Safety of Extended Use and Reuse of N95 Respirators

Editorial note: Updated May 13, 2020, to add newly published systematic reviews of N95 decontamination and four bench studies testing decontamination methods directly on SARS-CoV-2. Two new guidelines: Infectious Diseases Society of America recommends N95 use and reuse during critical shortages, and the Occupational Safety and Health Administration (OSHA) endorses steaming, ultraviolet germicidal irradiation, and vaporized hydrogen peroxide as appropriate methods for N95 decontamination.

Single-use N95 respirators are critical to protect staff and patients from airborne infections, but shortages may occur during disease outbreaks and other crisis situations. Wearing an N95 respirator for hours at a time (i.e., extended use) or donning and doffing the same respirator several times (i.e., reuse) are practices used to ease shortages. The potential risks and benefits of these practices may vary greatly across locations and may evolve rapidly during a crisis. This report’s conclusions are not intended as a practice endorsement or call to action. Rather, this report is intended to provide practical guidance on the potential risks and benefits that clinical centers should consider when deciding on N95 respirator reuse or extended use.

Published clinical studies are not available to assess the safety of N95 respirator reuse and extended use during critical shortages, so we examined laboratory studies (22 described in 3 systematic reviews and 11 additional studies) that may provide at least some rational basis for actions during a crisis. Also, clinical studies are likely unavailable and infeasible because of major ethical and logistical barriers because N95 reuse/extended use practices are associated with sporadic, unpredictable, variable crisis situations. Nonetheless, evidence from laboratory studies supports prioritizing extended use over reuse because N95s may readily spread infection by touch if donned and doffed and are prone to mechanical failure upon reuse. Studies testing more than 30 N95 respirator models found that covering respirators with surgical masks had no clinically significant effect on breathing effort and gas exchange. Decontaminating N95 respirators by steam, hydrogen peroxide vapor, or ultraviolet germicidal irradiation (UVGI) may be safe and effective in some settings, but each method needs to be tested on each model because model materials vary. The available studies support prioritizing N95 extended use over reuse because of the following:

- The reported pathogen transfer risk from N95s is high by contact (donning and doffing) but low by aerosol (spread by breathing through a used mask).
- Use of surgical masks or similar disposable covers over N95s during extended use is unlikely to result in significant adverse effects.
- Mechanical failure (e.g., broken straps and poor sealing between the mask and the user’s face) with only a few reuses was common across FDA-cleared (medical use) N95s.
- Disinfection methods to prepare respirators for reuse, while shown to be adequate in some laboratory settings, are highly variable in efficacy and require more validation on each N95 model to ensure safe implementation.

Evidence limitations: Laboratory studies may not reflect risks and outcomes in actual clinical settings. Most findings were reported in single studies and may not fully generalize across different N95 models and testing protocols. Results varied significantly across cleaning methods and N95 models and therefore need more validation. Validation studies would be of great value in helping healthcare provider and policymaker decisions.

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Executive Summary

Conclusions

In the absence of clinical studies, we reviewed 3 systematic reviews (SRs) of laboratory studies and 11 additional laboratory studies focusing on N95 reuse and extended use.

- **N95 respirator contamination risks**: Two studies found that 4% to 18% of H1N1 virus particles and >10% of M2 bacteriophage particles were viable after 4 to 6 days on 3M 8210 filters at room temperature. One of the studies (Brady et al. 2017) reported that 2% to 15% of M2 particles transferred to the users who donned contaminated N95s. The other study (Fisher et al. 2012) reported minimal M2 aerosolization (<0.2%) from contaminated N95s in simulated cough tests.

- **N95 disinfection/decontamination**: Twenty-two laboratory studies synthesized in 3 SRs reported that use of autoclaves, steaming, moist heat, bleach, benzalkonium chloride, vaporized hydrogen peroxide, and ultraviolet-C (UV-C) (1 to 2 J/cm²) achieved >1,000-fold reduction in microbial load on N95s contaminated with bacterial and viral pathogens and nonpathogenic microbial surrogates (Gertsman et al. 2020, O’Hearn 2020a, O’Hearn 2020b). Three laboratory studies reported similar effective SARS-CoV-2 neutralization on N95s with 70% alcohol, peracetic acid fogging, vaporized hydrogen peroxide, and UVGI (Oral et al. 2020, Kumar et al. 2020, Smith et al. 2020).

- **N95 integrity**: Two studies (Vuma et al. 2019, Bergman et al. 2012) reported that 7% to 8% of N95s failed fitting after 2 uses and >20% failed after 5 fittings. Gerstman et al. found that autoclaving compromised N95 integrity while steaming did not. O’Hearn et al. (2020a) found vaporized hydrogen peroxide to cause minimal or no reduction to mask filtering and fit while alcohol and bleach caused damage to several N95 models. O’Hearn et al. (2020b) also found that single UVGI cycles did not compromise N95 function, but repeated cycles may damage some models.

- **Adverse event risks**: Two studies (Sinkule et al. 2013, Roberge et al. 2010) on more than 30 models found that covering respirators with surgical masks had no clinically significant effect on breathing effort and gas exchange.

Evidence

Search dates: January 1, 2000, through May 7, 2020. We reviewed full text of 3 SRs and 8 laboratory studies and abstracts of 3 laboratory studies. See full report for study details.

- We reviewed full text of published studies available through open access and abstracts of other studies.

- 4 studies of simulated N95 reuse or extended use: 2 studies (Vuma et al. 2019, Bergman et al. 2012) tested N95 fit after up to 20 successive donnings by 10 experienced users (n = 16, n = 10). 2 studies reported on changes to breathing effort and gas exchanges with N95s covered with surgical masks using a breathing simulator (Sinkule et al. 2013) and 10 human subjects (Roberge et al. 2010).

- 4 studies of simulated N95 contamination: 2 studies reported on H1N1 (Coulliette et al. 2013) and M2 (Fisher et al. 2019) viral particle persistence on contaminated N95s. 2 studies reported on M2 viral particle transfer by touch (Brady et al. 2017) or simulated cough (Fisher et al. 2012) from contaminated N95s.

- 3 SRs and 3 studies of N95 decontamination: 3 overlapping SRs (22 unique studies) assessed bacterial and viral pathogen decontamination with heat-based methods (Gertsman et al. 2020, 11 studies), chemical disinfectants (O’Hearn et al. 2020a, 12 studies), and UVGI (O’Hearn et al. 2020b, 13 studies) and reported on microbial load and N95 integrity and function. 1 study included in the SRs (Kumar et al. 2020) and 2 additional studies not in the SRs (Oral et al. 2020 and Smith et al. 2020) focused on SARS-CoV-2 decontamination with ethanol, peracetic acid, vaporized oxygen peroxide, and UVGI.

Clinical Guidelines and Recommendations

Searched PubMed, EMBASE, and ECRI Guidelines Trust® (EGT) for relevant documents on N95 respirator use from January 1, 2000, through May 4, 2020. We identified 11 documents.

- Guidelines have been published by the U.S. Centers for Disease Control and Prevention (CDC), FDA, Infectious Diseases Society of America (IDSA), National Institute for Occupational Safety and Health (NIOSH), Occupational Safety and Health Administration (OSHA), Society of American Gastrointestinal and Endoscopic Surgeons, and the World Health Organization (WHO).
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Background

According to the CDC website, approximately 3 million U.S. healthcare workers are required to wear respiratory protection of some type. OSHA classifies respiratory protection devices according to the air source, the type and characteristics of the contaminants removed, and whether they require a partial or full seal between the respirator and the wearer’s face.

N95 Respirators

Filtering half-mask respirators, also called filtering facepiece respirators (FFRs), are the most commonly used respiratory protection in healthcare. FFRs are designed to fit around the user’s nose and mouth, creating an airtight seal with the face. Most FFRs are intended as disposable, single-use devices, but reusable models are available. In the United States, these filters bear the N95 designation to indicate they are not resistant to oil or solvents (N) and that they are intended to filter at least 95% of airborne particles >0.3 µm in size. (For more information, see CDC’s website, CDC’s Guideline for Infection Control in Health Care Personnel, 1998, NIOSH’s Approved Particulate Filtering Facepiece Respirators, and the OSHA website for a video titled, Respirator Types.)

N95 filters are made of several layers of woven synthetic material treated to sustain an electrostatic charge (i.e., an electret). In addition to creating a mechanical barrier against aerosols, N95 filters retain charged particles, such as bacteria. However, N95 filters provide no protection against fumes, oils, or vapors. In the healthcare setting, N95 filters provide adequate protection from most airborne pathogens (e.g., influenza, tuberculosis). (For more information, see the FDA article N95 Respirators and Surgical Masks [Face Masks].)

