are used in different situations that have peculiarities, such as the time of use, the shape, the movement of the professional and the adequacy of their handling throughout daily practice at the institution. Therefore, the discussion of these studies was justified in the present review⁽²⁶⁻²⁷⁾, as it was clearly found that it is necessary to consider that there is a natural wear on this equipment that must be analyzed, often not depending only on a physical or chemical process that deteriorates its functionality and integrity properties⁽²⁶⁻²⁸⁾.

Another study used a cough simulator programmed to cough aerosol particles containing the H1N1 influenza virus, and a breathing simulator used to collect viruses in

N95 masks⁽²⁹⁾. It was found that 68% of the virus strains remained active and infectious after 24 hours, which prevented the reuse of these device⁽²⁹⁾. The study, despite not being included herein, since it was not about the validation of decontamination methods, brought an important discussion to be considered regarding the risk of reusing N95 masks in procedures that generated aerosols.

However, to meet the needs of the health emergency, the FDA proposed the guideline that indicates the reuse of N95 masks on March 25, 2020, given that mechanical integrity tests are carried out, validation of viral load reduction, especially coronavirus, micro bacteria and spores, as well as the filtration performance of the respirator⁽⁵⁾. The agency also suggests that decontamination by hydrogen peroxide vapor has low toxicity and an easy catalytic reduction of oxygen and water and, therefore, if adequate parameters of concentration, time and humidity were determined for the reuse of the mask, it could be feasible, provided it is validated⁽⁵⁾.

Given this reality and the uncertainties generated in health institutions about the process of reusing the N95 mask during the Covid-19 pandemic period, the FDA, through a study carried out by the *Battelle Memorial Institute*, recommended hydrogen peroxide vapor as a viable method of decontamination of N95 masks⁽¹⁶⁾. The limitations of the *Battelle* study, however, are that it tested only one manufacturer's model and, despite having tested parameters of decontamination cycles, did not use specific laboratory tests to verify the efficiency of different types of filtration performance microorganisms, including the coronavirus, or the integrity of the filter^(3,7). Although Chart 1 presents some studies^(16,19,20,22) that used hydrogen peroxide vapor as a probable method for decontamination of a certain number of cycles, many limitations of these studies can be verified, such as, for example, absence of microstructural integrity tests, divergence in the recommended decontamination parameters in the autoclave, laboratory analysis methods and different manufacturers of the tested N95 masks, to serve as a gold standard recommendation for reuse.

It should also be considered that both the CDC, the FDA and, in Brazil, the National Health Surveillance Agency recommend that, if the N95 mask is contaminated with blood or respiratory secretions or after use in procedures that generate aerosols, it cannot be reused, and should be discarded^(5-6,30).

The fact that there is no visible dirt or moisture due to aerosols does not mean that, before decontaminating the mask, it does not have to go through a cleaning process, followed by disinfection and then sterilization in essential steps for reprocessing. The term decontamination adopted in this review is due to the process called by the CDC as a

strategy to enable the reuse of N95 masks with the intention of using disinfection or sterilization methods that allow the device to be reused⁽⁶⁾.

In this study, none of the methods used cleaning prior to the tested decontamination processes. It is assumed, therefore, that although some methods have been tested and found to be viable for the reuse of N95 masks, two relevant limitations of the studies analyzed need to be considered: the failure to carry out validation tests to maintain reuse safety properties, such as filtration, integrity and sealing tests together, as minimum parameters and, in addition, the absence of prior cleaning or any reference to it in any of the protocols, which defies the current concept for good health product processing practices. These highlights should be rethought in order to recommend reuse, even in situations of crisis and shortages, considering the different realities of the country and the reflection of WHO itself in its concern with the standardization of reuse, since the N95 masks do not they can be cleaned without losing their integrity and functionality⁽³¹⁾. According to the WHO, the decontamination of N95 masks alone, without validation of the methods by tests of functionality, filtration capacity, sealing and integrity, does not make them safe for reuse⁽³¹⁾.

ANVISA, unlike the FDA and CDC, only recommends extending the time of use of N95 masks exceptionally for a period of up to 12 hours, provided they are kept dry, clean and intact^(5,6,30). On the other hand, it does not specify decontamination methods for the reuse of the N95 mask, possibly due to the validation difficulties, considering the reality of health services of not having equipment that allows the safe performance of these tests in a pandemic period, whose demand for mask use is high, and the fact that access for validation of all processes that guarantee the quality of the device for reuse may not be common to the different realities, in addition to the aspect of the risk of high transmissibility of the virus.

Thus, in this context of the pandemic, public policies and managers of health institutions should invest in the minimum necessary to guarantee the quality of protection for health professionals, since, to date, there is no validation of the reuse of N95 masks, which can favor the autoinoculation of the virus and its active conservation for possible cross-contamination^(18-22,32).

■ CONCLUSION

It is concluded that the safe decontamination of N95 masks is not possible, since, to date, the maintenance of safe characteristics, such as functionality, filtration capacity, integrity and sealing, together, for their reuse, have not been demonstrated. A limitation of the studies included in this review was that none of them performed experimental tests on humans, probably due to the risk of contamination and exposure to adverse events for health professionals. Trials were limited to laboratories, with equipment that generated aerosols in N95 masks with realistic simulation mannequins.

This study, however, may contribute to the nursing area, especially for professionals who work in the front line of care for patients with Covid-19, due to the high risk of contamination, since multiple reuse and decontamination of such devices is not safe and will not protect a healthcare professional from being infected.

Indications of respirator decontamination, even though they may be strategies to compensate the scarcity of devices generated by the pandemic, can lead to a negative impact for the health institution due to the lack of safety guarantees for professionals, risk of adverse events and the creation of indicators that do not guarantee the quality of care provided.

Exposing devices, whether to physical or chemical processes, means initiating degradation processes not visible to the naked eye that can cause nursing professionals to take serious risks with the reuse of respirators, such as contamination with SARS-Cov-2, due to self-inoculation or the lack of original protection by the N95 mask resulting from improper adjustment, deformations and compromising the integrality and functionality of the device.

The reduced number of publications to date has limited this study to a possible indication of the maximum number of reprocessing cycles for N95 masks. This investigation may also contribute to the realization of randomized and experimental clinical studies that could demonstrate evidence to indicate the number of possible reuses/reprocessing for N95 masks and the effect of not cleaning this equipment, in addition to considering the characteristics of the products of different manufacturers and diversities of procedures that, in clinical practice, generate greater challenge and quantity of aerosols.

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