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CLINICAL EVIDENCE ASSESSMENT

Safety of Extended Use and Reuse of N95 Respirators

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 wear) or reusing a respirator several times (i.e., donning and doffing between uses) 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 during decision making about N95 respirator reuse or extended use.

Published clinical studies are not available to assess the safety of N95 reuse and extended use during critical shortages, so we examined 21 laboratory studies because they 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 since N95 reuse/extended use practices are associated with sporadic, unpredictable, variable crisis situations. Nonetheless, limited 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 respirator N95 models found that covering respirators with surgical masks had no clinically significant effect on breathing effort and gas exchange. Decontamination of N95 respirators by steam, disinfectants (e.g., bleach, 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 are 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 (i.e., for medical use) N95s.
- Commonly effective disinfection methods can achieve adequate disinfection, with some filter performance loss.

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. 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.

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Executive Summary

Conclusions

In the absence of clinical studies, we reviewed 21 laboratory studies on N95 reuse and extended use.

- *N95 respirator contamination risks*: 2 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. 1 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*: 3 studies reported that autoclaves, steaming, moist heat, bleach, benzalkonium chloride, and ultraviolet-C (UV-C) (1 to 2 J/cm^2) achieved >10,000-fold reduction in H5N1 (Lore et al. 2012), H1N1 (Heimbuch et al. 2011), and *S. aureus* (Heimbuch et al. 2014) loads on contaminated N95s; however, Heinbuch et al. (2011) found UVGI ineffective on some N95 models, and 1 of the studies reported that inoculation patterns affected UCGI (Woo et al. 2012).
- *N95 integrity*: 2 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. 1 study (Lin et al. 2017) reported reduced filtration in a N95 model cleaned with bleach, 70% ethanol, steaming, or autoclaving; however, 1 study (Bergman et al., 2010) reported that 6 models still filtered >95% of 300 mn particulate after 3 cleanings with bleach, hydrogen peroxide, steaming, moist heat (65 °C for 20 minutes), or UVGI (1 to 2 J/cm^2). The same group (Viscusi et al. 2011) reported that cleaned N95s fit well, but 1 study (Lindsey et al. 2015) reported that filters and straps were damaged by UVGI doses >120 J/cm^2.
- *Adverse event risks*: 2 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. 1 study (Salter et al. 2010) reported no toxic residue in N95s decontaminated with bleach, hydrogen peroxide, or UVGI, but ethylene oxide treatment resulted in detectable toxins.

Evidence

Search dates: January 1, 2000, through March 23, 2020. We reviewed 21 bench and simulation studies, 16 as full-text articles and 5 as published abstracts. See full report for study details.

- We reviewed full text of published studies available through open access or our library subscriptions and abstracts of other studies.
- *4 studies of simulated N95 reuse or extended use:* 2 studies (Vuma et al. 2019, Bergaman 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.
- *13 studies of N95 decontamination:* 5 studies reported on microbial load (Lin et al. 2018, Heimbuch et al. 2011, Fisher et al. 2011, Fisher and Shaffer 2011, Mills et al. 2018, Woo et al. 2012,), 3 studies reported on filter performance and integrity (Lin et al. 2017, Bergman et al. 2010, Lindsey et al. 2015), and 3 studies reported on both (Heimuch et al. 2014, Lore t al. 2012, and Viscusi et al. 2011). 1 study reported on residual chemical levels (Salter et al. 2010).

Clinical Guidelines and Recommendations

Searched PubMed, EMBASE, and ECRI Guidelines Trust® (EGT) for relevant documents on N95 respirator use from January 1, 2000, through March 23, 2020. We identified 7 documents.

- These guidelines have been published by the U.S. Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), Occupational Safety and Health Administration (OSHA), and 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 devices 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 filtrate 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*, the National Institute for Occupational Safety and Health's [NIOSH] 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 um to receive the CE mark. (For more information, see the OSHA Technical Manual Section VIIII, 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, nor do they require manufacturers to include disinfection recommendations in the labeling of single-use N95s. Nonetheless, several proposed methods for single-use N95 disinfection have been evaluated in bench studies by NIOSH and other agencies. 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 $mW.s/cm^2$ for most organisms but varies depending on the pathogen, surface type, exposure mode, and ambient humidity. Penetrance 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 needed uses, 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

Examples of actions taken in response to a critical shortage of N95 respirators during the COVID-19 outbreak include the following:

- 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."
- 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 homemade mask use 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 may change if conventional surgical masks become completely unavailable.

- New legislation let U.S. manufacturers sell N95 masks made for industrial uses to hospitals without fear of liability.
- CDC published a document listing considerations to inform release of stockpiled FFRs beyond their manufacturer-designated shelf life.
- AFP Hong Kong published a warning against steaming facemasks for reuse.
- FDA issued a guidance document, *Enforcement Policy for Face Masks and Respirators during the Coronavirus (Covid-19) Disease Public Health Emergency* to "provide a policy to help expand the availability of general use face masks for the general public and particulate filtering facepiece respirators (including N95 respirators) for health care professionals during this pandemic."
- In a letter to stakeholders, FDA "concluded based on the totality of scientific evidence available that certain imported disposable FFRs that are not NIOSH-approved are appropriate to protect the public health or safety."
- 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."
- The University of Nebraska used ultraviolet light to decontaminate masks.

