

Extended Use and Layering of N95 Respirators and Use of Expired Personal Protective Equipment: Supplemental Information

Key Messages

This supplemental information was generated to support decision-making around the extended use and layering of N95 respirators and use of expired personal protective equipment (PPE) during the novel coronavirus disease (COVID-19 or SARS-CoV-2) pandemic.

We examined the recommendations from national and international health authorities and organizations and completed a targeted search of published literature to determine what is known about extended use and layering of PPE and use of expired PPE, and found the following:

- Extended use of N95 respirators is preferred over reuse
- Layering of masks or face shields over N95 respirators may reduce droplet spray surface contamination
- In times of shortage, use of expired N95 respirators, surgical masks, isolation gowns, and gloves can be considered. Users should visibly inspect the product before use and if there are concerns with its integrity (such as degraded materials or visible tears), the product should be discarded

Background and Context

On April 1, Ontario Health (Quality) received a request from the Ontario Health Secretariat for recommendations related to the layering of personal protective equipment (PPE) to enable extended use of PPE and use of expired PPE during the COVID-19 pandemic, with an emphasis on N95 respirators. In response to that request, this supplemental information provides a summary of recommendations from national and international health authorities, organizations, and grey literature.

Moving forward, alerts have been set up to monitor emerging evidence in addition to this summary.

Guidance on Extended Use of Respirators (i.e., Wearing a Respirator for Hours at a Time)

Extended use is defined as the wearing of a disposable respirator during serial patient encounters without the removal or re-donning of the device between encounters.ⁱ Both extended use and reuse pose a transmission risk to health care personnel due to potential respirator contamination. This transmission risk can be minimized if health care personnel adhere stringently to hand hygiene before and after handling the respiratory protection device.ⁱ

European Centre for Disease Prevention and Control Technical Reportⁱⁱ: “Infection Prevention and Control for COVID-19 in Health Care Settings”

Approaches to economizing the use of PPE in the event of shortages

- In the event of shortages, to reduce consumption and maximize the use of PPE, it is acceptable for staff to wear the same respirator while caring for multiple patients with COVID-19 for up to 4 to 6 hours. This is on the condition that the respirator is not removed between patients and is not damaged, soiled, or contaminated, or unless specifically contraindicated by the manufacturer (as per World Health Organization COVID-19 guidanceⁱⁱⁱ).
- Surgical masks are designed for single use. Respirators are also usually discarded after use, but in the event of a shortage, they can be reused a limited number of times unless there is a risk of contamination through the deposition of infectious particles on the surface. Contamination of the surface of respirators and surgical masks entails a risk of infection when putting the device on again (donning) for reuse. Because SARS-CoV-2 survives in the environment, including on the surfaces of various materials such as tissue, there is a risk that the outer surface of respirators and surgical masks used during patient care may become contaminated. The risk of respiratory droplets contaminating the surface of surgical masks and respirators is considered to be lower when they are covered with a visor. In such cases, reuse of the respirator/surgical mask may be considered as a last-resort option to economize on use of PPE.

Association for Professionals in Infection Control and Epidemiologyⁱ (APIC): “APIC Position Paper: Extending the Use and/or Reusing Respiratory Protection in Healthcare Settings During Disasters”

- Extending the use or reusing respiratory protection is preferred over prioritizing the allocation of N95 respirators and surgical/procedure masks based on exposure risk
- Extended use is preferred over reuse
- Practices for extending the use and/or reusing a respirator:
 - The respirator should only be worn and/or reused by a single wearer
 - The respirator should not be removed, adjusted, or touched during patient care activities
 - Avoid contamination during use by not touching the outside of the respirator
 - Care should be taken to prevent touching the inside of the respirator
 - The respirator should be discarded after being used during an aerosol-generating procedure
 - The respirator should be discarded if it becomes grossly contaminated with the patient’s bodily fluids, including blood or respiratory secretions. Note: this may be difficult for the wearer to discern. Health care personnel should be aware that even if not visibly soiled, the external surface of the respirator is always considered contaminated after use
 - The respirator must be discarded if it becomes obviously soiled or damaged (e.g., creased, torn, or saturated) or if breathing through the device becomes difficult
 - Consider using a surgical/procedure mask or face shield over the respirator to reduce/prevent contamination of the device. If masks are also in short supply, face shield use should be encouraged to help conserve masks.

