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# An educational module comparing decontamination strategies for the safe utilization of post-decontaminated N95 filtering facepiece respirators by anesthesia providers.

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An educational module comparing decontamination strategies for the safe utilization of postdecontaminated N95 filtering facepiece respirators by anesthesia providers.

A DNP Project Presented to the Faculty of the Nicole Wertheim College of Nursing and Health Sciences

Florida International University

In partial fulfillment of the requirements for the Degree of Doctor of Nursing Practice

By

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# TABLE OF CONTENTS

ABSTRACT	4
INTRODUCTION	<i>6</i>
Problem Statement	
Problem Identification	
Background	8
Scope of the Problem	8
Consequences of the Problem	9
Knowledge Gaps	9
Systematic Review Rationale	9
The Objective of the Systematic Review	10
LITERATURE SEARCH METHODOLOGY	10
Search Strategy	10
Table 1. Search Methodology	12
Study Selection and Screening Method	13
Identification	14
Eligibility	12
Included	14
Screening	14
Collection, Analysis, and Data Items	15
RESULTS OF LITERATURE REVIEW	15
Study Selection	15
Study Characteristics	16
MATRIX TABLES	17
DISCUSSION	30
Effects of Decontamination on the Functional Integrity of N95 FFRs	30
Effects of Decontamination on the Structural Integrity of N95 FFRs	32
Efficacy of Decontamination Method for Pathogen Inactivation	33
Summary of Evidence	32
Limitations of the Systematic Review	36
Recommendations for Future Research	36
INTERVENTION METHODOLOGY	36
Setting	36
Recruitment	37
Participants	37

Intervention	37
Procedure	37
Description of Approach	38
Protection of Human Subjects	38
Data Collection and Analysis	38
Data Management and Measurement	38
Pre/Post-Test Demographics	40
Pre-Test Knowledge of Decontamination Procedures for N95 Respirators	40
Differences in Pre-and Post-Test Comprehension	41
Summary	42
Limitations	42
Future Implications for Advanced Nursing Practice	43
CONCLUSION	43
REFERENCES	44
Appendix A	49
Appendix B	50
Appendix C	51
Appendix D	54
Appendix F	66
Appendix G	67
Appendix H	68

#### **ABSTRACT**

#### **Title**

An Evidence-Based Comparison of Decontamination Strategies for the Safe Utilization of Post-Decontaminated N95 Filtering Facepiece Respirators by Anesthesia Providers

### Background/Purpose/Question

Because the current pandemic threatens a limited supply of N95 filtering facepiece respirators (FFRs), many anesthesia providers have resorted to the decontamination and reuse of single-use FFR. There is little evidence of the relative safety and efficacy of the different decontamination methods. The lack of concrete evidence and guidance regarding the reuse of FFR is a cause for concern for anesthesia providers, who are at constant risk of exposure to airborne diseases. This evidence-based review seeks to answer the proposed question, "In anesthesia providers, does the reuse of post-decontaminated N95-type FFRs increase the risk of airborne diseases compared to anesthesia providers who use one-time disposable use N95-type FFRs?"

#### Methods/Evidence Search

An electronic search was conducted in the Cumulative Nursing and Allied Health Literature (CINAHL), Embase, and MEDLINE/PubMed. The search parameters included articles written in English and published in 2014–2021. The following search terms were used: "anesthesia providers," "reuse," "post decontaminates," "N95 FFR," and "risk of airborne disease." The search initially resulted in 140 articles. Duplicate articles and titles with abstracts deemed irrelevant were then eliminated from the review. The inclusion criteria for research articles were based on the article's applicability to the comfort level of N95 FFR wearers after decontamination, the concerns of N95 FFR wearers after decontamination, and determining which decontamination methods would be most practical and safe considering the available resources. An educational module containing both a pre and post assessment was created based on findings from literature review.

### Synthesis of Literature/Results/Discussion

Thirteen sources met the inclusion criteria for the evidence-based review. The literature revealed that solution-based decontamination methods such as hydrogen peroxide and bleach should be avoided because they degrade the masks' integrity and efficiency. Heat minimally alters the integrity of the mask; however, after 20–50 cycles, there was evidence of decreased efficiency and mask degradation. Other factors, such as multiple donning, also affected the integrity of the FFR. Statistical analysis showed that the fit gradually decreased after donning the FFR 5 times. The most effective methods noted within this evidence-based review were ultraviolet germicidal irradiation (UVGI), moist heat, dry heat, and hydrogen peroxide vapor (VHP). Data analysis of the pre and post assessment from the educational module indicate an increase in provider knowledge on reuse of decontaminated N95-type FFRs. Because the pandemic continues due to the spread of different strains, mask integrity should continue to be researched to assist anesthesia providers and their employers in making informed decisions regarding personal protective equipment for anesthesia providers.

#### **Conclusion/Recommendations for Practice**

Anesthesia providers are at increased risk of acquiring airborne pathogens. If the reuse of post-decontaminated N95 FFRs remains a practice used to conserve mask supply during a pandemic, then appropriate information regarding the potential risks of reuse and decontamination should be available. Studies seem to indicate that the reuse of N95 FFRs can conserve the supply of N95 FFR in times of short supply. However, this conservation method must be studied further to determine the risk to anesthesia providers. Much remains unknown, which can pose an increased risk to providers who have no choice but to adopt these practices. It is also essential to consider the feasibility of the selected decontamination method and its cost-effectiveness. Organizations should consider the N95 FFR models they provide when instructing providers to conserve supplies by decontaminating and reusing FFRs.

### **Conflict of Interest**

The authors have declared they have no financial relationships with any of the commercial interests related to the content of this review. There is no conflict of interest.

### INTRODUCTION

Personal protective equipment (PPE) is an invaluable tool in the delivery of safe, high-quality healthcare. Healthcare providers must protect themselves from infection with contagious diseases and avoid becoming a mode of transmission to their patients. The current pandemic has resulted in critical shortages of available PPE, leading to healthcare organizations and regulatory bodies exploring unconventional approaches to conserve the remaining supply. One such process involves the decontamination and reuse of N95-type filtering facepiece respirators (FFRs). This issue is of utmost importance to anesthesia providers, who, by nature of their profession, are already at an increased risk of acquiring airborne diseases due to their level of exposure to aerosolized airway secretions.

Intubating, mask ventilating, suctioning, and extubating are all procedures that aerosolize secretions and are regular activities performed by anesthesia providers.<sup>3</sup> This places anesthesia providers at an increased risk of contracting airborne pathogens, necessitating optimal performance from their PPE, such as N95 FFRs. The Center for Disease Control and Prevention (CDC), National Institute of Occupational Safety and Health (NIOSH), Occupational Safety and Drug Administration (OSHA), and the Food and Drug Administration (FDA) all aid in developing regulations and recommendations for the use of respiratory protection in healthcare settings.<sup>4</sup> NIOSH is responsible for developing guidance on using N95 FFRs in the healthcare environment to protect workers and certifying these FFRs.<sup>5</sup>

NIOSH-certified N95 FFRs were designed to capture 95% of solid or water-based non-oil (N) particulates.<sup>6</sup> This filtering capacity is tested with uncharged sodium chloride (NaCl) aerosolized particles measuring up to 300 nm in diameter.<sup>6</sup> Viral particles can range in size from 20 to 300 nm, much smaller than NaCl particles.<sup>6</sup> The filtration efficiency of N95 FFRs is achieved by three filtration principles.<sup>7</sup> The first of these principles is inertial impact, or the inertia of large particles, greater than or equal to 1 micron, that prevents them from flowing

around the mask's fibers, filtering them from inspired air via impact.<sup>7</sup> The second principle is diffusion and applies to smaller particles, with a diameter of 0.1 microns or less.<sup>7</sup> These particles undergo Brownian movement and stick to the porous matrix of the filter.<sup>7</sup> The last principle is electrostatic attraction, which employs electrocharged polymer fibers that attract and trap large and small particles carrying the opposite charge.<sup>7</sup>

#### **Problem Statement**

Although the possibility of acquiring an airborne disease, particularly in the field of anesthesia, is not a new risk, the highly contagious nature of the novel coronavirus (COVID-19) has presented a new set of unforeseen challenges to anesthesia providers. One such challenge was the availability of personal protective equipment (PPE), namely N-95 FFRs.<sup>2</sup> With the initial unpredictable spread of the virus and no foreseeable resolution to the pandemic, healthcare facilities soon found themselves with FFRs in short supply and implemented strategies to combat the increased demand for this piece of PPE that was initially designed for one-time use, such as the reuse of decontaminated N-95 FFRs.<sup>2</sup> According to the Center for Disease Control and Prevention (CDC), there is no way to determine the maximum number of safe reuses for N95 FFRs.<sup>8</sup> This project seeks to determine if the anesthesia providers who currently reuse post-decontaminated N95 FFRs are at increased risk of acquiring airborne diseases compared with providers who use disposable N95 FFRs only once.

#### **Problem Identification**

In light of the current pandemic threatening a limited supply of N95 FFRs, many anesthesia providers have resorted to the decontamination and reuse of single-use FFRs. Various studies have questioned the functional and structural integrity of FFRs after unintended extended use and reuse after the use of different decontamination methods. Furthermore, there is limited evidence of the relative safety and efficacy of various decontamination methods. The lack of

concrete evidence and guidance regarding the reuse of FFRs is a cause for concern for anesthesia providers, who are at constant risk of exposure to airborne diseases.

### **Background**

Aerosol-generating procedures have been shown to increase the odds of respiratory infection.<sup>3</sup> Anesthetists constantly perform these aerosol-generating procedures when they intubate, bag-mask ventilate, suction, and extubate patients throughout their workdays. Intubation may be the highest risk procedure for the transmission of airborne diseases.<sup>3</sup> Adding to this risk is the possibility of false-negative results from the commonly used nasopharyngeal and oropharyngeal screening tests before surgery.<sup>10</sup> Even with the relatively high sensitivity of reverse transcriptase-polymerase chain reaction screening tools, the risk of false-negative results remains significant.<sup>10</sup>

With the increased risk to anesthesia providers, the current practices of reusing decontaminated FFRs must be evaluated to determine if additional danger is incurred. There are three major categories of N95 FFR decontamination designed to inactivate pathogens, like COVID-19, in ways that may affect the proper function of FFRs.<sup>4</sup> These decontamination methods include chemical, physical, and energetic decontamination.<sup>4</sup> Warm, moist heat and microwave-generated heat are physical methods that utilize heat to denature proteins.<sup>4,5</sup> Chemical decontamination, such as vaporized hydrogen peroxide (VHP), and energetic methods, such as ultraviolet germicidal irradiation (UVGI), both cause DNA/RNA disruption.<sup>4,5</sup> The results of these decontamination methods on the effectiveness of N95 FFR also vary among the many different N95 models.<sup>4</sup>

### **Scope of the Problem**

This issue's scope is considerable in that it affects anesthesia practitioners and indirectly affects patient safety by potentially limiting the number of available and healthy providers. With the mounting prevalence of COVID-19, the scope of this problem continues to increase. One simulation study meant to assess the adequacy of national stockpiles of PPE based on World

Health Organization (WHO) definitions and guidelines determined that supplies were insufficient for a similar future outbreak.<sup>11</sup> This may lead to the continued and even increased practice of reusing post-decontaminated N95 FFRs.

### **Consequences of the Problem**

Reduced respiratory protection resulting in the transmission of harmful airborne pathogens to healthcare providers is highly likely if this issue is not properly addressed. Patients may also be indirectly placed at risk with the reuse of FFRs, as inadequately decontaminated masks may act as fomites for the transmission of infectious agents. This would add further strain on a largely unprepared healthcare system and an economy forced to shut down in an attempt to reduce the spread of infection.