Clinical Guidelines and Recommendations

Searches of PubMed, EMBASE, EGT, and other web-based resources identified seven relevant guidelines published between January 1, 2000, and March 23, 2020, as follows:

- CDC: *Strategies for Optimizing the Supply of N95 Respirators: Contingency Capacity Strategies: Administrative Controls*. 2020. This guidance describes the following measures that may be considered in the setting of a potential impending shortage of N95 respirators:
    - Use of N95 respirators beyond the manufacturer-designated shelf life for training and fit testing
    - Extended use of N95 respirators
- CDC. *Strategies for Optimizing the Supply of N95 Respirators: Conventional Capacity Strategies: Engineering Controls*. 2020. This guidance describes strategies that can be considered in healthcare settings during a potential N95 respirator shortage before implementing the contingency strategies, including:

    Use 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 where feasible. All of these alternatives will provide equivalent or higher protection than N95 respirators when properly worn.
- CDC. *Strategies for Optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies*. 2020. This guidance 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 for COVID-19 patients
    - Prioritize the use of N95 respirators and facemasks by activity type
    - During severe resource limitations: Exclude HCP 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.

- State of California. *Cal/OSHA Interim Guidance on Coronavirus for Health Care Facilities: Severe Respirator Supply Shortages*. 2020. This guidance offers the following recommendations that may enable employers to extend their existing respirator supply:

  • Use non-disposable respirators instead of filtering facepiece respirators

  Elastomeric half-mask, full-facepiece and powered air-purifying respirators (PAPRs) can be disinfected and re-used multiple times.

  • Use filtering facepiece respirators for extended periods

  Health care employees may be able to keep the same respirator on during encounters with several patients without removing the respirator between patient encounters. Employers must ensure that the respirators are kept clean, sanitary, and in good working order at all times.

  • Developing policies for employees to reuse (redon) a filtering facepiece respirator

  Generally filtering facepiece respirators should not be reused, particularly for diseases such as COVID-19 for which contact precautions are recommended. Facilities should develop procedures for safe reuse of filtering facepiece respirators, which include removal (doffing), safe storage, inspection and donning. Employers may adopt methods for sanitization between uses, so long as they effectively destroy pathogens and do not compromise the respirator functionality and effectiveness. Employees must be trained in the employer's procedures.

  • Use industrial filtering facepiece respirators in health care

  On March 2, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) allowing the use of certain industrial N95 respirators in health care settings.

  • Use filtering facepiece respirators after their expiration date

  NIOSH has approved use of certain expired fileting facepiece respirators under specific conditions. See Release of Stockpile N95 Filtering Facepiece Respirators Beyond the Manufacturer-Designated Shelf Life: Consideration for the COVID-19 Response.

  • Use filtering facepiece respirators certified to a foreign standard

  On March 24, 2020, the FDA issued a "Non-NIOSH Approved Respirator Emergency Use Authorization" allowing use of non-NIOSH-approved respirators in healthcare that have been approved in other countries. Respirators not currently on this list may be submitted to the FDA for EUA. The CDC recognizes several standards as equivalent to the NIOSH N95 certification.

  • Allow employees to wear their own PPE if it complies with Cal/OSHA requirements standard

  Title 8 CCR Section 3380 permits employee-provided PPE as long as the employer ensures the PPE complies with Cal/OSHA standards and is properly maintained. Employers should not prohibit employee-provided PPE in compliance with Cal/OSHA standards when the employer is unable to provide it. Disciplining an employee for choosing to bring compliant PPE to work could subject the employer to claims of retaliation claims under Sections 1102.5 and 6310 through 6312 of the Labor Code.

- WHO. *Rational Use of Personal Protective Equipment for Coronavirus Disease 2019 (COVID-19): Interim Guidance*. 2020. This guidance states the following:

  Evidence indicates that respirators maintain their protection when used for extended periods. However, using one respirator for longer than 4 hours can lead to discomfort and should be avoided

- 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.
  - 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.