Recommendations on Reuse of Respirators (i.e., Donning and Doffing Between Uses)

Reuse consists of removing and re-donning the same disposable respirator between serial patient encounters.ⁱ Both extended use and reuse pose a transmission risk to health care personnel due to potential contamination.ⁱ This transmission risk can be minimized if health care personnel adhere stringently to hand hygiene before and after handling the respiratory protection device.ⁱ

ECRI Clinical Evidence Assessment^{iv}: “Safety of Extended Use and Reuse of N95 Respirators”

- 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
 - Two studies (Vuma et al. 2019^v and Bergman et al. 2012^{vi}) reported that 7% to 8% of N95s failed fitting after two uses and more than 20% failed after five uses
- Two studies found that 4% to 18% of H1N1 virus particles and more than 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^{vii}) reported that 2% to 15% of M2 particles transferred to the users who donned contaminated N95s. The other study (Fisher et al. 2012^{viii}) reported minimal M2 aerosolization (< 0.2%) from contaminated N95s in simulated cough tests

Guidance on Layering Personal Protective Equipment

Layering involves wearing more than one piece of PPE at the same time, which may be complementary items that provide protection to the same area (e.g., an N95 respirator with a face shield on top) or more than one of the same item (e.g., double gloves).

Centers for Disease Control (CDC)^{ix}: “Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings”

- Consider using a cleanable face shield (preferred) over an N95 respirator and/or other steps (e.g., masking patients, using engineering controls) to reduce surface contamination
- 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., using barriers to prevent droplet spray contamination)

CDC^x: “Interim Domestic Guidance on the Use of Respirators to Prevent Transmission of SARS”

- If N95 respirators are reused for contact with SARS patients, implement a procedure for safer reuse to prevent contamination through contact with infectious droplets on the outside of the respirator
 - Consider wearing a loose-fitting barrier that does not interfere with fit or seal (e.g., surgical mask, face shield) over the respirator
 - Remove the barrier upon leaving the patient’s room and perform hand hygiene. Surgical masks should be discarded; face shields should be cleaned and disinfected
- Respiratory protective devices with a filter efficiency of 95% or greater (e.g., N95, N99, N100) may not be available in some settings due to supply shortages or other factors. In this situation, a surgical (procedure) mask should be worn. Surgical masks will provide barrier protection against large droplets, which are considered to be the primary route of SARS transmission. However, surgical masks may not adequately protect against aerosol or airborne particles, primarily because they allow for leakage around the mask and cannot be fit-tested. The mask should resist fluid penetration and fit tightly around the mouth and nose when properly applied to the face

Institute of Medicine^{xi}: “Reusability of Facemasks During an Influenza Pandemic”

Recommendation summary for extending the life of an N95 respirator for individual users

- Avoiding contamination will allow for limited reuse. If an individual user needs to reuse their own disposable N95 respirator, the committee recommends that it be done in the following manner:
 - Protect the respirator from external surface contamination when there is a high risk of exposure to influenza (i.e., by placing a medical mask or cleanable face shield over the respirator in such a way that prevents surface contamination but does not compromise the device’s fit)

- Use and store the respirator in such a way that the physical integrity and efficacy of the respirator will not be compromised
- Practice appropriate hand hygiene before and after removal of the respirator and, if necessary and possible, appropriately disinfect the object used to shield it

ECRI Clinical Evidence Assessment^{iv}: “Safety of Extended Use and Reuse of N95 Respirators”

- Two studies (Sinkule et al. 2013^{xii} and Roberge et al. 2010^{xiii}) of more than 30 models found that covering respirators with surgical masks had no clinically significant effect on breathing effort, gas exchange, and perceptions of comfort and exertion