### **Knowledge Gaps**

National Institute of Occupational Safety and Health (NIOSH)-approved respirators, N95s, are fit-tested to ensure that 95% of airborne droplets are filtered out of inspired air. <sup>12</sup> The majority of the masks are intended for a single use; the CDC has acknowledged that there is no way to determine the maximum number of safe reuses. Regulatory body-supported research determining the filter efficacy and efficiency after routine decontamination is limited. UVGI, which is becoming popular, may not penetrate all layers of the FFR. Structural degradation may also accompany high doses of ultraviolet radiation. Heat and HPV decontamination seem promising but the number of safe cycles and reuses has yet to be determined with these and many other methods. The results of decontamination on filter efficiency have been shown to differ by model. In the existing studies, the filter performance, fit, and comfort of the user varied depending on the mask and decontamination method used.

### **Systematic Review Rationale**

This literature review seeks to determine whether reusing N95 FFRs after utilizing each decontamination method increases the risk of anesthesia providers contracting an airborne disease compared with providers who use N95 FFRs one time. Pathogen deactivation, functionality, and

structural integrity after decontamination will be assessed to determine the level of risk. Factors of functional integrity include the maintenance of filtration capacity and electrostatic charge.

Structural integrity is ensured by not compromising fit.

### The Objective of the Systematic Review

In a pandemic setting, healthcare organizations were forced to resort to PPE-sparing strategies to provide care amid a supply shortage. Many anesthesia providers, including students, continue to provide care with reused post-decontaminated N95 FFRs with no clear guidance on the limits of reusing these masks and the potential risk they undertook. This study will help to clarify these uncertainties by comparing the risk associated with reuse after decontamination with the one-time use of FFRs. Ultimately, this will educate and raise the awareness of anesthesia providers to possible threats and help implement organizational guidelines to promote provider safety.

### LITERATURE SEARCH METHODOLOGY

#### **Search Strategy**

The literature search methods were initially guided by the population, intervention, comparison, and outcome (PICO) question, "In anesthesia providers, does the reuse of post-decontaminated N95-type filtering facepiece respirators (FFRs) increase the risk of airborne diseases in comparison to anesthesia providers who use one-time disposable N95-type filtering facepiece respirators (FFRs)?" Keywords were identified from the question, including "anesthesia providers" and its synonyms, "reuse," "post-decontaminated N95-type FFR," "increased risk of airborne disease," and synonyms for the airborne disease. The Boolean operators "AND" and "OR" were used to connect keywords that were independent or related, respectively.

After the keywords were determined, appropriate databases were selected for the searches.

These databases included CINHAL, Embase, and MEDLINE/ PubMed. When applicable,
keywords were translated into subjects to broaden the search. The search was conducted after the

subjects were added to the search phrase and limits were applied. Primary research studies, randomized control trials (RCT), and systematic reviews were included. Studies and observations had to have been conducted within the last five years and were limited to the English language.

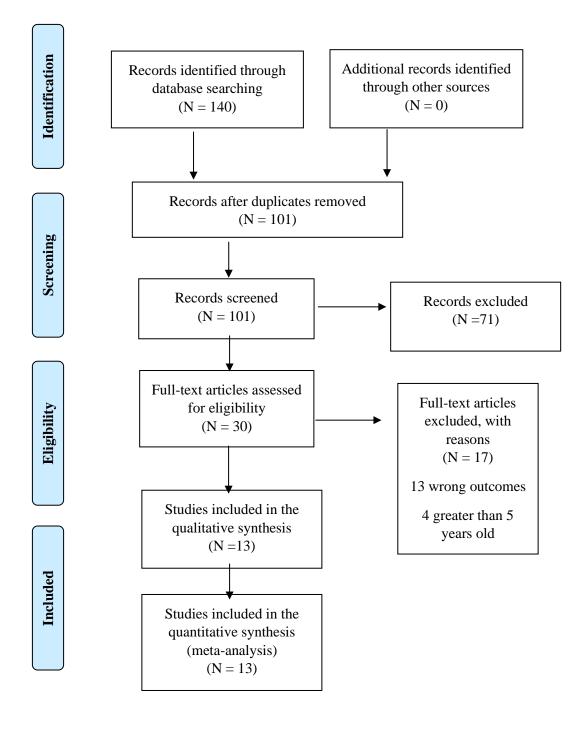
No geographical limits were applied. The search methodology is detailed in Table 1.

**Table 1. Search Methodology** 

Keywords	Truncation	Synonyms	Connecting keywords
Anesthesia providers	"Anesthesia providers"	"Anesthesia providers," "anesthetist," "nurse anesthetist," "anesthesiologist"	("Anesthesia providers" OR "anesthetist" OR "nurse anesthetist" OR "anesthesiologist") AND
Reuse	"Reuse"	Reuse, "extended use," "multiple uses"	(Reuse OR "extended use" OR "multiple uses") AND
Post-decontaminated	"Post decontaminate*"	"Post decontaminated," "disinfection"	("Post decontaminated" OR "disinfection") AND
N95 FFR	"N95 FFR"	"N95 FFR," "N95 mask"	("N95 FFR" OR "N95 mask") AND
Risk of airborne disease	"Risk of airborne disease*"	"Risk of airborne disease, *" "risk of airborne pathogen," "risk of airborne illness"	("Risk of airborne disease *" OR "risk of airborne pathogen" OR "risk of airborne illness")
Databases		Keywords translated into subjects	
CINAHL		(MH "Equipment Reuse/CT/ES/NU/PC/SD") AND "Equipment Reuse" AND "Anesthesia providers" AND (MH "Decontamination, Hazardous Materials/ES") AND "Decontamination, Hazardous Materials" AND (MH "Sterilization and Disinfection+/ES/PC") AND (MH "Respiratory Protective Devices/CT/NU/SD") AND "facial facepiece respirator" AND "risk of airborne disease"  "Reuse of post decontaminated n95" OR	
		(reuse AND of AND) decontaminated AND	
MEDLINE/PubMed		N95 Respirators/ or M Disinfectants/ or Deco decontaminate.mp. or Equipment Reuse/ or	ontamination/ or Disinfection/ AND

### **Study Selection and Screening Method**

All titles and abstracts were initially screened for relevance to the PICO question. Selected studies were imported into RefWorks in a folder titled "All studies." The find duplicate function in RefWorks was applied to the "All studies" folder. Precisely, the "exact match" function, which compares titles, authors, and publication dates, was used, leaving 101 studies from the original 140 after duplicates from the initial search were removed. Of the remaining 101 studies, 71 were excluded because they were not primary studies, RCTs, or systematic reviews. A full-text screening process was then conducted on the remaining 30 studies. The full-text screen resulted in 4 studies being excluded because they were published more than five years ago and 13 excluded because they measured outcomes irrelevant to this review. The relevant outcomes included the comfort level of FFR wearers after decontamination, concerns of FFR wearers after decontamination, and determining which decontamination methods would be most practical in terms of available resources. This resulted in a total of 13 studies that were included in this review.



### Collection, Analysis, and Data Items

The John Hopkins Research Evidence Appraisal Tool was used to assess each study's level of evidence and quality. According to this appraisal tool, the level of proof is primarily determined by study design. <sup>14</sup> The higher grades of evidence are assigned to research studies, with RCTs being the highest, level I, followed by quasi-experimental and non-experimental methods at levels II and III, respectively. <sup>14</sup> Systematic reviews were appraised similarly, with those studies reviewing only RCTs rated with the highest level of evidence, level I. Systematic reviews of a combination of RCTs and quasi-experimental designs are rated level II. <sup>14</sup> Reviews of non-experimental studies combined with level II-rated reviews are rated level III. <sup>14</sup>

The John Hopkins Research Evidence Appraisal Tool provided a set of questions to assess the quality of each study. A separate set of questions evaluates research studies and systematic reviews. Studies and reviews were considered "high" quality if they contained consistent, generalizable results, sufficient sample sizes, and definitive conclusions. <sup>13</sup> If results were reasonably consistent and conclusions were fairly final, studies were considered "good" quality. <sup>14</sup> "Low" quality studies or reviews were those with inconsistent results, insufficient sample size, and failing to draw conclusions. <sup>14</sup>

#### RESULTS OF LITERATURE REVIEW

### **Study Selection**

After data analysis and screening, 13 studies were found suitable to be included in this review. Of the 13, 6 were systematic reviews of primary research. The remaining 7 studies were all primary research, with the majority consisting of a pre-test-post-test control group experimental design and one using a repeated measure experimental design where fit tests were performed by the same subjects over different periods. Full-text analysis by the investigators resulted in the inclusion of studies that compared the outcomes of several decontamination methods on FFR performance and fit, excluding those that only investigated a single process. Studies that did not discuss the effects of decontamination methods in terms of microbial

inactivation, filter performance, and changes to fit were also excluded. No additional studies were identified from any other sources or after screening the references of the selected studies.

### **Study Characteristics**

Each systematic review only included primary research studies. All 6 systematic reviews selected compared multiple decontamination methods and their effects on N95 FFR. The studies assessed in these reviews examined an extensive range of decontamination methods, including ultraviolet germicidal irradiation (UVGI), microwave-generated steam (MGS), moist heat (MH) or moist heat incubation (MHI), autoclaving, dry heat, hydrogen peroxide vapor (VHP), hydrogen peroxide gas plasma (HPGP), liquid hydrogen peroxide (LHP), ethylene oxide (EtO), dimethyl dioxirane (DMDO), a hypochlorite solution wipe, a benzalkonium chloride wipe, bleach, alcohols, and soap and water. The studies examined in the systematic reviews also varied by the type of pathogen used to test the microbiocidal effectiveness of the different decontamination methods. Some studies used enveloped viruses similar to the pandemic coronavirus, while others used resistant strains of bacteria and bacterial spores. Various N95 FFR models were used in the different studies.

The remaining 7 studies were primary research, most of which involved a control group of FFRs. One study specifically examined the effects of multiple donning and doffing of N95 FFRs independent of any decontamination method, an essential factor to consider when assessing the safety of the reuse of N95 masks. The other primary research studies all measured the outcomes of decontamination methods with similar parameters and technology. The results measured included fit, usually measured by a fit factor, and filter performance, determined by filter penetration and changes in airflow resistance across the filter. Matrix tables 1–13 summarize the details of each study.

# MATRIX TABLES

# Table 1

Citation and	Liao L, Xiao W, Zhao M, et al. Can N95 respirators be reused after
Theme of the	disinfection? How many times? ACS NANO. 2020;14(5):6348-6356.
article	doi:10.1021/acsnano.0c03597.
Design/	Pre-test-post-test control group experimental design
Method	
Sample/	N = 12 These models included 3M 8210 (NIOSH N95), 4C Air, Inc. (GB2626
Setting	KN95), ESound (GB2626 KN95), and Onnuriplan (KFDA KF94).
Major	Independent variable: Disinfection methods, which included heat, steam,
Variables	alcohol, chlorine, and UVGI treatments.
Studied and	Dependent variable: Filter efficiency and drop pressure. Efficiency and
Their	pressure drop are determined by 100 – P, where P represents the penetration
Definitions	of particles through the filter. <sup>5</sup> Drop pressure indicates how much pressure is
	lost to the filter.
Measurement	All samples were tested using the Automated Filter Tester 8130A, using a
and data	flow rate of 85L/min and NaCl as the aerosol. Average measurements were
analysis	calculated from at least three individual sample measurements.
Findings	Ethanol filter efficiency and pressure drop, respectively: $56.33 \pm 3.03$ and $7.7$
	$\pm$ 0.6. Chlorine filter efficiency and pressure drop, respectively: $73.11 \pm 7.32$
	and $9.0 \pm 1.0$ . Dry heat at 75 degrees Celsius filter efficiency and pressure
	drop, respectively: $96.67 \pm 0.65$ and $6.0 \pm 1.0$ . UVGI filter efficiency and
	pressure drop, respectively: $95.50 \pm 1.59$ and $7.0 \pm 0.0$ .
Results	Solution-based treatments drastically decrease the filter efficiency. Heat
	minimally alters filter efficiency when temperatures below 125 degrees
	Celsius are used. UVGI shows a decrease in filter efficiency after 20 cycles.
Conclusions	Solution-based methods should be avoided as they degrade static charge. The
	heating method can preserve filter efficiency. UVGI may be useful, but the
	output dose must be determined.
Appraisal:	Strength: This is an experimental study; therefore, level 1 evidence. This is a
Worth to	high-quality study as the results are consistent and generalizable. Limitations:
Practice/	Knowledge of the depth of penetration of ultraviolet radiation and the
Level	appropriate dose is lacking.