— OHSA. *Pandemic Influenza Preparedness and Response Guidance for Healthcare Workers and Healthcare Employers*. 2007. This guidance states:

- Once worn in the presence of an infectious patient, the respirator should be considered potentially contaminated with infectious material, and touching the outside of the device should be avoided. Upon leaving the patient's room, the disposable respirator should be removed and discarded, followed by proper hand hygiene.
- If a sufficient supply of respirators is not available during a pandemic, healthcare facilities may consider reuse as long as the device has not been obviously soiled or damaged (e.g., creased or torn), and it retains its ability to function properly. Data on reuse of respirators for infectious diseases are not available. Reuse may increase the potential for contamination; however, this risk must be balanced against the need to provide respiratory protection for healthcare workers.
- Reuse of a disposable respirator should be limited to a single wearer (i.e., another wearer should not use the respirator). Consider labeling respirators with a user's name before use to prevent reuse by another individual.
- If disposable respirators need to be reused by an individual user after caring for infectious patients, employers should implement a procedure for safe reuse to prevent contamination through contact with infectious materials on the outside of the respirator.
- One way to address contamination of the respirator's exterior surface is to consider wearing a faceshield that does not interfere with the fit or seal over the respirator. Wearers should remove the barrier upon leaving the patient's room and perform hand hygiene. Face shields should be cleaned and disinfected. After removing the respirator, either hang it in a designated area or place it in a bag. Store the respirator in a manner that prevents its physical and functional integrity from being compromised.
- In addition, use care when placing a used respirator on the face to ensure proper fit for respiratory protection and to avoid unnecessary contact with infectious material that may be present on the outside of the mask. Perform hand hygiene after replacing the respirator on the face.

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 March 23, 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 and reviewed 21 studies, as follows:

— 4 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. 1 study included 16 subjects and tested 3M 1860 and 3 unlisted N95 models.(1) 1 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 Huei.(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 studies reported 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)

— 13 studies reported on N95 decontamination:

- 3 studies reported on viable M2 load reduction with 0.1 J/cm^2 UVGI in 4 3M and Kimberly Clark N95s, with 1 mW/cm^2 UVGI for 30 minutes on 3M 1870 filters, and with microwave steaming on 6 3M, Cardinal Health, Kimberly-Clarke, and Moldex N95s, respectively.(9-12)
- 2 studies reported viable H1N1 load reduction in 6 N95 models decontaminated with microwave steaming, moist heat (65°C for 30 minutes), or UVGI (1.6 to 2.0 W/cm^2 for 15 minutes) and in 15 N95 models decontaminated with UVGI (1J/cm^2), respectively.(13, 14)
- 1 study reported on H5N1 virus RNA load reduction and particle penetration changes in 3M 1870 filters decontaminated with microwave steaming, moist heat, or UVGI (1.8 J cm^2).(13)
- 1 study reported on viable *Bacillus subtilis* spore load reduction on a N95 model decontaminated with bleach, ethanol, autoclaving, or steaming, and UVGI.(15)
- 1 study reported on viable *S. aureus* load reduction with commercially available benzalkonium chloride (3M) and sodium hypochlorite (Current Technologies, Inc.) wipes in 3M and Kimberly-Clarke N95s.(16)
- 1 study reported on particle penetrance and airflow resistance changes in a N95 model decontaminated with bleach, 70% ethanol, microwave or oven steaming, and autoclaving.(17)
- 1 study reported on particle penetrance in 6 N95 models decontaminated with three successive cycles of bleach, liquid (3%) or gas hydrogen peroxide, microwave or oven steaming, moist heat, and UVGI (1.8 W/cm^2 at 15 min/cycle).(9)
- 1 study reported on particle penetrance and material integrity in 4 3M, Gerson, and Kimberly-Clark N95 models exposed to high-dose UVGI (120 to 950 J/cm^2).(18)
- 1 study reported on seal quality in N95 models subject to microwave steaming, moist heat, and UVGI successfully and fit-tested by 10 subjects.(19)
- 1 study reported on chemical residue levels on 6 N95 models decontaminated with bleach, 3% hydrogen peroxide, vaporized hydrogen peroxide, ethylene oxide, or UVGI.(6)

Table 1 provides summaries of studies. We reviewed full-text articles available with open access and articles of other studies. We excluded from review mathematical modelization and *in silico* studies.

Evidence limitations and discussion: The laboratory studies relevant to N95 extended use and reuse risks are subject to major limitations to interpretation because many of the findings were reported in single studies or may not fully generalize across studies with 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 review studies support prioritizing N95 extended use over reuse because 1) reported pathogen transfer risk from N95s was high by contact but low by re-arosolization, 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. Laboratory Studies

Reference	Study Aim	Setup and Outcomes Assessed	Results	Authors' Conclusions
Reuse				
Vuma et al. 2019(1) South Africa Reviewed abstract	To measure "the effect on respirator fit of multiple donning and doffing of N95 filtering facepiece respirators (FFRs)"	"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."	"Two subjects (8%) had an overall fit factor <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 either 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."	"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 <100 supports this contention."

Reference	Study Aim	Setup and Outcomes Assessed	Results	Authors' Conclusions
Brady et al. 2017(7) United States Reviewed full text	To "characterize the transfer of bacteriophage MS2 and fluorescein between [FFRs] and the wearer's hands during three simulated use scenarios."	"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."	"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]."	"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."
Coulliette et al. 2013(5) United States Reviewed full text	To "evaluate the persistence and infectivity of pH1N1 on FFRs, specifically N95 respirators, under various conditions of absolute humidity (AH) ($4.1 \times 10(5)$ mPa, $6.5 \times 10(5)$ mPa, and $14.6 \times 10(5)$ 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)."	"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."	"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 ($P \leq 0.01$) reductions in virus concentrations at time points beyond 24 to 72 h (-0.52-log10 reduction) and 144 h (-0.74) at AHs of $6.5 \times 10(5)$ mPa (-0.53) and $14.6 \times 10(5)$ mPa (-0.47)."	"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."

