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COVID-19: Evaluation of Disinfection Options for N95 Filtering Facepiece Respirators in the Context of the Pandemic

CENTRE D'EXPERTISE EN RETRAITEMENT DES DISPOSITIFS MÉDICAUX – INTERIM SCIENTIFIC OPINION

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The elements of responses presented here are based on the information available at the time of writing this evaluation. Given that the situation and knowledge about the SARS-CoV-2 virus (COVID-19), as well as the authorizations issued by Health Canada for new disinfection technologies for N95 filtering facepiece respirators (FFRs), are evolving, the elements covered and the conclusions and recommendations in this document are subject to change. Health care facilities must therefore verify that the technologies, at the time of their use, are still authorized by Health Canada under the Interim Order for COVID-19 (Health Canada, 2021a). In case of conflicting information between the manufacturer's instructions and the studies cited in this document or any other study, the manufacturer's instructions shall take precedence.

Foreword

This publication uses the term “disinfection” of single-use N95 filtering facepiece respirators (FFRs) (also called N95 masks) to refer to the chemical or physical process that inactivates infectious agents. It should be noted that the various reference publications and documents on the subject consulted by the Centre d’expertise en retraitement des dispositifs médicaux (CERDM) use the terms "decontamination," "disinfection," or both. The CERDM has chosen the term “disinfection” to conform to the reprocessing nomenclature that is generally accepted in Canada (CSA Z314.18). According to this nomenclature, the term decontamination is more general and includes the process of cleaning followed by the inactivation of infectious agents. However, in the context of reprocessing of N95 FFRs, only one step, aimed at inhibiting various pathogenic microorganisms, is performed; therefore, it seems more accurate to use the term “disinfection”.

Context

At the start of the COVID-19 pandemic, the CERDM evaluated the available options for disinfecting N95 FFRs (INSPQ, 2021a). This process falls within the context of efforts aimed at identifying alternative strategies that could be added to the measures already available, to provide the best possible protection for health care workers in the event of a shortage. Thus, control measures that differ from those which are usually accepted may have been implemented, alone or in combination. These measures are unprecedented and highlight the need for the various authorities to develop solutions to respond proactively to an anticipated shortage of N95 FFRs[1] and to be able to distribute them to workers during a real shortage of N95 FFRs.[2]

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[1] Strategies to be applied in the event of an anticipated shortage, but while supplies are available (after verification with the procurement department and the Ministère de la Santé et des Services sociaux (MSSS)).

[2] Strategies to be applied in the event of a known shortage (after verification with the procurement department and the MSSS).

Given this context, the Comité sur les infections nosocomiales du Québec (CINQ) issued interim recommendations concerning the reuse of N95 FFRs (by the same user) and for their rational use (INSPQ, 2020a, 2021b). Disinfection of N95 FFRs is a solution of last resort, in the event of a shortage (INSPQ, 2021c). In addition, under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, Health Canada has authorized the disinfection of N95 FFRs by means of various disinfection devices (Health Canada, 2021a). A summary of the technologies and equipment approved by Health Canada is presented in a document produced by the CERDM (INSPQ, 2021a).

As of the date of this document, all of Health Canada's approvals for N95 FFR disinfection remain in effect (Health Canada 2021a), although the Food and Drug Administration (FDA) has revoked its approvals. Indeed, the FDA considers that American health care facilities should no longer face shortages of FFRs, owing to increased domestic production. Therefore, the disinfection of N95 FFRs is no longer authorized in the United States (FDA, 2021a,b,c). In Canada, local production and supply of FFRs has improved, but uncertainties regarding the evolving health situation remain. Health care facilities must follow the guidelines of the ministère de la Santé et des Services sociaux (MSSS) to assess the status of an N95 FFR shortage. In addition, N95 FFRs may only be disinfected using a technology authorized by Health Canada (2021a) under the Interim Order for COVID-19 and in accordance with the manufacturers' instructions. The CERDM also recommends following the guidelines for the process of collecting, disinfecting and storing N95 FFRs (INSPQ, 2021d).

