

COVID-19 CADTH HORIZON SCAN

# Optimization of N95 Respirator Masks During Supply Shortages — Round-Up

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To produce this report, CADTH used a modified approach to the selection, appraisal, and synthesis of the evidence to meet decision-making needs during the COVID-19 pandemic. Care has been taken to ensure the information is accurate and complete, but it should be noted that international scientific evidence about COVID-19 is changing and growing rapidly.

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Based on the evidence available as of September 2020:

- During the COVID-19 pandemic many facilities experienced shortages of personal protective equipment, including N95 respirator masks for health care workers.
- Various strategies have been proposed to optimize N95 mask supplies, including:
  - use of N95 respirator mask supplies beyond the manufacturers' recommended shelf life
  - use of N95-equivalent respirator masks approved in other countries with similar standards and methods for the evaluation of masks to those of the US National Institute for Occupational Safety and Health (NIOSH)
  - use of non-medical N95 equivalent respirator masks (such as those used in industry)
  - use of reusable elastomeric respirators rather than disposable N95 respirator masks
  - use of powered air purifying respirators in settings where health care workers need personal protective equipment for long periods of time (such as in the intensive care unit)
  - extended use of N95 respirator masks for a continuous period in cohorts of patients (i.e., without donning or doffing masks)
  - limited reuse of N95 respirator masks without reprocessing between uses
  - reprocessing masks using various methods for decontamination (such as ultraviolet light germicidal irradiation, vaporized hydrogen peroxide, and heat-based methods) before reuse.

## Context

N95 respirator masks (also called filtering facepiece respirators) are half-face masks that provide a close seal over the nose and mouth and filter out at least 95% of airborne particles and aerosols.<sup>1,2</sup> They are a type of personal protective equipment (PPE) that is used with other protective equipment, such as face shields and goggles, to protect health care workers.<sup>3</sup> Not to be confused with surgical masks (which provide less filtration), N95 respirator masks are used "... to reduce the risk of inhaling hazardous airborne particles and aerosols" (such as respiratory viruses and bacteria).<sup>1</sup>

Most N95 respirator masks are single-use medical devices with a specified storage or shelf life.<sup>1,4,5</sup> During a global pandemic, the need for N95 respirator masks may exceed the available supply. Various agencies, research groups, and manufacturers have looked at other options for potentially increasing the availability of N95 respirator masks in times of shortage, including:

- alternatives to reuse (such as use of N95 respirator masks beyond their recommended shelf life or extended use)
- methods for reprocessing (decontaminating) N95 respirator masks for reuse.

Health Canada has expedited the review and approval pathway for masks and respirators and for reprocessing equipment during the COVID-19 pandemic.<sup>1,6</sup> Health Canada accepts the US National Institute for Occupational Safety and Health (NIOSH) evaluation and certification of N95 respiratory masks, and equivalent standards from other agencies.<sup>1</sup> It is stated that any method for optimizing use of N95 respirator masks should follow standard practices and checks to ensure proper performance and fit.<sup>1</sup>

The guidance included in this summary was developed to address temporary supply shortages during the COVID-19 pandemic.

## About This document

This publication summarizes information identified through a limited literature search and is intended to provide an overview of potential strategies to optimize the supply of N95 respirator masks during the COVID-19 pandemic. It is not a systematic review and has neither included critical appraisal of studies, nor has it been peer reviewed. Administrative, engineering, and other strategies to minimize exposure to occupational hazards and the need for N95 respirator masks, for example, using virtual visits or installing physical barriers, are not included here.<sup>7,8</sup> This summary does not provide recommendations. Care has been taken to ensure the information is accurate and complete, but scientific evidence about COVID-19 is changing rapidly.

## Alternatives to the Single-use of N95 Respirator Masks

### Additional Sources of N95 Respirator Masks

Based on recommendations from health organizations, potential options for optimizing the supply of N95 respirator masks during the COVID-19 pandemic include:

- use of N95 respirator masks beyond the manufacturer's recommended shelf life, provided the components of the mask that affect fit and seal (such as the straps and nose bridge) have not degraded<sup>1,4,5,9-12</sup>
- use of N95 respirator masks approved in other countries that have similar standards and evaluation methods for respirator masks to those of the US NIOSH<sup>1,7,9</sup>
- sourcing N95 respirator masks from medical settings that may not need all of their current inventory, such as universities or veterinary clinics<sup>9</sup>
- use of commercial, non-medical N95 respirator masks, if medical N95 respirator masks are not available<sup>1,7,9,13</sup>
- use of reusable elastomeric respirators (half and full face masks) with protocols for their cleaning, disinfection, and reuse<sup>7,9,10</sup>
- use of powered air purifying respirators in non-surgical settings where health care providers need protective equipment for extended periods of time, such as the intensive care unit.<sup>7,9</sup>