Regulation

In the United States, N95 filters are subject to performance testing and certification by NIOSH. Also, FDA regulates N95 respirators for healthcare use as Class II devices, which are exempt from 510(k) premarket notification under product codes MSH, ONT, and ORW. In Europe, the closest equivalent to N95s are FPP2 respirators, which are required to achieve 94% elimination of particles greater than 0.6 µm to receive the CE mark. (For more information, see the OSHA Technical Manual Section VIII, OSHA’s webpage for Respiratory Protection, the FDA article N95 Respirators and Surgical Masks [Face Masks], and 3M’s [St. Paul, MN, USA] technical bulletin Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes.)

N95 Extended Use and Reuse

Single-use N95 respirators are intended to be discarded after each encounter or procedure warranting use of a respirator; used respirators are considered potentially biohazardous waste and should be disposed of accordingly. Nevertheless, N95s are designed to function for days to weeks at airflow rates consistent with breathing, and in theory, N95 protection should provide effective protection as long as the seal between respirator and face remains tight. During times of supply disruption and/or extraordinary utilization, such as airborne disease outbreaks, healthcare providers and responders have historically leveraged these properties by implementing N95 extended use and reuse protocols. Extended use involves continued use for up to several hours during successive encounters, typically when disease spread risks are minimal or irrelevant. Reuse involves removing and donning the respirator for several successive encounters, with or without respirator decontamination in between.

NIOSH and CDC guidelines do not include recommendations for decontamination of single-use N95 respirators and do not require manufacturers to include disinfection recommendations in the labeling of single-use N95s. Nonetheless, bench studies by NIOSH and other agencies have evaluated several proposed methods for single-use N95 disinfection. These methods fall into three broad categories:

- Humid heat with autoclaves, pressure cookers, or microwavable steam bags. Steam sterilization requires 10 minutes at 121°C at a minimum to be effective. Steam is widely available, nontoxic, and fully penetrant to porous materials, such as N95 filters, but may damage polymer fibers in the filter and compromise its performance.

- Chemical cleaners, applied by soaking or wiping and followed by rinsing and drying. Many options are available but may not be appropriate because of toxicity and chemical incompatibility with filter materials; the latter should be determined on a case-by-case basis. Minimum concentrations and contact times required may also
vary according to the pathogen. For a list of agents with known efficacy against COVID-19, see the ECRI Guidance document, *Disinfectant Concentrations and Contact Times for EPA's List of Products Effective against Novel Coronavirus SARS-CoV-2, the Cause of COVID-19.*

- **UVGI** with 200 to 400 nm UV lamps. Required dose typically ranges in the order of tens to low-hundreds mW.s/cm² for most organisms but varies depending on the pathogen, surface type, exposure mode, and ambient humidity. Penetration may be incomplete in multilayered N95 filters. UVGI leaves no toxic residue but requires enclosed spaced or shielded devices to protect users from UV exposure. UVGI equipment is generally expensive, and availability may be a significant barrier to use during crisis situations. (For more information, see the review *Understanding Ultraviolet Light Surface Decontamination In Hospital Rooms: A Primer.*)

**Risks Associated with N95 Extended Use and Reuse**

While extended use and reuse may help conserve N95s during shortages, these practices are associated with significant risks and drawbacks, including:

- **Discomfort:** Heat and increased breathing effort may make extended use uncomfortable or intolerable for some users and may constitute a barrier to compliance.

- **Loss of fit:** Typically, N95s are secured with light metal clips or elastic bands not meant to be durable. Wear from extended use or repeated donning may make fitting difficult, and complete failure is common, especially with reuse. Closely inspecting respirators before reuse, observing proper donning techniques, and conducting seal checks are critical steps to limit this risk. Limiting the number of reuses may also reduce this risk, but optimization requires case-by-case consideration because N95 models vary greatly in durability. CDC recommends following the manufacturer’s guidance and reusing respirators no more than five times during shortages.

- **Loss of filtration effectiveness:** This risk is minimal for extended N95 use or reuse without decontamination as long as the proper fit is maintained. However, decontamination procedures may compromise the filter depending on the method and the N95's materials and design, as discussed above.

- **Risk of infection spread:** Pathogen-loaded N95s may become inert sources of infection (i.e., fomites). Contaminated N95s may spread infection in two ways: by spreading airborne particles during use or by touch during removal and donning (hand-to-mask contamination). Generally, experts prioritize this risk in considering the appropriateness of N95 conservation measures. For pathogens at less risk of transmission by touch, such as tuberculosis, N95 reuse is a widely endorsed and adopted practice. However, CDC and other government agencies have endorsed N95 extended use and reuse only for dealing with highly infectious agents at times when widespread N95 shortages were likely. Measures to reduce the risk of mask-to-hand contamination include:
  - Patient cohorting (i.e., limiting encounters to only infected or noninfected patients)
  - Prioritizing extended use over reuse
  - Discarding respirators visibly contaminated with body fluids or other potential pathogen sources
  - Covering N95s with surgical masks that are changed after each patient encounter
  - Using proper hand hygiene and gloves when handling potentially contaminated N95s
  - Storing used N95s in designated areas between reuses
  - Decontaminating N95s between reuses

With the exception of single-use N95 decontamination, all the above measures are consistent with guidance provided by CDC and other U.S. agencies.

**Complementary Conservation Measures**

Extended use and reuse of single-use N95s are intended to be part of a multicomponent optimization effort at times of expected or likely N95 shortages. Extended use and reuse implementation should ideally take place alongside appropriate practices to mitigate the risks of device failure and contamination, as outlined in the previous section. Furthermore, extended use and reuse are not mutually exclusive and may complement each other if applied in discretionary fashion across different clinical settings, depending on the nature of N95 shortages. Hospitals and healthcare agencies should also consider administrative and engineering controls to minimize the need for N95s.
Administrative controls are all practices intended to reduce the need for N95s by reducing the number of encounters that require a respirator. These changes include restricting hospital visitors, use of telemedicine, patient cohorting, and early discharge of noninfected patients in an epidemic. Engineering controls are technical barriers to airborne infection, such as airflow control and air-purification systems. (For additional information, see the CDC guidance Strategies for Optimizing the Supply of N95 Respirators, the WHO guidance Rational Use of Personal Protective Equipment [PPE] for Coronavirus Disease [COVID-19], and the ECRI Custom Response Ultraviolet Light Air-purification Systems for Preventing Healthcare-associated Infections.)

**Alternatives to Single-use N95 Respirators**

When conservation measures are insufficient to ensure that N95s are available for all needs, hospitals will need to consider partial or full substitution by adopting alternative devices that provide the best possible protection, including the following:

- **N95-equivalent devices**: Non-NIOSH-approved respirators can be expected to provide full protection if manufactured under regulatory standards that enforce performance testing equivalent to N95, such as FP2 (Europe), KPN95 (China), or P2 (Australia). See the CDC website for a list of equivalent regulatory designations.

- **Reusable N95s and other respirators**: Elastomeric full-face N95s, N100s, and self-contained breathing apparatuses provide full protection but are typically available in limited numbers and will need to be reserved for critical procedures with high contamination risk. These devices should be cleaned and decontaminated as per standard procedures, which may be labor-intensive.

- **Expired N95 stocks**: Devices beyond their labeled shelf life may retain adequate filter performance if stored properly, but aged rubber bands and other elastic parts may not ensure a proper fit. Also, heat and humidity can compromise the filter material. Devices should be closely inspected for signs of damage (e.g., discoloration, residue shedding) and fit-tested before use.

- **N95s not certified for medical use**: These include respirators certified by NIOSH but not cleared by FDA (e.g., for industrial use) and face covers pieced together from N95 filter materials or from conventional cloth (e.g., biking masks, bandanas). These devices may not provide a tight fit or additional protection other than a mechanical barrier to aerosol. CDC states: “as a last resort, it may be necessary for healthcare personnel to use masks that have never been evaluated or approved by NIOSH or homemade masks. Use of these unapproved masks may be considered for care of patients with COVID-19, tuberculosis, measles, and varicella. However, caution should be exercised when considering this option.” According to ECRI experts, chosen alternatives should at least provide a tight fit and should be disposable or compatible with sterilization by autoclaving or soaking with 0.5% sodium hypochlorite (1:10 household bleach).

**Response to N95 Shortage during the 2019-20 COVID-19 Outbreak**

Actions taken through May 7, 2020, in response to a critical shortage of N95 respirators during the COVID-19 outbreak include the following:

- May 7, 2020: FDA issued an Emergency Use Authorization (EUA) to Duke University (Chapel Hill, NC, USA) for “a self-contained decontamination product that uses vapor phase hydrogen peroxide (VHP) for decontamination of compatible N95 or N95-equivalent respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic organisms.” Duke’s system “is a combination of Bioquell VHP systems, Drager X-am 5100, and PortaSens II/PortaSens III hydrogen peroxide monitoring equipment, and five rooms within the Duke University Health System, that are specifically designated for use with each Bioquell VHP system.”

