

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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Bottom Line: Based on the evidence available as of April 17, 2020:

- Within the context of the COVID-19 pandemic, N95 respirator mask supply shortages are being experienced; there are several ways of optimizing N95 respirator mask supply.
- Health Canada is accepting applications from reprocessors and manufacturers of reprocessing devices, and has stated that Canada’s approach will align internationally, including with the US FDA’s intended approach for Emergency Use Authorization for masks and respirators.¹
- With the rapidly changing environment, new technologies may be approved for reprocessing. Any method used for reprocessing should incorporate standard protocols.
- Reprocessing using ultraviolet light germicidal irradiation (UVGI), vaporous hydrogen peroxide, and heat-based decontamination may be effective methods of decontamination for the reuse of N95 respirator masks.
- Alternative sourcing of N95 respirator masks (e.g., beyond shelf life) and extended use may also be an option.
- Much of the evidence available is based on the Centers for Disease [Control and Prevention \(CDC\) recommendations](#)² and [ECRI](#) reports.³

Context

N95 respirator masks (also called filtering facepiece respirators) are half-face masks that provide a closed seal over the nose and mouth and filter out at least 95% of airborne particles and aerosols.⁴ They are a type of personal protection equipment used with other protective equipment such as face shields and goggles to protect health care workers.⁴ Not to be confused with surgical masks (which provide less filtration), N95 respirator masks are used to reduce the risk of exposure to airborne infectious respiratory diseases caused by viruses and bacteria.⁴ 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.⁴ In Canada, N95 respirator masks are normally used for aerosolized procedures; however, they are sometimes being used for other patient interactions during the COVID-19 pandemic.⁵

N95 respirator masks are single-use medical devices with a specified storage or shelf life. During a pandemic, the need for N95 respirator masks may exceed the available supply. Various agencies, research groups, and manufacturers are looking into other options for potentially increasing the availability of N95 respirator masks in times of shortage, including:

- alternatives to reuse (such as extended use or the use of N95 respirator masks past their shelf lives)
- methods for reprocessing for reuse (such as sterilizing, disinfecting or decontaminating, and reusing N95 respirator masks)
- limited reuse.

Health Canada has expedited the review and approval pathway for masks and respirators, and for reprocessing equipment during the COVID-19 pandemic.^{1,4} Any method for optimizing the use of N95 respirator masks should incorporate standard protocols and ensure proper performance and fit.¹ The sources of information included were produced with the context of supply shortage during the pandemic and are based on the best

alternative practice to single use. As work on COVID-19 is developing rapidly, this document reflects the evidence available at the time of publication; it will be updated as information becomes available.

About This Document

This publication summarizes information identified through a limited literature search and is intended to provide an overview of methods to optimize the supply of N95 respirator masks. It is not a systematic review and has not included a critical appraisal of studies, nor has it been peer-reviewed. It is not intended to provide recommendations. 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. This document will be updated as additional evidence becomes available.

Alternatives to the Single Use of N95 Respirator Masks

Additional Sourcing of N95 Respirator Masks

Health Canada provides information regarding potential options for increasing the supply of N95 respirator masks during the COVID-19 pandemic. These include:

- the 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
- the use of N95 respirator masks with similar standards approved in other countries that have not been evaluated by the US NIOSH
- the use of commercial, non-medical N95 respirator masks if medical N95 respirator masks are not available.^{3,4,6}

Sources:

- [Optimizing the use of masks and respirators during the COVID-19 outbreak](#). Health Canada; April 17, 2020.
- [Strategies for Optimizing the Supply of N95 Respirators](#). Centers for Disease Control and Prevention (CDC); updated April 22, 2020.
- [Safety of Extended Use and Reuse of N95 Respirators](#). ECRI; updated April 16, 2020.
- [N95 Masks: New Guidance for Addressing Shortages](#) [webinar]. ECRI; April 15, 2020.

Extended Use of N95 Respirator Masks

Bottom line for the extended use of N95 respirator masks: based on the information available as of April 17, 2020:

- As of the writing of this document, information was not identified from Canadian organizations such as the Public Health Agency of Canada or Health Canada regarding the extended use of N95 respirator masks in the context of the COVID-19 pandemic (April 17, 2020).
- The CDC suggests that extended use alone is unlikely to degrade respiratory protection and that an N95 respirator mask can be worn as long as it retains its fit and function (within the context of a COVID-19 cohort).
- ECRI states that the use of a face shield may extend N95 respiratory masks' use by reducing surface contamination.³
- The CDC suggests discarding N95 respirator masks following aerosol-generating procedures and contamination with bodily fluids.²