Table 2

Citation	Steinberg BE, Aoyama K, McVey M, et al. Efficacy and safety of
and Theme	decontamination for N95 respirator reuse: A systematic literature search and
of the	narrative synthesis. Can J Anesth. 2020. https://www-embase-
article	com.ezproxy.fiu.edu/search/results?subaction=viewrecord&id=L2005691767&f
	rom=export. doi: 10.1007/s12630-020-01770-w
Design/	Systematic review
Method	
Sample/	N = 26. 26 studies were identified.
Setting	
Major	Independent variables: heat, autoclave, HPV, hydrogen peroxide gas vapor
Variables	(HPGV), ionized hydrogen peroxide iHV, ethylene oxide EtO, and UV.
Studied	Dependent variables: filter integrity, fit, virus inactivation, and irritation or
and Their	health concern to the user. <sup>7</sup>
<b>Definitions</b>	
Measureme	Literature was reviewed to determine if all decontamination methods were
nt and data	tested against severe acute respiratory syndrome-associated coronavirus 2
analysis	(SARS-CoV-2). Various retesting strategies, such as the NIOSH standard
	aerosolized sodium chloride, were also evaluated to determine post-
	decontamination performance.
Findings	Systematic review gathering information from the databases MEDLINE,
	Embase, Cochrane CENTRAL, and ClinicalTrials.gov. The search involved
	information on N95 FFR decontamination and subsequent testing for integrity
	and fit. 26 studies were identified from the mentioned databases as well as
	from manual searches from health agencies.
Results	Heat treatment up to 50 cycles did not decrease the filter efficiency. Significant
	mask degradation was observed with autoclaving. The chemical
	decontamination methods utilizing hydrogen peroxide were all shown to be
	effective at inactivating the virus. Inactivation of the virus by UV is unclear as
	UV penetration is limited by dose, and the appropriate dose has not yet been
	determined. <sup>7</sup>
Conclusion	Only two methodologies are supported as providing proper mask cleaning while
S	maintaining physical integrity: HPV and moist heat at 65–80 °C for 20–30 min
	at a relative humidity of 50%–85%.
Appraisal:	Strength: This is a systematic review of only experimental studies, making the
Worth to	level of evidence a II. The quality of the study is considered "good" because
Practice/	although the results are consistent and generalizable, the data on the topic are
Level	limited, which limits the sample size.

Table 3

Citation and	Wharton K, Rieker M. N95 respirator decontamination and reuse: current
Theme of the	state of the evidence. AANA Journal. 2020;88(3):245. Accessed October 18,
article	2020.
	https://www.aana.com/docs/default-source/aana-journal-web-documents-
	1/online-content-N95-respirator-decontamination-and-reuse-current-state-of-
	the-evidence-aana-journal-june-2020.pdf?sfvrsn=4f59405e_
Design/	Pre-test-post-test control group experimental design
Method	
Sample/	N = 12. 12 studies were identified.
Setting	
Major	Independent variable: Decontamination methods that included warm moist
Variables	heat, microwave-generated steam, HPV, antimicrobial wipes, and UVGI.
Studied and	Dependent variable: Post decontamination performance (PDP) and
Their	contaminant reduction, measured as log reduction (LR). <sup>4</sup>
<b>Definitions</b>	
Measurement	Post decontamination performance was measured by filter performance and
and data	structural integrity. Filter performance was determined by 300nm particle
analysis	penetration. The decontaminant reduction was measured on a logarithmic
	scale.
Findings	UVGI showed a greater than or equal to 3 LR with no initial changes to PDP
	but a decrease in structural integrity. Antimicrobial wipes showed a 3–5
	contaminant LR and no change in PDP. Microwave-generated steam and
	warm moist heat showed a greater than 3 and greater than 4 contaminant LR,
	respectively. Warm moist heat did not show any significant change in PDP. 2
	out of 6 studies evaluating microwave-generated steam showed a decrease in
	fit. <sup>4</sup>
Results	HPV decontamination was found to decrease the number of contaminants.
	Microwave-generated steam and UVGI were found to be less effective than
	warm moist heat at decontamination. UVGI was found to be an effective
	decontamination method, but appropriate exposure time varied among N95
	FFR models.
Conclusions	Moist heat and HPV are relatively reliable methods of decontamination.
	Chemical decontamination methods, such as HPV, were found to be more
	structurally destructive than physical decontamination methods.
Appraisal:	Strength: This is a systematic review at level III strength. This review is
Worth to	considered "Good" quality because it provides reasonably consistent
Practice/	recommendations based on a relatively comprehensive literature review with
Level	references to scientific evidence. Limits: All studies in this review used a
	small sample of the many different N95 models that exist.

Table 4

Citation and Theme of the article	Viscusi DJ, Bergman MS, Eimer BC, Shaffer RE. Evaluation of five decontamination methods for filtering facepiece respirators. <i>Ann Occup Hyg</i> . 2016;53(8):815-827. <a href="http://ezproxy.fiu.edu/login?url=http://search.ebscohost.com.ezproxy.fiu.edu/login.aspx?direct=true&amp;db=rzh&amp;AN=105242405&amp;site=ehost-live&amp;scope=site">http://ezproxy.fiu.edu/login?url=http://search.ebscohost.com.ezproxy.fiu.edu/login.aspx?direct=true&amp;db=rzh&amp;AN=105242405&amp;site=ehost-live&amp;scope=site</a> . doi: annhyg/mep070.
Design/ Method	Pre-test-post-test control group experimental design
Sample/ Setting	N = 162
Major Variabl es Studied and Their Definiti ons	Independent variables: UVGI, EtO, VHP, microwave oven radiation, and bleach. Dependent variables: physical appearance, odor, and performance (filter aerosol penetration and filter airflow resistance).
Measur ement and data analysis	The observational analysis included inspection for visible degradation, respirator texture, and odor. Filter aerosol penetration was tested with a model 8130 Automated Filter tester using NIOSH certification test procedures of 85L/min. Airflow resistance was also tested with a model 8130 Automated Filter tester. Airflow resistance was measured in millimeters of water column height pressure (mmHg).1
Finding s	Results were considered statistically significant if p-values were less than 0.05. A one-way analysis of variance (ANOVA) was performed for all nine mask models. P-values of all models were greater than 0.05 for post-test filter penetration. Only one model of N95 FFR had a p-value greater than 0.05 for post-test airflow resistance. <sup>1</sup>
Results	Results were considered statistically significant if p-values were less than 0.05. A one-way analysis of variance (ANOVA) was performed for all nine mask models. P-values of all models were greater than 0.05 for post-test filter penetration. Only one model of N95 FFR had a p-value greater than 0.05 for post-test airflow resistance. <sup>1</sup>
Conclus	Bleach or EtO decontamination methods are not recommended mainly due to the irritation and potential harm to the user of the FFR. HPV is limited by cellulose-based products. Microwave oven irradiation to produce dry heat caused structural deformation in some models.
Apprais al: Worth to Practice / Level	Strength: As this is an experimental study, the strength level is I. This is a high-quality study as it contained consistent, generalizable results with adequate controls. Limitations: Failure to determine if decontamination methods effectively inactivated the virus.

Table 5

Citation and	Bergman MS, Viscusi DJ, Zhuang Z, et al. Impact of multiple consecutive
Theme of the	
	donning on filtering facepiece respirator fit. AJIC: American Journal of
article	<i>Infection Control.</i> 2016;40(4):375-380. doi:10.1016/j.ajic.2011.05.003.
- · ·	
Design/	This is a repeated measure experimental design in which fit tests are
Method	performed by the same subjects over different periods.
Sample/	17 individuals who each passed an OSHA-accepted 8-exercise fit test and
Setting	were experienced respirator test subjects were selected to perform multiple
	donnings and doffings of nine different NIOSH-certified N95 FFR models.
Major	Independent variable: The number of donning and doffing of N95 FFRs and
Variables	the N95 model.
Studied and	Dependent variable: Changes in fit factor (FF) or fit.
Their	
<b>Definitions</b>	
Measurement	A model 8020 Portacount Plus Fit Tester and an 8095 N95 Companion
and data	accessory were used to conduct fit testing. FF was calculated as the ratio of
analysis	the ambient particle concentration divided by the mask concentration. A FF
	greater than or equal to 100 was considered passing. Anything less was
	considered failing. Finally, paired 1-tailed <i>t</i> -tests were used to compare the
	mean values from the first set of 5 donnings (1–5) with those of the second set
	(6-10), the third set $(11-15)$ , and the fourth set $(16-20)$ . The relationship
	between donning interval and the percentage of fit tests with an FF greater
	than or equal to 100 was evaluated via regression analysis. <sup>15</sup>
Findings	For each donning set, 1–5, 6–10, 11–15, and 16–20, R <sup>2</sup> progressively
. 8	increased, 0.04, 0.23, 0.30, and 0.48, respectively. P-values less than 0.05
	were obtained for the regression models of donnings 1–10, 1–15, and 1–20. 15
Results	Statistical analysis showed that fit decreased gradually after multiple
	donnings. The best fit was observed for donnings 1–5. A FF greater than or
	equal to 100 was found in 55% to 65% of donning number 20. 15.
Conclusions	Multiple donnings affected six of the FFR models tested. Statistics indicate
	that in these models, an average of 5 donnings can be performed before FF
	consistently decreases below 100.15
Appraisal:	Strength: This is an experimental study making it level I evidence. This study
Worth to	contained consistent, generalizable results with fairly definitive conclusions
Practice/	giving it a quality grade of "good." The small number of FFR models tested
Level	
Levei	was a limitation of the experiment.

Table 6

<b>article</b> Infection. January 2020. doi:10.1016/j.jhin.2020.09.032.	
<b>Design</b> / Pre-test-post-test control group experimental design	
Method	
Sample/ 4 different models of 3M N95 FFR were tested.	
Setting	
Major Independent variable: Gravity steam decontamination method.	
Variables Dependent variables: Microorganism inactivation and functionality te	esting,
<b>Studied and</b> including filter efficiency, fit evaluation, and strap integrity.	
Their	
Definitions	
<b>Measurement</b> A bacterial inactivation test was performed after FFRs were inoculate	
and data Geobacillus stearothermophilus spore suspension. Residual bacterial	growth
<b>analysis</b> was assessed after 14 days. The Vitek system was used for microbial	
identification. Filtration efficiency was measured with a model 8130A	
Automated Filter tester with a NaCl aerosol and a flow of 85L/min. T	
test was conducted on a static mannequin head form with a TSI Porta	
PRO+ 8038 instrument operating in "N95 Enabled" mode. An Instron	ı® 5943
Tensile Tester was used to test strap integrity. <sup>16</sup>	
<b>Findings</b> All models but one had a p-value greater than 0.05 in filter efficiency	
One model had a significant reduction in filter efficiency (p-value = 0	
Two models had p-values greater than 0.05 for mannequin fit testing	
treatment. The same model that showed a significant reduction in filte	
efficiency also had a p-value of 0.04 for fit testing post-decontaminat	
models showed p-values of 0.00002 and 0.027 for the top and bottom	
respectively. One model had a p-value greater than 0.05 after three cy  No treated models showed bacterial growth. The model that showed	cies.
6	wad na
statistically significant changes in filter efficiency and fit testing show significant change in strap integrity after 3 cycles. <sup>16</sup>	veu 110
Conclusions Gravity steam reprocessing is an effective and safe option for N95 FF	R ranga
although results vary by model.	K Teuse,
Appraisal: Strength: This is an experimental study, making the level of evidence	a I
Worth to Limitations: A small number of N95 models were tested.	u I.
Practice/	
Level	