Reference	Study Aim	Setup and Outcomes Assessed	Results	Authors' Conclusions
Bergman et al. 2012(2) United States Reviewed full text	"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."	"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."	"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." "In addition, when the regression analyses were performed separately for each model for all 20 donnings, the regression models for all 6 FFR models demonstrated statistical significance (P <.05) and R2 values ranging from 0.40 (for [surgical] N95-D) to 0.78 (for N95-B) [models were anonymized as surgical or nonsurgical N95-A to F]."	"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."
Reuse after Decontamination				
Mills et al. 2018(14) United States Reviewed full text	To "evaluate the ultraviolet germicidal irradiation (UVGI) decontamination efficiency of influenza-contaminated FFRs in the presence of soiling agents using an optimized UVGI dose."	"Twelve samples each of 15 N95 FFR models [3M 18060, 18070, and VFlex 1805; Alpha Protech 695; Gerson 1730; Kimberly-Clark PFR; Moldex 1512, 1712, and EZ-22; Precept 65-3395; Prestige Ameritech RP88020; Sperian HC-NB095 and HC-NB295F; U.S. Safety AD2N95A and AD4N95] were contaminated with H1N1 influenza (facepiece and strap), then covered with a soiling agent-artificial saliva or artificial skin oil. For each soiling agent, 3 contaminated FFRs were treated with 1 J/cm(2) UVGI for approximately 1 minute, whereas 3 other contaminated FFRs remained untreated. All contaminated surfaces were cut out and virus extracted. Viable influenza was quantified using a median tissue culture infectious dose assay."	"Significant reductions (≥3 log) in influenza viability for both soiling conditions were observed on facepieces from 12 of 15 FFR models and straps from 7 of 15 FFR models." "For mucin-soiled straps, the mean viable virus recovered from UV-treated samples was statistically significantly lower than control samples for all FFR models tested except the VFlex 1805 (3M Company, Maplewood, MN), Alpha Protech 695 (Alpha Protech, Markham Canada), Moldex EZ 22, and the U.S. Safety AD2N95A (Dentech Safety Specialists, Lenexa, KS)." "For sebum-soiled straps, the mean viable virus recovered from UV-treated samples was significantly lower than control samples for all FFR models tested except the 3M 1860, Alpha Protech, and Moldex EZ 22."	"These data suggest that FFR decontamination and reuse using UVGI can be effective. Implementation of a UVGI method will require careful consideration of FFR model, material type, and design."

Reference	Study Aim	Setup and Outcomes Assessed	Results	Authors' Conclusions
Lin et al. 2018(15) Taiwan Reviewed abstract	To "determine the relative survival of Bacillus subtilis spores loaded on an N95 FFR after decontamination by five methods under worst-case conditions."	"Relative survival (RS) was obtained by testing after decontamination and after storing the FFRs at 37°C and 95% relative humidity for 24 hours. The decontamination methods involved ethanol, bleach, ultraviolet irradiation (UVA 365 nm, UVC 254 nm), an autoclave, and a traditional electric rice cooker (TERC) that was made in Taiwan."	"Without decontamination, 59 ± 8% of the loaded spores survived for 24 hours. When 70% ethanol was added to the N95 FFR at a packing density of 0.23, the RS was 73 ± 5% initially and decayed to 22 ± 8% in 24 hours. [RS] remained above 20% after 20 minutes of UVA irradiation. The other four decontamination measures achieved 99%-100% biocidal efficacy, as measured immediately after the methods were applied to the test FFRs."	"Relative survival is a useful parameter for measuring sterilization or degree of disinfection. Bleach, UVC, an autoclave, and a TERC provide better biocidal efficacy than ethanol and UVA. Not only a higher filter quality but also a lower value of RS produced the most decontaminated FFR."
Lin et al. 2017(17) Taiwan Reviewed full text	To "investigate the effects of five decontamination methods on the filter quality (qf) of three commercially available electret masks—N95, Gauze and Spunlace nonwoven masks."	"The overall filter quality (q(f,o)) and the q(f) ratio were applied to evaluate the effectiveness of decontamination methods for respirators. A scanning mobility particle sizer is utilized to measure the concentration of polydispersed particles with diameter 14.6–594 nm. The penetration of particles and pressure drop (Δp) through the mask are used to determine q(f) and q(f,o)."	"Decontamination increased the sizes of the most penetrating particles, changing the q(f) values of all of the masks: q(f) fell as particle size increased because the penetration increased. Bleach increased the Δp of N95, but destroyed the Gauze mask. However, the use of an autoclave reduces the Δp values of both the N95 and the Gauze mask. Neither the rice cooker nor ethanol altered the Δp of the Gauze mask. Chemical decontamination methods reduced the q(f,o) values for the three electret masks."	"The values of q(f,o), particularly for PM(0.1) [100-nm particulate matter], reveal that for the tested treatments and masks, physical decontamination methods are less destructive to the filter than chemical methods. Nevertheless, when purchasing new or reusing FFRs, penetration should be regarded as the priority."

