

N95 RESPIRATOR DECONTAMINATION METHODS UNPROVEN AND UNSAFE

An Updated Review of the Scientific Literature



National
Nurses
United

SUMMARY

Nurses and other health care workers are in the midst of responding to the worst global pandemic in recent history. Because of their employers' dangerous practices, nurses and other health care workers are becoming infected at high rates and many have died. N95 filtering facepiece respirators are vital pieces of equipment, necessary to protect nurses and other health care workers from exposure to potentially life-threatening infection.

Many hospitals and other health care employers have turned to decontaminating single-use N95 filtering facepiece respirators for reuse, given reports of personal protective equipment (PPE) shortages during the COVID-19 pandemic. Many states have now begun reopening but have not taken substantial action to increase production of N95 respirators and other essential PPE. Instead, states and employers are relying on potentially dangerous decontamination methods to reuse single-use PPE.

In March 2020, National Nurses United (NNU), the largest labor union for registered nurses in the United States, published an evaluation of the available scientific literature on methods to decontaminate N95 respirators: *N95 Respirator Decontamination and Reuse is Unsafe* [1][2]. NNU's initial evaluation found that no decontamination method had been shown to be both safe and effective.

Since NNU's first evaluation, multiple studies have been published evaluating a variety of decontamination methods. Therefore, NNU conducted a follow-up review to evaluate the newly available scientific literature on methods to decontaminate N95 respirators published up to July 3, 2020. NNU's second review confirms the findings of the first review: no decontamination method has been shown to be safe or effective. In fact, several methods appear to be ineffective, to damage N95 respirators, and may pose a hazard to workers wearing decontaminated N95 respirators.

Despite a lack of evidence establishing safety and effectiveness, nurses report widespread adoption of PPE decontamination and reuse practices by their employers. NNU recently surveyed nurses across the U.S. about the impacts of reopening on their working conditions: 54% of hospital nurses reported their employer has implemented a decontamination program to "clean" single-use PPE between uses [3]. Only 12% of nurses were notified by their employer of the risks associated with using decontaminated PPE.

Employers' embrace of untested and unproven decontamination methods that may damage N95 respirators or present a hazard to nurses is irresponsible, unethical. It means, in effect, that employers are experimenting on nurses and other health care workers without their consent.

No decontamination method has been shown to be safe or effective. In fact, several methods appear to be ineffective, to damage N95 respirators, and may pose a hazard to workers wearing decontaminated N95 respirators.

DECONTAMINATION METHODS MUST BE SHOWN TO BE BOTH SAFE AND EFFECTIVE

For a decontamination method to be shown to be both safe and effective it must meet the following criteria:

- (1) The decontamination method must effectively inactivate SARS-CoV-2 and other pathogens of concern in health care settings;
- (2) The decontamination method must not degrade the performance of the respirator including filtration, structural integrity, and face seal; and

- (3) The decontamination method must not introduce an additional hazard to the worker wearing the decontaminated respirator.

If an employer implements a decontamination method without full validation of its efficacy and safety, then that employer is, in effect, conducting an experiment on their employees.

EMPLOYERS MUST PROVIDE A SAFE AND HEALTHFUL WORKPLACE

Employers are legally and morally obligated to provide a safe and healthful workplace to employees. To prevent exposure to and transmission of COVID-19, health care employers must implement comprehensive precautions, based on the precautionary principle. The precautionary principle states that we should not wait for scientific proof of harm before taking action to protect people's health.

Health care employers must implement comprehensive workplace protections to prevent health care worker exposure to SARS-CoV-2, including procedures to screen all patients for SARS-CoV-2 infection using testing, symptoms, and epidemiological history, establishing designated COVID-19 units, and converting rooms, units, floors, or entire facilities to negative pressure. Nurses and other health care workers must also be provided full, optimal PPE for all encounters with COVID-positive patients

and persons under investigation. A minimum of an N95 filtering face piece respirator must be provided to nurses and other health care workers caring for patients with suspected or confirmed COVID-19, in addition to eye protection, coveralls or isolation gowns, gloves, and other protections [4].

Where N95 respirators are not available, employers should turn to respiratory protection designed to be reused and decontaminated safely, including powered air-purifying respirators (PAPRs) and elastomeric respirators. A recent study reported on the implementation of an elastomeric respirator and PAPR program at a hospital system in Pennsylvania. In addition to providing a higher level of protection to employees, the elastomeric respirator and PAPR program was ten times cheaper than a program to decontaminate and reuse N95 respirators would have been over the course of just one month [5].

FDA EMERGENCY USE AUTHORIZATIONS DO NOT INCLUDE FULL SAFETY AND EFFECTIVENESS EVALUATIONS

The U.S. Food and Drug Administration (FDA) has granted emergency use authorizations (EUA) for multiple systems to decontaminate N95 filtering facepiece respirators.

What is an emergency use authorization? The FDA may grant an emergency use authorization to allow unapproved medical products to be used when a public health emergency is declared and remains in effect until the precipitating emergency has ended. An EUA does not constitute FDA approval.

Does an EUA mean the product or process is safe and effective? No. Because EUAs are not the same as traditional FDA approvals or clearance, they have

a much lower burden of evidence. The process used by the FDA to issue an EUA lacks scientific rigor because the safety and effectiveness of the product do not need to be proven.

What are the conditions of EUA authorization? The FDA establishes safeguards or conditions for each EUA that must be followed, including information on emergency use, fact sheets, and reporting and monitoring of adverse events. Nurses must be adequately informed if a health care facility plans to or is currently decontaminating N95 respirators. This applies whether an employer is conducting decontamination onsite or has outsourced to another company.

LITERATURE SEARCH AND INCLUSION CRITERIA

Scientific papers were gathered using multiple search engines, including Google Scholar, Pubmed, and the World Health Organization's COVID-19 database [6]. References and citing papers were also reviewed for inclusion. Papers were included in our review if they met the following inclusion/exclusion criteria:

- The study must evaluate one of the three criteria needed to establish the safety and effectiveness of a decontamination method (see page 3). If the study reported only on feasibility or procedures to set up a decontamination method, it was excluded.
- The study must evaluate impact on N95 filtering facepiece respirators. If the study evaluated only surgical masks or KN95s, then it was excluded.
- If the full text of the study was not available, the study was excluded. The review was limited to studies available in English. Close review of a study's methodology is vital to understanding the meaning and implications of its results.

RESULTS

NNU's review of the scientific literature included 57 papers evaluating a wide variety of decontamination methods (see Table 1). Overall, the scientific literature on decontamination methods is fractured and lacking. Despite a significant number of studies, very little can be said with surety about the effectiveness and safety of decontamination methods.

Nearly every study evaluated a distinct decontamination method. Even for a particular decontamination system, e.g., those manufactured by STERRAD, there were variations in the equipment used between studies. Even slight variations between methods can impact efficacy and safety. For example, slight variations in temperature, UV dose, or hydrogen peroxide vapor concentration can mean the difference between effectiveness, respirator damage, or not.

Additionally, nearly every study had significant methodological issues that limit the applicability of their results to real-life situations. Common methodological issues include:

- Most studies that inoculated N95 respirators do so with liquid media rather than by drawing aerosols containing the virus or bacteria test organisms through N95 respirators. Liquid interacts with the N95 filter matrix differently from aerosols. In real-life scenarios, direct inoculation with liquid media is an unlikely source of contamination for N95 respirators. Liquid splashes or sprays may occur but, in those situations, N95 respirators should be discarded as soiled per the FDA's EUAs. N95 respirators are designed to filter out harmful particles, such as those containing virus. A significant concern for many decontamination methods is whether they successfully eradicate pathogens trapped within the N95 filter matrix. This difference between study and real-life conditions means results may not be directly applicable to real-life exposure

scenarios and more study is required to establish effectiveness.