Table 7

Citation and Theme of the article	Seresirikachorn K, Phoophiboon V, Chobarporn T, et al. Decontamination and reuse of surgical masks and N95 filtering facepiece respirators during the COVID-19 pandemic: A systematic review. <i>Infect Control Hosp Epidemiol</i> . 2021;42(1):25-30. <a href="https://www-embase-com.ezproxy.fiu.edu/search/results?subaction=viewrecord&amp;id=L633019673&amp;from=export">https://www-embase-com.ezproxy.fiu.edu/search/results?subaction=viewrecord&amp;id=L633019673&amp;from=export</a> . doi: 10.1017/ice.2020.379.
Design/	Systematic review
Method	Bystematic review
Sample/	N = 15
Setting	15 studies were identified.
Major	Independent variable: Decontamination methods.
Variables	Dependent variables: Bacterial and viral disinfection, post-decontamination
Studied and	filtration efficiency, and physical structure degradation.
Their	
Definitions	
Measureme	This systematic review followed the PRISMA format. Studies were selected
nt and data	based on predetermined inclusion and exclusion criteria. Inclusion criteria
analysis	consisted of studies that evaluated the performance of decontaminated FFRs,
	any study design, method, or FFR model, including N95. 16 The exclusion
	criteria consisted of languages other than English, nonexperimental studies, and studies without original data. <sup>17</sup>
Findings	14 decontamination methods were identified. These methods included
9	ultraviolet germicidal irradiation, moist heat, microwave-generated steam,
	hydrogen peroxide vapor, microwave steam bag, bleach, steam, dry heat,
	ethanol or isopropyl alcohol, ethylene oxide, hydrogen peroxide gas plasma,
	liquid hydrogen peroxide, microwave irradiation, and soap and water. 17
Results	Of the 14 methods, only 4 were found to disinfect the FFR while maintaining
	filter efficiency and the physical structure of the mask. <sup>17</sup>
Conclusion	Of the 14 methods, only 4 were found to disinfect the FFR while maintaining
S	filter efficiency and the physical structure of the mask. <sup>17</sup>
Appraisal:	Strength: This is a systematic review of only experimental studies, making the
Worth to	level of evidence a II. The quality of the study is considered "good" because
Practice/	although the results are consistent and generalizable, the data on the topic are
Level	limited, which limits the sample size.

Table 8

Citation and Theme of the article	Gnatta JR, Souza RQD, Lemos CDS, et al. Safety in the practice of decontaminating filtering facepiece respirators: A systematic review. <i>Am J Infect Control</i> . 2020. <a href="https://www-embase-com.ezproxy.fiu.edu/search/results?subaction=viewrecord&amp;id=L2010477137&amp;from=export">https://www-embase-com.ezproxy.fiu.edu/search/results?subaction=viewrecord&amp;id=L2010477137&amp;from=export</a> . doi: 10.1016/j.ajic.2020.11.022.
Design/	Systematic review
Method	NY 40
Sample/	N = 40
Setting	40 studies were identified.
Major	Independent variable: Decontamination methods.
Variables	Dependent variables: Microbial disinfection and FFR integrity.
Studied	
and Their Definitions	
Measureme	This systematic review followed the DDICMA format. Studies were selected
nt and data	This systematic review followed the PRISMA format. Studies were selected based on predetermined inclusion and exclusion criteria. Inclusion criteria
analysis	consisted of studies that were in the English, Spanish, and Portuguese languages
anarysis	and evaluated decontamination methods by FFR integrity, filtration, and
	microbiological safety. Exclusion criteria included articles referring to reusable
	FFR, letters to editors, research letters, and opinion letters.
Findings	40 studies fitting the search criteria were identified. Within the 40 studies, 20 decontamination methods were assessed on N95 FFRs. Various N95 models were used in the different studies. <sup>18</sup>
Results	Of the 20 decontamination methods assessed, only dry heat, moist heat, VHP, and UVGI were found to inactivated microbes while maintaining functional and structural integrity of the FFR. <sup>18</sup>
Conclusion	Promising decontamination methods include dry heat, moist heat, VHP, and
S	UVGI. These decontamination methods need to be further evaluated because
	their results do vary with different N95 models. 18
Appraisal:	Strength: This is a systematic review of only experimental studies, making the
Worth to	level of evidence a II. The quality of the study is considered "good" because
Practice/	although the results are consistent and generalizable, the data on the topic are
Level	limited, which limits the sample size.

Table 9

Citation and Theme of the article	Grillet AM, Nemer MB, Storch S, et al. COVID-19 global pandemic planning: Performance and electret charge of N95 respirators after recommended decontamination methods. <i>Exp Biol Med</i> . 2020. <a href="https://www-embase-com.ezproxy.fiu.edu/search/results?subaction=viewrecord&amp;id=L2007624111&amp;from=export">https://www-embase-com.ezproxy.fiu.edu/search/results?subaction=viewrecord&amp;id=L2007624111&amp;from=export</a> . doi: 10.1177/1535370220976386.
Design/ Method	Pre-test-post-test control group experimental design
Sample/ Setting	3M 1870 FFR (N = 11), 3M 1860 (N = 7), new 3M 1870 + AURA (N = 2), new 3M 1860 (N = 5)
Major Variables Studied and Their Definitions	Independent variable: Decontamination methods including UV, HPV, wet heat, bleach, isopropanol (IPA), and soap.  Dependent variables: fit, filtration efficiency, and pressure drop, along with the relation-ship between the surface charge of the electret layer and the elastic properties of the strap. 19
Measureme nt and data analysis	Filter efficiency and pressure drop were tested with a filter penetration testbed (FPT) that generates a 0.25% poly-dispersed sodium chloride mixture with a TSI Model 3076 Constant Output Atomizer as the challenge aerosol. Pressure drop was measured with a Dwyer Magnehelic differential pressure gauge (Model 2010). Quantitative Fit Testing was performed with a PortaCount Pro + Respirator Fit Tester Model 8038. Electrostatic testing was performed with two electrostatic voltmeters. The mechanical measurements of the straps were performed on an Anton Paar Modular Compact Rheometer (MCR702) with a Twin Drive linear stage.
Findings	IPA and soap showed the only statistically significant changes in electret charge. <sup>19</sup> A significant change in elastic strap integrity was measured after multiple donnings and HPV treatments. <sup>19</sup>
Results	Filter efficiency and pressure drop were not affected by bleach, HPV, UV, or wet heat. IPA and soap treatment caused a drop in filter efficiency, secondary to the change in electret charge. Both multiple donnings and HPV treatment result in significant changes in elastic strap integrity, although multiple donnings are predominantly responsible. <sup>19</sup>
Conclusion s	The decontamination methods UV, wet heat, and HPV did not affect FFR fit or filter performance.
Appraisal: Worth to Practice/ Level	Strength: This is an experimental study based on primary research. The level of evidence associated with this research is a I. The quality of evidence is "good" because although the results are consistent, the sample size is small.

Table 10

Citation	Jena AK, Sharan J. Decontamination strategies for filtering facepiece respirators
and	(FFRs) in healthcare organizations: A comprehensive review. <i>Annals of Work</i>
Theme	Exposures & Health. 2021;65(1):26-52.
of the	http://ezproxy.fiu.edu/login?url=http://search.ebscohost.com.ezproxy.fiu.edu/login.
article	aspx?direct=true&db=rzh&AN=148168776&site=ehost-live&scope=site. doi:
	10.1093/annweh/wxaa090.
	Torroys, annivers writing of
Design/	Systematic review.
Method	Systematic Tevievit
Sample/	N = 38.38 studies were identified.
Setting	TO SOLDO SIGNATOR WELL INCIDENT
Major	Independent variable: Decontamination methods.
Variabl	Dependent variables: Microbial disinfection and FFR fit and integrity.
es	Dependent variables, interoblar distincetion and 11 it in and integrity.
Studied	
and	
Their	
Definiti	
ons	
Measur	Studies in the English language were identified through the PubMed, NCBI, and
ement	Google Scholar databases. Terms used for the electronic search were:
and	"Decontamination" OR "Sterilization" OR "Disinfection" OR "Re-use" OR
data	"Respirator" OR "Filtering Facepiece Respirator" OR "FFR" OR "N95 respirator"
analysis	OR "N95 FFR" OR "Respiratory Protection Equipment." <sup>20</sup>
Finding	14 decontamination methods were identified. These methods included ultraviolet
S	germicidal irradiation, moist heat, microwave-generated steam, hydrogen peroxide
	vapor, bleach, dry heat, ethanol or isopropyl alcohol, ethylene oxide, liquid
	hydrogen peroxide, autoclaving, a hypochlorite solution wipe, a benzalkonium
	chloride wipe, DMDO, and soap and water.
Results	VHP does not affect the fit or filter performance of FFRs after multiple
	decontamination cycles. <sup>20</sup> EtO left residual gas and harmful toxins. UVGI
	effectively decontaminates, but the appropriate dose and level of penetration are
	unclear. 20 Autoclaving reduces the fit and filter efficiency. MGS may produce
	various fit effects depending on the power of the microwave. Moist heat is time-
	sensitive. <sup>20</sup> Dry heat is effective but may melt the FFR. <sup>20</sup> Bleach leaves an irritating
	chlorine residue. Liquid hydrogen peroxide, DMDO, and disinfectant wipes all lack
	evidence of effective viral inactivation. <sup>20</sup> Alcohol and soap and water affect filter
	performance.
Conclus	HPV, UVGI, and dry heat were found to be suitable decontamination methods,
ions	although not without limits.
Apprais	Strength: This is a systematic review of only experimental studies, making the level
al:	of evidence a II. The report provides consistent results with definitive conclusions.
Worth	The report also makes consistent recommendations based on a comprehensive
to	literature review, making the quality rating of this review "good."
Practice	
/ Level	

Table 11

Citation and Theme of the article	Paul D, Gupta A, Maurya AK. Exploring options for reprocessing of N95 filtering facepiece respirators (N95-FFRs) amidst COVID-19 pandemic: A systematic review. <i>PLoS ONE</i> . 2020;15(11 November). <a href="https://www-embase-com.ezproxy.fiu.edu/search/results?subaction=viewrecord&amp;id=L2010139020&amp;from=export">https://www-embase-com.ezproxy.fiu.edu/search/results?subaction=viewrecord&amp;id=L2010139020&amp;from=export</a> . doi: 10.1371/journal.pone.0242474.
Design/	Systematic review.
Method Sample/	N = 17.17 studies were identified.
Setting	17 - 17. 17 studies were identified.
Major	Independent variable: Decontamination methods.
Variables	Dependent variables: Physical changes, user accept-ability, respirator fit, filter
Studied	efficiency, microbicidal efficacy, and presence of chemical residues.
and Their	
<b>Definitions</b>	
Measureme nt and data	Five databases, PubMed, Google Scholar, Crossref, Ovid, and ScienceDirect, were searched. The references of the identified articles were also searched for
analysis	relevant studies. <sup>21</sup>
Findings	This review identified 21 decontamination methods that included 9 physical or
1 manago	energetic methods, 3 gaseous chemical methods, 6 liquid chemical methods, and 3 wipes. <sup>21</sup>
Results	Studies involving UVGI, specifically UV-C, found that this method preserved fit and filter performance and effectively inactivated microbes. Moist heat from an autoclave was observed to physically destroy FFRs, while moist heat from a microwave or an incubator was effective at maintaining the fit and filter performance and deactivating microbes for up to 3 cycles. Dry heat provided by an electric rice cooker showed 99 to 100% biocidal efficacy against <i>Bacillus subtilis</i> spores. <sup>21</sup>
Conclusion	UVGI has been shown to be an effective microbiocidal while maintaining fit
S	and filter efficiency. <sup>21</sup> Many variables, such as penetration and effective dose, vary by FFR model. <sup>21</sup> Moist heat was also shown to be an effective decontamination method. Dry heat via electric rice could also be a suitable
	decontamination method. HPV via a commercial HPV generator was found to
	decontaminate and physically maintain FFRs after 50 cycles. <sup>21</sup>
Appraisal: Worth to Practice/ Level	Strength: This is a systematic review of only experimental studies, making the level of evidence a II. The report provides consistent results with fairly definitive conclusions. The report also makes consistent recommendations based on a comprehensive literature review, making the quality rating of this review "good."