Objectives

The present document analyzes current knowledge about available disinfection options for N95 FFRs and puts into perspective the advantages and limitations of each disinfection process identified. The authorizations that have been issued by Health Canada are also specified. Finally, the recommendations of the CERDM are presented.

Method

The CERDM carried out a non-exhaustive review of the literature on the options for disinfecting N95 FFRs and contacted manufacturers of available equipment to identify the steps they have taken to validate such an approach. Initiatives taken within the health network that were reported to the CERDM were also taken into account. The CERDM evaluated the options identified based on the following criteria:

Safety of health care workers

- Effectiveness of the process in reducing pathogen burden for the different FFR models tested;
- Integrity of the FFR after disinfection (adequate facepiece fit and filtration efficiency);
- Absence of residual chemical hazard in the FFR after disinfection.

Feasibility

- Availability of disinfection equipment;
- Performance (number of N95 FFRs disinfected per day);
- Process requirements.

These criteria are consistent with those of Health Canada (2020a) for the authorization of a technology under the Interim Order for COVID-19. It should be noted that Health Canada requires the manufacturer to demonstrate a sterility assurance level (SAL) of 10^{-6} for the inactivation of spore-forming bacteria and a 4-log reduction for SARS-CoV-2 or recognized analogous viruses (Health Canada, 2021a).

A complete evaluation of options and the validation of criteria required multidisciplinary expertise. Thus, the CERDM consulted various experts in order to support the initiatives identified within the network:

- the Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST) for validation of the filtration efficiency of N95 FFRs after disinfection, as well as for the post-disinfection aeration time,
- the Laboratoire de santé publique du Québec (LSPQ) for microbiological testing, and
- the TransMedTech Institute for support and assistance in analyzing technologies with its institutional partners.

Table A1 (see Annex) compares the different disinfection processes for N95 FFRs selected by the CERDM (hydrogen peroxide, moist heat and UVC combined with other technologies), based on safety and feasibility criteria.

Single-use N95 FFRs

N95 filtering facepiece respirators are used by health care workers who are in contact with patients who have an infection transmitted by inhalation of aerosols. This type of facepiece respirator reduces the worker's exposure to particles, including small particle aerosols and coarse droplets that can transport bacteria and viruses. The N95 FFR filters out at least 95 % of particles greater than or equal to 300 nm. The "N" stands for "not oil resistant" and the "95" stands for 95 % filtration efficiency. Choosing an N95 FFR with an adequate fit (fit tested) optimizes the seal around the edges of the FFR and reduces leakage to a minimum.

The duration of effectiveness of a single-use N95 FFR can vary. Normally, the length of time an N95 disposable FFR is worn depends on the moisture created by exhalation and perspiration in the FFR. As moisture builds, the user gradually finds it more difficult to breathe. When this happens, the FFR must be replaced. This type of facepiece respirator is not designed to be reused. Ideally, it should be discarded when the user has come in contact with the patient and/or after aerosol-generating procedures. It should also be discarded if it is damaged or deformed; the facepiece fit is no longer adequate; it becomes moist or is visibly soiled; breathing becomes difficult; or it gets contaminated with blood, respiratory or nasal secretions or other bodily fluids.

There are several models of N95 FFRs on the market with different shapes (convex, elliptical, duckbill, with flaps, etc.) and with or without an exhalation valve. These N95 FFRs are generally made of polypropylene, polyurethane, polyester and plastic for the different layers of the FFR, thermoplastic elastomer or polyamide/elastane for the straps and aluminium for the nose clip.

Precautions to be considered

Inspection of N95 FFRs

When disinfecting a single-use N95 FFR, due to its composition, the cleaning step cannot be performed, as required by good practices for reprocessing reusable medical devices. As a result of this, disinfection may be less effective.

Only N95 FFRs that are identified as reusable can be disinfected. Thus, the N95 FFR cannot be disinfected if it is damaged or deformed; the facepiece fit is no longer adequate; it becomes moist or is visibly soiled; breathing becomes difficult; or it is contaminated with blood, respiratory or nasal secretions or other bodily fluids.