- Most studies used pristine N95 respirators that had not been worn or had at most been fit tested once. This does not reflect real-life circumstances in health care settings during the COVID-19 pandemic where N95 respirators are commonly being used for one or more shifts before being decontaminated. Repeated use of N95 respirators is known to damage these respirators [7][8][9]. This difference between study and real-life conditions means results are not directly applicable to real-life scenarios and more study is required.
- Most studies evaluated decontamination methods using a limited number of N95s and a limited number of different models of N95 respirators. There are hundreds of N95 filtering facepiece respirators that have been approved by the National Institute for Occupational Safety and Health (NIOSH). The studies included in this evaluation only evaluated a tiny fraction of the N95 models available for use in workplaces in the United States.

Table 1 summarizes the scientific literature evaluating the safety and effectiveness of decontamination methods for N95 respirators. If even one study found inadequate effectiveness, damage to an N95 respirator, or indication of potential hazard to wearers, that method is marked as "Failed." Evidence is marked as "insufficient" if there was some evidence but not enough to fully evaluate the required criteria. If none of the included studies evaluated a criterion, the evidence is marked as "none." N95 respirators are life-saving devices and the safety and effectiveness of a decontamination method must be fully assured before implementation.

| Table 1: Studies Included in NNU's Review | | Summary Evaluation | | |
|--|---|-----------------------------|-----------------------------|--------------------------------|
| Decontamination Method | Studies Evaluated | Criterion #1: Effectiveness | Criterion #2: Impact on N95 | Criterion #3: Hazard to Wearer |
| HYDROGEN PEROXIDE | | | | |
| Battelle | [10]; [11] | ? | X | ? |
| STERIS | [12]*; [13]; [14]*; [15]* | ? | X | - |
| STERRAD | [12]*; [14]*; [16]; [17]; [18]; [19]* | ? | X | ? |
| SteraMist | [20]; [21]* | ? | ? | ? |
| Bioquell | [16]; [19]*; [22]*; [23] | ? | ? | ? |
| Other | [24]; [25]*; [26]*; [27]; [28]; [29]; [30] | X | X | ? |
| DRY HEAT | | | | |
| Low temperatures, <80°C | [27]; [31]; [32]*; [33]; [34]*; [35]; [36]*; [37]*; [38] | X | X | - |
| Middle temperatures, 80-100°C | [12]*; [19]; [33]; [39]; [40]* | X | X | - |
| High temperatures, >100°C | [18]; [41]; [42]; [43]; [44] | X | X | - |
| MOIST HEAT | | | | |
| Autoclave | [12]*; [14]*; [18]; [40]*; [41]; [42]; [43]; [45]; [46]; [47]; [48]*; [49] | ? | X | - |
| Microwave/microwave-generated steam | [16]; [18]; [44]; [50]; [51] | ? | X | - |
| Other humid heat | [12]*; [19]*; [16]; [32]*; [51]; [52]*; [53]* | X | X | - |
| Steam | [33]; [35]; [39]; [54]*; [55]; [56] | X | X | - |
| RADIATION | | | | |
| UV-C | [12]*; [16]; [17]; [18]; [25]; [30]; [31]; [33]; [35]; [36]*; [43]; [51]; [57]; [58]*; [59]*; [60]; [61]; [62]* | X | X | ? |
| Other UV | [17]; [19]*; [27] | X | X | ? |
| Gamma radiation | [49]; [63]* | - | X | - |
| CHEMICALS | | | | |
| Ethylene oxide | [14]*; [17]; [18]; [19]* | ? | ? | ? |
| Ethanol/isopropyl alcohol | [12]*; [18]; [27]; [30]; [33]; [35]; [42]; [43]; [47]; [64]* | X | X | - |
| Bleach/chlorine-based solutions | [16]; [17]; [18]; [24]; [33]; [42]; [43] | ? | X | X |
| Hydrogen peroxide liquid | [16]; [18] | - | ? | - |
| Ozone | [65]*; [66]*; [67] | ? | X | - |
| Peracetic acid | [14]*; [31]; [68]* | X | ? | ? |
| Soap and Water | [18] | - | X | - |
| * marks pre-prints; - marks none, ? marks insufficient, X marks failed | | | | |

Section 1: Hydrogen Peroxide

Multiple methods using hydrogen peroxide vapor are available commercially. While most studies on hydrogen peroxide vapor evaluated five major brands, there was significant variability in the specific method evaluated in each study. While hydrogen peroxide vapor likely kills SARS-CoV-2 and other pathogens under certain conditions, it is unclear

whether these methods kill SARS-CoV-2 present on and trapped within an N95 respirator. Several methods utilizing hydrogen peroxide vapor may damage N95 respirators. Hydrogen peroxide residue may pose a hazard to workers wearing a decontaminated N95 respirator.

Battelle

Battelle's methods have not been proven to be safe or effective. In fact, Battelle's methods may damage N95 respirators and may pose a hazard to workers wearing an N95 decontaminated by Battelle.

Battelle's Critical Care Decontamination System was the first N95 decontamination method to be issued an emergency use authorization by the FDA [69]. The U.S. federal government has issued a \$400 million contract to make Battelle's systems available across the country [70].

Battelle's process uses vaporized hydrogen peroxide to decontaminate N95 respirators. Tens of thousands of N95s are placed inside a large shipping container and hydrogen peroxide is vaporized into the container. The N95s remain in the chamber for a period of time. They are then removed and returned to the originating health care facility or to another health care facility [10, 11].

Battelle Criterion #1 (Effectiveness): Insufficient

Battelle provides insufficient evidence to fully evaluate the effectiveness of this method. Battelle states that they have verified their process on SARS-CoV-2 but the tests they used are insufficient. They tested their method on small cut-outs of the N95 filter material ("coupons"). This means they did not test the efficacy of their method on the straps, nose clip, folds and seams, foam, and other parts of a whole N95.

Battelle cites several additional studies to show the efficacy of their process on other pathogens, but many of these studies actually used a different method (STERIS) and may not be fully comparable to Battelle. While hydrogen peroxide likely kills SARS-CoV-2 under some conditions, it is not clear whether Battelle's method kills SARS-CoV-2 present in and on N95 respirators.

There are several additional concerns about Battelle's methodology that may impact the effectiveness:

- It is unclear whether hydrogen peroxide levels are evenly distributed throughout the large container. Battelle put chemical indicators in 4 corners and 1 in center during their validation tests, according to their technical bulletin, but that may be insufficient given the size of these operations [11].
- Battelle's photos show inconsistent placement of the N95 respirators. Other studies have found the orientation of the N95s to be important to whether the hydrogen peroxide reaches all surfaces [71]. Battelle states that placement is not a factor but does not seem to have evaluated this part of their process.

Battelle Criterion #2 (Impact on N95): Failed

Battelle maintains that their process does not degrade N95 respirators for up to 20 decontamination cycles. However, other studies have used methods similar to Battelle's and found that N95 performance is impacted after two or three cycles [72].

Battelle's own research showed degradation of N95s after decontamination. One model's elastic straps were elongated and degraded (textured surface). Another model had a char-like odor after decontamination. A third model had a hard, brown spot that appeared after decontamination. Battelle did not investigate and deemed this N95 good-to-go. Other models' fit was damaged and wearers reported feeling air leakage around the nose after decontamination.

Battelle uses a physical and visual inspection to determine whether respirators are impacted by the decontamination process. This is a severely flawed methodology. You cannot tell just by looking if the N95 filter or fit has been degraded. This is like if a car mechanic just looked at the outside of a car and said it looks fine.

**? Battelle Criterion #3 (Hazard to Wearer):
Insufficient**

Battelle has only conducted limited evaluation of off-gassing of hydrogen peroxide from decontaminated N95 respirators. Breathing in hydrogen peroxide can cause upper airway irritation, hoarseness, shortness of breath, and a sensation of burning

or tightness in the chest. Exposure to high concentrations can cause severe mucosal congestion of the trachea and bronchi and delayed accumulation of fluid in the lungs. Prolonged dermal exposure can cause irritation and temporary bleaching of skin and hair.