Table 12

Citation	Kumar A, Kasloff SB, Leung A, et al. Decontamination of N95 masks for re-
and Theme	use employing 7 widely available sterilization methods. <i>PLoS ONE</i> . 2020;15(12)
of the	December). https://www-embase-
article	com.ezproxy.fiu.edu/search/results?subaction=viewrecord&id=L2010476232&f
	rom=export. doi: 10.1371/journal.pone.0243965.
Design/	Pre-test-post-test control group experimental design
Method	
Sample/	This study does not provide the specific number of masks used. It does mention
Setting	that 6 different FFRs were used.
Major	Independent variable: Decontamination methods: autoclave, ethylene oxide
Variables	(ETO), low-temperature hydrogen peroxide gas plasma (LT-HPGP), vaporous
Studied	hydrogen peroxide (VHP), peracetic acid dry fogging (PAF), ultraviolet C
and Their	irradiation (UVCI), and moist heat (MH)
<b>Definitions</b>	Dependent variables: Effectiveness of decontamination and impact of
	decontamination on FFR structural and functional integrity.
Measureme	Viral titers were observed for cytopathic effects to determine the level of
nt and data	decontamination. <sup>22</sup> Titers were expressed as 50% tissue culture infective dose
analysis	(TCID <sub>50</sub> )/mL. The effects on structural and functional integrity were determined
	by visual observation, while quantitative fit tests were performed with TIS
	PortaCount 8038+ to determine the fit factor. <sup>22</sup> Filtration efficiency was
	calculated as the persistent fraction of aerosolized 0.1 µm latex microbeads in
	the air before and after passage through the N95 mask. <sup>22</sup>
Findings	Control groups showed 4.4 to 6.1 log TICD <sub>50</sub> /mL, which varied by mask
	model. <sup>22</sup> All decontamination methods except for UVCI show 0 log growth of
	viral titers. <sup>22</sup> UVCI showed persistent viable <i>Vesicular stomatitis</i> virus (VSV). <sup>22</sup>
	All mask models passed fit testing after the first decontamination cycle.
	Autoclaving resulted in functional failure, while EtO and UVCI maintained
	function for up to 5 cycles. <sup>22</sup> HGPG failed fit testing after the first cycle. VHP,
	PAF, and MHT maintained integrity.
Results	All decontamination methods except for UVCI completely decontaminated all
	types of pathogens tested. Filtration testing demonstrated congruent
	deficiencies in filtration efficiency. <sup>22</sup>
Conclusion	MHT, PAF, and HPV were shown to be highly effective at viral inactivation as
S	well as the maintenance of structural and functional integrity. <sup>22</sup>
Appraisal:	Strength: This is an experimental study based on primary research. The level of
Worth to	evidence associated with this research is a level I. The quality of evidence is
Practice/	"good" because although the results are consistent, the sample size is small.
Level	

Table 13

Citation	Rodriguez-Martinez C, Sossa-Briceño MP, Cortés JA. Decontamination and reuse
and	of N95 filtering facemask respirators: A systematic review of the literature. Am J
Theme	Infect Control. 2020;48(12):1520-1532.
of the	http://ezproxy.fiu.edu/login?url=http://search.ebscohost.com.ezproxy.fiu.edu/login.
article	aspx?direct=true&db=rzh&AN=147070778&site=ehost-live&scope=site. doi:
	10.1016/j.ajic.2020.07.004.
Design/	Systemic review
Method	
Sample/	N = 15. 15 studies were identified.
Setting	
Major	Independent variable: Decontamination methods: autoclave, UVGI, VHP, EtO,
Variabl	microwave oven, bleach, heat treatment, ethanol, LHP, autoclave, isopropyl
es	alcohol, wipe products, tap water, soap and water, and electric rice cooker.
Studied	Dependent variables: Inactivation of infectious material, filtration performance,
and	structural integrity, and potentially toxic chemicals post decontamination.
Their	
Definiti	
ons	
Measur	Decontamination was measured by the reduction in viral recovery, expressed as
ement	log10 TCID <sub>50</sub> /mL reduction. <sup>23</sup> Filter performance was measured by filter
and	penetration (P%) and airflow resistance (pressure drop in
data	mmH2O column height pressure). <sup>23</sup> Fit was measured by the fit factor on a
analysis	mannequin head.
Finding	UVGI, VHP, EtO, and heat treatment showed a significant reduction in viral or
S	bacterial spore recovery as well as no significant reduction in fit or filter
	performance. <sup>23</sup>
Results	UVGI, VHP, heat, and EtO are all efficacious against SARS-CoV-2 while
	maintaining fit and filter efficiency. <sup>23</sup>
Conclus	UVGI and VHP are the most promising decontamination methods based on their
ions	reduction of microbes, maintenance of FFR function, and lack of residual toxicity. <sup>23</sup>
Apprais	Strength: This is a systematic review of only experimental studies, making the level
al:	of evidence a II.
Worth	
to	
Practice	
/ Level	

#### DISCUSSION

### Effects of Decontamination on the Functional Integrity of N95 FFRs

Functional integrity is discussed in terms of factors that affect filter performance. Liao L, Xiao W, Zhao M, et al. described filter performance through filter efficiency and drop pressure.<sup>5</sup> Filter performance was tested with the Automated Filter Tester 8130A. This study found that chlorine and ethanol significantly decreased filter performance due to a loss of electrostatic charge after treatment.<sup>5</sup> According to the authors, the decrease in performance was not related to structural damage to the filter, as evidenced by the maintenance of drop pressure.<sup>5</sup> A significant reduction in filter efficiency was also noted after 5 cycles of steam treatment, while FFRs subjected to dry heat treatment up to 125 degrees Celsius maintained filter performance for up to 20 cycles.<sup>5</sup> UVGI treatment resulted in a decrease in filter performance after 20 cycles.<sup>5</sup>

Steinberg BE, Aoyama K, McVey M, et al. found that after 50 cycles of dry heat treatment up to 85 degrees Celsius, the filter efficiency of N95 FFRs was maintained. The same review found that filter efficiency remained unchanged for up to 20 cycles of HPV treatment but was significantly reduced after 5 cycles of HPGV treatment. This review reported no data on the effects of iHV on filter efficiency. According to this review, as the appropriate dose of ultraviolet radiation could not be determined, neither could its effects on filter performance.

Viscusi DJ, Bergman MS, Eimer BC, Shaffer RE measured filter performance in terms of aerosol filter penetration with a model 8130 Automated Filter tester. This study found no significant change in filter performance after UVGI, EtO, VHP, and bleach decontamination methods. Aljabo A, Mueller E, Abdul-Azeez D, Hoare T, Jain A. measured filter efficiency with a model 8130A Automated Filter tester using a NaCl aerosol and a flow of 85L/min. The researchers found that of the four models of N95 FFRs they tested with the gravity steam reprocessing method, all but one model retained filter efficiency after decontamination. All but one model retained filter efficiency after decontamination.

Of the 15 studies reviewed by Seresirikachorn K, Phoophiboon V, Chobarporn T, et al., only 4 methods were recommended by the authors for use because they maintained filter

efficiency and structural integrity post decontamination and were found to decontaminate N95 FFRs effectively. These methods were UVGI, moist heat, MGS, and HPV.<sup>17</sup> The authors did not discuss how filter efficiency was determined in these experiments. Of 4 studies that evaluated bleach as a decontamination method, 1 found that filter efficiency decreased after treatment. 2 out of 3 studies showed that the filter efficiency of the FFR decreased with the use of steam in an autoclave.<sup>17</sup> Filter efficiency was unchanged after dry heat treatment at less than 160 °C and a treatment duration of fewer than 22 minutes.<sup>16</sup> Filter efficiency decreased after treatment with ethanol or isopropyl alcohol. Although filter efficiency remained unchanged after treatment with EtO, HPGP, LHP, or microwave irradiation, the authors did not list these as viable options due to physical changes post decontamination.

The review by Wharton K. and Rieker M. found that warm moist heat, UVGI, and MGS did not significantly reduce post-decontamination filter performance. VHP was found to maintain filter performance for up to 30 cycles. 4 Chemical decontamination methods such as isopropanol, ethanol, and bleach were found to be destructive to filter performance because of their effects on the electret. 4 Studies reviewed by Gnatta JR, Souza RQD, Lemos CDS, et al. also found that liquid decontamination methods involving ethanol, bleach, and isopropanol significantly reduced filter performance. 18 Dry heat, moist heat, UVGI, and VHP were all shown to maintain filter efficiency according to the studies included in this review. Similarly, Grillet AM, Nemer MB, Storch S, et al. found that VHP, UVGI, and moist heat did not degrade filter performance. 19 Again, similar to most studies, they found that isopropanol and soap treatments resulted in decreased filter performance. 19 Jena AK and Sharan J. found that VHP, EtO, MGS, and UVGI maintained filter performance.<sup>20</sup> The reviews by Paul D, Gupta A, and Maurya AK and Rodriguez-Martinez C, Sossa-Briceño MP, Cortés JA., as well as the study by Kumar A, Kasloff SB, Leung A, et al., found that UVGI, VHP, and moist heat effectively maintained filter performance. 21,22,23 Additionally, Kumar A, Kasloff SB, Leung A, et al. found that peracetic acid dry fogging (PnAF) decontamination maintained filter performance.<sup>22</sup>

### Effects of Decontamination on the Structural Integrity of N95 FFRs

Structural integrity is discussed in terms of factors that affect fit. The review conducted by Steinberg BE, Aoyama K, McVey M, et al. found that decontamination methods using heat ranging from 60 to 85 °C and high humidity did not affect fit. Autoclaving was observed to result in significant structural degradation of N95 FFRs. Viscusi DJ, Bergman MS, Eimer BC, Shaffer RE found that microwave oven irradiation used to produce dry heat caused structural deformation in some models. Bergman MS, Viscusi DJ, Zhuang Z, Palmiero AJ, Powell JB, Shaffer RE found that, in multiple models, a significant change in fit occurred after 5 donnings. Of the 4 N95 FFRs tested by Aljabo A, Mueller E, Abdul-Azeez D, Hoare T, Jain A, only one model showed a significant change in mannequin fit testing after gravity steam reprocessing was used for decontamination. 16

The review by Seresirikachorn K, Phoophiboon V, Chobarporn T, et al., found that only 4 of the 14 decontamination methods identified maintained structural integrity of the FFR while also maintaining functional integrity, and the ability to deactivate certain pathogens. These 4 methods were UVGI, moist heat, MGS, HPV, and microwave steam bags. Three studies found that physical structure was unchanged following UVGI, however at doses above 590 J/cm² physical strength and strap strength were reduced. According to the authors, the optimal dose should be less than 2 J/cm². When moist heat was used as the decontamination method, 1 study found that the physical structure was unchanged, while 3 studies reported changes in the physical structure. Three studies showed that there was some separation on the inner foam nose cushion when MGS was used, however this small structural change did not affect the fit test passing rate of 90 to 100%. No physical structural change was noted after HPV treatment. Ethylene oxide, HPGP, LHP, and microwave irradiation denomination methods all produced physical degradation of the FFR after treatment. Soap and water treatment also maintained structural integrity of the mask.