Following disinfection of an N95 FFR, an inspection of the FFR must be carried out before reuse, to ensure its integrity. The N95 FFR must not be reused if any deterioration is observed (discolouration, loss of elasticity of the elastic bands, etc.).

Compatibility between N95 FFR models and disinfection technologies

Special care must be taken when using technology for the disinfection of N95 FFRs since certain processes can only be applied to some FFRs. For example, N95 FFRs containing cellulose or paper are not compatible with disinfection by hydrogen peroxide. Manufacturers' instructions may vary, so it is important to follow those specific to the device being used.

Number of disinfection cycles authorized

The number of disinfection cycles authorized by the manufacturer must be respected: some authorize only two disinfection cycles, while others permit a greater number of cycles. In fact, the facepiece fit of some N95 FFR models is affected after five cycles of donning and doffing of the FFR, without a disinfection cycle (Bergman et al., 2012), and sometimes after even two cycles following low temperature disinfection (Lieu et al., 2020). Thus, it is necessary to verify whether the disinfected N95 FFR provides an adequate facepiece fit.

Single wearer

As a precaution, the N95 FFR should be limited to a single wearer. In this regard, manufacturers' instructions may vary and the CERDM recommends following the instructions of the manufacturer of the device used.

Aerosol-generating medical procedures

Health Canada has provided clarification regarding the disinfection of N95 FFRs and aerosol-generating medical procedures (AGMPs). Indeed, it has been noted (Health Canada, 2021b) that disinfected N95 FFRs “can be used for AGMP when: correctly fitted and used with other appropriate personal protective equipment (PPE).”

However, Health Canada also specifies that N95 FFRs used during an AGMP cannot then be disinfected for subsequent use; they must be discarded. To the best of the CERDM's knowledge, this added precaution of Health Canada’s had not been required by the FDA.

Health care facility disinfection procedure

The health care facility's medical device reprocessing department (MDRD) is responsible for developing an internal disinfection procedure in accordance with the instructions of the manufacturer of the technology used and with reference to the CERDM's interim guidelines (INSPQ, 2021d). The facility's infection prevention and control (IPC) department must collaborate on validation of these internal procedures. Quality controls must be included as part of the facility's disinfection process.

Trained and qualified personnel must be assigned to the N95 FFR disinfection process. To avoid cross-contamination in the MDRD, additional precautions, such as the following, must be planned and implemented: a dedicated disinfection room for storage, sorting and, if required, bagging of N95 FFRs, a dedicated sterilizer for use with N95 FFRs, additional IPC measures, post-use cleaning of surfaces and equipment, etc.

Health Canada authorizations for the disinfection of N95 FFRs

Health Canada issued a notice outlining the regulatory requirements for two separate reprocessing strategies for single-use N95 FFRs (2020a) and issued authorizations (Health Canada, 2021a) under the Interim Order for COVID-19:

- Devices that are manufactured and sold to reprocess N95 FFRs;
- Companies that reprocess and distribute N95 FFRs to health care facilities.

The devices authorized by Health Canada and the technologies they use are detailed in the following section and are summarized in the Annex (see table A2).

Disinfection processes

Through a non-exhaustive review of the literature, several processes for disinfecting single-use N95 FFRs were identified. Those that seemed the most promising, given the safety and feasibility criteria cited above, were selected. These were, namely:

1) using hydrogen peroxide,

2) using heat and

3) using ultraviolet (UVC) irradiation.

Deep disinfection of N95 FFRs is a major challenge. Indeed, although most disinfection processes allow for the surface disinfection of N95 FFRs, it is important to ensure disinfection of the different layers composing the FFR. In addition, the disinfection process must allow for disinfection of all pathogens present on the surface and in the different layers of the N95 FFR, not just SARS-CoV-2.

The studies currently available and cited in this document present experimental results obtained at pilot scale. These studies are heterogeneous in approach and followed different protocols. Thus, validation of the SARS-CoV-2 viral burden reduction may either be based on scientific knowledge concerning the resistance of infectious agents similar to SARS-CoV-2 to the various disinfection processes, or it may have been carried out experimentally using masks inoculated with SARS-CoV-2 or with other pathogens. Several of these studies performed filtration tests and/or seal checks following disinfection of one or more N95 FFR models. Indeed, several models of N95 FFRs are available and have a different design and composition. Thus, some models are not compatible with certain disinfection processes.