STERIS

STERIS decontamination methods have not been proven to be safe or effective. In fact, STERIS methods appear to damage N95 respirators and may pose a hazard to workers wearing an N95 decontaminated by STERIS.

The FDA issued an EUA for specific STERIS systems on April 9, 2020 and updated the EUA on June 6, 2020. The FDA has authorized the use of the following STERIS systems to decontaminate N95 respirators: V-PRO 1 Plus, V-PRO maX, V-PRO maX2, V-PRO 60, and V-PRO s2 [73].

Four studies evaluated four different systems manufactured by STERIS: the LTS-V system, V-PRO, V-PRO max, and the ARD system used in a glove box [12-15]. These methods vaporize hydrogen peroxide into a chamber. Studies evaluating STERIS did not always specify which cycle was used on the different systems, limiting our ability to fully compare and synthesize the literature on STERIS.

**? STERIS Criterion #1 (Effectiveness):
Insufficient**

Two studies used SARS-CoV-2 as the test organism to evaluate the effectiveness of a STERIS system [13, 14]. While both studies reported a significant reduction in SARS-CoV-2 after decontamination, they used a methodology that limits the application of their results. These studies only evaluated the effectiveness on small coupons cut from N95 respirators, not full N95 respirators. None of the included studies evaluated the effectiveness of a STERIS system using bacterial test organisms. Two studies did not evaluate the effectiveness of the decontamination method [12, 13].

**X STERIS Criterion #2 (Impact on N95):
Failed**

Damage to N95 respirators was observed in several studies. Methodological issues were present in multiple evaluations of the impact of STERIS systems on N95 fit, filtration, and function. The four studies that evaluated STERIS systems only assessed seven N95 models, which is a very limited evaluation considering the hundreds of N95 respirators approved by NIOSH. Two studies conducted a limited evaluation of the impact on both N95 fit and filtration using NIOSH protocols [13, 15]. Chen et al. [12] only evaluated impact on filtration while Kumar et al. [14] only looked at fit. Damage was noted in three studies, including decreased filtration after treatment, bleeding of ink on one model, and reports that reprocessed masks were tighter and more uncomfortable on the face [12-14].

**■ STERIS Criterion #3 (Hazard to Wearer):
None**

None of the four studies included in our review evaluated the potential for the STERIS systems to pose a hazard to the worker wearing the decontaminated N95. Breathing in hydrogen peroxide can cause upper airway irritation, hoarseness, shortness of breath, and a sensation of burning or tightness in the chest. Exposure to high concentrations can cause severe mucosal congestion of the trachea and bronchi and delayed accumulation of fluid in the lungs. Prolonged dermal exposure can cause irritation and temporary bleaching of skin and hair.

STERRAD

STERRAD decontamination methods have not been proven to be safe or effective. In fact, STERRAD methods appear to damage N95 respirators and may pose a hazard to workers wearing an N95 decontaminated by STERRAD.

The FDA issued an EUA on April 11, 2020 and updated on June 6, 2020 for STERRAD systems manufactured by Advanced Sterilization Products, Inc. [74]. Approved STERRAD systems include: 100S, NX, and 100NX. The EUA specifies which type of cycle must be used with each model when decontaminating N95 respirators.

Six studies evaluated three different STERRAD systems: 100S, NX, and 100NX [12, 14, 16-19]. These STERRAD systems use hydrogen peroxide gas plasma. Hydrogen peroxide gas plasma is created when hydrogen peroxide is turned into a gas and then the gas molecules are excited using radiation to create free radicals. The studies evaluating STERRAD systems did not all specify which cycle was used in their studies, limiting our ability to fully compare and synthesize the literature on STERRAD.

STERRAD Criterion #1 (Effectiveness): Insufficient

Only two studies evaluated the effectiveness of STERRAD systems. One of these studies used SARS-CoV-2 and other viral test organisms and the other used a combination of viral and bacterial test organisms [13, 18]. While both studies reported a significant reduction in test organisms after decontamination, they used a methodology that limits the application of their results. These studies only evaluated the effectiveness on small coupons cut from N95 respirators, not full N95 respirators. The remaining four studies did not evaluate the effectiveness of STERRAD systems.

STERRAD Criterion #2 (Impact on N95): Failed

Damage to N95s was observed in several studies. Methodological issues were also present in several studies that evaluated the impact of STERRAD systems on N95 fit, filtration, and function. The six studies evaluating STERRAD systems only specified eight N95 models; several studies did not report the specific N95 models they evaluated.

Four studies evaluated the impact of STERRAD methods on N95 filtration [12, 16, 18, 19]. Bergman et al. [16] reported significant damage to the filtration of N95s after treatment that correlated with the order N95s were stacked in the decontamination pouches. When Bergman et al. ran a follow-up cycle with N95s packaged individually, they reported that half of the N95s were still damaged by the STERRAD process. Other studies also reported significant damage to N95s, including severe degradation of filtration ability, damage to nose foam leading to leakage around the nose, and tarnished nose pieces [12, 18].

One study evaluated the impact of STERRAD system on N95 fit only, reporting that N95s failed after just one cycle of decontamination [14].

STERRAD Criterion #3 (Hazard to Wearer): Insufficient

Only one study evaluated the potential for STERRAD systems to pose a hazard to the worker wearing the decontaminated N95 [17]. While Salter et al. concluded that there was no health risk posed to N95 users, they noted significant variation between N95 models in the amount of hydrogen peroxide detected on the N95s. In our view, Salter et al.'s results reinforce concerns about potential hazards to users of decontaminated N95s and underline the need for each specific N95 model to be evaluated for compatibility with each decontamination method before use.

SteraMist

SteraMist decontamination methods have not been proven to be safe or effective. In fact, SteraMist methods may damage N95 respirators and may pose a hazard to workers wearing an N95 decontaminated by SteraMist.

The FDA has not issued an EUA for SteraMist decontamination systems that utilize hydrogen peroxide (as of July 1, 2020).

Two studies evaluated two different systems sold by SteraMist: an iHP ceiling unit and a SteraMist Surface Unit [20, 21]. SteraMist systems create ionized hydrogen peroxide mist.

SteraMist Criterion #1 (Effectiveness): Insufficient

Both studies reported significant reduction in test organisms but had significant methodological issues. One study placed biological indicator strips near PPE being decontaminated, which is a methodology that severely limits the applicability of their results and tells us little about decontamination of N95 respirators by that system [21]. The other study inoculated N95s with a liquid containing a viral test organism

only [20]. Liquid inoculation does not directly translate to a real-life scenario where an N95 respirator may have pathogens trapped in filter media in addition to present on the surface (see page 5 for a more detailed description of this limitation).

SteraMist Criterion #2 (Impact on N95): Insufficient

Only one study evaluated the impact of a SteraMist system on filtration and fit of N95 respirators and reported no significant changes [21]. However, Cramer et al. only evaluated five N95 models, a limited sample.

SteraMist Criterion #3 (Hazard to Wearer): Insufficient

Only one study evaluated the potential for a SteraMist system to pose a hazard to the worker wearing the decontaminated N95. This study measured the level of hydrogen peroxide near the N95 surface and reported it dropped to undetectable levels at three hours [20]. However, it is important to note that this study only evaluated four total N95s and the authors noted that off-gassing may be variable.

Bioquell

Bioquell decontamination methods have not been proven to be safe or effective. In fact, Bioquell methods may damage N95 respirators and may pose a hazard to workers wearing an N95 decontaminated by Bioquell.

The FDA has not issued an EUA for Bioquell decontamination systems that utilize hydrogen peroxide (as of July 1, 2020).

Four studies evaluated four different Bioquell decontamination systems: BQ-50, Q-10, Clarus, and a Bioquell facility. These Bioquell systems create hydrogen peroxide vapor.