Jena AK and Sharan J. reviewed a study that noted that VHP might structurally compromise FFR models containing cellulose due to the cellulose's absorbance of the hydrogen peroxide, resulting in its degradation. <sup>20</sup> In a study reviewed by Rodriguez-Martinez C, Sossa-Briceño MP, and Cortés JA., dry heat up to 80 °C for 60 minutes was an effective decontamination method that maintained structural integrity. <sup>23</sup> However, above this temperature, many FFR components began to melt, compromising fit. <sup>23</sup>

### Efficacy of Decontamination Method for Pathogen Inactivation

It is important to note that not all studies determined the efficacy of the tested decontamination methods with the same virus or bacteria. Some studies used SARS-C0V-2 or the influenza virus because they are in the same group of lipid bilayer-enveloped viruses.<sup>17</sup> Other studies tested decontamination methods on B. subtilis and G. stearothermophilus because the spores of these bacteria are more difficult to deactivate than viruses. 17 According to the review by Steinberg BE, Aoyama K, McVey M, et al., SARS-CoV-2 was found to be more susceptible to heat than to cold or ambient temperatures.<sup>7</sup> This review also found that humidity was beneficial for viral inactivation on N95 FFRs. There was no evidence for the effectiveness of autoclaving on the inactivation of SARS-CoV-2, but steam alone was found to successfully decontaminate avian coronavirus. Chemical decontamination methods, including HPV, HPGP, and iHP, were all found effective at inactivating pathogens more resistant than SARS-CoV-2 on N95 FFRs, according to the findings of this review. This review found no data on the effectiveness of EtO gas for viral inactivation. This same review reported that no studies found live viruses postdecontamination with ultraviolet radiation. One study found that ultraviolet light in the range of 100 nm to 280 nm was virucidal, while other studies questioned whether UVGI could penetrate sufficiently to inactivate viruses on the inner layers of N95 FFRs.<sup>7</sup>

Wharton K and Rieker M illustrated contamination reduction as log reduction. UVGI showed decontamination greater than or equal to 3 LR.<sup>4</sup> Antimicrobial wipes showed a 3–5 contaminant LR.<sup>4</sup> Microwave-generated steam, and warm moist heat showed a greater than 3 and

greater than 4 contaminant LR.<sup>4</sup> HPV decontamination was only tested on one N95 FFR model and was found to decrease the amount of contaminant by 6 LR.<sup>4</sup> After gravity steam reprocessing, Aljabo A, Mueller E, Abdul-Azeez D, Hoare T, Jain A. found that none of the four tested models showed any bacterial growth.<sup>16</sup>

The studies reviewed by Seresirikachorn K, Phoophiboon V, Chobarporn T, et al. showed that UVGI effectively inactivated influenza viruses H1N1 and H5N1 as well as B. subtilis spores. 17 B. subtilis was found to be extremely resistant to sterilization processes and was used to represent a worst-case scenario, making the validation of reprocessing efficacy for killing spores indicative of broader-scale disinfection performance. <sup>16</sup> The authors did mention that the studies reviewed varied in the UV dose used, the distance between the UV source and FFR, the number of cycles, total exposure time, and the exposed surface of FFRs.<sup>17</sup> Moist heat effectively inactivated H1N1 and H5N1 virus.<sup>17</sup> The studies reviewed did not assess bacterial deactivation. MGS resulted in a greater than a 4-log reduction of the virus. The studies did not measure bacterial inactivation after this decontamination method. HPV was effective for G. stearothermophilus spore inactivation, but this method's viral inactivation was not assessed.<sup>17</sup> One study that assessed microwave steam bags found that this method was effective in inactivating Bacteriophage MS2, a surrogate for pathogenic viruses. Its bacterial inactivation was not assessed.<sup>17</sup> Bleach, steam, dry heat, and ethanol or isopropyl alcohol treatments were all effective against B. subtilis spores. 17 The inactivation of viruses or bacteria was not assessed after the other decontamination methods in the remaining studies reviewed.

### **Summary of Evidence**

Reusing post-decontaminated N95 FFRs is intended to optimize PPE supply in times of critical shortage while preventing the transmission of pathogenic airborne disease by self-inoculation or patient-to-provider contact. For a decontamination method to successfully prevent transmission, it must inactivate the pathogenic microbe, maintain the structural and functional integrity of the FFR, and not present harm to the wearer by the method itself. Of the many

decontamination methods reviewed in these studies, only 4 seem to meet all the necessary criteria to be considered promising. These 4 include VHP, UVGI, dry heat, and moist heat.

A majority of the decontamination methods reviewed in the included studies could inactivate pathogenic microbes without sacrificing vital aspects crucial to the proper functioning of the FFRs. However, the four aforementioned promising methods seem to present viable possibilities for extending the usability of N95 FFRs. Nearly every study that tested VHP found it to be a reliable method of decontamination boasting the advantage of being able to decontaminate many FFRs simultaneously.<sup>22</sup> The N95 model used is an essential factor to consider with all decontamination methods, particularly with VHP.<sup>24</sup> Studies found wide variation in the models used and the possible number of cycles before mask failure.<sup>24</sup> VHP was also an ineffective decontamination method for N95 models containing cellulose.<sup>22</sup> Although highly effective, VHP is also limited in its practicality. Large institutions with many resources may have no problem using this method, but smaller institutions with fewer available resources may find it a challenge.

Most studies that assessed the effectiveness of UVGI as a decontamination method did so with ultraviolet light-C (UV-C). UV-C is a lower wavelength than UV-A or UV-B, at around 254 nm.<sup>17</sup> At these wavelengths, the DNA and RNA of pathogens are susceptible to damage through dimerization.<sup>17</sup> UV-C was found to be effective at pathogenic deactivation while maintaining the safe functionality of N95 FFRs, but these results differed by the N95 model. The effective dose of UV was found to be less than 2 J/cm2.<sup>17</sup> Higher doses of UV resulted in structural damage to the FFRs. The penetration of UV radiation to inner mask layers was also a cause for concern; however, if the electret is not neutralized, self-inoculation is of little concern as the wearer will not come into contact with these inner layers.<sup>23</sup> N95 FFRs were found to be reusable after 10 to 20 UVGI cycles in most studies and UV-C lamps are readily available and inexpensive.<sup>23</sup>

Dry heat was also found to be an effective decontamination method within a particular heat range. Pathogenic microbes were effectively inactivated and the structural and functional integrity of N95 FFRs was maintained at around 70 °C.<sup>25</sup> Structural degradation began to occur

around 80 °C.<sup>25</sup> Moist heat at 70 °C and a relative humidity of 50% to 70% was found to be more effective at deactivating bacteria on N95 FFRs than dry heat.<sup>26</sup> Thermal disinfection may represent a widely available and cost-effective decontamination strategy for N95 conservation.<sup>26</sup>

### **Limitations of the Systematic Review**

Many studies from multiple authors published at different times were assessed to determine the risk to anesthesia providers of reusing post-decontaminated FFRs. The selected studies used a variety of microorganisms and viruses to test the different decontamination methods' microbe inactivation. There were also incongruities in how filtration performance and structural integrity were measured among the selected studies as well as the model of N95 used. These differences limit the conclusions drawn from the overall systematic review.

### **Recommendations for Future Research**

Based on the limitations of this review, future research should require some standardization for how decontamination methods are tested. Standardized testing will allow results to be compared. The standards should be determined by the exact minimum requirements NIOSH uses to assess the safety of N95 FFRs.

### INTERVENTION METHODOLOGY

### **Setting**

The setting is a 716-bed urban community acute care hospital and level 1 trauma center in South Florida. The anesthesia department provides services for the operating department, which contains 19 operating rooms and one hybrid room. Anesthesia services are also rendered at offsite locations in the hospital, such as the endoscopic suite, electrophysiology and catheterization laboratory, labor and delivery, and the trauma resuscitation bay. The patient population served by this hospital is noticeably diverse, typical of many communities in South Florida. The intervention was conducted through an online survey and a PowerPoint educational module with the members of the anesthesia department from Anesco Anesthesia Services at Broward Health Medical Center.

### Recruitment

The target population consists of anesthesia providers employed by Anesco and working at Broward Health Medical Center. Providers were emailed an invitation to participate in the educational module.

### **Participants**

Anesco anesthesia providers at Broward Health Medical Center were invited to participate in an educational module designed as a pre-and post-test model. Participants included certified registered nurse anesthetists and anesthesiologists. Participants were drawn from an email list of anesthesia providers supplied by Broward Health Medical Center. The anticipated number of participants was between 15 and 20 anesthesia providers.

### Intervention

The educational module consists of a pre-test followed by a PowerPoint presentation discussing the risk to anesthesia providers associated with the reuse of decontaminated N95 FFRs. The presentation discusses the latest promising methods of decontamination that offer the least risk to the providers with the reuse of N95 FFRs. After viewing the presentation, the providers were asked to take the post-test, which consists of the same ten questions in the pre-test. The educational module is intended to inform providers of the possible risks associated with several decontamination methods as well as to educate them on the decontamination methods that permit limited reuse with little threat to the N95 wearer.

### **Procedure**

An informational email was sent to all Anesco anesthesia providers at Broward Health Medical Center. The email contained an anonymous link to the educational module where there was a pre-and post-education survey to be completed on either a mobile device or desktop computer via the Qualtrics survey platform. A unique code identifier was generated by the Qualtrics platform and presented to the participant. No personally identifiable information was captured and there was no way to link responses to identifying information.

### **Description of Approach**

The primary approach of this educational module was via the online Qualtrics platform. Implementation involved initially conducting a pre-assessment meant to gauge anesthesia providers' existing knowledge regarding the risk associated with the reuse of N95 FFRs after decontamination with existing methods and the current, promising decontamination methods. The pre-evaluation tool used to assess this knowledge was a 10-question survey or questionnaire.

The primary means of learning was a voiceover PowerPoint presentation that discusses the current risk of acquiring airborne pathogens through the regular tasks of the profession, measures taken to conserve PPE, such as N95 FFRs, in times of critical shortage, and suitable methods of decontamination that allow the safe reuse of FFRs. A post-assessment survey, identical to the pre-assessment questionnaire, determined whether learning occurred and providers' perception of the intervention.

### **Protection of Human Subjects**

With unique code identifiers, anesthesia providers participating in the survey remained anonymous and the data are secure. The use of passwords and spyware protects digital data.

Protective measures were taken to ensure the safety of the data.

### **Data Collection and Analysis**

Pre- and post-assessments were used to determine the effectiveness of the educational module. The data from the pre- and post-surveys were analyzed with inferential statistics. The survey consisted of 10 questions designed to assess baseline knowledge on the effects of decontamination on N95 FFRs and the potential risk to the user, the change in knowledge after the educational module intervention, and the change in provider behavior after the educational module.

### **Data Management and Measurement**

The principal investigators obtained an email list of anesthesia providers at Broward Health Medical Center to distribute surveys and educational modules. The responses were measured to determine the change in knowledge and behavior. No personal identifiers were recorded to protect the confidentiality of all participants. The first 8 questions were used to assess knowledge on the subject matter, while the final 2 questions were designed to evaluate changes in the providers' behaviors and attitudes. Data were collected and stored with a password-protected laptop computer.

### **Results of Educational Module Intervention**

### **Pre/Post-Test Demographics**

The pre-test demographics are shown below.

**Pre-Test Participant Demographics** 

Demographic	
Total Participants	N = 9
Gender	
Male	2 (22%)
Female	7 (78%)
Age	
25–29	0 (0%)
30–49	7 (78%)
> 50	2 (22%)
Ethnicity	
White	6 (67%)
Black or African American	2 (22%)
Other	1 (20%)
Asian	0 (0%)
American Indian or Alaska Native	0 (0%)
Native Hawaiian or Pacific Islander	0 (0%)

Nine CRNAs participated in the pre- and post-test survey. Most of the respondents in the survey were female (N = 7 or 78%), while males made up (N = 2 or 22%). The nationalities that were represented were: white (N = 3 or 67%), Black or African American (N = 2 or 22%), and other (N = 1 or 11%).

### **Pre-Test Knowledge of Decontamination Procedures for N95 Respirators**

Before the presentation, the participants' knowledge of decontamination procedures for the safe reuse of decontaminated N95 FFRs was assessed with a pre-test. Most participants (N = 8 or 89%) were aware that the standard practices performed by anesthesia providers increased their risk of contracting airborne pathogens and of the potential risk associated with N95 FFR reuse. Similarly, most participants (N = 7 or 78%) understood which factors constituted a viable decontamination method and which methods were considered promising. More than half (56%) of participants were aware of the concerns regarding the effectiveness of UVGI and the same

number of participants understood that factors other than structural damage could reduce filter performance. When asked about other factors that can reduce the effectiveness of decontamination, 89% of participants were aware that the decontamination method could vary by N95 model. When asked about the maximum number of safe reuses of N95 FFRs, 67% of participants answered correctly. Only 33% of participants were likely to reuse N95 FFRs after employing recommended decontamination methods and requested guidelines from their employers for the safe reuse of post-decontaminated N95 FFRs.