#### Sources:

- [COVID-19 medical masks and respirators: information for health professionals](#). Health Canada; June 26, 2020.
- [Optimizing the supply of personal protective equipment during the COVID-19 pandemic: recommendations from Ontario Health](#). Ontario Health; September 22, 2020.
- [COVID-19: emergency prioritization in a pandemic. Personal protective equipment \(PPE\) allocation framework](#). BC Centre for Disease Control / BC Ministry of Health; March 25, 2020. [Strategies for optimizing the supply of N95 respirators](#). Centers for Disease Control and Prevention (CDC); June 28, 2020.

- [Considerations for release of stockpiled N95s beyond the manufacturer-designated shelf life: stockpiled N95 respirators](#). Centers for Disease Control and Prevention (CDC); July 20, 2020.
- [Implementing filtering facepiece respirator \(FFR\) reuse, including reuse after decontamination, when there are known shortages of N95 respirators: Decontamination & reuse of N95 respirators](#). Centers for Disease Control and Prevention (CDC); August 4, 2020.
- [Safety of extended use and reuse of N95 respirators](#). ECRI; May 13, 2020.
- [N95 masks: new guidance for addressing shortages](#) [webinar]. ECRI; April 15, 2020.
- [Strategies for addressing expected or known N95 respirator shortages](#). ECRI; April 8, 2020.
- [Rational use of personal protective equipment for coronavirus disease \(COVID-19\) and considerations during severe shortages. Interim guidance](#). World Health Organization; April 6, 2020.
- [Options for the decontamination and reuse of respirators in the context of the COVID-19 pandemic](#). European Centre for Disease Prevention and Control; June 8, 2020.
- [Technical and regulatory aspects of the extended use, reuse, and reprocessing of respirators during shortages](#). Pan American Health Organization (PAHO); June 10, 2020.

## Extended Use of N95 Respirator Masks

**Extended use** of N95 respirator masks is defined as a health care provider wearing one mask continuously, without removing (doffing) or replacing (donning) the mask between patient encounters.<sup>9,14,15</sup> N95 respirator masks are intended for single use for each patient encounter. However, in the event of mask shortages during an outbreak of infectious respiratory disease, it has been stated that a health care worker may wear one N95 respirator mask for several consecutive hours if working with a cohort of patients with the same respiratory illness who are grouped in a separate treatment area.<sup>7,9,15</sup> Further recommendations concerning extended use include:

- maximum recommended periods of extended use vary from six hours to twelve hours.<sup>2,7</sup> However, as the mask can only be donned and doffed once, practical considerations usually limit the duration of use (such as meal or restroom breaks)<sup>15</sup>
- extended use of N95 respirator masks is generally recommended over reuse of masks because it would involve less handling of the mask and less risk of contact transmission of disease<sup>2,13,15,16</sup>
- extended use guidance differs as to whether N95 respirator masks used during an aerosol generating procedure should be discarded after use or whether masks that are not soiled or damaged may be collected for reprocessing.<sup>9,15,16</sup>

Limited reuse refers to multiple donning and doffing of a single N95 respirator mask by a health care worker, without reprocessing (decontaminating) the mask between uses. WHO does not recommend this practice<sup>9,15</sup>, as handling the masks during donning and doffing could be a source of contamination.<sup>11</sup> However, the US CDC considers limited rotation and reuse of a series of masks by a single health care worker an option in times of shortage.<sup>17</sup>

- Layering (the use of a face shield, surgical mask, or other disposable cover) over an N95 respirator mask may extend its use by reducing surface contamination.<sup>9,12,13,15</sup>
- Collecting for reprocessing<sup>9,18</sup> or discard<sup>15,19,20</sup> N95 respirator masks after use during aerosol generating procedures.

- Discarding N95 respirator masks that are wet, soiled or damaged, contaminated with bodily fluids, or those used during close contact with a patient co-infected with other infectious diseases that require contact precautions.<sup>15</sup>
- Ensuring proper fit, the CDC recommends that, if manufacturer guidance is not available, N95 respirator masks be donned no more than five times, though for some models, fit may still be adequate after more than five donnings.<sup>7,17</sup>
- Rotating use of masks is another reuse strategy proposed by the CDC. In this strategy each health care worker caring for patients with, or suspected of having, COVID-19, receives five N95 respirator masks. Staff can wear one mask each day, store them in breathable paper bags and use a five-day rotation between use of each mask to allow pathogens to die off between uses.<sup>12,17</sup>