Bioquell Criterion #1 (Effectiveness): Insufficient

Two studies evaluated the effectiveness of Bioquell systems. One used aerosolized viral test organisms to inoculate N95 respirators and found that the Bioquell system they evaluated eradicated the viral

indicators [22]. The other study's methodology was severely limited, inoculating N95 coupons with liquid containing bacterial and viral indicators [19]. The remaining two studies evaluating Bioquell systems did not assess effectiveness of these systems to decontaminate N95 respirators.

Bioquell Criterion #2 (Impact on N95): Insufficient

All four studies evaluating Bioquell systems had significant methodological issues. In total, the four studies evaluated only five specified N95 models plus an unknown number of unspecified models. One reported only using visual inspection to evaluate impact on N95 respirators [22]. Wigginton et al. tested the impact on N95 filtration using a custom set-up based on, but deviating significantly from, NIOSH protocols [19]. This limits our ability to understand and compare their results to other studies. Bergman et al. evaluated filtration but not fit and reported no significant difference between treated N95s and controls [16]. However, Bergman et al.

repeatedly submerged control N95s in deionized water and allowed to dry, which could have damaged the control N95 respirators and skewed the results of their study. The fourth study evaluating Bioquell systems looked only at fit for two individuals, reporting that N95s passed quantitative fit tests after decontamination [23]. Fit testing on two individuals is not representative given wide variations in face shape and size that impact fit with different N95 models.

Bioquell Criterion #3 (Hazard to Wearer): Insufficient

Only one study evaluated the potential for a Bioquell system to pose a hazard to the worker wearing the decontaminated N95 [23]. Schwartz et al. conducted a smell test and reported detecting no odors, which is unsurprising because hydrogen peroxide is odorless. They also used a direct reading instrument to determine hydrogen peroxide levels from N95s after decontamination and reported 0 ppm at four hours post-decontamination.

Other Vaporized Hydrogen Peroxide

Other decontamination methods using vaporized hydrogen peroxide have not been proven to be safe or effective. In fact, these methods appear to damage N95 respirators and may pose a hazard to workers wearing a decontaminated N95.

The FDA has issued EUAs for additional systems that utilize vaporized hydrogen peroxide [75]. However, these EUAs do not overlap with the other methods evaluated in the scientific literature.

Seven studies evaluated four different systems that used vaporized hydrogen peroxide to decontaminate N95 respirators [24-30]. These systems included Curis, Panasonic MCO-19AIC-PT incubator with VHP, a room Halo Disinfection System, and four studies did not specify what system they evaluated.

Other Vaporized Hydrogen Peroxide Methods Criterion #1 (Effectiveness): Failed

Two studies inoculated N95s with SARS-CoV-2 as the test organism [27, 30]. Smith et al. inoculated N95s while Fischer et al. only inoculated coupons from N95s. Smith et al. reported detection of SARS-CoV-2 on N95 respirators after decontamination with vaporized hydrogen peroxide. Two additional studies evaluated the effectiveness of vaporized hydrogen peroxide using viral and bacterial test organisms [26, 29]. Both reported significant reduction in test organisms after treatment. The remaining studies did not evaluate the effectiveness of vaporized hydrogen peroxide systems.

Other Vaporized Hydrogen Peroxide Methods Criterion #2 (Impact on N95): Failed

All studies evaluating vaporized hydrogen peroxide systems had significant methodological issues. Four

studies evaluated only N95 fit after decontamination [26-28, 30]. All four reported N95 respirators passed quantitative fit tests after decontamination. Fischer et al. reported results indicating that vaporized hydrogen peroxide damaged N95 respirators, though these authors ignored their own results when concluding that vaporized hydrogen peroxide did not damage N95s [27]. The number of individuals fit tested in each study was low or not reported, limiting the generalizability of their results.

Three studies evaluated the filtration efficiency of N95s after decontamination [24, 25, 27]. All three studies reported damage to N95 respirators after decontamination with vaporized hydrogen peroxide. However, all three of these studies reported using custom experimental set-ups to evaluate filtration of N95s. This limits our ability to understand and compare their results to other studies.

One study reported only visual inspection of N95s using a scanning electron microscope [29]. While this method can provide interesting information about microscopic details of N95 filter media, it is not sufficient for evaluation of whether decontaminated N95 respirators provide respiratory protection to the wearer.

Other Vaporized Hydrogen Peroxide Methods Criterion #3 (Hazard to Wearer): Insufficient

One study used a smell test to evaluate off-gassing from N95s treated with vaporized hydrogen peroxide [28]. Hankenson et al. reported no odors, which is unsurprising because hydrogen peroxide is odorless.

Section 2: Heat

Multiple methods using heat at different temperatures, different humidities, and for different lengths of time have been evaluated in the scientific literature. Very few studies evaluated the same specific method. While heat under particular circumstances may eradicate some pathogens, it is not clear under what specific circumstances SARS-CoV-2 may be

killed by heat when present on and trapped within an N95 respirator. Heat may damage an N95 respirator. It is unclear whether heat may create an additional hazard to the wearer, but possible that heating causes toxic chemicals to be released from N95 materials.

Dry heat, lower temperatures (<80°C)

Dry heat (<80°C) decontamination methods have not been proven to be safe or effective. In fact, these methods appear to be ineffective, may damage N95 respirators, and may pose a hazard to workers wearing a decontaminated N95.

The FDA has not issued any EUAs for decontamination methods using dry heat (<80°C) as of July 1, 2020.

Nine studies evaluated six different methods to use dry heat (<80°C) to decontaminate N95 respirators [27, 31-38]. These systems included: a food cabinet at 70°C, an incubator at 70°C, and an oven at 60°C, 75°C, or 77°C.

Williams et al. evaluated temperature levels throughout a food warming cabinet and reported variability between regions within the cabinet [37]. This study presents a significant variable that must be considered. Variable temperature could result in ineffective decontamination of some N95s and damage to others within the same decontamination cycle.

X Dry heat (<80°C) Criterion #1 (Effectiveness): Failed

One study used SARS-CoV-2 as a test organism and reported length of time to eradication for each method studied, though their results are limited in applicability because they only evaluated N95 coupons not full N95 respirators [27]. Two stud-

ies used bacterial and viral indicators to evaluate the effectiveness of dry heat at low temperatures to decontaminate N95s [31, 38]. While Xiang et al. reported successful inactivation of test organisms, Cadnum et al. reported limited effectiveness of dry heat against test organisms. Massey et al. inoculated N95 coupons using a viral indicator and reported no viral activity after treatment with dry heat [34].

X Dry heat (<80°C) Criterion #2 (Impact on N95): Failed

The studies that evaluated the impact of dry heat (<80°C) on N95 respirator fit, filtration, and performance had methodological issues. In total, these studies only evaluated ten different N95 models plus an unknown unspecified number. Two studies evaluated only one N95 model, limiting the applicability of their results to any other N95 model [27, 34].

Two studies evaluated the impact of dry heat (<80°C) on N95 filtration and reported no significant impact [33, 38]. Four studies evaluated the impact of dry heat (<80°C) on N95 fit using quantitative fit testing [27, 32, 34-36]. One study reported damage to the N95 respirators after treatment with dry heat (<80°C), including visible signs of softening and melting and broken straps [34].

■ Dry heat (<80°C) Criterion #3 (Hazard to Wearer): None

None of the studies included in this review evaluated this criterion.

Dry heat, middle temperatures (80°C-100°C)

Dry heat (80°C-100°C) decontamination methods have not been proven to be safe or effective. In fact, these methods appear to be ineffective, may damage N95 respirators, and may pose a hazard to workers wearing a decontaminated N95.

The FDA has not issued any EUAs for decontamination methods using dry heat (80°C-100°C) as of July 1, 2020.

Five studies evaluated four different methods to use dry heat (80°C-100°C) to decontaminate N95 respirators [12, 19, 33, 39, 40]. These methods include: an industrial washer on dry cycle and an oven at 95°C or 100°C for different periods of time.