### **Differences in Pre-and Post-Test Comprehension**

Questions	Pre-	Post-	
	test	test	Difference
What regular activity performed by anesthesia providers result in aerosolization of secretions placing providers at increased risk of contracting airborne pathogens?	89%	100%	11%
Reuse of N95 respirators can potentially result in:	89%	100%	11%
Viable decontamination methods should:	78%	100%	22%
Promising decontamination methods include:	78%	78%	0%
Concerns regarding UVGI effectiveness are associated with promising decontamination methods include:	56%	66%	10%
Other than structural damage, some decontamination methods can also reduce filter performance by?	56%	62%	6%
Effectiveness of decontamination method may also vary related to?	89%	100%	11%
What is the maximum number of safe reuses post decontamination?	67%	78%	11%
How likely are you to reuse an N95 FFR after employing a recommended decontamination method?	33%	33%	0%
How likely are you to request guidelines from your healthcare facility regarding safe reuse of post decontaminated FFR?	33%	44%	11%

After the pre-test, the participants were asked to view and listen to a PowerPoint presentation that explained this study. After the presentation, the participants completed the post-test. All of the respondents demonstrated a better understanding of the procedures performed by anesthesia providers that resulted in aerosolized secretions and placed the providers at an

increased risk of contracting airborne pathogens (N = 9 or 100%). These activities are mask ventilation, suctioning, intubating, and extubating. After the post-test, all respondents were also able to identify that the reuse of N95 respirators could potentially result in contact transmission and the reduction of the respirator performance. There was a 22% increase in the knowledge of what factors are necessary for a decontamination method to be considered viable. No difference was observed in the pre- and post-survey questions regarding which decontamination methods were promising (N = 9 or 0%). The post-test survey revealed that a higher percentage of participants were able to identify that UV dose penetration is a concern with UVGI decontamination and that neutralization of electrocharged polymer fibers in N95 FFRs by some decontamination methods can reduce the filter performance, a 10% and 6% increase, respectively. After the educational module, 100% of the respondents knew that the decontamination effectiveness varied by the N95 model. A higher percentage of participants were able to identify that the maximum number of safe reuses post-decontamination has yet to be determined and varies by method.

### **Summary**

Overall, the data show an increase in participant knowledge of the reuse of decontaminated N95 FFRs. In each question that assessed a change in ability, there was an increase in correct answers except for the question discussing promising decontamination methods, where the pre- and post-test accuracy remained the same. The data also show no overall change in the likelihood of participants employing a recommended decontamination method. However, there was an increase in the possibility that participants would seek more information regarding guidelines for the safe reuse of N95 FFRs after decontamination.

### Limitations

The major limitation of this study was the small sample size. After an email was sent to all anesthesia providers in the Broward Health Medical Center system, only 9 providers completed the pre- and post-surveys and watched the educational module. Larger sample sizes

may have more clearly reflected the knowledge and attitudes related to the reuse of postdecontaminated N95 FFRs among anesthesia providers at this facility.

### **Future Implications for Advanced Nursing Practice**

Further education is needed for anesthesia providers regarding acceptable methods of decontamination that allow for the reuse of FFRs. Some decontamination methods may be readily available. However, information about the risks related to decontamination methods as well as the compatibility of various N95 models should also be available. Anesthesia providers should understand that each decontamination method has a limited number of cycles, after which reuse is no longer recommended, and that this also varies with the N95 model.

### CONCLUSION

The anesthetist is an integral part of the healthcare team that provides an invaluable service to patients by limiting pain and discomfort during surgical and diagnostic procedures and to other healthcare providers by ensuring the patient's safety while providing optimal surgical conditions. By the very nature of their practice, these providers are at an increased risk of acquiring airborne pathogens. If the reuse of post-decontaminated N95 FFRs continues to conserve supply in the middle of a pandemic, then appropriate information regarding the potential risk associated with reuse and decontamination should be available. Studies seem to indicate that the reuse of N95 FFRs can conserve PPE supply in cases of shortage. However, these conservation methods should be studied further to determine the risk to anesthesia providers. Much remains unknown, which can pose an increased risk to providers who have no choice but to adopt these practices. It is also essential to consider the feasibility of the selected decontamination method and its cost-effectiveness. Organizations should consider the N95 FFR models provided when instructing providers to conserve supplies by decontaminating and reusing FFRs.

Healthcare facilities should also follow OSHA guidelines for the reuse of decontaminated N95 FFRs as part of their respiratory protection programs.

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### Appendix A



### Office of Research Integrity Research Compliance, MARC 414

### MEMORANDUM

To: Dr. Yasmine Campbell CC: Cosma Pochette

From: Maria Melendez-Vargas, MIBA, IRB Coordinator

W

Date: April 7, 2021

Protocol Title: "An educational module comparing decontamination strategies for safe

utilization of post decontaminated N95 filtering facepiece respirators in

anesthesia providers"

The Florida International University Office of Research Integrity has reviewed your research study for the use of human subjects and deemed it Exempt via the Exempt Review process.

IRB Protocol Exemption #: IRB-21-0135 IRB Exemption Date: 04/07/21

TOPAZ Reference #: 110222

As a requirement of IRB Exemption you are required to:

- Submit an IRB Exempt Amendment Form for all proposed additions or changes in the procedures involving human subjects. All additions and changes must be reviewed and approved prior to implementation.
- approved prior to implementation.

  2) Promptly submit an IRB Exempt Event Report Form for every serious or unusual or unanticipated adverse event, problems with the rights or welfare of the human subjects, and/or deviations from the approved protocol.
- and/or deviations from the approved protocol.

  3) Submit an IRB Exempt Project Completion Report Form when the study is finished or discontinued.

Special Conditions: N/A

For further information, you may visit the IRB website at http://research.fu.edu/irb.

MMV/em

### Appendix B



Institutional Review Board - Human Research Protections

Broward Health Medical Center Broward Health Coral Springs Broward Health Imperial Point Broward Health North

Salah Foundation Children's Hospital Broward Health Weston Community Health Services Broward Health Physician Group

DATE: 04/28/2021

TO: Cosma Pochette, BSN

FROM: Broward Health Institutional Review Board

RECORD NUMBER: 2021-056

STUDY TITLE: An educational module comparing decontamination strategies for safe utilization of post decontaminated N95 filtering facepiece respirators in anesthesia providers.

RE: NOT HUMAN SUBJECT RESEARCH DETERMINATION

Dear Cosma Pochette, BSN:

This is to advise you that your project, "An educational module comparing decontamination strategies for safe utilization of post decontaminated N95 filtering facepiece respirators in anesthesia providers." was reviewed on behalf of the Broward Health Institutional Review Board and was declared "not research involving human subjects" based on the definitions provided in the U.S. Department of Health and Human Services Code of Federal Regulations found at 45 CFR 46.102.

Please note, this determination does not absolve the Principal Investigator from complying with other federal, state, or local laws or institutional policies and procedures that may be applicable in the conduct of this project. This determination applies to your project in the form and content as submitted to the IRB for review. Any variations or modifications to this project involving the participation of human subjects must be approved by the IRB prior to implementing such changes. Please maintain a copy of this determination for your records.

Thank you for submitting your project to the IRB for consideration.

The Broward Health Institutional Review Board – FWA00001248 operates in accordance with the Office of Human Research Protections and U.S. Food and Drug Administration (FDA) regulations. The Broward Health Institutional Review Board complies with the ICH guidelines on Good Clinical Practice (GCP) where they are compatible with the FDA and HHS regulations.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Broward Health IRB's records.

### Appendix C



### ADULT ONLINE CONSENT TO FARTICIPATE IN A RESEARCH STUDY

"Use Of A Structured Educational Program To Improve Healthcare Provider Knowledge Of The Comparison Of Decontamination Strategies For Safe Utilization Of Post Decontaminated N95 Filtering Facopiece Respirators"

### SUMMARY INFORMATION

Things you should know about this study:

- <u>Furnese</u>: The purpose of this project is to improve healthcare provider knowledge of the compension of decontamination strategies for safe utilization of post decontaminated N95 filtering facepiece respirators.
- <u>Procedures</u>: If you choose to participate, you will be asked to complete an emailed pretent/posttent and watch a virtual educational voiceover power point.
- Duration: This will take about 20 minutes of your time
- <u>Risks</u>: The risk or discomfort from this research is minimal
- Benefits: The main benefit to you from this research is: Potential benefits to
  perticipants include improved knowledge of safe utilization of post decontaminated
  N95 filtering facepiece respirators.
- <u>Alternatives</u>: There are no known alternatives available to you other than not taking part in this study.
- · Farticination: Taking part in this research project is voluntary.

Please carefully read the entire document before agreeing to participate.

### PURPOSE OF THE PROJECT

You are being asked to be in a quality improvement project. The purpose of this project is to improve healthcare provider knowledge of the comparison of decontamination strategies for safe utilization of post decontaminated N95 filtering facepiece respirators.

### NUMBER OF STUDY PARTICIPANTS

If you decide to be in this study, you will be one of 20 people in this research study.

### DURATION OF THE PROJECT

Your participation will require about 20 minutes of your time.

### PROCEDURES

If you agree to be in the project, we will ask you to do the following things:

 Complete an online 10 question pre test survey via Qualiries, an online survey product for which the URL link is provided

- Review the educational PowerPoint module lasting 10 minutes via Qualitries, and onlye survey for which the URL link is provided
- Complete the online 10 question post test survey via Qualtries, an online survey product for which the URL link is provided

### RISKS AND/OR DISCOMPORTS

The risks are minimal for participating in this project.

### BENEFITS

The following benefits may be associated with your participation in this project: Potential benefits to participants include improved knowledge of safe utilization of post decontaminated N95 filtering facepiece respirators. The overall objective of the program is to increase the quality of healthcare delivery, improving the health indicator of our petients, and increase patient engagement.

### **ALTERNATIVES**

There are no known alternatives available to you other than not taking part in this project. However, if you like to receive the educational material given to the participants in this project, it will be provided to you at no cost.

### CONFIDENTIALITY

The records of this project will be kept private and will be protected to the fullest extent provided by law. If, in any sort of report, we might publish, we will not include any information that will make it possible to identify you as a participant. Records will be stored securely, and only the project team will have access to the records.

### COMPENSATION & COSTS

There is no cost or payment to you for receiving the health education and/or participating in this project.

### RIGHT TO DECLINE OR WITHDRAW

Your perticipation in this project is voluntary. You are free to perticipate in the project or withdraw your consent at any time during the project. Your withdrawal or lack of perticipation will not affect any benefits to which you are otherwise entitled. The investigator reserves the right to remove you without your consent at such time that they feel it is in the best interest.

### RESEARCHER CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues relating to this research project, you may contact Cosma Pochette at 305-467-3277, epoch502@fin.edu or Dr. Yazmine Campbell, 305-348-9894 yearmbel@fin.edu.

IRB CONTACT INFORMATION

If you would like to talk with someone about your rights of being a subject in this project or about ethical issues with this project, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at <a href="mailto:ori@fin.edu">ori@fin.edu</a>

### PARTICIPANT AGREEMENT

I consent by perticipating in the survey. I have read the information in this consent form and agree to participate in this project.

### Appendix D



### Protest and Porttest Questionnaire:

### Post Decontamination Reuse of N95 Fittering Facepiece Respirators

### INTRODUCTION

The primary sim of this QI project is to improve the knowledge of CRNAs pertaining to the comparison of decontamination strategies for safe utilization of post decontaminated N95 filtering facepiece respirators (FFR) in anesthesis providers. Please answer the question below to the best of your ability.