- April 14, 2020: FDA issued an EUA to Stryker Medical Corp. (Kalamazoo, MI, USA) for the Sterizone VP4 N95 Respirator Decontamination Cycle, “for use in decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, for a maximum of 2 decontamination cycles per respirator, for single-user reuse by [healthcare personnel] to prevent exposure to pathogenic airborne particulates during the COVID-19 pandemic.” The Sterizone VP4 is a hydrogen peroxide vaporizer.

- April 11, 2020: FDA issued an EUA to Advanced Sterilization Products, Inc. (Irvine, CA, USA) “for the STERRAD Sterilization Cycles that has the potential to decontaminate approximately 4 million N95 or N95-equivalent respirators per day in the U.S. for single-user reuse by health care workers in hospital settings.”
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April 10, 2020: FDA issued an EUA “to STERIS Corporation for the STERIS V-PRO 1 Plus, maX and maX2 Low Temperature Sterilization Systems using the STERIS N95 Decontamination Cycle (nonlumen cycle), which uses vaporized hydrogen peroxide.”

April 8, 2020: Essentia Health (Duluth, MN, USA) began to decontaminate and reuse the N95 masks using ultraviolet light.

April 5, 2020: N95DECON, a volunteer group of scientists, engineers, clinicians, and students from 10 U.S. universities, published a cautionary fact sheet on N95 decontamination methods.

April 3, 2020: FDA issued an EUA for non-NIOSH-approved N95 respirators made in China, which makes KN95 respirators eligible for authorization if certain criteria are met, including evidence demonstrating that the respirator meets certain standards.

April 2, 2020: a news article announced that CPAC Equipment, Inc. (Leicester, NY, USA) was manufacturing “a tabletop RH-N95 Decontamination System to help the healthcare industry overcome and alleviate N95 mask shortages during the Covid-19 outbreak.”

April 1, 2020: N95DECON released a report that complements CDC recommendations issued on March 31, 2020, by providing a data-driven fact-sheet and detailed summary of recommended N95 decontamination methods (i.e., UVGI, vaporous hydrogen peroxide, and moist heat).

March 29, 2020: FDA authorized Batelle, an Ohio-based nonprofit, on March 29, 2020, “to decontaminate up to 10,000 compatible respirators per chamber load in a new machine that decontaminates the safest masks against coronavirus and can allow 20 re-uses of the devices.”

March 28, 2020: FDA issued an EUA permitting use of disposable FFRs that have marketing authorization as follows: European CE mark, Australian Register of Therapeutic Goods, Certificate of Inclusion, Health Canada Licence, Japan Pharmaceuticals and Medical Device Ministry of Health, Labour, and Welfare.

March 26, Duke University clinical teams began “using existing vaporized hydrogen peroxide methods to decontaminate the masks so they can be reused.”

March 20, 2020: 3M issued a technical bulletin that states, “based on currently available data, 3M does not recommend or support attempts to sanitize, disinfect, or sterilize 3M FFRs.”


March 20, 2020: the New York Times reported the University of Nebraska was using ultraviolet light to decontaminate masks.

March 20: Companies (e.g., Stitchroom, Inc.) and individuals began to produce washable cloth masks crafted with fabric pieces and elastic. Techniques, materials, and intended use vary. Homemade masks may give the wearer a false sense of confidence. According to an ECRI health device expert, “simple cotton fabric or paper masks will not prevent liquid penetration; however, if a homemade mask designed to prevent liquid penetration is worn over an N95 mask, it could help reduce external N95 contamination and extend N95 use.” A few homemade or 3D-printed masks claim they force all air being exchanged during breathing through a filter, but ECRI experts remain skeptical about their performance unless the manufacturer can demonstrate this claim through particle testing using standard methods. As of March 26, 2020, ECRI health device experts do not recommend healthcare workers wear homemade mask because most have not undergone testing to verify they can provide the performance intended and because surgical-type masks are generally available (although sometimes in short supply). ECRI’s position on homemade mask use by healthcare professionals may change if conventional surgical masks become completely unavailable.

February 3, 2020: AFP Hong Kong published a warning against steaming facemasks for reuse.

Clinical Guidelines and Recommendations

Searches of PubMed, EMBASE, EGT, and other web-based resources identified 11 relevant guidelines published between January 1, 2000, and May 4, 2020, as follows:

- CDC: Strategies for Optimizing the Supply of N95 Respirators. 2020. This guidance describes the following practices in during an N95 respirator shortage:
Use NIOSH approved alternatives to N95 respirators where feasible. These include other classes of filtering facepiece respirators, elastomeric half-mask and full facepiece air purifying respirators, powered air purifying respirators (PAPRs). All of these alternatives will provide equivalent or higher protection than N95 respirators when properly worn. NIOSH maintains a searchable, online version of the certified equipment list identifying all NIOSH-approved respirators. Every other NIOSH approved filtering facepiece respirators is at least as protective as the N95. These include N99, N100, P95, P99, P100, R95, R99, and R100.

This guidance also describes the following measures that are not commensurate with current U.S. standards of care but may need to be considered during periods of expected or known N95 respirator shortages:

- Use of respirators beyond the manufacturer-designated shelf life for healthcare delivery for care of patients with COVID-19, tuberculosis, measles, and varicella can be considered.
- Use of respirators approved under standards used in other countries that are similar to NIOSH-approved N95 respirators
- Limited re-use of N95 respirators
- Use of additional respirators beyond the manufacturer-designated shelf life
- Prioritize the use of N95 respirators and facemasks by activity type
- When No Respirators are Left: Exclude healthcare provider at higher risk for severe illness from COVID-19 from contact with known or suspected COVID-19 patients. Designate convalescent healthcare personnel for provision of care to known or suspected COVID-19 patients.
- In settings where N95 respirators are so limited that routinely practiced standards of care for wearing N95 respirators and equivalent or higher level of protection respirators are no longer possible, and surgical masks are not available, as a last resort, it may be necessary for healthcare personnel to use masks that have never been evaluated or approved by NIOSH or homemade masks. It may be considered to use these masks for care of patients with COVID-19, tuberculosis, measles, and varicella. However, caution should be exercised when considering this option.

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**CDC. Decontamination and Reuse of Filtering Facepiece Respirators.** 2020. This document states:

Disposable filtering facepiece respirators (FFRs) are not approved for routine decontamination and reuse as standard of care. However, FFR decontamination and reuse may need to be considered as a crisis capacity strategy to ensure continued availability. Based on the limited research available, ultraviolet germicidal irradiation, vaporous hydrogen peroxide, and moist heat showed the most promise as potential methods to decontaminate FFRs. This document summarizes research about decontamination of FFRs before reuse.

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**CDC: Considerations for Release of Stockpiled N95s beyond the Manufacturer-designated Shelf Life.** 2020. This document includes preliminary information gained in a study that evaluated stockpiled N95s from 10 geographically dispersed facilities with a range of storage conditions and states:

Many models have continued to perform in accordance with NIOSH performance standards. Accordingly, CDC/NIOSH believes the following products, despite being past their manufacturer-designated shelf life, should provide the expected level of protection to the user if the stockpile conditions have generally been in accordance with the manufacturer-recommended storage conditions and an OSHA-compliant respiratory protection program is used by employers. In alphabetical order, these models are: 3M 1860, 3M 1870, 3M 8210, 3M 9010, 3M 8000, Gerson 1730, Medline/Alpha Protech NON27501, Moldex 1512, Moldex 2201. Firm conclusions cannot be drawn for stockpiled N95 models beyond those tested in this study.

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**IDSA. Infectious Diseases Society of America Guidelines on Infection Prevention in Patients with Suspected or Known COVID-19.** 2020. The guideline recommends:
During contingency or crisis capacity settings (respirator shortages), the IDSA guideline panel recommends that health care personnel caring for patients with suspected or known COVID-19 use a surgical mask or reprocessed respirator instead of no mask as part of appropriate PPE*. (Strong recommendation, moderate certainty of evidence)

During contingency or crisis capacity settings (respirator shortages), the IDSA guideline panel suggests that health care personnel involved with aerosol-generating procedures on suspected or known COVID-19 patients use a REPROCESSED N95 respirator for reuse instead of surgical masks as part of appropriate PPE*. (Conditional recommendation, very low certainty evidence)

During contingency or crisis settings (respirator shortages), the IDSA guideline panel recommends that health care personnel involved with aerosol-generating procedures on suspected or known COVID-19 patients add a face shield or surgical mask as a cover for the N95 respirator to allow for EXTENDED use as part of appropriate PPE*. (Strong recommendation, very low certainty evidence). Comment: this recommendation assumes correct doffing sequence and hand hygiene is performed before and after removing the face shield or surgical mask covering the respirator.