X Dry heat (80°C-100°C) Criterion #1 (Effectiveness): Failed

Only two studies evaluated the effectiveness of dry heat (80°C-100°C) to decontaminate N95 respirators [19, 39]. Both studies used at least one bacterial test organism and one viral test organism. Li et al. reported that dry heat (80°C-100°C) did not effectively reduce either the bacterial or viral test organism [39]. Wigginton et al. reported that dry

heat (80°C-100°C) combined with UV was insufficient to reduce viral indicators [19].

X Dry heat (80°C-100°C) Criterion #2 (Impact on N95): Failed

Two studies evaluated both filtration and fit of N95 respirators [12, 40]. Meisenhelder et al. reported that while N95 filtration was not significantly degraded by dry heat (80°C-100°C), some damage was noted including delamination of the nose foam piece on one model and blurring of the manufacturer's ink [40]. Chen et al. reported decreased filtration of the N95 after several cycles of dry heat (80°C-100°C) [12].

One study evaluated only the filtration of N95 respirators after decontamination [33]. Liao et al. reported little impact on filtration with dry heat (80°C-100°C). Wigginton et al. evaluated impact of dry heat (80°C-100°C) on N95 filtration and fit using a custom set up and qualitative fit testing methods [19]. These methodological issues limit the applicability of their results.

■ Dry heat (80°C-100°C) Criterion #3 (Hazard to Wearer): None

None of the studies included in this review evaluated this criterion.

Dry heat, high temperatures (>100°C)

Dry heat (>100°C) decontamination methods have not been proven to be safe or effective. In fact, these methods appear to be ineffective, may damage N95 respirators, and may pose a hazard to workers wearing a decontaminated N95.

The FDA has not issued any EUAs for decontamination methods using dry heat (>100°C) as of July 1, 2020.

Five studies evaluated four different methods using dry heat (>100°C) to decontaminate N95 respirators [18, 41-44]. These methods included: an autoclave on dry cycle, an electric rice cooker with no water, and an oven at 150°C or 160-180°C.

X Dry heat (>100°C) Criterion #1 (Effectiveness): Failed

One study inoculated N95 respirators by nebulizing a bacterial test organism and loading them onto the N95 by suction, which is much closer to real-life

conditions than the coupon method [43]. However, this study also divided each N95 into six pieces before decontamination, limiting our understanding of how well the decontamination may or may not work in real-life.

A second study used a viral test organism to inoculate both whole N95s and coupons from N95s. The authors tested the impact of dry heat (>100°C) for different lengths of time [44]. They found that the viral test organisms were still present on the N95 straps after treatment with dry heat (>100°C).

The remaining three studies did not evaluate the effectiveness of dry heat (>100°C).

X Dry heat (>100°C) Criterion #2 (Impact on N95): Failed

All four studies that evaluated the impact of dry heat (>100°C) on N95 fit, filtration, and performance had methodological issues that limit the generalizability of their results. In total, these studies only evaluated

three N95 models plus an unknown number unspecified. One study evaluated fit, filtration, and other aspects of N95 performance and reported being unable to distinguish between new N95s and decontaminated N95s [41]. However, these authors share very limited information about their methodology, making it difficult to fully assess their study. In addition, this was an extremely small study where they tested methods using only one or two N95 respirators.

One study evaluated only the fit of N95s after treatment with dry heat (>100°C) [44]. They reported no significant impact to fit before and after decontamination. This study only evaluated one model of N95s

and did not report the number of people fit tested, limiting the generalizability of their results.

Two studies evaluated the impact of dry heat (>100°C) on the filtration of N95 respirators [18, 42]. Viscusi et al. reported that dry heat (>100°C) resulted in melting the N95 respirators in their study [18]. Lin et al. reported no significant change in N95 filtration [42].

■ **Dry heat (>100°C) Criterion #3 (Hazard to Wearer): None**

None of the studies included in this review evaluated this criterion.

Autoclave (moist heat)

Decontamination methods using autoclaves have not been proven to be safe or effective. In fact, these methods appear to damage N95 respirators and may pose a hazard to workers wearing a decontaminated N95.

The FDA has not issued any EUAs for decontamination methods using autoclaves as of July 1, 2020.

Eleven studies evaluated seven different variations of autoclave use to decontaminate N95 respirators [12, 14, 18, 40-43, 45-49]. These variations included: 121°C @103kPa for different time frames, 115°C, 130°C for different time frames, and two studies that did not specify the conditions of their autoclave use.

? **Autoclaves Criterion #1 (Effectiveness): Insufficient**

Several studies reported using biological and/or chemical indicator strips in the autoclave cycles to evaluate effectiveness of these methods. This is an insufficient evaluation. Placing an indicator strip near N95 respirators does not provide the necessary information to determine whether the decontamination method is effective on all the varied surfaces, creases, seams, and parts of an N95 respirator.

One study used SARS-CoV-2 and other viruses as the test organism to inoculate coupons from N95 respirators [14]. Kumar et al. reported inactivation of viral test organisms. Another study aerosolized a bacterial test organism to inoculate N95 respirators, but divided N95 respirators into six pieces before decontamination [43]. Lin et al. reported significant reduction in test organisms after autoclave treatment.

X **Autoclaves Criterion #2 (Impact on N95): Failed**

Three studies evaluated both filtration and fit of N95 respirators after treatment with an autoclave. Meisenhelder et al. reported significant degradation of filtration after repeated autoclave treatment in addition to delamination of nose foam on one model and shrinkage of other models [40]. One model failed fit tests after just one autoclave cycle. De Man et al. reported no significant impact on N95 respirators after autoclave treatment but provided limited information about methodology [41]. Bopp et al. reported that one N95 model failed fit tests while passing filtration tests, underlining the importance of evaluating all aspects of N95 functionality [45].

Seven studies evaluated the impact of autoclave treatment on filtration of N95 respirators. All seven reported damage to N95s with autoclave treatment [12, 18, 42, 45, 47-49]. In particular, Harskamp et al. reported that the impact on filter efficiency varied by model, with some impacted more severely than others [48]. This underlines the importance of evaluating the compatibility of each N95 model with each decontamination method.

Two studies evaluated the impact of autoclave treatment on the fit of N95 respirators. Carrillo et al. reported that N95 respirators passed quantitative fit tests after autoclave treatment [46]. Kumar et al. reported that some N95 models failed quantitative fit tests following autoclave treatment [14].

■ **Autoclaves Criterion #3 (Hazard to Wearer): None**

None of the studies included in this review evaluated this criterion.

Microwaves (moist heat)

Decontamination methods using microwaves have not been proven to be safe or effective. In fact, these methods appear to damage N95 respirators and may pose a hazard to workers wearing a decontaminated N95.

The FDA has not issued any EUAs for decontamination methods using microwaves as of July 1, 2020.

Five studies evaluated three different methods using microwaves to decontaminate N95 respirators [16, 18, 44, 50, 51]. These methods included: placing an N95 directly inside a microwave, placing an N95 inside a microwave with a container of water, and placing N95s inside a steam bag in the microwave.

Microwaves Criterion #1 (Effectiveness): Insufficient

Three studies evaluated the effectiveness of microwave methods to decontaminate N95 respirators. All three studies utilized viral indicators only. One study sprayed droplets containing viral indicators onto N95s, reporting that average decontamination efficiency was high but varied between N95 models and steam bag types [50]. Another study inoculated N95s with virus-containing aerosols and reported significant reduction in viral indicators after microwave treatment [51]. The third study inoculated N95 coupons with liquid containing viral indicators and

reported significant reduction after three minutes on all N95 segments except the straps [44]. Zulauf et al. also reported variability in reduction of the viral indicator on different parts of the N95.