Reference	Study Aim	Setup and Outcomes Assessed	Results	Authors' Conclusions
Lindsley et al. 2015(18) United States Reviewed full text	To "determine if UVGI exposure could degrade the ability of a disposable respirator to protect the worker."	"We exposed both sides of material coupons and respirator straps from four models of N95 FFRs [3M 1868 and 9210, Gerson 1730, and Kimberly-Clark 46727] to UVGI doses from 120-950 J/cm(2). We then tested the particle penetration, flow resistance, and bursting strengths of the individual respirator coupon layers, and the breaking strength of the respirator straps."	"We found that UVGI exposure led to a small increase in particle penetration (up to 1.25%) and had little effect on the flow resistance. UVGI exposure had a more pronounced effect on the strengths of the respirator materials. At the higher UVGI doses, the strength of the layers of respirator material was substantially reduced (in some cases, by >90%). The changes in the strengths of the respirator materials varied considerably among the different models of respirators. UVGI had less of an effect on the respirator straps; a dose of 2360 J/cm(2) reduced the breaking strength of the straps by 20-51%."	"Our results suggest that UVGI could be used to effectively disinfect disposable respirators for reuse, but the maximum number of disinfection cycles will be limited by the respirator model and the UVGI dose required to inactivate the pathogen."
Heimbuch et al. 2014(16) United States Reviewed full text	To "evaluate the ability of commercially available wipe products to clean FFRs contaminated with either infectious or noninfectious aerosols."	"Three models of surgical N95 FFRs [3M 1860 and 1870 and Kimberly-Clarke PFR] were contaminated with aerosols of mucin or viable Staphylococcus aureus then cleaned with hypochlorite [Hype-Wipes (Current Technologies, Inc.] benzalkonium chloride [3M 504/07065 Respirator Cleaning Wipes], or nonantimicrobial wipes [Pampers]. After cleaning, FFRs were separated into components (nose pad, fabrics, and perforated strip), and contaminants were extracted and quantified. Filtration performance was assessed for cleaned FFRs."	"Mucin removal was <1 log for all wipe products on all components. Inert wipes achieved ~1-log attenuation in viable S aureus on fabrics from all FFR models--removal was less effective from nose pads and perforated edges. Both antimicrobial wipes achieved 3-5-log attenuation on most components, with smaller reductions on nose pads and greater reductions on perforated strips. Particle penetration following cleaning yielded mean values <5%. The highest penetrations were observed in FFRs cleaned with benzalkonium chloride wipes."	"FFRs can be disinfected using antimicrobial wipe products, but not effectively cleaned with the wipes evaluated in this study. This study provides informative data for the development of better FFRs and applicable cleaning products."

Reference	Study Aim	Setup and Outcomes Assessed	Results	Authors' Conclusions
Woo et al. 2012(10) United States Reviewed full text	To "determine the effects of transmission mode and environmental conditions on decontamination efficiency by ultraviolet (UV).	"Filters [3M 1870] were contaminated by different transmission pathways (droplet and aerosol) using three spraying media (deionized water [DI], beef extract [BE], and artificial saliva [AS]) under different humidity levels (30% [low relative humidity {LRH}], 60% [MRH], and 90% [HRH]). UV irradiation at constant intensity was applied for two time intervals at each relative humidity condition."	"The highest inactivation efficiency (IE), around 5.8 logs, was seen for DI aerosols containing MS2 on filters at LRH after applying a UV intensity of 1.0 mW/cm(2) for 30 min. The IE of droplets containing MS2 was lower than that of aerosols containing MS2. Absorption of UV by high water content and shielding of viruses near the center of the aggregate are considered responsible for this trend."	"Across the different media, IEs in AS and in BE were much lower than in DI for both aerosol and droplet transmission, indicating that solids present in AS and BE exhibited a protective effect. For particles sprayed in a protective medium, RH is not a significant parameter."
Lore et al. 2012(13) United States Reviewed full text	To "examine the effectiveness of three energetic decontamination methods [ultraviolet germicidal irradiation (UVGI), microwave-generated steam, and moist heat] on two [NIOSH]-certified N95 FFRs (3M models 1860s and 1870) contaminated with H5N1."	"An aerosol settling chamber was used to apply virus-laden droplets to FFRs in a method designed to simulate respiratory deposition of droplets onto surfaces." Microwaved for 2 minutes at 1,250 W in an oven containing a water pan, stored at 65°C and 100% for 20 min, or irradiated with a 254 nm UV lamp at 1.8 J/cm^2.	"All three decontamination methods were effective, reducing virus load by > 4 log median tissue culture infective dose. Analysis of treated FFRs using a quantitative molecular amplification assay (quantitative real-time polymerase chain reaction) indicated that UVGI decontamination resulted in lower levels of detectable viral RNA than the other two methods. Filter performance was evaluated before and after decontamination using a 1% NaCl aerosol. As all FFRs displayed <5% penetration by 300-nm particles, no profound reduction in filtration performance was caused in the FFRs tested by exposure to virus and subsequent decontamination by the methods used."	"These findings indicate that, when properly implemented, these methods effectively decontaminate H5N1 on the two FFR models tested and do not drastically affect their filtering function; however, other considerations may influence decisions to reuse FFRs."