During contingency or crisis settings (respirator shortages), the IDSA guideline panel suggests that health care personnel involved with aerosol-generating procedures on suspected or known COVID-19 patients add a face shield or surgical mask as a cover for the N95 respirator to allow for REUSE as part of appropriate PPE*. (Conditional recommendation, very low certainty evidence). Comment: this recommendation assumes correct doffing sequence and hand hygiene is performed before and after removing the face shield or surgical mask covering the respirator.

NIOSH. Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings. 2018. This guidance includes the following extended respirator use recommendations:

- Extended use is favored over reuse because it is expected to involve less touching of the respirator and therefore less risk of contact transmission.
- A key consideration for safe extended use is that the respirator must maintain its fit and function.
- If extended use of N95 respirators is permitted, respiratory protection program administrators should ensure adherence to administrative and engineering controls to limit potential N95 respirator surface contamination (e.g., use of barriers to prevent droplet spray contamination) and consider additional training and reminders (e.g., posters) for staff to reinforce the need to minimize unnecessary contact with the respirator surface, strict adherence to hand hygiene practices, and proper Personal Protective Equipment (PPE) donning and doffing technique.
- Healthcare facilities should develop clearly written procedures to advise staff to take the following steps to reduce contact transmission after donning:
  - Discard N95 respirators following use during aerosol generating procedures.
  - Discard N95 respirators contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.
  - Discard N95 respirators following close contact with, or exit from, the care area of any patient co-infected with an infectious disease requiring contact precautions.
  - Consider use of a cleanable face shield (preferred) over an N95 respirator and/or other steps (e.g., masking patients, use of engineering controls) to reduce surface contamination.
  - Perform hand hygiene with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the respirator (if necessary for comfort or to maintain fit).
Extended use alone is unlikely to degrade respiratory protection. However, healthcare facilities should develop clearly written procedures to advise staff to discard any respirator that is obviously damaged or becomes hard to breathe through.

NIOSH guidance also includes the following respirator reuse recommendations:

- If reuse of N95 respirators is permitted, respiratory protection program administrators should ensure adherence to administrative and engineering controls to limit potential N95 respirator surface contamination (e.g., use of barriers to prevent droplet spray contamination) and consider additional training and/or reminders (e.g., posters) for staff to reinforce the need to minimize unnecessary contact with the respirator surface, strict adherence to hand hygiene practices, and proper PPE donning and doffing technique, including physical inspection and performing a user seal check.

- Healthcare facilities should develop clearly written procedures to advise staff to take the following steps to reduce contact transmission:
  - Discard N95 respirators following use during aerosol generating procedures.
  - Discard N95 respirators contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.
  - Discard N95 respirators following close contact with any patient co-infected with an infectious disease requiring contact precautions.
  - Consider use a cleanable face shield (preferred) or a surgical mask over an N95 respirator and/or other steps (e.g., masking patients, use of engineering controls), when feasible to reduce surface contamination of the respirator.
  - Hang used respirators in a designated storage area or keep them in a clean, breathable container such as a paper bag between uses. To minimize potential cross-contamination, store respirators so that they do not touch each other and the person using the respirator is clearly identified. Storage containers should be disposed of or cleaned regularly.
  - Clean hands with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the respirator (if necessary for comfort or to maintain fit).
  - Avoid touching the inside of the respirator. If inadvertent contact is made with the inside of the respirator, perform hand hygiene as described above.
  - Use a pair of clean (non-sterile) gloves when donning a used N95 respirator and performing a user seal check. Discard gloves after the N95 respirator is donned and any adjustments are made to ensure the respirator is sitting comfortably on your face with a good seal.

- To reduce the chances of decreased protection caused by a loss of respirator functionality, respiratory protection program managers should consult with the respirator manufacturer regarding the maximum number of donnings or uses they recommend for the N95 respirator model(s) used in that facility. If no manufacturer guidance is available, preliminary data suggests limiting the number of reuses to no more than five uses per device to ensure an adequate safety margin.


If respiratory protection must be used, and acceptable alternatives are not available for use in accordance with OSHA’s previous COVID-19 enforcement memoranda, NIOSH has identified limited available research that suggests the following methods offer the most promise for decontaminating FFRs:

- Vaporous hydrogen peroxide;[9]
- Ultraviolet germicidal irradiation; and/or
- Moist heat (e.g., using water heated in an oven).
If such methods are not available, the above-referenced NIOSH-evaluated research showed the following methods could also be suitable decontamination options:

- Microwave-generated steam;
- Liquid hydrogen peroxide.

Based on the above-referenced NIOSH-evaluated research, employers should not use the following methods unless objective data that sufficiently demonstrate the safety and effectiveness of such methods become available:

- Autoclaving;
- Dry heat;
- Isopropyl alcohol;
- Soap;
- Dry microwave irradiation;
- Chlorine bleach; and/or
- Disinfectant wipes, regardless of impregnation (i.e., chemical saturation); and/or
- Ethylene oxide (EtO).

— OHSA. Enforcement Guidance for Respiratory Protection and the N95 Shortage Due to the Coronavirus Disease 2019 (COVID-19) Pandemic. 2020. This guidance for employers states:

- In the event extended use or reuse of N95 FFRs becomes necessary, the same worker is permitted to extend use of or reuse the respirator, as long as the respirator maintains its structural and functional integrity and the filter material is not physically damaged, soiled, or contaminated (e.g., with blood, oil, paint). ...Extended use is preferred over reuse due to contact transmission risk associated with donning/doffing during reuse. When respirators are being re-used, employers should pay particular attention to workers’ proper storage of the FFRs in between periods of reuse.

- Users should perform a user seal check each time they don a respirator and should not use a respirator on which they cannot perform a successful user seal check.

- Employers should train workers to understand that if the structural and functional integrity of any part of the respirator is compromised, it should be discarded, and that if a successful user seal check cannot be performed, another respirator should be tried to achieve a successful user seal check.

- If reuse of respirators is necessary, an appropriate sequence for donning/doffing procedures should be used to prevent contamination, and training needs to address appropriate donning/doffing procedures.

- In the event that N95s are not available and the employer has shown a good faith effort to acquire the respirators or to use alternative options, as outlined below, Certified Safety and Health Officials should exercise enforcement discretion for the use of N95 FFRs beyond the manufacturer’s recommended shelf life, including surgical N95s.

  - Employers may use only previously NIOSH-certified expired N95 FFRs. Workers should be notified that they are using expired N95s.
  - Purchasers and users of personal protective equipment should not co-mingle products that are past their manufacturer’s recommended shelf life (i.e., expired) with items that are within their shelf life.
  - Employers should visually inspect, or ensure that workers visually inspect, the N95 FFRs to determine if the structural and functional integrity of the respirator has been compromised. Over time, components such as the straps, nose bridge, and nose foam material may degrade, which can affect the quality of the fit and seal.
Where an employer has expired N95s available from their own stored cache (i.e., not from the U.S. Strategic National Stockpile), the employer should seek assistance from the respirator manufacturer or independent lab regarding testing of those stored respirators prior to use.

OHSA. Enforcement Guidance for Use of Respiratory Protection Equipment Certified under Standards of Other Countries or Jurisdictions during the Coronavirus Disease 2019 (COVID-19) Pandemic. 2020. This guidance for employers states:

- Make a good-faith effort to provide and ensure workers use the most appropriate respiratory protection available for the hazards against which workers need to be protected. This should be accomplished through, in this order:
  - Implementing the hierarchy of controls in an effort first to eliminate or substitute out workplace hazards, then using engineering controls, administrative controls, and safe work practices to prevent worker exposures to respiratory hazards.
  - Prioritizing efforts to acquire and use equipment in the following order:
    - NIOSH-certified equipment; then
    - Equipment certified in accordance with standards of other countries or jurisdictions except the People’s Republic of China, unless equipment certified in accordance with standards of the People’s Republic of China is manufactured by a NIOSH certificate holder[6]; then
    - Equipment certified in accordance with standards of the People’s Republic of China, the manufacturer of which is not a NIOSH certificate holder[6]; then
    - Facemasks (e.g., medical masks, procedure masks).

- Prioritizing efforts to acquire and use equipment that has not exceeded its manufacturer’s recommended shelf before allowing workers to use equipment that is beyond its manufacturer’s recommended shelf life. Equipment used beyond its manufacturer’s recommended shelf life must be used in accordance with OSHA’s April 3, 2020 memorandum.