Microwaves Criterion #2 (Impact on N95): Failed

Four studies evaluated the impact of microwave treatment on the filtration of N95 respirators only. Bergman et al. reported damage to N95s with microwave-generated steam treatment, including partial separation of the nose foam, melting of head straps, and sparking from the metallic band while microwaving [16]. Viscusi et al. reported no significant damage at two minutes, but at four minutes N95s were melted and formed visible holes [18]. Fisher et al. reported that the filtration of one N95 model was significantly impacted by microwave treatment [50]. Lore et al. reported no significant reduction in filtration of N95s treated in microwave [51].

Zulauf et al. evaluated the impact of microwave treatment on the fit of N95 respirators only, reporting no changes in quantitative fit testing results after microwave treatment [44].

Microwaves Criterion #3 (Hazard to Wearer): None

None of the studies included in this review evaluated this criterion.

Other Humid Heat Methods

Decontamination methods using other methods to generate humid heat have not been proven to be safe or effective. In fact, these methods appear to damage N95 respirators and may pose a hazard to workers wearing a decontaminated N95.

The FDA has not issued any EUAs for decontamination methods using other methods to generate humid heat as of July 1, 2020.

Seven studies evaluated multiple methods using humid heat, including: an oven with a container with water, an incubator or cabinet that creates humid heat (50-80% relative humidity, different temperatures for different periods of time), an oven with N95s in Ziploc containers with water/wetted paper towels (different temperatures for different periods of time) [12, 16, 19, 32, 51-53].

Other Humid Heat Methods Criterion #1 (Effectiveness): Failed

Four studies evaluated the effectiveness of humid heat methods to decontaminate N95 respirators. Three studies utilized both bacterial and viral indicators [19, 32, 53]. Oral et al. reported that not all viral indicators were effectively reduced by moist heat treatment [53]. Wigginton et al. reported that only some bacterial and viral indicators were effectively reduced by humid heat treatment [19]. Daeschler et al. assessed the impact of humid heat using bacterial indicators only and reported significant reduction with high humidity [32]. Three studies did not evaluate the effectiveness of humid heat methods to decontaminate N95 respirators.

X Other Humid Heat Methods Criterion #2 (Impact on N95): Failed

Three studies evaluated the impact of humid heat on both filtration and fit of N95 respirators. Two studies reported significant impact on N95 respirators after humid heat treatment. Daeschler et al. reported that quantitative fit test results were not impacted by treatment but filtration efficiency was significantly degraded with multiple cycles of humid heat treatment [32]. Anderegg et al. reported damage to N95 respirators, including delamination of the nose bridge and blurring of manufacturer's ink, though they reported that filtration efficiency was

not impacted [52]. Wigginton et al. reported no significant impact of moist heat on filtration efficiency of N95 respirators [19].

Three studies evaluated the impact of humid heat on filtration of N95 respirators only. Two of these studies reported damage to N95s, including reduction of filtration efficiency or structural damage [12, 16].

Other Humid Heat Methods Criterion #3 (Hazard to Wearer): None

None of the studies included in this review evaluated this criterion.

Steam

Decontamination methods using steam have not been proven to be safe or effective. In fact, these methods appear to be ineffective, damage N95 respirators, and may pose a hazard to workers wearing a decontaminated N95.

The FDA has issued one EUA to a method utilizing steam to decontaminate N95 respirators: AMSCO Medium Steam Sterilizers manufactured by STERIS Corporation [76].

Six studies evaluated the effectiveness of methods using steam to decontaminate N95 respirators [33, 35, 39, 54-56]. The methods using steam included: commercial steamer for different periods of time and custom steamers (e.g., placing N95 in a plastic bag and suspending it over boiling water).

X Steam Criterion #1 (Effectiveness): Failed

Three studies evaluated the effectiveness of steam methods to decontaminate N95 respirators. Two used both bacterial and viral indicators and reported significant reduction in all but one indicator [39, 55]. Ma et al. had significant methodological issues that limit the applicability of their results to real-life situations. In their study, they placed viral indicators in a closed tube and did not inoculate N95 respirators to test effectiveness [56].

X Steam Criterion #2 (Impact on N95): Failed

Two studies evaluated the impact of steam methods on N95 fit only. Li et al. reported no significant impact on fit after treatment [55]. Ou et al., however, reported that N95s failed fit tests after several cycles of steam treatment [35].

Three studies evaluated the impact of steam methods on N95 filtration only. Doshi et al. reported that filtration efficiencies remained above minimum requirements after several cycles of steam treatment, but that methods that placed N95 respirators inside Ziploc bags damaged filtration efficiency [54]. Liao et al. reported damage to filtration efficiency of N95 respirators after treatment with steam [33]. Ma et al. used a custom method to evaluate N95 filtration, but did not report the results of their filtration efficiency tests [56].

Steam Criterion #3 (Hazard to Wearer): None

None of the studies included in this review evaluated this criterion.

Section 3: Radiation

Electromagnetic radiation, including ultraviolet radiation and gamma radiation, has been used for different sanitizing and sterilizing applications for many years. Ultraviolet (UV) radiation is typically divided into three ranges: UV-A (315-400 nm wavelength), UV-B (280-315 nm wavelength), and UV-C (100-280 nm wavelength). Gamma radiation is a type of penetrating radiation with extremely short wavelengths.

UV-C Radiation

Decontamination methods using UV-C radiation have not been proven to be safe or effective. In fact, these methods appear to damage N95 respirators and may pose a hazard to workers wearing a decontaminated N95.

The FDA has not issued any EUAs for decontamination methods using UV-C radiation as of July 1, 2020.

Eighteen studies evaluated decontamination methods using UV-C radiation [12, 16-18, 25, 30, 31, 33, 35, 36, 43, 51, 57-62]. These methods included several different types of UV-C sources: 6W handheld lamp, 8W handheld lamp, labhoods with UV, custom constructed boxes with UV, sterilization cabinets, room UV-C decontamination devices, and unspecified sources of UV-C radiation.

X UV-C Radiation Criterion #1 (Effectiveness): Failed

Nine studies evaluated the effectiveness of UV-C to decontaminate N95 respirators. Three studies used viral indicators [30, 51, 61]. Lore et al. reported that high-intensity UV was effective at reducing viral test organism on N95 respirators. Mills et al. also reported a significant reduction in viral test organism but also observed a wide range in reduction levels for filters and inadequate reduction on straps.

Two studies evaluated bacterial indicators [43, 57]. Both studies reported significant reduction in test organisms. However, Fisher et al reported that the level of reduction differed statistically significantly between different N95 models [57].

Cadnum et al. used multiple bacterial and viral test organisms and reported that the level of reduction was variable [31]. The effectiveness of UV-C varied

A significant concern in the application of radiation, especially UV, to decontaminate N95 respirators is the ability of the radiation to penetrate multiple layers of an N95. N95 respirators are designed to trap particles within the filter matrix, including infectious pathogens. A decontamination method's ability to eradicate pathogens inside the filter matrix is an important element in establishing effectiveness.

between N95 models and was inconsistent on different surfaces of one N95.

Two studies evaluated the UV-C dose in different N95 layers [58, 59]. These studies reported significant variation in the level of UV-C that is able to reach each layer of an N95 respirator, with the outer layers receiving more UV-C radiation than inner layers. Additionally, they reported that the dose distribution is not homogeneous across the surface of an N95, with some areas receiving a higher dose than others. This variability in UV-C radiation methods creates significant concern about the effectiveness of this method to decontaminate the inner layers of N95s.

X UV-C Radiation Criterion #2 (Impact on N95): Failed

One study evaluated the impact of UV-C treatment on both filtration and fit of N95 respirators and found no significant impact [35].

Eight studies evaluated impact of UV-C on N95 filtration only. Six of these studies reported no significant impact of UV-C treatment on N95 filtration efficiency [16, 18, 25, 33, 51, 57]. Two studies reported damage to N95 respirator filtration efficiency with UV-C treatment. Lindsley et al. reported decreased filtration efficiency after UV-C treatment and that the strength of most N95 layers decreased after UV exposure in a dose-dependent manner [60]. Strap strength also decreased after UV treatment. Chen et al. reported dose-dependent photochemical damage of N95 respirators and decreased filtration efficiency after UV-C treatment [12].