The experimental protocols of the studies presented below are in no sense disinfection protocols recommended by the manufacturers of the technologies authorized by Health Canada.

Hydrogen peroxide

Some devices using hydrogen peroxide can be used to disinfect single-use N95 FFRs in the event of a shortage. These are either a low-temperature sterilizer (hydrogen peroxide plasma or vaporized hydrogen peroxide) or a hydrogen peroxide vaporizer (room disinfection device) (N95Decon, 2020a,b).

However, tests conducted in Québec using the Nocospray device have shown that hydrogen peroxide nebulization could not eliminate the pathogen burden and resulted in an accumulation of silver nitrate in the N95 FFR following disinfection cycles. This technology is not authorized by Health Canada for the disinfection of N95 FFRs.

Low-temperature sterilizers (hydrogen peroxide plasma or vaporized hydrogen peroxide)

The use of a low-temperature sterilizer is effective in disinfecting several models of N95 FFRs (Health Canada, 2021a, FDA, 2020a) while preserving their integrity (Bergman et al., 2010; Viscusi et al., 2009; 3M, 2021).

The use of low-temperature sterilizers to disinfect N95 FFRs can be quickly implemented in MDRDs that have this type of technology. Nevertheless, consideration should be given to the fact that this equipment is possibly already being used for the regular activities of MDRDs and there is a risk of cross-contamination of the environment within the clean and sterile areas of the MDRD. Although this technology requires less time for the completion of a disinfection cycle than does a hydrogen peroxide vaporizer (room disinfection device), its performance (number of N95 FFRs disinfected) is significantly lower.

Based on the results of the study conducted by the IRSST (2020), a drying period of at least one hour before disinfection is recommended depending on the time elapsed between the end of use and collection. In addition, an aeration period of 24 hours following the disinfection cycle is recommended for N95 FFRs, with the pouch closed. These CERDM recommendations apply to the process for disinfecting N95 FFRs using low-temperature sterilizers.

Currently, three manufacturers of low-temperature sterilizers have had their technology approved by Health Canada under the Interim Order for COVID-19 (Health Canada, 2021a) and have issued disinfection instructions:

- Stryker (2020): Sterizone VP4;
- ASP (2021): STERRAD 100S, STERRAD NX and STERRAD 100NX;
- Steris (2020a): V-PRO 1Plus, V-PRO maX, V-PRO maX2, V-PRO S2.

It should be noted that the manufacturer ASP (2021) has added to its instructions additional restrictions on the types of N95 FFRs that can be disinfected (see table A2).

Hydrogen peroxide vaporizer (room disinfection device)

Vaporized hydrogen peroxide is generated by vaporizing an aqueous solution of hydrogen peroxide, which is then diffused into a room by means of a disinfection device.

The use of a hydrogen peroxide vaporizer (room disinfection device) is effective in disinfecting several models of N95 FFRs while preserving their integrity (Battelle, 2016; Bergman et al., 2010; Fischer et al., 2020; Smith et al, 2020). This effectiveness has been demonstrated for bacterial spores (*Geobacillus Stearothermophilus*) (Battelle, 2016), as well as for SARS-CoV-2 (Fischer et al., 2020). This process also allows for several disinfection cycles (without affecting the integrity of the FFRs) and therefore several reuses of the same FFR (Battelle, 2016; Bergman et al., 2010; Fischer et al., 2020; Smith et al., 2020).

Several factors can influence the duration of the disinfection cycle, including the size of the room. The larger the room used, the longer it takes to reach the required concentration and the longer it takes to ventilate the room after disinfection; on the other hand, the greater the number of FFRs that can be disinfected at the same time (after validation, approximately 1,000 N95 FFRs per disinfection cycle is possible). However, this process requires equipment that is currently rarely found within the Québec health network, although some facilities now have access to it.