- Prioritizing efforts to use equipment that has not exceeded its intended service life (e.g., disposable FFRs used for the first time) before implementing protocols for extended use or reuse of equipment.

- Using homemade masks or improvised mouth and nose covers only, as a last resort (i.e., when no respirators or facemasks are available). Improvised masks are not personal protective equipment and, ideally, should be used with a face shield to cover the front and sides of the face.

- Ensure users perform a user seal check each time they don a respirator, regardless of whether it is a NIOSH-certified device or device certified under standards of other countries or jurisdictions, and do not use a respirator on which a user cannot perform a successful user seal check.

- Train workers to understand that if the structural and functional integrity of any part of the respirator is compromised, it should be discarded, and that if a successful user seal check cannot be performed, another respirator should be tried to achieve a successful user seal check.

- Visually inspect, or ensure that workers visually inspect, the FFRs to determine if the structural and functional integrity of the respirator has been compromised. Over time, components such as the straps, nose bridge, and nose foam material may degrade, which can affect the quality of the fit and seal.

- Avoid co-mingling products from different categories of equipment. NIOSH-certified equipment, equipment that was previously NIOSH-certified but that has surpassed its manufacturer’s recommended shelf life, equipment certified under standards of other countries or jurisdictions, and equipment that was previously certified under standards of other countries or jurisdictions but that has surpassed its manufacturer’s recommended shelf life should be stored separately.
Train employees on the procedures for the sequence of donning/doffing to prevent self-contamination.

FDA. Enforcement Policy for Face Masks and Respirators during the Coronavirus Disease (COVID-19) Public Health Emergency (revised): Guidance for Industry and Food and Drug Administration Staff. 2020. This guidance states:
  - In general, FDA recommends that health care providers follow current Centers for Disease Control and Prevention (CDC) guidance regarding personal protective equipment (PPE) that should be used during the COVID-19 outbreak.
  - For the duration of the public health emergency, to facilitate the safe reuse and conservation of PPE for a medical purpose, FDA is interested in interacting with manufacturers on the decontamination of otherwise disposable face masks and filtering facepiece respirators to facilitate marketing authorization through an emergency use authorization (EUA) for decontaminated devices.

Society of American Gastrointestinal and Endoscopic Surgeons. N95 Re-use Strategies. This guidance states:

There is no definitive “best practice” for N95 re-use and re-processing. Based on the resources available at each institution, the optimal strategy for each person or institution will vary.

WHO. Rational Use of Personal Protective Equipment for Coronavirus Disease 2019 (COVID-19) and Considerations During Severe Shortages. 2020. This guidance states the following:

WHO stresses that these temporary measures should be avoided as much as possible when caring for severe or critically ill COVID-19 patients, and for patients with known co-infections of multi-drug resistant or other organisms transmitted by contact (e.g. Klebsiella pneumoniae) or droplets (e.g. influenza virus).

The following temporary measures could be considered independently or in combination, depending on the local situation:
1. PPE extended use (using for longer periods of time than normal according to standards);
2. Reprocessing followed by reuse (after cleaning or decontamination/sterilization) of either reusable or disposable PPE;
3. Considering alternative items compared with the standards recommended by WHO.

The reuse of any item without a reprocessing/decontamination process is considered inadequate and unsafe.

Methods for reprocessing masks or respirators are not well established nor standardized, and therefore should be considered only when there is critical PPE shortage or lack of PPE.

Clinical Literature

We searched PubMed, EMBASE, Google Scholar, the Cochrane Library, and selected web-based resources for clinical studies published between January 1, 2010, and May 7, 2020, and reporting on risks to patients and healthcare workers during N95 extended use and reuse and with associated practices (e.g., N95 decontamination, N95 doubling with surgical masks) relevant to this topic. Our search strategies included the following keywords: clean, decontaminate, disinfect, extend, masks, N95, respirator, reuse, and sterilization. Please see the Selected Resources and References section for detailed search strategies.

We did not identify any studies reporting outcomes from N95 extended use or reuse in actual clinical settings. Therefore, we extended our searches to include all laboratory studies. We also included the following surrogate outcomes of infection and adverse event risks in our assessment: N95 integrity and filter performance; microbial burden, persistence, and transfer; and user breathing, comfort, and chemical exposure.

We identified many laboratory studies of N95 decontamination and reviewed only SRs of this practice to reflect the best available evidence. We also reviewed individual studies of N95 decontamination focusing on SARS-Cov-2, which
are of especial relevance because of the COVID-19 outbreak ongoing at the time of this review. We reviewed 3 SRs and 11 additional laboratory studies, as follows:

- 4 laboratory studies reporting on simulated N95 extended use or reuse:
  - 2 studies reported on seal quality during successive N95 donnings by experienced users using automated testers. One study included 16 subjects and tested 3M 1860 and 3 unlisted N95 models.(1) One study included 10 subjects and tested N95 six 3M, Kimberly-Clark, and Moldex N95 models.(2)
  - 1 study reported on resistance to breathing and inhaled gas pressures with surgical mask-covered N95s using a breath simulator 30 N95 models by 3M, AO Safety, Crews, Dragger, Innovel, Kimberly-Clarke, Moldex, and San Hui.(3)
  - 1 study reported on heart rate and blood gas levels in 10 subjects who wore N95s covered with surgical masks during light or heavy work for 1 hour at a time.(4)

- 4 laboratory studies reporting on simulated N95 contamination:
  - 2 studies reported on H1N1 influenza virus and M2 bacteriophage persistence, respectively, on inoculated 3M 8210 filters stored for 4 to 6 days at room temperature (18 to 25°C) and moderate humidity (20% to 60%).(5,6)
  - 1 study reported on M2 virus particles and fluorescein transfer to the hands of subjects who donned inoculated 3M 1860 N95s.(7)
  - 1 study reported on M2 phage aerosolization from inoculated Gerson 1730 N95s using a cough simulator.(8)

- 3 SRs of laboratory studies and 3 laboratory studies reporting on N95 decontamination:
  - 3 overlapping SRs including 22 unique studies assessed N95 decontamination with chemical disinfectants (e.g bleach, vaporized hydrogen peroxide (13 studies), heat-based method (13 studies), and UVGI (11 studies), respectively, and reported on microbial load and mask integrity and fit.(9-11) Studies covered many commonly used N95 brands, including AO Safety, 3M, Cardinal Health, Kimberly-Clarke, Moldex, and others. Pathogens included pathogenic bacteria (C. difficile, S. aureus), respiratory viruses (H5N1, H1N1, SARS-CoV-2), and nonpathogenic surrogates (B. subtilis, M2 bacteriophage).
  - 3 laboratory studies reported on viral load, filter integrity and fit of 3M N95 models contaminated with SARS-CoV-2 and subject to decontamination with vaporized hydrogen peroxide, 70% ethanol, peracetic acid fogging, and UVGI.(12-14) One study is included in one of the SRs.(14)

Table 1 summarizes the SRs. Table 2 summarizes the laboratory studies. We reviewed full-text articles available with open access and articles of other studies. We excluded from review mathematical simulation studies, correspondence articles, and conference presentation abstracts.

Evidence limitations and discussion: The individual laboratory studies we reviewed and those that were included in the SRs are subject to major limitations to interpretation because many of the findings were reported in single studies or may not fully generalize across different N95 models and testing protocols. Furthermore, laboratory studies may not reflect risks and outcomes in actual clinical settings and may not support conclusions on clinical practices or interventions. Nonetheless, clinical studies of N95 extended use or reuse are subject to major ethical and logistical barriers because the practices are associated with crisis situations that are sporadic, unpredictable, and very variable in nature. In their absence, laboratory studies may at least provide a rational basis for action during a crisis.

In this context, the reviewed studies support prioritizing N95 extended use over reuse because 1) reported pathogen transfer risk from N95s was high by contact but low by re-aerosolization, 2) use of surgical masks or similar disposable covers to protect N95s during extended use are unlikely to result in significant adverse effects, 3) mechanical failure was common with few reuses across widely, FDA-cleared N95s, and 4) commonly effective disinfection methods can achieve adequate disinfection with minor filter performance loss, but results varied significantly across cleaning methods and N95 models and therefore would need at least small-scale, case-by-case validation for safe implementation in clinical centers.
Nevertheless, these conclusions are not intended as a practice endorsement or a call to action because the risks and potential benefits of N95 extended use and reuse in time of crisis may vary greatly across different locations and may also evolve rapidly. Rather, this report is intended to provide guidance on the risks and relative benefits that clinical centers should consider during decision making. Circumstantial validation of the reviewed findings during times of crisis by manufacturers and government evidence, even in a limited capacity, would be of great value in helping healthcare provider and policymaker decisions.