Two studies evaluated the impact of UV-C on N95 fit only. Both studies reported significant degradation of N95 fit and integrity after UV-C treatment [30, 36]

UV-C Radiation Criterion #3 **(Hazard to Wearer): Insufficient**

One study evaluated the presence of residual chemicals after UV-C treatment [17]. The results indicated the presence of harmful chemicals after UV-C treatment, but the authors report that the reasons are

unclear. Their methodology utilized a solvent to process samples, but that did not fully explain their results. This study indicates that UV-C could create harmful residual chemicals that could pose a health risk to wearers. Further investigation is required.

Other UV Radiation

Decontamination methods using other UV radiation have not been proven to be safe or effective. In fact, these methods appear to damage N95 respirators and may pose a hazard to workers wearing a decontaminated N95.

The FDA has not issued any EUAs for decontamination methods using other UV radiation as of July 1, 2020.

Three studies evaluated decontamination methods using UV radiation outside the UV-C range [17, 19, 27]. These ranges included 260-285 nm, 200-315 nm, and UV-B radiation.

Other UV Radiation Criterion #1 **(Effectiveness): Failed**

Two studies evaluated the effectiveness of UV radiation to decontaminate N95 respirators. Fischer et al. inoculated N95 coupons with SARS-CoV-2 and reported the time required to significant reduction of the virus with UV radiation [27]. Wigginton et al. inoculated N95 coupons with bacterial and viral test organisms and reported poor inactivation of bacte-

rial test organisms and incomplete reduction of viral test organisms with UV treatment [19].

Other UV Radiation Criterion #2 (Impact on N95): Failed

Two studies evaluated the impact of UV radiation on N95 fit, filtration, and function. Wigginton et al. evaluated filtration efficiency using a custom set-up, limiting the applicability of their results [19]. Fischer et al. evaluated the impact on filtration and fit and reported that multiple cycles of UV treatment damaged the N95 respirators [27].

Other UV Radiation Criterion #3 (Hazard to Wearer): Insufficient

One study evaluated the presence of residual chemicals after UV-C treatment [17]. The results indicated the presence of harmful chemicals after UV-C treatment, but the authors report that the reasons are unclear. Their methodology utilized a solvent to process samples, but that did not fully explain their results. This study indicates that UV-C could create harmful residual chemicals that could pose a health risk to wearers. This question requires further investigation.

Gamma Radiation

Decontamination methods using gamma radiation have not been proven to be safe or effective. In fact, these methods appear to damage N95 respirators and may pose a hazard to workers wearing a decontaminated N95.

The FDA has not issued any EUAs for decontamination methods using gamma radiation as of July 1, 2020.

Two studies evaluated two different methods using gamma radiation to decontaminate N95 respirators [49, 63]. These methods evaluated several different levels of radiation.

Gamma Radiation Criterion #1 **(Effectiveness): None**

Neither study evaluated this criterion.

Gamma Radiation Criterion #2 **(Impact on N95): Failed**

Both studies reported significant reduction in filtration efficiency of N95 respirators with gamma radiation treatment [49, 63]. These studies evaluated a total of five N95 models and an unknown number of unspecified models.

Gamma Radiation Criterion #3 **(Hazard to Wearer): None**

Neither study evaluated this criterion.

Section 4: Chemicals

Multiple methods utilizing different chemicals to decontaminate N95 respirators have been evaluated in the scientific literature. Very few studies evaluated the same specific method. While some chemicals under certain circumstances may eradicate some pathogens, it is not clear under what circumstances

SARS-CoV-2 may be killed when present on and trapped within an N95 respirator. These chemical methods may also damage N95 respirators and residues can pose serious health hazards to workers wearing decontaminated N95s.

Ethylene Oxide

Decontamination methods using ethylene oxide have not been proven to be safe or effective. In fact, these methods may damage N95 respirators and may pose a hazard to workers wearing a decontaminated N95. Ethylene oxide is a known carcinogen.

The FDA has not issued any EUAs for decontamination methods using ethylene oxide as of July 1, 2020.

Four studies evaluated four different systems using ethylene oxide to decontaminate N95 respirators [14, 17-19]. These systems included: 3M Sterivac 4XL, 3M Sterivac 5XLP, 3M SteriVac 5XL, and Amsco Eagle 3017 EO sterilizer.

Ethylene Oxide Criterion #1 (Effectiveness): Insufficient

Two studies evaluated the effectiveness of decontamination methods using ethylene oxide. Kumar et al. inoculated N95 respirators with a viral indicator and reported that ethylene oxide treatment effectively inactivated the viral indicator [14]. Wigginton et al. inoculated N95 coupons with bacterial and viral indicators and reported significant reduction in viral indicators [19]. However, Wigginton et al. also

conducted limited evaluation of ethylene oxide due to concerns about hazard to wearers.

Ethylene Oxide Criterion #2 (Impact on N95): Insufficient

Three studies evaluated the impact of ethylene oxide treatment on N95 fit, filtration, and function. These studies evaluated a total of eight specified N95 models. Viscusi et al. reported darkening of N95 straps and decreased filtration efficiency of N95s after ethylene oxide treatment, though it was still within NIOSH requirements [18]. Wigginton et al. evaluated the impact of ethylene oxide treatment on filtration efficiency using a custom set up, limiting the applicability of their study [19]. Kumar et al. only evaluated the impact of ethylene oxide on N95 fit and reported no significant impact [14].

Ethylene Oxide Criterion #3 (Hazard to Wearer): Insufficient

Only one study evaluated the potential for chemical residue to pose a hazard to wearers of N95s after treatment with ethylene oxide [17]. This study reported no ethylene oxide present on N95s after treatment, though they did find other trace contaminants incident to the process. More study is required given the carcinogenic nature of ethylene oxide.

Ethanol/Isopropyl Alcohol

Decontamination methods using ethanol or isopropyl alcohol have not been proven to be safe or effective. In fact, these methods appear to damage N95 respirators and may pose a hazard to workers wearing a decontaminated N95.

The FDA has not issued any EUAs for decontamination methods using ethanol or isopropyl alcohol as of July 1, 2020.

Ten studies evaluated multiple methods to decontaminate N95 respirators using ethanol or isopropyl

alcohol [12, 18, 27, 30, 33, 35, 42, 43, 47, 64]. These methods included: dunking or soaking N95s in different solutions of alcohol (70%, 75%, 100%), pipetting the alcohol onto the N95, pouring the alcohol onto the N95, spraying the N95 with the alcohol, and atomizing the alcohol into a fume hood.

Ethanol/Isopropyl Alcohol Criterion #1 (Effectiveness): Failed

Three studies evaluated the effectiveness of ethanol/isopropyl alcohol to decontaminate N95 respirators. Fischer et al. and Smith et al. applied SARS-CoV-2 to N95 respirators and reported effec-

tive reduction in virus after treatment with UV [27, 30]. Lin et al. inoculated N95 respirators with aerosols containing bacterial test indicators but divided the N95 into six pieces before decontamination [43]. Lin et al. reported that ethanol did not reduce the bacterial test organism as well as other methods tested.

X Ethanol/Isopropyl Alcohol Criterion #2 **(Impact on N95): Failed**

Two studies evaluated the impact of ethanol/isopropyl alcohol treatment on N95 filtration and fit. Ou et al. reported significant damage to N95 filtration efficiency after treatment [35]. Fischer et al. reported no significant damage to N95s after treatment [27].

Six studies evaluated the impact of ethanol/isopropyl alcohol treatment on only N95 filtration [12, 18, 33, 42, 47, 64]. All six reported significant damage to N95 filtration efficiency after treatment with ethanol/isopropyl alcohol.

One study evaluated the impact on N95 fit only, reporting that ethanol treatment significantly degraded N95 integrity [30].