**Sources:**

- [Optimizing the supply of personal protective equipment during the COVID-19 pandemic: recommendations from Ontario Health](#). Ontario Health; September 22, 2020.
- [Strategies for optimizing the supply of N95 respirators](#). Centers for Disease Control and Prevention (CDC); June 28, 2020.
- [Implementing filtering facepiece respirator \(FFR\) reuse, including reuse after decontamination, when there are known shortages of N95 respirators: Decontamination & reuse of N95 respirators](#). Centers for Disease Control and Prevention (CDC); August 4, 2020.
- [Recommended guidance for extended use and limited reuse of N95 filtering facepiece respirators in healthcare settings](#). Centers for Disease Control and Prevention (CDC)/ National Institute for Occupational Safety and Health (NIOSH); March 27, 2020.
- [N95 respirators, surgical masks, and face masks](#). US Food & Drug Administration (FDA); August 20, 2020.
- [Safety of extended use and reuse of N95 respirators](#). ECRI; July 31, 2020.
- [Strategies for addressing expected or known N95 respirator shortages](#). ECRI; April 8, 2020.
- [Infectious Diseases Society of America \[IDSA\] guidelines on infection prevention in patients with suspected or known COVID-19. Recommendation 6: Reuse/extended use of N95 respirators vs. surgical masks \(aerosol-generating procedures\)](#). IDSA; April 27, 2020.
- [Technical and regulatory aspects of the extended use reuse, and reprocessing of respirators during shortages](#). Pan American Health Organization (PAHO); June 10, 2020.
- [Options for the decontamination and reuse of respirators in the context of the COVID-19 pandemic](#). European Centre for Disease Prevention (ECDC); June 8, 2020.

**Reprocessing (Disinfection, Sterilization, or Decontamination) of N95 Respirator Masks for Reuse**

Most N95 respirator masks are intended for single use; however, when supplies are limited, reprocessing (decontaminating using disinfection or sterilization) masks for reuse may be an option.<sup>1,2,6,16</sup> Guidance for the reprocessing of N95 respirator masks was developed for consideration during “crisis” shortages of PPE.<sup>17,19</sup> 2 Any method for reprocessing N95 respirator masks must ensure that it inactivates the virus, without damaging the filtration or the fit of the respirator, as well as leaving the respirator safe for the health care worker to wear.<sup>21,22</sup>

Currently, there is limited clinical evidence for reprocessing N95 respirator masks for use during the COVID-19 pandemic.<sup>26</sup> Health Canada is accepting applications from reprocessors and manufacturers through the Medical Device Regulations or through the Interim Order pathway, and has stated that Canada's approach will align with the US FDA's approach for Emergency Use Authorization for masks and respirators.<sup>6</sup> A list of medical devices authorized for use in reprocessing N95 masks during the COVID-19 pandemic is available on the [Health Canada website](#). The CDC noted that ultraviolet germicidal irradiation (UVGI), hydrogen peroxide vapour, and moist heat appear to be the most promising methods for decontaminating N95 respirator masks.<sup>17</sup> However, a recent ECRI assessment, mainly based on laboratory studies, cautions that, because of the variations in mask materials, each model of N95 respirator mask should be tested with each reprocessing method.<sup>13</sup>

In June 2020, the US FDA revised some Emergency Use Authorizations to indicate certain respirators that should not be reprocessed for reuse, including respirators manufactured in China, and those made of cellulose.<sup>23</sup>

Health Canada guidance states that all N95 respirator masks should be evaluated after reprocessing to ensure they have not been damaged and that they still maintain a tight fit.<sup>19</sup>

The following section presents information about the N95 respirator mask reprocessing techniques that organizations such as the CDC, ECRI, and the COVID-19 Healthcare Coalition have reported as the most promising to date.<sup>17,24</sup>

- ultraviolet germicidal irradiation with UV-C light
- vaporous hydrogen peroxide
- moist (humid) heat or steam, and
- dry heat (heat inactivation).

**Sources:**

- [Important regulatory considerations for the reprocessing of single use N95 respirators during the COVID-19 response: notice](#). Health Canada; May 10, 2020.
- [N95 mask re-use strategies](#). Society of American Gastrointestinal and Endoscopic Surgeons (SAGES); April 17, 2020.
- [Reprocessing of N95 respirators for healthcare professionals – notice](#). Health Canada; April 17, 2020.
- [Safety of extended use and reuse of N95 respirators](#). ECRI; May 13, 2020. Note: a July 31, 2020 update has been published but is only accessible to ECRI subscribers.