Table 1. Systematic Reviews

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<tr>
<td>O’Hearn et al. 2020(10) Reviewed full text</td>
<td>“To synthesize existing data on the effectiveness and safety of using disinfectants to decontaminate N95 FFR [filtering facepiece respirators]”</td>
<td>Searched EMBASE, MEDLINE, Global Health, Google Scholar, World Health Organization (WHO) feed, and MedRxiv in March 2020 for studies of N95 decontamination with alcohol, hydrogen peroxide, or sodium hypochlorite. Included 13 studies.</td>
<td>“A single cycle of vaporized H2O2 successfully removes infectious pathogens without affecting mask function or fit, and with little change in FFR physical appearance. Residual hydrogen peroxide levels following decontamination were below the safety limit. More than one decontamination cycle of vaporized H2O2 may be possible but further information is required on how multiple cycles would affect mask fit in a real world setting before the upper limit can be established. Although immersion in liquid H2O2 does not appear to adversely affect mask function, there is no available data on its ability to remove infectious pathogens from FFRs or its impact on mask fit. Sodium hypochlorite, ethanol, isopropyl alcohol and EtO are not recommended.”</td>
<td>“Further research is required before the acceptability of decontamination using liquid H2O2 can be determined. Sodium hypochlorite, ethanol, isopropyl alcohol and EtO are not recommended.”</td>
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<tr>
<td>O’Hearn et al. 2020(11) Reviewed full text</td>
<td>“To synthesize existing data on the effectiveness of ultraviolet germicidal irradiation (UVGI) on N95 FFR decontamination.”</td>
<td>Searched EMBASE, MEDLINE, Global Health, Google Scholar, WHO feed, and MedRxiv in March 2020 for studies of N95 decontamination with UVGI. Included 13 studies.</td>
<td>“FFRs consistently maintained certification standards following UVGI. Aerosol penetration averaged 1.19% (0.70-2.48%) and 1.14% (0.57-2.63%) for control and UVGI arms respectively. Airflow resistance for the control arms averaged 9.79 mm H2O (7.97-11.70 mm H2O) vs 9.85 mm H2O (8.33-11.44 mm H2O) for UVGI arms. UVGI protocols employing a cumulative dose &gt;20,000 J/m2 resulted in a 2 log reduction in viral load. A &gt;3 log reduction was observed in 7 UVGI arms using &gt;40,000 J/m2. Impact of UVGI on fit was evaluated in two studies (16,200; 32,400 J/m2) and did not find evidence of compromise.”</td>
<td>“The function of N95 masks, based on aerosol penetration and airflow filtration, is maintained following a single cycle of UVGI. Decontamination using UV light in the laboratory setting suggests that this can be a successful method of removing infectious pathogens from FFRs.”</td>
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### CLINICAL EVIDENCE ASSESSMENT

**Safety of Extended Use and Reuse of N95 Respirators**

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<td>Gertsman et al. 2020(9)</td>
<td>“To collect and synthesize existing information on decontamination of N95 FFRs using microwave and heat-based treatments.”</td>
<td>Searched EMBASE, MEDLINE, Global Health, JISRP, and JEFF in March 2020 for studies of N95 decontamination with heat-based methods. Included 11 studies.</td>
<td>“Interventions successfully destroyed viral/bacterial contaminants. Other than autoclaving, which significantly increased aerosol penetration, moist and dry microwave and heat conditions did not significantly impact functional parameters or fit. However, several conditions caused physical damage to at least one N95 model.”</td>
<td>“Microwave irradiation and heat provides safe and effective decontamination options for N95 FFR reuse during critical shortages. However, autoclaving masks is not recommended by the evidence in this review.”</td>
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**Table 2. Laboratory Studies**

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<td>Vuma et al. 2019(1)</td>
<td>To measure “the effect on respirator fit of multiple donning and doffing of N95 filtering facepiece respirators (FFRs)”</td>
<td>“16 women and 9 men employed by the National Institute for Occupational Health (NIOH), Johannesburg, donned their same N95 FFR six times.” “Four models of respirators were used: the six who did not use respirators at work (novice subjects) were issued a 3M 1860 FFR and the others used their currently supplied one.” “Fit was measured after each of seven exercises and then an overall fit factor was computed. Only individuals who achieved an initial overall fit factor of ≥100 were allowed to continue.”</td>
<td>“Two subjects (8%) had an overall fit factor &lt;100 at fit Test 2, 6 (24%) at Test 3, and 8 (32%) at Tests 4, 5, and 6. Thirteen respirator users (52%) achieved ≥100 throughout the fit testing, so 12 had at least one failure at each Tests 2-6... There was a significant difference between the median first and sixth overall fit factors (195 versus 150; P = 0.0271), but not between the second and sixth (161 versus 150; P = 0.3584). Men and women had similar overall fit factors, but infrequent users had larger average overall fit factors than frequent users after all six donnings.”</td>
<td>“Forty-eight percent of study subjects failed at least one fit test after re-donning an N95 FFR. The fit test data suggest that donning practices probably accounted for the fit test failures. The 50% of subjects who produced overall fit factors ≥100 after a test of &lt;100 supports this contention.”</td>
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<td>Brady et al. 2017(7)</td>
<td>To “characterize the transfer of bacteriophage MS2 and fluorescein between [FFRs] and the wearer’s hands during three simulated use scenarios.”</td>
<td>“FFRs were contaminated with MS2 and fluorescein in droplets or droplet nuclei. Thirteen test subjects performed [FFR] [3M 1860 model] use scenarios including improper doffing, proper doffing and reuse, and improper doffing and reuse. Fluorescein and MS2 contamination transfer were quantified.”</td>
<td>“The average MS2 transfer from [FFRs] to the subjects’ hands ranged from 7.6-15.4% and 2.2-2.7% for droplet and droplet nuclei derived contamination, respectively. Handling [FFRs] contaminated with droplets resulted in higher levels of MS2 transfer compared to droplet nuclei for all use scenarios (p = 0.007). MS2 transfer from droplet contaminated [FFRs] during improper doffing and reuse was greater than transfer during improper doffing (p = 0.008) and proper doffing and reuse (p = 0.042). Droplet contamination resulted in higher levels of fluorescein transfer compared to droplet nuclei contaminated for all use scenarios (p = 0.009). Fluorescein transfer was greater... for improper doffing and reuse when compared improper doffing (p = 0.017) and proper doffing and reuse (p = 0.018) for droplet contaminated [FFRs].”</td>
<td>“The findings suggest that the results of fluorescein and MS2 transfer were consistent and highly correlated across the conditions of study. The data supports CDC [Centers for Disease Control and Prevention] recommendations for using proper doffing techniques and discarding [FFRs] that are directly contaminated with secretions from a cough or sneeze.”</td>
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<td>Coulliette et al. 2013(5)</td>
<td>To “evaluate the persistence and infectivity of pH1N1 on FFRs, specifically N95 respirators, under various conditions of absolute humidity (AH) (4.1 × 10(5) mPa, 6.5 × 10(5) mPa, and 14.6 × 10(5) mPa), sample matrices (2% fetal bovine serum [FBS], 5 mg/ml mucin, and viral medium), and times (4, 12, 24, 48, 72, and 144 h).”</td>
<td>“pH1N1 was distributed onto N95 coupons (3.8 to 4.2 cm(2)) [3M 8210 model] and extracted by a vortex-centrifugation- filtration process, and the ability of the remaining virus to replicate was quantified using an enzyme-linked immunosorbent assay (ELISA) to determine the log10 concentration of the infectious virus per coupon.”</td>
<td>“Overall, pH1N1 remained infectious for 6 days, with an approximately 1-log10 loss [−0.4 to −0.8 log10 change] of virus concentrations over this time period. Time and AH both affected virus survival. We found significantly higher (P ≤ 0.01) reductions in virus concentrations at time points beyond 24 to 72 h (-0.52-log10 reduction) and 144 h (-0.74) at AHs of 6.5 × 10(5) mPa (-0.53) and 14.6 × 10(5) mPa (-0.47).”</td>
<td>“This research supports discarding respirators after close contact with a person with suspected or confirmed influenza infection due to the virus’s demonstrated ability to persist and remain infectious.”</td>
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<td>Bergman et al. 2012(2)</td>
<td>“This study investigated the impact of multiple donnings on the facepiece fit of 6 N95 FFR models [3M 1860, 1870, 8000, and 8210; Kimberly Clark PFR95-270; and Moldex 2200] using a group of 10 experienced test subjects per model.”</td>
<td>“The TSI PORTACOUNT Plus and N95 Companion accessory were used for all tests. After qualifying by passing a standard Occupational Safety and Health Administration [OSHA] fit test, subjects performed up to 20 consecutive tests on an individual FFR sample using a modified protocol. Regression analyses were performed for the percentage of donnings resulting in fit factors (FFs) ≥100 for all 6 FFR models combined.”</td>
<td>“Regression analyses showed statistical significance for donning groups 1-10, 1-15, and 1-20. The mean percentage of donnings with an FF ≥100 was 81%-93% for donning group 1-5, but dropped to 53%-75% for donning group 16-20.”</td>
<td>“Our results show that multiple donnings had a model-dependent impact on fit for the 6 N95 models evaluated. The data suggest that 5 consecutive donnings can be performed before FFs consistently drop below 100.”</td>
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<td>Fisher and Shaffer 2010(6)</td>
<td>To “examine the potential for FFRs to act as fomites using bacteriophage MS2.”</td>
<td>“Virus was applied to FFR coupons [3M 8210] as an aerosol or liquid drops and stored at 22°C and 30% relative humidity. Viability of the virus was monitored every 24 hours from 1 to 5 days with a final sampling occurring on day 10.”</td>
<td>“At least 10% of the initial MS2 load was able to survive for 4 days on the FFR coupons regardless of the deposition method. All coupons contained detectable levels of MS2 on the tenth day. MS2 viability did not appear to be affected by the location of deposition within the layers of the coupon under the test conditions.”</td>
<td>“The results indicate that FFRs have the potential to serve as a fomite.”</td>
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**Reuse after Decontamination**