Guidance on the Use of Expired Personal Protective Equipment

Most PPE items, including N95 respirators, surgical masks, and isolation gowns, have a limited shelf life, after which they should be discarded. According to Health Canada, the CDC, and the FDA, in times of increased demand and decreased supply, such as during the COVID-19 pandemic, consideration can be made to use PPE past its manufacturer-designated shelf life. The length of time an N95 respirator is stored beyond its shelf life or recommended conditions of storage may affect its performance.^{xiv} This includes not only the filter media but also the headbands and nose-foam components, which may affect the seal.^{xiv} The user should visibly inspect the PPE item before use, and if there are concerns (such as degraded materials, visible holes or tears, or discolouration) the product should be discarded.^{xv}

According to Health Canada, there are two main types of medical gowns: isolation gowns and surgical gowns. Medical gowns distributed and sold in Canada are grouped by category and level of risk. There are four levels of risk that can be broken down into two categories: low risk (levels 1 and 2) and high risk (levels 3 and 4)^{xvi}:

Low-risk category

- Level 1—minimal risk; use for standard precautions/isolation and simple procedures
- Level 2—low risk; use for minimally invasive surgery

High-risk category

- Level 3—moderate risk; use for open gastrointestinal surgeries
- Level 4—high risk; use for open cardiovascular and trauma procedures

Available guidance (below) on the use of expired gowns is not specific to category and level of risk.

Health Canada^{xiv}: “Optimizing the Use of Masks and Respirators During the COVID-19 Outbreak”

Use of N95 masks beyond their shelf life

- N95 masks that are past their designated shelf life are no longer CDC National Institute for Occupational Safety and Health (NIOSH)–approved, as all manufacturer-designated conditions of use must be met to maintain CDC NIOSH approval. However, in times of increased demand and decreased supply, consideration can be made to use these expired N95 respirators. An expired mask can still be effective at protecting the health care provider if:
 - The straps are intact
 - There are no visible signs of damage
 - They can be fit-tested
- Health care providers should inspect the mask and perform a seal check
- There is no specific timeframe beyond the expiry dates for N95 respirators at which they would no longer be considered suitable for use

Use of surgical masks beyond their shelf life

- Masks can still be used beyond their shelf life to protect health care providers. Health care providers should check that the straps are intact and there are no visible signs of damage. There is no specific timeframe beyond the expiry dates for masks at which they would no longer be considered suitable for use

CDC^{xvii}: “Release of Stockpiled N95 Filtering Facepiece Respirators Beyond the Manufacturer-Designated Shelf Life”

The CDC has tested samples of N95 masks past their expiration date (manufactured between 2003 and 2013) and found that many models continue to perform in accordance with CDC NIOSH performance standards. Therefore, the 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 masks have been stored properly. These models are:

- 3M 1860
- 3M 1870
- 3M 8210
- 3M 9010
- 3M 8000
- Gerson 1730
- Medline/Alpha Protech NON27501
- Moldex 1512
- Moldex 2201

Models that are not tested but expected to perform in the same manner:

- 3M 1860S (a smaller version of 3M 1860)
- 3M 8000 (if the straps are intact and there are no visible signs of damage)

Models that may not provide the expected level of protection:

- Kimberly-Clark 46827 (size small) and Kimberly-Clark 46727 (size regular) when past their manufacturer-designated shelf life of 5 years

The CDC NIOSH recommends that users should take the following precautionary measures before using an expired respirator in the workplace:

- Visually inspect the N95 to determine if its integrity has been compromised
- Check that components such as the straps, nose bridge, and nose foam material did not degrade, which can affect the quality of the fit and seal and therefore the effectiveness of the respirator
- If the integrity of any part of the respirator is compromised, or if a successful user seal check cannot be performed, discard the respirator and try another
- Users should perform a user seal check immediately after they don each respirator and should not use a respirator upon which they cannot perform a successful user seal check

CDC^{xviii}: “Strategies for Optimizing the Supply of Isolation Gowns”

Most isolation gowns do not have a manufacturer-designated shelf life. According to the CDC, those that do and that are past their manufacturer-designated shelf life can be considered for use. If there is no date available on the gown label or packaging, facilities should contact the manufacturer.