N95 respirator masks are intended for a single patient, single use. In the event of a shortage of personal protective equipment during an outbreak of infectious respiratory disease (such as the current COVID-19 pandemic), information from the CDC⁶ and ECRI³ state that one N95 respirator mask might be used by a health care worker for several consecutive hours when working with a cohort of patients confirmed to have the same respiratory illness, in dedicated wards or areas of the hospital or care facility. It is important to note that there are risks to extended use — particularly contact transmission to the wearer caused by touching a contaminated respirator; and the potential for cross-contamination of other pathogens (i.e., methicillin-resistant *Staphylococcus aureus*, or MRSA) within the patient population cohort. Multiple donning and doffing of a single N95 respirator mask by a health care worker is known as “limited reuse” rather than extended use.^{3,4,7-10}

In the context of extended use, the N95 respirator mask is donned and doffed only once but may be worn for several hours, as long as it retains its fit and function. Rather than a time limitation, there are usually practical and hygienic considerations that limit the duration:

- practical — the wearer must remove the mask to eat or to use the bathroom, or the structure of the mask is compromised in some way
- hygienic — the mask is soiled.

The CDC provides the following guidance regarding discarding an N95 respirator mask and ending its cycle of use:^{2,7}

- Discard N95 respirator masks following their use during aerosol-generating procedures.
- Discard N95 respirator masks contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.
- Discard N95 respirator masks following close contact with, or exit from, the care area of any patient co-infected with an infectious disease requiring contact precautions.

The CDC additionally provides the following guidance regarding extending N95 respirator mask use.

Consider the use of a cleanable face shield (preferred³) over an N95 respirator mask and/or other steps (e.g., masking patients, the use of engineering controls) to reduce surface contamination.^{2,7} As well:

- 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, health care facilities should develop clearly written procedures to advise staff to discard any respirator that is obviously damaged or becomes hard to breathe through.

Sources:

- [Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings](#). National Institute for Occupational Safety and Health (NIOSH); March 27, 2020.
- [N95 Respirators and Surgical Masks \(Face Masks\)](#). US Food & Drug Administration (FDA); April 5, 2020.
- [Safety of Extended Use and Reuse of N95 Respirators](#). ECRI; April 16, 2020.
- [Optimizing the use of masks and respirators during the COVID-19 outbreak](#). Health Canada; (last modified) April 17, 2020.
- [COVID-19 – What We Know So Far About... Reuse of Personal Protective Equipment](#). Public Health Ontario, April 4, 2020.

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

Bottom line for reprocessing of N95 respirator masks: Based on the information available as of April 17, 2020:

- Health Canada is accepting applications from reprocessors and manufacturers, and has stated that Canada’s approach will align with the US FDA’s intended approach for Emergency Use Authorization for masks and respirators.¹
- Based on the information identified, reprocessing using UVGI and vaporized hydrogen peroxide may be promising.
- The US CDC advises that reprocessed devices should not be used while performing or present during an aerosolizing procedure.²
- Respirators should be evaluated after each reprocessing cycle to ensure they have not been damaged by the process and that they still maintain a tight seal to the face.
- 3M recommends against reprocessing its N95 respirator mask devices using ethylene oxide, ionizing radiation, microwave or high temperature, autoclave or steam.¹¹ (April 8, 2020)

N95 respirator masks are intended as single use-devices; however, in the context of a shortage, reprocessing may be a viable alternative. The guidance and recommendations for the reprocessing of N95 respirator masks is available from organizations such as the CDC, ECRI; others were developed to be considered under “crisis” scenarios.

According to the information reviewed by CADTH, there is limited clinical evidence for the use of any disinfection, sterilization, or decontamination technique and there is currently (as of April 8, 2020) no published evidence examining the use of these techniques to destroy

the SARS-CoV-2 virus. This section presents information about the efficacy, device degradation, and limitations of four promising reprocessing techniques:

- UVGI
- vaporous hydrogen peroxide
- moist heat
- dry heat.

Ultraviolet Germicidal Irradiation

UVGI devices emit ultraviolet C (UVC) light — which degrades nucleic acids in DNA and kills pathogens. UVGI seems to be suggested as a potentially advantageous technique for N95 respirator mask reprocessing, as it does not involve a chemical that could leave residue and potentially be harmful to the wearer of the reprocessed device; however, UVC light is harmful and contact with it must be avoided. The following documents present recommendations and considerations for the use of UVGI for N95 respirator mask reprocessing:

- [Disinfection of N95 Respirators: UV Light May Be Considered For Limited Reuse Situations](#). ECRI; updated April 6, 2020.
- [Decontamination and Reuse of Filtering Facepiece Respirators](#). CDC; April 9, 2020.
- [Safety of Extended Use and Reuse of N95 Respirators](#). ECRI; March 2020.
- [Evaluation of Decontamination Techniques for the Reuse of N95 Respirators](#). COVID-19 Healthcare Coalition; April 3, 2020.
- [COVID-19 – What We Know So Far About... Reuse of Personal Protective Equipment](#). Public Health Ontario; April 4, 2020.