<p>| Oral et al. 2020(12)          | “Here, we explored the benefits of using vaporized H2O2 (VHP) treatment of N95 respirators for emergency decontamination and reuse to alleviate PPE shortages for healthcare workers in the COVID-19 emergency.” | “N95 respirators (3M, 1860S; n=10) were processed in a VHP LTS-V (Steris, Mentor, Oh). This is a standard sterilization cycle for medical devices where a sterility assurance level (SAL) 10-6 requirement is verified on device surfaces by using biological indicators.” | “VHP treatment of respirators intentionally contaminated with SARS-CoV-2 reduced the infectious virus load to below the limit of detection (1.3 log10), which is calculated based on the volumes of eluate used in the experiments and the premise that 1 PFU could be detected by the assays. There were no plaque forming units for samples treated with VHP. This corresponded to &gt;3.8 log10 reduction in infectious virus load compared to the virus stock and a &gt;2.6 log10 reduction compared to the infectious virus load on the respirators.” | “In this study, one standard cycle of VHP sterilization (Steris LTS-V) for one type of N95 respirator was found to be feasible in terms of preserving fit and filter efficiency.” |</p>
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<td>Kumar et al. 2020(14)</td>
<td>“We sought to test the ability of 5 different decontamination methods... to decontaminate a variety of different N95 masks of experimental contamination with SARS-CoV-2.”</td>
<td>“The masks utilized were 3M’s VFlex 1804, Aura 1870, 1860, 8210 and 9210 respirator models as well as AO Safety 1054S (Pleats Plus) Respirator.” “Vaporous hydrogen peroxide (VHP) treatment was performed with the VHP® ARD System (Steris, Mentor, OH).” “For peracetic acid, a dry fogging system... was run until the relative humidity rose to 80-90%... and the masks exposed for 1 hr.”</td>
<td>“Mask materials inoculated with SARS-CoV-2 had no recoverable virus following autoclaving, VHP and peracetic acid dry fogging treatments... the demonstrated log reduction ranged from 5.2-6.3. We could not validate the effectiveness of EtO and LT-HPGP [Low temperature hydrogen peroxide gas plasma] against SARS-CoV-2 as they were not available at the National Microbiology Laboratory.”</td>
<td>“We found that one cycle of treatment with all modalities was effective in decontamination... Vaporous hydrogen peroxide, peracetic acid dry fogging and autoclave treatments were associated with no loss of structural or functional integrity to a minimum of 10 cycles for the mask models tested.”</td>
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<td>Smith et al. 2020(13)</td>
<td>“Here we investigate the effect of different decontamination methods on disposable N95 mask integrity and on removing the infectious potential of SARS-CoV-2.”</td>
<td>“We... tested if decontamination with 70% ethanol [spray], ultraviolet light [0.5 J/cm² for 30 min.], or VHP [vaporized hydrogen peroxide, 420 ppm for 60 min.] on SARS-CoV-2 changed viral RNA levels or viral infectivity... applied to portions of [3M] 1860, 1870+, or 8511 disposable N95 masks and straps.”</td>
<td>“All three N95 mask types in the positive control cell culture infectivity study had substantially lower cycle thresholds (higher amount of virus) than RNA detected immediately after decontamination corresponding to ~ three log-fold increase in SARS-CoV-2 RNA... No RNA was detected in cell culture in any of the three masks treated with 70% ethanol.”</td>
<td>“We found that any ethanol exposure significantly altered mask integrity, as previously reported... Consistent with prior studies, we did observe a decline in SARS-CoV-2 infectivity (as assessed by Vero E6 culture) after certain decontamination strategies.”</td>
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<td>Sinkule et al. 2013(3)</td>
<td>To “measure breathing air quality and breathing resistance when using FFRs with [FDA]-cleared surgical mask cover (SM) and without SM”</td>
<td>“Thirty [NIOSH]-approved FFR models [3M 1860, 1870, 8000, 8210, 8212, 9210, and 9211; Innovel 3002, AO Safety N9504C and N9505C; Crews RPN951, RPN952, RPFN95, and RPFN952; Gerson 1730 and 1740; Moldex 2200, 2300, 2600, and 2700; Kimberly-Clark 46727; Drager Piccola; Wilson N9520FM, and San Huei SH2950, SH2950Vm SH3500, and SH3500 V] with and without SM were evaluated using the NIOSH Automated Breathing and Metabolic Simulator (ABMS) through six incremental work rates.”</td>
<td>“For most work rates, peak inhalation and exhalation pressures were statistically higher in FFR+SM as compared with FFR-only. The type of FFR and the presence of exhalation valves (EVs) had significant effects on average inhaled CO(2), average inhaled O(2), and breathing pressures. The evidence suggests that placement of an SM on one type of FFR improved inhaled breathing gas concentrations over the FFR without SM; the placement of an SM over an FFR+EV probably will prevent the EV from opening, regardless of activity intensity; and, at lower levels of energy expenditure, EVs in FFR do not open either with or without an SM. “At the lower levels of energy expenditure, this investigation provided evidence to suggest that the IOM [Institutes of Medicine] recommendation of adding an SM over FFRs, would produce clinically small changes in inhaled breathing gases and breathing pressures resulting in a minimal effect on physical work performance, and the amount and direction of change is affected by the type of FFR and shape of the SM.”</td>
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<td>Fisher et al. 2012(8)</td>
<td>“To assess the reaerosolization characteristics of VCPs [virus containing particles] from highly contaminated NIOSH-certified FFRs during simulated user-generated airflow (e.g. cough).”</td>
<td>“Reaerosolization of virus particles from contaminated FFRs [Gerson 1730] was examined using bacteriophage MS2 as a surrogate for airborne pathogenic viruses. MS2 was applied to FFRs as droplets or droplet nuclei. A simulated cough (370 l min(-1) peak flow) provided reverse airflow through the contaminated FFR. The number and size of the reaerosolized particles were measured using gelatin filters and an Andersen Cascade Impactor (ACI).”</td>
<td>“Two droplet nuclei challenges produced higher percentages of reaerosolized particles (0.21 and 0.08%) than a droplet challenge (&lt;0.0001%). Overall, the ACI-determined size distribution of the reaerosolized particles was larger than the characterized loading virus aerosol.”</td>
<td>“This study demonstrates that only a small percentage of viable MS2 viruses was reaerosolized from FFRs by reverse airflow under the conditions evaluated, suggesting that the risks of exposure due to reaerosolization associated with extended use can be considered negligible for most respiratory viruses.”</td>
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## Reference

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study Aim</th>
<th>Setup and Outcomes Assessed</th>
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<td>Roberge et al. 2010(4) United States Reviewed abstract</td>
<td>“To determine the physiological impact on the wearer of using a surgical mask as an outer barrier over a FFR to extend wear.”</td>
<td>“A surgical mask was worn over an N95 filtering facepiece respirator by 10 healthcare workers for 1 h at each of two work rates. Heart rate, respiratory rate, tidal volume, minute volume, oxygen saturation, transcutaneous carbon dioxide levels and respirator dead space gases were monitored and compared with controls (N95 filtering facepiece respirator without a surgical mask). Subjective perceptions of exertion and comfort were assessed by numerical rating scales.”</td>
<td>“There were no significant differences in physiological variables between those who used surgical masks and controls. Surgical masks decreased dead space oxygen concentrations of the [FFRs] at the lesser work rate (P = 0.03) and for filtering facepiece respirators with an exhalation valve at the higher work rate (P = 0.003). Respirator dead space oxygen and carbon dioxide levels were not harmonious with Occupational Safety and Health Administration workplace ambient atmosphere standards. Exertion and comfort scores were not significantly impacted by the surgical mask.”</td>
<td>“Use of a surgical mask as an outer barrier over N95 [FFRs] does not significantly impact the physiological burden or perceptions of comfort and exertion by the wearer over that experienced without use of a surgical mask.”</td>
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## Selected Resources and Reference

### Search Summaries

The following databases were used to identify the literature and related materials.