The manufacturer Bioquell has had its technology approved by Health Canada (2021a) under the Interim Order for COVID-19:

- Ecolab Bioquell (2020): BQ50, L4, PROTEQ, Q10.

Heat

The use of heat to disinfect single-use N95 FFRs could constitute a widely accessible and economical solution. Various heat-based methods for disinfecting N95 FFRs have been studied in the literature, including by means of moist or dry heat.

The company 3M recommends not exceeding a temperature of 75 °C to maintain the integrity of the N95 FFRs (3M, 2021).

The inactivation of SARS-CoV-2 or other infectious agents using heat would be highly sensitive to the temperature, humidity and duration of the treatment cycle. Even a minor deviation from any of these predefined parameters could have a significant effect on the efficacy of viral inactivation (N95Decon, 2020d).

Moist heat

In MDRDs, the conditions required for the generation of moist heat are met by high-temperature sterilizers.

High-temperature sterilizers (steam sterilizers)

Moist heat had been identified by the United States Centers for Disease Control and Prevention as one of the methods that could be used to disinfect N95 FFRs (CDC, 2020). The data currently available suggest that exposure for at least 30 minutes to temperatures of 60 to 85 °C and relative humidity of over 50 % is effective at inactivating of several infectious agents (including SARS-CoV-2 and *Escherichia coli* colonies) in several N95 FFR models while maintaining their integrity after 5 to 15 treatment cycles (Rockey et al., 2020; McDevitt et al., 2010; N95Decon, 2020c,d; Daeschler et al., 2020).

Two manufacturers have had their technology approved by Health Canada under the Interim Order for COVID-19 (Health Canada, 2021a) and have issued disinfection instructions for the following models:

- Steris (2020b): Amsco 400, Century medium;
- SciCan Ltd. (2021): BRAVO 17V, BRAVO 21V.

In the case of the sterilizer manufactured by Steris, this technology has the advantage of being compatible with certain N95 FFR models that contain cellulose and thus offers a method that is complementary to other authorized disinfection methods that do not allow for the disinfection of N95 FFRs with cellulose. However, it is necessary to consider the fact that it is impossible to move Steris steam sterilizers from the setting in which they are used. This carries an increased risk of cross-contamination between the regular activities of the MDRD and the disinfection of N95 FFRs. Devices that cannot be moved to a room dedicated to disinfection carry a risk of cross-contamination, as is the case for low-temperature sterilizers. In addition, the Steris steam sterilizer must be programmed to perform a cycle specific to the disinfection of N95 FFRs (decontamination cycle). This non-standard cycle (65 °C for 30 minutes) carries a significant risk of error on the part of personnel since the inadvertent use of this cycle could compromise the achievement of sterility of medical devices.

The results obtained by different moist heat disinfection methods with regard to worker safety criteria: viral inactivation efficiency, filtration efficiency and FFR integrity after disinfection are presented in an annex.

Dry heat

This disinfection process requires high temperatures and long cycle times to allow for viral inactivation, which could affect the integrity of N95 FFRs. Although some studies have reported that exposure for 60 minutes to 70 °C temperatures reduced the activity of SARS-CoV-2 in some N95 FFR models (Daeschler et al., 2020; Fischer et al., 2020), its effectiveness at removing *E. coli* could not be demonstrated (Daeschler et al., 2020). Moreover, there is currently insufficient data in the literature to support a conclusion regarding the effectiveness of dry heat (Diptanu et al., 2020).

Recall that the disinfection process must enable the disinfection of all pathogens present on the surface and in the different layers of the N95 FFR, and not only of SARS-CoV-2.

Dry heat disinfection of N95 FFRs is not been authorized by Health Canada.

Ultraviolet

Of the three types of ultraviolet (UV) radiation, UVC has the most energy and the shortest wavelength. UVA and UVB do not have sufficient germicidal efficacy to be used for disinfection purposes (Health Canada, 2020b).