Vaporous Hydrogen Peroxide

Hydrogen peroxide is a known disinfectant that is already used in the context of hospital infection control and is a virucide. In the context of pandemic shortages, it may be an option for disinfection. The following documents present recommendations and considerations for the use of vaporous hydrogen peroxide for N95 respirator mask reprocessing:

- [Decontamination and Reuse of Filtering Facepiece Respirators](#). CDC; April 9, 2020.
- [Evaluation of Decontamination Techniques for the Reuse of N95 Respirators](#). COVID-19 Healthcare Coalition; April 3, 2020.
- [Safety of Extended Use and Reuse of N95 Respirators](#). ECRI; April 16, 2020.
- [COVID-19 – What We Know So Far About... Reuse of Personal Protective Equipment](#). Public Health Ontario; April 4, 2020.

Moist Heat Disinfection

Heat is a known method of disinfection and decontamination used in health care settings. Moist heat disinfection uses a laboratory grade incubator or equivalent device and water to raise the temperature around the N95 respirator mask to between 60^o C and 75^o C, and a relative humidity of 80% or greater. The following documents present recommendations and considerations for the use of moist heat for N95 respirator mask reprocessing:

- [Decontamination and Reuse of Filtering Facepiece Respirators](#). CDC; April 9, 2020.

- [Evaluation of Decontamination Techniques for the Reuse of N95 Respirators](#). COVID-19 Healthcare Coalition; April 3, 2020.
- [Safety of Extended Use and Reuse of N95 Respirators](#). ECRI; April 16, 2020.

Dry Heat Inactivation

Heat is a known method of disinfection and decontamination used in health care settings. Dry heat uses a laboratory grade incubator or an equivalent device to raise the temperature of the N95 respirator mask to 80^o C to 100^o C. The following document presents recommendations and considerations for the use of dry heat for N95 respirator mask reprocessing:

- [Evaluation of Decontamination Techniques for the Reuse of N95 Respirators](#). COVID-19 Healthcare Coalition; April 3, 2020.

Reuse

Reuse refers to donning and doffing the same N95 respirator mask multiple times (by the same person) without any decontamination or disinfection. This practice is generally not encouraged, particularly if other methods of optimization are available; N95 respirator masks may readily spread infection by touch if donned and doffed, and are prone to mechanical failure upon reuse.³ Contaminated N95 respirator masks may become inert sources of infection and may spread infection in two ways: by spreading airborne particles during use or by touch during removal and donning (hand-to-mask contamination).

Outside the context of infection control, there are physical limits to the N95 respirator mask; some evidence shows that 7% to 8% of N95 respirator masks failed fitting after two uses and more than 20% failed after five fittings.³ The following CDC document provides guidance intended to reduce the risk associated with N95 respirator mask reuse in the context of a crisis shortage:

- [Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings](#). NIOSH; March 27, 2020.

Technologies for Decontamination

The following provides information regarding several technologies that have been suggested for use in the decontamination of N95 respirator masks during the COVID-19 pandemic. The type of technology, how it works, and specifications such as throughput (if available) are provided. It is not an exhaustive list and it will be updated as additional information becomes available. The products approved by Health Canada under the interim order are updated daily at <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/products-authorized-interim-order.html#t1>.

ActivShield (AptarGroup, Inc.)

- The Aptar ActivShield uses chlorine dioxide to disinfect N95 respirator masks. Each N95 respirator mask is placed in a plastic bag with one strip of ActivShield. The bag is sealed, and the disinfection process takes three hours. Potentially, health care workers could each keep and disinfect their own mask.