**ECRI Institute Resources [searched January 1, 2000, through May 1, 2020]**

Search Strategy:

(n95 OR respirator OR mask) AND (reuse OR re-use OR clean OR disinfect OR decontaminate OR sterilize OR extend OR recycl* OR reprocess*); scan of COVID-19 resource center

Results: We identified 29 related reports.

- Cloth face coverings worn by public to reduce transmission of viral respiratory infection. [Hotline Response]. 2020 Apr 16.
- COVID-19 resources for supply chain. [Resource Center]. [cited 2020 Apr 10].
- COVID-19 supply chain FAQs – your questions answered. [cited 2020 Apr 10].
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Safety of Extended Use and Reuse of N95 Respirators

- Disinfectant concentrations and contact times for EPA’s list of products effective against novel coronavirus SARS-CoV-2, the cause of COVID-19. [Evaluations and Guidance]. 2020 Apr 1.
- Personal protective equipment (PPE) supply equivalents. [PriceGuide]. [updated 2020 Apr 7].
- Should reusable respirators be used more often in healthcare settings? [Risk Management News]. 2018 Dec 12.
- Strategies for addressing expected or known N95 facemask shortages. [ECRI Exclusive Hazard Report]. 2020 Apr 22.
- Strategies for addressing expected or known N95 respirator shortages. [Medical Device Special Report]. 2020 Apr 8.
- Sterizone VP4 Sterilizer. [FDA Approvals & Clearances]. 2020 Apr 16.


Search Strategy:

#1 (“Masks”[Mesh:NoExp] OR mask* OR “Respiratory Protective Devices”[Mesh] OR respirator*) AND (N95 OR N99 OR N100 OR “N 95” OR “N 99” OR “N 100”)
#2 “Sterilization”[Mesh] OR “Equipment Reuse”[Mesh] OR sterilis* OR steriliz* OR disinfect* OR decontamin* OR clean* OR “re use*” OR “re using” OR “re us*” OR reus* OR extend* OR recyl* OR reprocess* 
#3 #1 AND #2

Results: We identified 39 records.


Search Strategy:

#1 (“mask”/exp OR mask* OR respirator*) AND (n95 OR ‘n95 respirator’/exp OR ‘n95 respirator’ OR n99 OR n100 OR ‘n 95’ OR ‘n 99’ OR ‘n 100’)
#2 “disinfection”/de OR ‘recycling’/de OR sterilis* OR steriliz* OR disinfect* OR decontamin* OR clean* OR “re use*” OR “re using” OR “re us*” OR reus* OR extend* OR recyl* OR reprocess* 
#3 #1 AND #2

Results: We identified 13 records.
Guidelines and Standards [searched January 1, 2000, through May 4, 2020]

Search Strategy:
N95 AND (reus* OR extend*); scan of relevant site indexes

Results: We identified 9 relevant documents.

Selected Standards and Guidelines

- Centers for Disease Control and Prevention (CDC). [cited 2020 May 4].
  - Decontamination and reuse of filtering facepiece respirators. [last reviewed 2020 Apr 30].
  - Release of stockpiled N95 filtering facepiece respirators beyond the manufacturer-designated shelf life: consideration for the COVID-19 response. [updated 2020 Apr 16].
  - Strategies for optimizing the supply of N95 respirators. [last reviewed 2020 Apr 22].

- Infectious Diseases Society of America (IDSA). Infectious Diseases Society of America guidelines on infection prevention in patients with suspected or known COVID-19. 2020 Apr 27.

- National Institute for Occupational Safety and Health (NIOSH). Recommended guidance for extended use and limited reuse of N95 filtering facepiece respirators in healthcare settings. [last reviewed 2020 Mar 27].

- Occupational Safety and Health Administration (OHSA). [cited 2020 May 4].
  - Enforcement guidance for respiratory protection and the N95 shortage due to the Coronavirus disease 2019 (COVID-19) pandemic. 2020 Apr 3.
  - Enforcement guidance for use of respiratory protection equipment certified under standards of other countries or jurisdictions during the Coronavirus Disease 2019 (COVID-19) pandemic. 2020 Apr 3.

- Society of American Gastrointestinal and Endoscopic Surgeons. (SAGES). N95 re-use strategies. [updated 2020 Apr 17].

- FDA. Enforcement policy for face masks and respirators during the Coronavirus disease (COVID-19) public health emergency (revised): guidance for industry and Food and Drug Administration staff. 2020 Apr.


Selected Web Resources. [searched May 8, 2020]

Manufacturers

  - STERRAD® Systems. [cited 2020 Apr 13].
    - 8 things to consider before reprocessing select N95 masks/respirators for the first time. 2020.
    - Fact sheet for healthcare personnel on emergency use of STERRAD® Sterilization systems to reprocess N95 respirators. 2020.
    - Instructions for use (IFU) & fact sheet. [cited 2020 May 4].


- Battelle Memorial Institute. [cited 2020 Apr 13].
  - Battelle CCDS Critical Care Decontamination System™. [cited 2020 Apr 13].
    - CCDS™ Overview. 2020 Mar.
    - CCDS™ technical 1-pager. 2020 Mar.
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Safety of Extended Use and Reuse of N95 Respirators

- Instructions for healthcare facilities. 2020 Mar 29.
- Instructions for healthcare personnel. 2020 Mar 29.
  - COVID-19 newsroom. [cited 2020 Apr 13].
- Sterilucent, Inc. [cited 2020 May 1].
  - HC 80TT Vaporized Hydrogen Peroxide Sterilizer. [cited 2020 May 1].
  - Instructions for healthcare personnel. 2020 Apr 20.
  - Instructions for healthcare facilities. 2020 Apr 20.
  - Instructions for healthcare personnel. 2020 Apr 20.
- STERIS Healthcare. [cited 2020 Apr 13].
  - STERIS decontamination solutions for compatible N95 or N95-equivalent respirators. [cited 2020 Apr 13].
  - Instructions for healthcare facilities. 2020 Apr 9.
  - Instructions for healthcare personnel. 2020 Apr 10.
  - Media fact sheet. [cited 2020 Apr 10].
  - Q&A V-PRO decontamination protocol. [cited 2020 Apr 13].
- Stryker Instruments. [cited 2020 May 1].
  - STERIZONE VP4. [cited 2020 May 1].
  - Instructions for healthcare personnel. 2020 Apr 14.
  - Instructions for healthcare facilities. 2020 Apr 14.
  - Instructions for healthcare personnel. 2020 Apr 14.

Other Selected Web Resources

  Note: may require subscription to read full text.
- Change in U.S. law will make millions more masks available to doctors and nurses, White House says. The Washington Post. 2020 Mar 20. Note: may require subscription to read full text.
- Dry heat ovens can effectively disinfect N95 masks. Stony Brook University News. 2020 Apr 9.

NIOSH-approved N95 particulate filtering facepiece respirators. The National Personal Protective Technology Laboratory (NPPTL). [last reviewed 2020 Mar 12].

NIOSH tool could help hospitals repurpose rooms for disinfecting N95 masks. NIST. 2020 Apr 16.

- Tool for evaluation of vaporized hydrogen peroxide disinfection of N95 masks in small rooms. NIST. [last updated 2020 Apr 7].

- Novel coronavirus: health experts warn against steaming face masks for reuse after misinformation on Chinese social media. AFP Fact Check. 2020 Feb 3.

- Phend, C. How many times can an N95 mask be sanitized and reused? Medpage Today. 2020 Apr 15.

- Steps for safe redonning (reuse) of N95 respirators. California Hospital Association. [cited 2020 Mar 23].


References Reviewed (PubMed and EMBASE search dates were January 1, 2000, through April 10, 2020)


Policy Statement

The information presented in this Clinical Evidence Assessment is highly perishable and reflects the state of the literature on this topic at the time at which searches were conducted and the Clinical Evidence Assessment was prepared. Clinical Evidence Assessments provide a guide to the published clinical literature and other information about a topic on which we received a client inquiry. The scope is customized to address the specific information needs of the requestor. The content reflects the information identified from searches of the available, published, peer-reviewed scientific literature, gray literature, and websites at the time the searches were conducted.

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