**Ultraviolet Germicidal Irradiation**

UVGI devices emit UV-C light, which damages DNA to destroy bacteria, viruses and other microorganisms.<sup>25</sup> A Canadian systematic review noted the technique has been used in hospital disinfection for many years, and concluded that it may also be useful for N95 respirator mask reprocessing.<sup>25</sup> However, UV-C light is hazardous to human health and exposure to it must be avoided.<sup>26</sup> In addition, high doses of ultraviolet light may degrade mask components, and repeated cycles of UV disinfection are likely to increase degradation.<sup>27,28</sup> The following documents present considerations for the use of UVGI for N95 respirator mask reprocessing:

- [COVID-19 – what we know so far about... reuse of personal protective equipment](#). Public Health Ontario, April 4, 2020.
- [APIC and N95DECON suggested guidance for infection prevention and workflow for UV-C decontamination of N95 FFRs during COVID-19](#). Association for Professionals in Infection Control and Epidemiology (APIC) and N95DECON; June 2020.
- [Disinfection of N95 respirators: UV light may be considered for limited reuse situations](#). ECRI; April 6, 2020.
- [Decontamination of N95 respirators: UV light may be considered for limited reuse situations](#). ECRI; September 3, 2020.
- [Safety of extended use and reuse of N95 respirators](#). ECRI, July 31, 2020.
- [Evaluation of decontamination techniques for the reuse of N95 respirators](#). COVID-19 Healthcare Coalition; May 27, 2020.
- [Step-by-step protocols for decontamination techniques for the reuse of N95 respirators](#). COVID-19 Healthcare Coalition; April 6, 2020.
- [Options for the decontamination and reuse of respirators in the context of the COVID-19 pandemic](#). European Centre for Disease Prevention (ECDC); June 8, 2020.
- [Technical and regulatory aspects of the extended use, reuse, and reprocessing of respirators during shortages](#). Pan American Health Organization (PAHO); June 10, 2020.

### Vaporized Hydrogen Peroxide

Hydrogen peroxide is an airborne disinfectant that is already used in hospital equipment and room disinfection.<sup>29,30</sup> A 2020 Canadian living systematic review of chemical disinfectants for decontaminating N95 respirator masks found vaporized hydrogen peroxide to be the “most promising” chemical method.<sup>31</sup> The following documents present considerations for the use of vaporized hydrogen peroxide for N95 respirator mask reprocessing:

- [COVID-19 – what we know so far about... reuse of personal protective equipment](#). Public Health Ontario, April 4, 2020.
- [Benefits, costs, and risks of vaporized hydrogen peroxide for disinfecting N95 respirators: beware of the hype](#). ECRI; June 16, 2020.
- [Safety of extended use and reuse of N95 respirators](#). ECRI, July 31, 2020.
- [Evaluation of decontamination techniques for the reuse of N95 respirators](#). COVID-19 Healthcare Coalition; May 27, 2020.
- [Step-by-step protocols for decontamination techniques for the reuse of N95 respirators](#). COVID-19 Healthcare Coalition; April 6, 2020.
- [Options for the decontamination and reuse of respirators in the context of the COVID-19 pandemic](#). European Centre for Disease Prevention (ECDC); June 8, 2020.
- [Technical and regulatory aspects of the extended use, reuse, and reprocessing of respirators during shortages](#). Pan American Health Organization (PAHO); June 10, 2020.

### Moist Heat Disinfection and Dry Heat Disinfection

Heat or steam sterilization is a commonly used procedure in health care settings. The following documents present considerations for the use of heat for N95 respirator mask reprocessing:

- [Decontamination and reuse of filtering facepiece respirators](#). CDC, April 1, 2020.



- [Evaluation of decontamination techniques for the reuse of N95 respirators](#). COVID-19 Healthcare Coalition; May 28, 2020.
- [Step-by-step protocols for decontamination techniques for the reuse of N95 respirators](#). COVID-19 Healthcare Coalition; April 6, 2020.
- [Safety of extended use and reuse of N95 respirators](#). ECRI, July 31, 2020.
- [Options for the decontamination and reuse of respirators in the context of the COVID-19 pandemic](#). European Centre for Disease Prevention (ECDC); June 8, 2020.
- [Technical and regulatory aspects of the extended use, reuse, and reprocessing of respirators during shortages](#). Pan American Health Organization (PAHO); June 10, 2020.

## Selected List of Technologies for Decontamination of N95 Respirator Masks

The following provides information on some of the technologies that have been developed for use for the decontamination of N95 respirator masks during the COVID-19 pandemic, known to be authorized by Health Canada for this purpose. It may not be a comprehensive list. The list of technologies approved by Health Canada under the Interim Order for use during the pandemic are updated regularly at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/products-authorized-interim-order.html#t1>.