U.S. Food and Drug Administration^{xix}: “Frequently Asked Questions on Shortages of Expired Gowns, Surgical Masks, and Medical Gloves”

According to the FDA, expired gowns, surgical masks, and gloves may still offer some protection. The user should visibly inspect the product before use and if there are concerns (such as degraded materials, visible holes or tears, or discoloration) the product should be discarded. As a conventional capacity strategy, expired products may be used for training and demonstration purposes where barrier protection is not needed.

ECRI Clinical Evidence Assessment^{iv}: “Safety of Extended Use and Reuse of N95 Respirators”

- Expired N95 stocks: Devices beyond their labelled 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.

Peer-Reviewed Publications on Use of Expired Personal Protective Equipment

Lin et al. (2020)^{xx} evaluated the filtration performance of five N95 filtering facepiece respirator (N95FFR) models following long-term storage, removal of charge using isopropanol alcohol (IPA), autoclaving, or treatment with gamma-radiation. The models evaluated were 3M-8210, 3M-1860, SH-2950, 3M-8511 and UVEX-3200, which were stockpiled by the Taiwanese CDC after the SARS outbreak. The study found that without decontamination by gamma irradiation or the use of an autoclave, all expired N95FFR models maintained acceptable filtration performance and still could be used to collect aerosol

effectively. Sterilization by gamma irradiation increased the penetration of aerosol into unexpired and expired N95FFR models, reducing their quality factor (qf). The qf of all N95FFR models, except UVEX-3200, was strongly affected by gamma irradiation, the removal of charge using IPA, autoclaving, and storage, in that order. The researchers suggested that the aging of straps and seal materials (rubbers, plastics) may affect N95FFRs' fit factor and effectiveness.

Viscusi et al. (2009)^{xxi} investigated 21 types of CDC NIOSH-certified N95FFR for use during flu pandemics. These respirators were manufactured from 1999 to 2001 and were stored for at least 6 years at temperatures between 15°C and 32°C with a relative humidity between 20% and 80%. Results indicated that most N95 filtering facepiece respirators stored for up to 10 years at warehouse conditions will likely have expected levels of filtration performance and that the degree of filtration-efficiency degradation is likely model specific.

Rottach and Lei (2017)^{xxii} evaluated the stability of the tensile properties of respirator straps taken from common N95 respirators of various ages (determined through date codes). The tension of the straps at a predetermined strain of 150% was found to differ by age for one respirator model, though whether this was due to age or due to manufacturing variations could not be determined. The straps from one manufacturer were found to have notable variation in length, indicating that minor variations in strap tensile properties may not result in significant differences in respirator seal quality. Based on the observations, prolonged storage may affect the tensile properties of headstraps for some models of N95 respirators.

Zaman et al.^{xxiii} developed a protocol to use an expired (2010 stock) Kimberly-Clark TecnoL Fluidshield PFR95 N95 Particulate Filter Respirator whose elastic bands had lost their tensile strength. One-inch wide latex-free tourniquet material was used to fashion two elastic straps to each corner of the duckbill-style mask. The tourniquet material and respirator were precisely hole-punched and were attached using two 4-inch zip-ties. After assembly, the respirator was donned by a test subject and a quantitative fit-test was performed. Fit-testing demonstrated a fit factor of at least 95 for all tested conditions. The procedure appears to update an otherwise defective N95 duckbill respirator into a functioning, sealed respirator for potential use as a protective means of last resort. The researchers have since made use of an assembly line to mass-produce these retrofitted respirators using volunteer workers at multiple stations. The assembly line was able to make up to 500 to 1,000 retrofitted expired-stock N95 respirators per day. Random samples of each half-day production run have been quantitatively fit-tested using a PortaCount quantitative fit-testing machine, with a 100% pass rate at the time of publication.

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