Reference	Study Aim	Setup and Outcomes Assessed	Results	Authors' Conclusions
Viscusi et al. 2011(19) United States Reviewed abstract	To "determine if UVGI, moist heat incubation (MHI), or microwave-generated steam (MGS) decontamination affects the fitting characteristics, odor, comfort, or donning ease of six N95 FFR models."	"10 experienced test participants performed a series of fit tests to assess respirator fit and completed surveys to evaluate odor, comfort, and donning ease with FFRs that were not decontaminated (controls) and with FFRs of the same model that had been decontaminated. Respirator fit was quantitatively measured using a multidonning protocol with the TSI PORTACOUNT Plus and the N95 Companion accessory."	"Two of the six FFRs demonstrated a statistically significant reduction ($p < 0.05$) in fit after MHI decontamination. However, for these two FFR models, post-decontamination mean fit factors were still ≥ 100. One of the other FFRs demonstrated a relatively small though statistically significant increase ($p < 0.05$) in median odor response after MHI decontamination."	"These data suggest that FFR users with characteristics similar to those in this study population would be unlikely to experience a clinically meaningful reduction in fit, increase in odor, increase in discomfort, or increased difficulty in donning with the six FFRs included in this study after UVGI, MHI, or MGS."
Heimbuch et al. 2011(20) United States Reviewed full text	To "evaluate the ability of microwave-generated steam [1,250 W for 2 min], warm moist heat [65 C for 30 min.], and [UVGI] at 254 nm [1.6 to 2 W/cm^2 for 15 min.] to decontaminate H1N1 influenza virus."	"Six commercially available FFR models were contaminated with H1N1 influenza virus as aerosols or droplets that are representative of human respiratory secretions. A subset of the FFRs was treated with the aforementioned decontamination technologies, whereas the remaining FFRs were used to evaluate the H1N1 challenge applied to the devices."	"All 3 decontamination technologies provided >4-log reduction of viable H1N1 virus. In 93% of our experiments, the virus was reduced to levels below the limit of detection of the method used."	"These data are encouraging and may contribute to the evolution of effective strategies for the decontamination and reuse of FFRs."

Reference	Study Aim	Setup and Outcomes Assessed	Results	Authors' Conclusions
Fisher et al. 2011(12) United States Reviewed full text	"The goal of this study is to evaluate the use of two commercially available steam bags, marketed to the public for disinfecting infant feeding equipment, for FFR decontamination.	"The FFRs were decontaminated with microwave generated steam [1,100 W] following the manufacturers' instructions then evaluated for water absorption and filtration efficiency for up to three steam exposures [3M 1860, 1870, and 8120; Cardinal Health; Moldex 2200; and Kimberly-Clark PFR95]... The decontamination efficacy of the steam bag was assessed using bacteriophage MS2 as a surrogate for a pathogenic virus."	"Water absorption of the FFR was found to be model specific as FFRs constructed with hydrophilic materials absorbed more water. The steam had little effect on FFR performance as filtration efficiency of the treated FFRs remained above 95%... tested steam bags [Medela Quick Clean™, Medela, McHenry, IL and Munchkin® Steam Guard™, Munchkin Inc., North Hills, CA] were found to be 99.9% effective for inactivating MS2 on FFRs; however, more research is required to determine the effectiveness against respiratory pathogens."	"The FFR filtration performance for the three cycle treatments was within acceptable levels of the selection criterion for each FFR model treated in each steam bag brand."
Fisher and Shaffer 2011(11) United States Reviewed full text	To "develop a method to assess model-specific parameters for ultraviolet-C (UV-C, 254 nm) decontamination of FFRs."	"Circular coupons, excised from the FFRs [3M 1860, 1870 and 8210; Kimberly-Clark PFR95-174; and two non-medical N95s] were exposed to aerosolized particles containing MS2 coliphage and treated with IFM-specific UV-C doses ranging from 38 to 4707 J m(-2)."	"Models exposed to a minimum IFM dose of 1000 J m(-2) demonstrated at least a 3 log reduction (LR) in viable MS2. Model-specific exposure times to achieve this IFM dose ranged from 2 to 266 min."	"UV-C transmits into and through FFR materials. LR of MS2 was a function of model-specific IFM UV-C doses."
Salter et al. 2010(21) United States Reviewed full text	To "measure the amount of residual chemicals created or deposited on six models of FFRs following treatment by each of 7 simple decontamination technologies."	"Decontamination technologies selected for this study comprise energetic, gaseous, and liquid agents... The gaseous technologies selected were vaporized hydrogen peroxide (VHP) and ethylene oxide (EO) sterilizers... The energetic device selected for the study was ultraviolet (UV) light [4.0 mW/cm2 of UV-B (302 nm) or 3.4 mW/cm2 UV-C (254 nm) for 1 h]... The commercially available aqueous (aq) solutions selected for the study were bleach (diluted to 0.6% hypochlorite) and 3% hydrogen peroxide."	"Measured amounts of decontaminants retained by the FFRs treated with chemical disinfectants were small enough that exposure to wearers will be below the permissible exposure limit. Toxic by-products were also evaluated, and two suspected toxins were detected after ethylene oxide treatment of FFR rubber straps [diacetone alcohol and ethylene glycol monoacetate]."	"The results suggest that most or all of the methods evaluated do not introduce major health risks, but this is only one of several performance criteria that must be met before any combination of decontamination technology and respirators can be recommended for reuse."