- Aptar is seeking US FDA Emergency Use Authorization and anticipates producing 10 million ActivShield strips per week by the end of April.
- Links: <https://news.aptar.com/solutions/aptar-requests-u-s-fda-emergency-use-authorization-for-N95-filtering-facepiece-respirator-decontamination-with-activshieldtm/>

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.¹²
- STERIS has received Health Canada authorization for the use of its decontaminating N95 and N95-compatible respirators during the COVID-19 pandemic (April 15, 2020).¹³
- Similarly, in the US, STERIS sterilization systems may be used for the decontamination of N95 respirators through the US FDA's Emergency Use Authorization during the COVID-19 pandemic.¹²
- Note: N95 respirators that contain cellulose are not suitable for decontamination with the STERIS system.¹²
- Links: <https://www.steris.com/healthcare/steris-decontamination-solutions-for-compatible-n95-or-n95-equivalent-respirators>

CCDS Critical Care Decontamination System (Battelle Memorial Institute)

- The system uses vaporized hydrogen peroxide to disinfect N95 respirator masks.
- N95 or N95-equivalent respirator masks must be shipped to Battelle's site in Ohio for processing.
- Note: N95 respirator masks that contain cellulose are not suitable for decontamination with the CCDS.
- The system is authorized for use by the US FDA under 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 Healthcare Mini (Clēan Works)

- The Clean Flow Healthcare Mini uses a combination of ultraviolet light, vaporized hydrogen peroxide, and ozone.¹⁴
- 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).¹³
- The Clean Flow system can process up to 800 N95 respirators per hour.¹⁴
- Links: <https://cleanworkscorp.com/>

Nocospray Disinfection System (A.M.G. Medical Inc.)

- Nocospray uses hydrogen peroxide vapor room disinfection.
- Nocospray is Health Canada approval as a sporicide against viruses.

- The manufacturer has developed a “temporary protocol” for use in disinfecting N95 respirator masks during the COVID-19 pandemic. In this protocol, masks may be placed on metal shelves in a designated hospital room, which is then sprayed with a specific dose of Nocolyse gas for at least 60 minutes. The process is currently being tested at certain hospitals in Quebec.¹⁵
- Links: <http://www.nocospray.ca/en/>

STERRAD sterilization systems (ASP–Advanced Sterilization Products)

- 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.
- On April 9, 2020, Health Canada issued an authorization for the use of STERRAD 100 S, STERRAD NX, and STERRAD 100NX sterilizers for the decontamination of N95 and N95-compatible respirators during the COVID-19 pandemic.¹³
- Similarly, in the US, STERRAD sterilization systems may be used for the 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.
- Note: N95 respirators that contain cellulose are not suitable for decontamination with the STERRAD systems.¹⁶⁻¹⁸
- Links: <https://web.asp.com/covid-19>

Sterizone VP4 Sterilizer (TS0₃/Stryker)

- The Sterizone VP4 Sterilizer uses a low temperature combined with hydrogen peroxide plasma and ozone.¹⁹
- Sterizone has Health Canada authorization for use in decontamination of N95 respirators during the COVID-19 pandemic (April 5, 2020).¹³
- Links: <https://www.tso3.com/> and https://www.tso3.com/media/application/media/STERIZONE_VP4_Sterilizer_Quick_Ref_Data_USA_R1.pdf

TERMINATOR CoV (Prescientx)

- The TERMINATOR CoV is a UVGI conveyor-style device designed to disinfect N95 respirator masks.
- The device uses UVC radiation to disinfect respirators on all sides.
- Intended for use in health care facilities.
- Has a throughput of up to 500 respirators per hour.
- The cost of the TERMINATOR CoV system is \$59,000.²⁰
- Links: <https://prescientx.com/terminator-cov>

Work in Progress — Methods for Decontamination and Extended Use

Appendix I includes additional sources that may be of interest; however, these have not been reviewed or assessed by CADTH. In addition, other organizations are reviewing evidence for N95 respirator masks.

The National Collaborating Centre for Methods and Tools at McMaster University is conducting the COVID-19 Rapid Evidence Reviews pertaining to the efficacy and safety of disinfectants for the decontamination of N95 respirator masks and microwave- and heat-based mask decontamination. <https://www.nccmt.ca/knowledge-repositories/covid-19-evidence-reviews>

The Oxford COVID-19 Evidence Service may be reviewing the challenges associated with the reuse and extended use of N95 respirator masks. The challenges to the reuse and extended use of equipment is being considered (<https://www.cebm.net/covid-19/current-questions-under-review/>).

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 (CRD) 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 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 also limited to English-language documents published between January 1, 2017 and April 7, 2020.

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Appendix 1: Additional Sources

The following sources have not yet been reviewed by CADTH staff but may provide further useful information.

- [Addressing COVID-19 Face Mask Shortages](#). Stanford Medicine. COVID-19 Evidence Service; March 22, 2020.
- [Assessment of N95 respirator decontamination and re-use for SARS-CoV-2](#) [preprint]. US National Institute of Allergy and Infectious Diseases, et al; April 15, 2020.
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