### AMSCO V-PRO Low Temperature Sterilization System (Models: 1 Plus, maX and maX 2) (STERIS)

- STERIS sterilization systems use vaporized hydrogen peroxide. The system must be operated in the non-lumen cycle when used for decontamination of N95 respirators.<sup>32</sup>
- STERIS has received Health Canada authorization for use in decontaminating N95 and N95 compatible respirators during the COVID-19 pandemic (April 15, 2020).<sup>33</sup>
- Similarly, in the US, STERIS sterilization systems may be used for decontamination of N95 respirators through the US FDA's Emergency Use Authorization during the COVID-19 pandemic.<sup>32</sup>
- Note: N95 respirators that contain cellulose are not suitable for decontamination with the STERIS system.<sup>32</sup>
- Links: <https://www.steris.com/healthcare/steris-decontamination-solutions-for-compatible-n95-or-n95-equivalent-respirators>

### Critical Care Decontamination System (Battelle Memorial Institute)

- The system uses vaporized hydrogen peroxide to disinfect N95 respirator masks.
- Note: N95 respirator masks that contain cellulose are not suitable for decontamination with the Critical Care Decontamination System (CCDS).
- The CCDS has received Health Canada Interim Order authorization for use during the COVID-19 pandemic.
- The system is authorized for use by the US FDA under the Emergency Use Authorization during the COVID-19 public health emergency (March 28, 2020).
- Links: <https://www.battelle.org/inb/battelle-critical-care-decontamination-system-for-covid19>.

### Clean Flow Health Care Mini (Clean Works Medical)

- The Clean Flow Health Care Mini uses a combination of ultraviolet light, vaporized hydrogen peroxide, and ozone.<sup>34</sup>
- The Clean Flow system has Health Canada authorization through the Interim Order for use in decontaminating N95 respirators during the COVID-19 pandemic (April 13, 2020).<sup>33</sup>
- The Clean Flow system can process up to 800 N95 respirators per hour.<sup>34</sup>
- Links: <https://cleanworkscorp.com/>.

### Hydrogen Peroxide Vapor (HPV) Generator (Bioquell)

- 35% hydrogen peroxide vapor technology.
- Bioquell has Health Canada authorization through the Interim Order for decontamination purposes.
- Links: [www.bioquell.com](http://www.bioquell.com).

### Sterizone VP4 Sterilizer (TS03 / Stryker)

- The Sterizone VP4 sterilizer uses low temperature combined with hydrogen peroxide plasma and ozone.<sup>35</sup>
- Sterizone has Health Canada authorization for use in decontamination of N95 respirators during the COVID-19 pandemic (April 5, 2020).<sup>33</sup>
- Links: <https://www.tso3.com/>;  
[https://www.tso3.com/media/application/media/STERIZONE\\_VP4\\_Sterilizer\\_Quick\\_Ref\\_Data\\_USA\\_R1.pdf](https://www.tso3.com/media/application/media/STERIZONE_VP4_Sterilizer_Quick_Ref_Data_USA_R1.pdf).

### STERRAD Sterilization Systems (Advanced Sterilization Products [ASP])

- STERRAD sterilizers use dry, low temperature sterilization, vaporized hydrogen peroxide gas plasma to sterilize various types of medical devices.
- STERRAD sterilizers are commonly available in hospitals throughout Canada and elsewhere.
- Health Canada issued an authorization for the use of STERRAD 100 S, STERRAD NX, and STERRAD 100 NX sterilizers for decontamination of N95 and N95 compatible respirators during the COVID-19 pandemic.<sup>33</sup>
- Similarly, in the US, STERRAD sterilization systems may be used for decontamination of N95 respirators through the US FDA's Emergency Use Authorization during the COVID-19 pandemic.
- N95 respirators may be reprocessed a maximum of two times using the STERRAD sterilizers.
- N95 respirators that contain cellulose are not suitable for decontamination with the STERRAD systems.<sup>36-38</sup>
- Links: <https://web.asp.com/covid-19>.

## Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE via OVID, Scopus, the Cochrane Library, the University of York Centre for Reviews and Dissemination databases, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and additional keywords. The main search concepts were masks and disinfection or prolonged use. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was limited to English language documents published between January 1, 2017 and April 7, 2020. An update search, using PubMed was run in May 2020 and a final update was run on September 16, 2020 and was limited to documents published in 2020. The CADTH COVID-19 grey literature checklist was also used in the update search to identify in-progress studies, systematic reviews, health technology assessments, and recent guidance documents.

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