Reference	Study Aim	Setup and Outcomes Assessed	Results	Authors' Conclusions
Fisher and Shaffer 2010(6) United States Reviewed full text	To "examine the potential for FFRs to act as fomites using bacteriophage MS2."	"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."	"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."	"The results indicate that FFRs have the potential to serve as a fomite."
Bergman et al. 2010(9) United States Reviewed full text	To "investigate three-cycle (3X) processing of eight different methods: [UVGI], ethylene oxide, hydrogen peroxide gas plasma, hydrogen peroxide vapor, microwave-oven-generated steam, bleach, liquid hydrogen peroxide, and moist heat incubation (pasteurization)."	"A Model 8130 Automated Filter Tester (AFT) (TSI, Inc., St Paul, MN, USA) was used to measure initial percent filter aerosol penetration (%P) and filter airflow resistance (pressure drop in mm H2O column height pressure) for all post-decontamination and control FFR samples." Microwave steam consisted of 2 min/cycle at 1,100 W. Moist heat consisted of 30 min/cycle at 60°C and 80% humidity. UVGI consisted of 1.8 mW/cm^2 for 15 min/cycle.	"Only the hydrogen peroxide gas plasma treatment resulted in mean penetration levels > 5% for four of the six FFR models; FFRs treated by the seven other methods and the control samples had expected levels of filter aerosol penetration (< 5%) and filter airflow resistance. Physical damage varied by treatment method."	"Further research is still needed before any specific decontamination methods can be recommended."

Reference	Study Aim	Setup and Outcomes Assessed	Results	Authors' Conclusions
Extended Use				
Sinkule et al. 2013(3) United States Reviewed abstract	To "measure breathing air quality and breathing resistance when using FFRs with [FDA]-cleared surgical mask cover (SM) and without SM"	"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, abd SH3500 V] with and without SM were evaluated using the NIOSH Automated Breathing and Metabolic Simulator (ABMS) through six incremental work rates."	"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 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."
Fisher et al. 2012(8) United States Reviewed full text	"To assess the reaerosolization characteristics of VCPs from highly contaminated NIOSH-certified FFRs during simulated user-generated airflow (e.g. cough)."	"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)."	"Two droplet nuclei challenges produced higher percentages of reaerosolized particles (0.21 and 0.08%) than a droplet challenge (<0.0001%). Overall, the ACI-determined size distribution of the reaerosolized particles was larger than the characterized loading virus aerosol."	"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."

Reference	Study Aim	Setup and Outcomes Assessed	Results	Authors' Conclusions
Roberge et al. 2010(4) United States Reviewed abstract	"To determine the physiological impact on the wearer of using a surgical mask as an outer barrier over a FFR to extend wear."	"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."	"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 filtering facepiece respirators 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."	"Use of a surgical mask as an outer barrier over N95 filtering facepiece respirators 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."

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 March 23, 2020]

Search Strategy:

covid; (n95 OR respirator) AND (reuse OR re-use OR clean OR disinfect OR decontaminate OR sterilize OR extend)

Results: We identified ten related reports.

- COVID-19 resources for supply chain. [Resource Center]. [cited 2020 Mar 20].
- CMS updates its guidance for industrial respirator use. [Risk Management News]. 2020 Mar 18.
- 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 Mar 10.
- Is your organization doing enough to protect staff against COVID-19? [News]. 2020 Mar 16.
- MaxAir CAPR System (Syntech International) for preventing infections agent transmission. [Product Brief]. 2019 Oct 15.
- OSHA updates enforcement guidance for its respiratory protection standard. [Risk Management News]. 2020 Mar 18.
- Personal protective equipment. [Healthcare Risk, Quality, and Safety Guidance]. 2015 Dec 10.
- Personal protective equipment (PPE) supply equivalents. [PriceGuide]. [updated 2020 Mar 18].
- Selecting respiratory protection for equipment servicers and other hospital personnel: lessons from the 2003 SARS outbreak. [Evaluations and Guidance]. 2020 Feb 18.
- Should reusable respirators be used more often in healthcare settings? [Risk Management News]. 2018 Dec 12.