■ Ethanol/Isopropyl Alcohol Criterion #3 **(Hazard to Wearer): None**

None of the studies included in this review evaluated this criterion.

Bleach/Chlorine-Containing Solutions

Decontamination methods using bleach or chlorine-containing solutions have not been proven to be safe or effective. In fact, these methods appear to damage N95 respirators and may pose a hazard to workers wearing a decontaminated N95. Bleach and chlorine-containing solutions can be toxic to breathe.

The FDA has not issued any EUAs for decontamination methods using bleach or chlorine-containing solutions as of July 1, 2020.

Seven studies evaluated several different decontamination methods using bleach or chlorine-containing solutions [16-18, 24, 33, 42, 43]. These methods included: dunking N95s into hypochlorite solutions (different concentrations and different times), pipetting hypochlorite solutions onto N95 respirators, and spraying chlorine-based solutions onto N95 respirators.

? Bleach/Chlorine-Containing Solutions Criterion #1 (Effectiveness): Insufficient

Only one study evaluated the effectiveness of bleach to decontaminate N95 respirators [43]. This study reported significant reduction in the one bacterial test organism used.

X Bleach/Chlorine-Containing Solutions Criterion #2 (Impact on N95): Failed

Five studies evaluated the impact of bleach/chlorine-based solution decontamination methods on N95 filtration only [16, 18, 24, 33, 42]. All four studies reported damage to N95 respirators after treatment, including decreased filtration efficiency, tarnished nosepieces, and stiffening of N95 filter material.

No studies evaluated impact on fit.

X Bleach/Chlorine-Containing Solutions Criterion #3 (Hazard to Wearer): Failed

Only one study evaluated the possibility of bleach/chlorine-based solution decontamination methods to pose a hazard to the wearer [17]. This study reported that all N95s tested retained bleach odor following decontamination and off-gassing. This residue and odor can cause irritation and health impacts to wearers.

Hydrogen Peroxide Liquid

Decontamination methods using liquid hydrogen peroxide have not been proven to be safe or effective. In fact, these methods may damage N95 respirators and may pose a hazard to workers wearing a decontaminated N95.

The FDA has not issued any EUAs for decontamination methods using hydrogen peroxide liquid as of July 1, 2020.

Two studies evaluated decontamination methods utilizing liquid hydrogen peroxide [16, 18]. These studies evaluated two different methods (soaking and dunking) utilizing 6% hydrogen peroxide.

Ozone

Decontamination methods using ozone have not been proven to be safe or effective. In fact, these methods appear to damage N95 respirators and may pose a hazard to workers wearing a decontaminated N95.

The FDA has issued only one EUA for a decontamination method using ozone. On April 4, 2020, FDA authorized the STERIZONE VP4 Sterilizer system, which uses ozone and hydrogen peroxide [77].

Three studies evaluated three different decontamination methods utilizing ozone [65-67]. These methods included: 25 ppm for 150 minutes, 500 ppm for two hours, and the SoClean system for cleaning personal CPAP machines.

Ozone Criterion #1 (Effectiveness): Insufficient

Three studies reported evaluating the effectiveness of ozone decontamination methods. Manning et al. inoculated pieces of an N95 respirator in liquid containing a bacterial test organism and reported effective reduction of the bacterial test organism after treatment with ozone [66]. Dave et al. inoculated N95 coupons with a viral test organism and reported significant reduction after treatment with ozone [65]. Neither study effectively evaluated real-life conditions.

Hydrogen Peroxide Liquid Criterion #1 (Effectiveness): None

Neither study evaluated this criterion.

Hydrogen Peroxide Liquid Criterion #2 (Impact on N95): Insufficient

Both studies evaluated the impact of liquid hydrogen peroxide treatment on N95 filtration, but not fit. Both studies reported decreased filtration efficiency after treatment, though it was still within NIOSH limits [16, 18].

Hydrogen Peroxide Liquid Criterion #3 (Hazard to Wearer): None

None of the studies included in this review evaluated this criterion.

Burkhart et al.'s study had serious methodological concerns. They reported that N95s were effectively cleaned by ozone treatment because they had a "characteristic" ozone smell [67].

Ozone Criterion #2 (Impact on N95): Failed

All three studies reported evaluation of the impact of ozone treatment on N95 respirators. Dave et al. evaluated the impact on N95 filtration only and reported that, while filtration efficiency was not reduced below NIOSH requirements, there was a severe degradation of the hydrophobic layer of the N95 respirators after ozone treatment [65]. Manning et al. evaluated the impact of ozone on both filtration and fit and similarly reported that while filtration efficiency was not significantly impacted, elastic bands on one model were cracked and had visible damage [66]. Burkhart et al. reported no damage to N95s but did not report their methodology [67].

Ozone Criterion #3 (Hazard to Wearer): None

No study explicitly evaluated the potential for hazard to the wearer with ozone treatment of N95s. Burkhart et al. reported residual odor on all treated N95s [67].

Peracetic acid

Decontamination methods using peracetic acid have not been proven to be safe or effective. In fact, these methods may damage N95 respirators and may pose a hazard to workers wearing a decontaminated N95. Peracetic acid can be hazardous to breathe.

The FDA has not issued any EUAs for decontamination methods using peracetic acid as of July 1, 2020.

Three studies evaluated methods using peracetic acid to decontaminate N95 respirators [14, 31, 68]. These methods included a peracetic acid room fogging system, a room disinfection system using peracetic acid mixed with hydrogen peroxide, and a room disinfection system using peracetic acid mixed with hydrogen peroxide and acetic acid.

X Peracetic Acid Criterion #1 (Effectiveness): Failed

Three studies evaluated the effectiveness of these methods to decontaminate N95 respirators. Cadnum et al. used multiple bacterial and viral test organisms to test the effectiveness of peracetic acid, hydrogen peroxide, and acetic acid [31]. They reported that it required two cycles to reach accepted decontamination levels on both the inside and outside of an N95 respirator. John et al. used viral and bacterial

indicators to test the effectiveness of peracetic acid and hydrogen peroxide and reported significant reduction in test organisms after treatment [68]. Kumar et al. used only SARS-CoV-2 as viral indicator to evaluate a peracetic acid fogging system and reported significant reduction after treatment [14].

? Peracetic Acid Criterion #2 (Impact on N95): Insufficient

Two studies evaluated the impact of peracetic acid decontamination methods on N95 fit, filtration, and performance. John et al. evaluated the filtration and structural integrity of N95 respirators following treatment with peracetic acid and hydrogen peroxide [68]. They reported no decline in filtration efficiency. However, they observed damage to the surface of treated N95s using a scanning electron microscope. Kumar et al. only evaluated the impact on N95 fit after treatment with peracetic acid and reported no significant impact.

? Peracetic Acid Criterion #3 (Hazard to Wearer): Insufficient

Only one study evaluated the potential for peracetic acid treatments to pose a hazard to wearers. John et al. measured off-gassing of peracetic acid and hydrogen peroxide for twenty minutes after treatment and observed 0.0 ppm during that limited timeframe [68].

Soap and Water

Decontamination methods using soap and water have not been proven to be safe or effective. In fact, these methods appear to damage N95 respirators and may pose a hazard to workers wearing a decontaminated N95.

The FDA has not issued any EUAs for decontamination methods using soap and water as of July 1, 2020.

One study evaluated a decontamination method using soap and water [18].

■ Soap and Water Criterion #1 (Effectiveness): None

Viscusi et al. did not evaluate the effectiveness of soap and water as a decontamination method for N95 respirators.

X Soap and Water Criterion #2 (Impact on N95): Failed

Viscusi et al. only evaluated the impact of soap and water on N95 respirator filtration efficiency. They reported significantly reduced filtration efficiency after treatment with soap and water.

■ Soap and Water Criterion #3 (Hazard to Wearer): None

Viscusi et al. did not evaluate this criterion.

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