### PERSONAL INFORMATION

1.	Goader: Male	Female	Other			
2.	Age:					
3.	Ethnicity:					
	Hispanic	Cancasian	African American	Acian		
Other						
4.	Podtine/Title:					
	Position/Title:			Masters		
		: Associates		Masten		
5.	Level of Education	: Associates	Bachelors	Masters		

Pege 1 of 4

### QUESTIONNAIRE

- What regular activity performed by unesthesis providers result in acrosolization of secretions placing providers at increased risk of contracting airborns pathogons?
  - s. Mask ventilation
  - b. Suctioning
  - c. Intubating
  - d. Extubeting
  - e. All the above
- 2. Rouse of N95 respirators can potentially result in
  - a. Contact transmission
  - b. Self-inoculation
  - c. Reduction in respirator performance
  - d. All the above
- 3. Viable decentamination methods should:
  - s. Maintain structural integrity of FFR.
  - b. Maintain functional integrity of FFR
  - c. Inactivate viruses or disease causing microorganisms
  - d. Produce minimal to no user discomfort
  - e. All the above
- 4. Promising decontamination methods include:
  - a. Moist host
  - b. Ultraviolet germicidal irradiation (UVGI)
  - c. Soep and water

Page 2 of 4

- d. Bleach
- e. All the above
- f. Only a and b
- 5. Questions regarding UVGI effectiveness are associated with:
  - a. User discomint
  - b. UV dose penetration
  - c. Harmful radiation to user
  - d. All the above
- 6. Other than structural damage, some decentamination methods can also reduce filter

### performance by:

- a. Neutralizing the electrocharged polymer fibers in the FFR.
- b. Clogging the filter
- c. Attracting more viral or pathogenic microorganism particles
- 7. Effectiveness of decentamination method may also vary related to:
  - a. Facility where decontamination is performed
  - b. Model of N95 FFR
  - c. Both a and b
- 8. What is the maximum number of sale reuses post decontamination?
  - a. 10
  - b. 5
  - The number of cycles of decontamination is yet to be determined and varies depending on method and model of N95 used.

Page 3 of 4

### 9. How likely are you to reuse an N95 FFR after employing a recommended

### decontemination method?

- a. Most likely
- b. Somewhat likely
- c. Somewhat unlikely
- d. Most unlikely

### 10. How likely are you to request guidelines from your healthcare facility regarding safe

### reuse of post decentaminated FFR?

- a. Most likely
- b. Somewhat likely
- c. Somewhat unlikely
- d. Most unlikely

### Appendix E



An educational module comparing decontamination strategies for safe utilization of post decontaminated N95 filtering facepiece respirators in anesthesia providers.

Cosma Pochette MSN, RN

Florida International University
Nicole Wertheim College of Nursing and Health Sciences

FLORIDA INTERNATIONAL UNIVERSITY

# Problem Epidemiology

- · Global pandemic
- Critical shortage of personal protective equipment (PPE)
  - Healthcare organizations and regulatory bodies explore unconventional options to conserve remaining PPE supply.
- · Increased risk of anesthesia providers
  - Intubating, mask ventilating, suctioning, and extubating result in aerosolization of secretions.<sup>2</sup>
- · Regulating bodies
  - Center of Disease Control and Prevention (CDC) <sup>3</sup>
  - National Institute of Occupational Safety and Health (NIOSH) <sup>3</sup>
  - Occupational Safety and Drug Administration (OSHA)
  - Food and Drug Administration (FDA) <sup>3</sup>

FIU

# Problem Epidemiology

- · Approaches to conservation
  - Extended use 4
  - Reuse<sup>4</sup>
- · Goal of decontamination
  - Inactivation of microbe <sup>5</sup>
  - Maintain structural integrity <sup>5</sup>
  - Maintain functional intergrity 5
  - Minimal chemical residues <sup>6</sup>
- · Possible risk to anesthesia providers



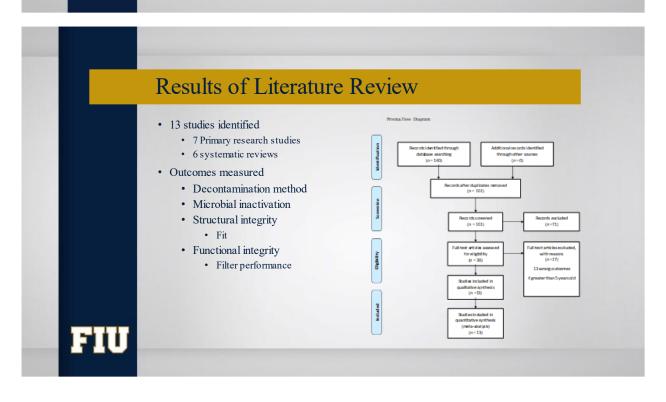


# PICO Clinical Question

In anesthesia providers, does the reuse of postdecontaminated N95-type filtering facepiece respirators (FFRs) increase the risk of airborne diseases in comparison to anesthesia providers who use disposable one-time use N95-type filtering facepiece respirators (FFRs)?



# Search Strategy Identify keywords Anesthesia provider, reuse, post -decontamination, N95 FFR Databases CINAHL, Embase, MEDLINE/PubMed Inclusion and exclusion criteria RCTs, primary studies, systematic reviews Greater than 5 years old, language other than English, full text articles Identify duplicates RefWorks find duplicate function Full text screening Level of evidence and quality John Hopkins Research Evidence Appraisal Tool



# **Decontamination Methods**

- Ultraviolet germicidal irradiation (UVGI)
- Vaporized hydrogen peroxide (VHP)
- Autoclave
- Microwave generated steam (MGS)
- 70% ethanol/70% isopropyl/100% isopropyl
- Moist heat
- · Dry heat
- Ethylene oxide
- (EtO)
- Hydrogen peroxide gas plasma (HPGP)
- Antiseptic wipes
- Liquid hy drogen peroxide
- Bleacl
- Dimethyldioxirane (DMDO)
- Soap and water







# Results Educational Module

- · Educational module
  - · Qualtrics platform
  - Pre-assessment
  - Presentation
  - · Post-assessment
- Results
  - 9 CRNAs
  - 10 survey questions
  - Overall increase in knowledge





# **Implications**

- Decontamination methods can be used
- Promising decontamination methods
  - HPV
  - Moist heat
  - · Dry heat
  - UVGI
- Limited provider knowledge
- Providers may be more inclined to employ decontamination methods with more education and guidance from employers and regulatory bodies.



# Conclusion

- Decontamination may be a feasible option for safe PPE conservation
- More research in needed
  - Different N95 models
  - · Number of safe cycles







FIU

# Quality Improvement Plan

- OSHA requires Respiratory Protection Program
- CDC optimization strategies
  - · Conventional capacity
  - Contingency capacity
  - Crisis Capacity
- FDA provides emergency use authorization (EUA)
  - · Determines approved decontamination method
  - · HPV and UVGI







# Quality Improvement Plan

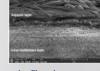
- Respiratory Protection Plan to include:
- Education on:
  - NIOSH approved N95 FFR
  - Promising decontamination methods
    - HPV
    - UVGI
    - Moist and dry heat
- Training on reuse of FFR
  - Limitations
  - Number of recommended cycles
  - N95 models





# N95 Facial Facepiece Respirator Education

- Combines particle filtering and a tight seal to effectively prevent inward transport of infectious particles.
- N94
  - N: nonresistant to oil <sup>7</sup>
  - 95: filters at least 95% of airborne particles greater than 0.3 micrometer
- · Mask construction
  - · Quasi-rigid outer layer
    - Provides support and mechanical filtration <sup>7</sup>
  - Polypropylene inner layer
    - Polypropylene is an electret able to hold a charge. Provides electrostatic filtration.
    - Significant part of FFR filtering capacity 7
  - · Metallic nose band
  - Elastic strap





# Promising Decontamination Methods

- HPV
  - Limitations
    - · Availability of resources
    - Ineffective in cellulose containing FFR
- Moist heat
- · Dry heat
  - · Heat range
- UVGI
  - Limitations
    - Unknown depth of penetration into inner layers of FFR
    - Undetermined minimum effective dose



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### Appendix F



### An Evidence Based Comparison of Decontamination Strategies for Safe Utilization of Post Decontaminated N95 Filtering Facepiece Respirators in Anesthesia



Cosma Pochette RN, BSN, Yasmine Campbell DNP, CRNA, APRNenisleimis Fernandez DNP, CRNA, APRN **Nicole Wertheim College of Nursing and Health Sciences** 

### **BACKGROUND**

Considering the current pandemic threatening a limited supply of N95 FFR, many anesthesia providers have resorted to decontamination and reuse of single-use FFR. There is limited evidence on the relative safety and efficacy of the different relative safety and emicacy of me almerent decontamination methods. The lack of concrete evidence and guidance regarding the reuse of FFR is a constant cause for concern for anesthesia providers, who are at risk of exposure to airborne diseases while working in the airway of patients.

### **CLINICAL SIGNIFICANCE**

Due to scarce resources of N95 filtering facepiece respirators (FFR) in healthcare systems, it is necessary to educate anesthesia providers on decontamination strategies for their wellbeing.

### METHODOLOGY



### PICO

In anesthesia providers, does the reuse of postdecontaminated N95-type filtering facepiece respirators (FFRs) increase the risk of airborne diseases compared to anesthesia providers who use disposable one time use N95-type filtering facepiece respirators (FFRs)?

### **Decontamination of Respirators & Masks** for the General Public, Health Care Workers And Hospital Environments 10 Cycles results in: ✓ Highly Efficient ✓ Fit is maintained \* + \* Steam Heat 30 min.

https://www.apsf.org/article/covid-9-pandemicdecontaminationof-respirators-and-masks-for-the-general-publishealth-care-workers-and-hospital-environments/							
Literature Review Table							
Author	Design Sample	Major findings					
Liao L, Xiao W, Zhao M, et al.	Pre-test-post-test control group experimental design	Solution-based method should be avoided since they degrade static charge. The heating method can preserve litter efficiency. U/GI may be useful, but the output dose needs to determined.	be				
Steinberg BE, Aoyama K, McVey M, et al.	Systematic review	Heat treatment up to 50 cycles did not decrease the filter efficiency. Autodave degrades integrify. Hydrogen peroxide effective in deactivating virus. UV unclear if it penetrated virus.	the				
Wharton K, RiekerM.	Pre-test-post-test control group experimental design	Moist heat and HPV are relatively reliable methods of decontamination. Chemical decontamination methods, such as HPV, were found to be more structurally destructive than physical decontamination methods.					
Viscusi DJ, Bergman MS, EimerBC, et al.	Pre-test-post-test control group experimental design	Bleach or EtO decontamination methods not recommended mainly due to the irritation and potential harm to the user of the FFR. HPV is limited by cellulasand products. Microwave oven irradiation to produce dry heat caused structural deformation in some models.					

### RESULTS

An extensive literature review revealed An extensive literature review revealed that solution-based methods such as hydrogen peroxide and bleach in decontamination should be avoided because it degrades the integrity and efficiency of the masks. Heat minimally alters the integrity of the mask however after 20-50 cycles, there was evidence of decrease efficiency and mask degradation of the FFR. Other factors such as multiple dromines also immarked the integrity of the donning also impacted the integrity of the FFR. A statistical analysis showed that the fit gradually decreased after donning the FFR 5 times. The most effective methods noted within this evidence-based review is gravity steam processing along with ultraviolet irradiation, moist heat microwave generated steam and hydrogen peroxide vapor.

### RECOMMENDATIONS **FOR PRACTICE**

CRNAs should make informed decisions on N95 FFRs based on the decontamination method used. Facilities should provide data on decontamination practices at the hospital. It is recommended that FFRs not be re-used > 5 times due to possible degradation and decreased fit.

Available upon request cpoch002@fiu.edu

### Appendix G



 $\Delta$  and recording and recording and recording and  $\Delta$ 

is pleased to acknowledge

Cosma Pochette, RN, BSN; Yasmine N. Campbell, DNP, CRNA, APRN; Yenisleimis Fernandez, DNP, CRNA, APRN

for research presented at the
AANA Foundation State of the Science General Poster Session
88th AANA Annual Congress
August 13-17, 2021

Austin, TX





Ron Castaldo, PhD, CRNA Chair, AANA Foundation

Celebrating 40 years of Nurse Anesthesia Research and Education

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# Appendix H

https://fiu.qualtrics.com/jfe/form/SV\_d6iKWKv9LgefbOm