PubMed. Bethesda (MD): National Library of Medicine [searched January 1, 2010, through March 23, 2020] Available from: http://www.pubmed.gov.

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*
- #3 #1 AND #2

Results: We identified 26 records.

EMBASE. Amsterdam (The Netherlands): Elsevier B.V. [searched January 1, 2000, through March 23, 2020]. Available from: www.embase.com. Subscription required.

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*
- #3 #1 AND #2

Results: We identified four records.

Cochrane Library. Hoboken (NJ): John Wiley & Sons [searched January 1, 2000, through March 23, 2020] Available from: http://www.thecochranelibrary.com. Subscription required.

Search Strategy:

- #1 MeSH descriptor: [Masks] this term only
- #2 MeSH descriptor: [Respiratory Protective Devices] explode all trees
- #3 (mask* OR respirator*):ti,ab,kw
- #4 #1 OR #2 OR #3
- #5 (N95 OR N99 OR N100 OR “N 95” OR “N 99” OR “N 100”):ti,ab,kw
- #6 #4 AND #5
- #7 MeSH descriptor: [Sterilization] explode all trees
- #8 MeSH descriptor: [Equipment Reuse] explode all trees
- #9 (sterilis* OR steriliz* OR disinfect* OR decontamin* OR clean* OR “re use*” or “re using” OR “re us*” OR reus* OR extend*):ti,ab,kw
- #10 #7 OR #8 OR #9
- #11 #6 AND #10

Results: We did not identify any unique relevant publications.

Guidelines and Standards [searched January 1, 2000, through March 28, 2020]

Search Strategy:

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

Results: We identified seven relevant documents.

Selected Standards and Guidelines

- Centers for Disease Control and Prevention (CDC). [cited 2020 Mar 21].
    - Strategies for optimizng the supply of N95 respirators. [updated 2020 Feb 29].
        - Strategies for optimizing the supply of N95 respirators: contingency capacity strategies. [last reviewed 2020 Feb 29].
        - Strategies for optimizing the supply of N95 respirators: conventional capacity strategies. [last reviewed 2020 Feb 29].
        - Strategies for optimizing the supply of N95 respirators: crisis/alternate strategies. [last reviewed 2020 Mar 17].
- 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 2018 Mar 28].
- Occupational Safety and Health Administration (OHSA). Pandemic influenza preparedness and respons guidance for healthcare workers and healthcare employers. 2007.
- State of California. Cal/OSHA interim guidance on COVID-19 for health care facilities: sever respirator supply shortages. 2020 Mar 28.
- World Health Organization. Rational use of personal protective equipment for coronavirus disease 2019 (COVID-19). 2020 Mar 19.

Selected Web Resources. [searched March 23, 2020]

- As coronavirus looms, mask shortage gives rise to promising approach. *The New York Times*. 2020 Mar 20. 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.
- COVID-19 strategies for optimizing PPE and re-use. Indiana State Department of Health. [cited 23 Mar 2020].
- Guidance for limited reuse of N95 respirators and PAPR hoods. UW Medicine. 2020 Mar 19.
- Nebraska Medicine COVID-19 PPE Guidance – extended use and limited reuse of disposable facemasks, respirators, and protective eyeware. [cited 2020 Mar 23].
- NIOSH-approved N95 particulate filtering facepiece respirators. The National Personal Protective Technology Laboratory (NPPTL). [last reviewed 2020 Mar 12].
- Novel coronavirus: health experts warn against steaming face masks for reuse after misinformation on Chinese social media. AFP Fact Check. 2020 Feb 3.
- Release of stockpiled N95 filtering facepiece respirators beyond the manufacturer-designated shelf life: considerations for the COVID-19 response. Centers for Disease Control and Prevention (CDC). 2020 Feb 28.
- Reusability of facemasks during an influenza pandemic: facing the flu. Institute of Medicine (IOM). 2006.
- Reusing respirators and managing N95 supplies while living up to OSHA expectations. HealthLeaders. 2009 Dec 29.
- Steps for safe redonning (reuse) of N95 respirators. California Hospital Association. [cited 2020 Mar 23].
- Vizient's recommended strategies to the federal government for avoiding healthcare supply chain disruption due to COVID-19. Vizient. 2020 Mar 19.

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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. Publications referenced in this Clinical Evidence Assessment are generally limited to the English language. Clinical Evidence Assessments are developed by a multidisciplinary staff of doctoral level research analysts, clinicians, and medical librarian information specialists. For quality assurance, all reports are subject to review within ECRI before publication. Neither ECRI nor its employees accept gifts, grants, or contributions from, or consult for medical device or pharmaceutical manufacturers. The Clinical Evidence Assessment may be based on review of abstracts of published articles as well as full text articles. Abstracts do not always accurately reflect the methods and findings of full-length articles and limit full interpretation of published data. This Clinical Evidence Assessment is not intended to provide specific guidance for the care of individual patients. ECRI implies no warranty and assumes no liability for the information contained in the Clinical Evidence Assessment.

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