The use of ultraviolet (UVC) irradiation to disinfect N95 FFRs relies on the fact that single-stranded RNA viruses, such as SARS-CoV-2, are generally inactivated by a dose of UVC radiation of 2 to 5 mJ/cm^2 (Lowe et al., 2020). Lowe et al., (2020) recommend exposing N95 FFRs at 60 mJ/cm^2, whereas ECRI (2020) reports doses found in the literature ranging from 59 to 7000 mJ/cm^2. The exposure time for most available devices would be on the order of a few minutes (ECRI, 2020).

The germicidal efficacy of UVC is mainly dose-dependent but also wavelength-dependent with maximum efficacy at about 260 nm (N95Decon, 2020e,f). The literature reports a 3-log inactivation of a SARS-CoV-2 analogous virus on the surface of N95 FFRs for a UVC irradiation dose greater than or equal to 1 J/cm^2 (ARA, 2019; N95Decon, 2020e,f) for the majority of FFR models tested. However, one limitation of the use of UVC for disinfection of N95 FFRs is the rate of penetration into the different layers composing the FFR. Moreover, a dose higher than 1 J/cm^2 is probably necessary to inactivate other infectious agents (e.g., spore-forming bacteria) (N95Decon, 2020f).

In addition, to be effective, the technology for disinfecting by means of UVC irradiation must ensure exposure with multiple angles of attack and without shading to ensure the disinfection of a fibrous/porous surface such as that of an N95 FFR. Thus, all surfaces (both inside and outside) of the FFR must be exposed. According to the experts consulted by the CERDM, it could be difficult to ensure that the UVC light from UVC towers to which the N95 FFRs are exposed inside rooms is uniformly distributed and that each part of the FFR is sufficiently exposed to ensure homogeneous disinfection of the FFR. Moreover, the use of a sealed enclosure device lined with a reflective surface could not demonstrate sufficient effectiveness to meet the criterion for pathogen burden reduction.

Health Canada has clarified the technical requirements with which UVC disinfection devices must comply in order to be authorized (Health Canada, 2020b). No disinfection device using UVC irradiation alone has been authorized by Health Canada.

Disinfection device combining UVC irradiation with other technologies

Some manufacturers have developed disinfection technologies for N95 FFRs that combine several technologies. Two manufacturers have had their technology approved by Health Canada under the Interim Order for COVID-19 (Health Canada, 2021a) and have issued disinfection instructions for the following models:

- Clean Works Medical (2020a,b): Clean Flow Health Care Mini;
- Medera Technologies Inc./PureTech™ (2021): PureTech™ disinfection device.

The Clean Flow Mini device combines UVC irradiation with hydrogen peroxide and ozone. It is used in the agri-food industry and could disinfect up to 800 N95 FFRs per hour.

The PureTech™ device combines several technologies (microwaves, hydrogen peroxide and ozone) with UVC irradiation according to the manufacturer's instructions, although Health Canada (2021a) has authorized it for disinfection under the UVC irradiation device category. It should be noted that the device must be placed in a specific microwave oven, which then becomes a disinfection station. The latter must be installed under a ventilation hood with external exhaust. This device can be used to disinfect an N95 FFR by first spraying the FFR with 3% hydrogen peroxide under the ventilation hood. Next, in the microwave oven, the N95 FFR is irradiated with UVC for one minute, then left to sit in the microwave oven for ten minutes. A 24-hour aeration period is also required after disinfection (PureTech™, 2021). This particular technology is primarily targeted at health care facilities that do not have a MDRD, that have a low volume of N95 FFRs to be disinfected, and that are willing to devote the necessary resources to the process.

To our knowledge, these two devices are not currently being used in Québec health care facilities.

Conclusion

This evaluation presents processes and devices for disinfecting single-use N95 FFRs authorized by Health Canada, as alternatives of last resort in the case of a shortage of N95 FFRs in the context of the COVID-19 pandemic. In fact, under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, Health Canada has authorized the disinfection of N95 FFRs using various devices (Health Canada, 2021a).

Low-temperature sterilizers and high-temperature sterilizers are two easily accessible options for the disinfection of N95 FFRs since they are available in MDRDs. However, devices that cannot be moved to a room dedicated to disinfection carry a risk of cross-contamination. Moreover, with respect to high-temperature sterilizers, the programming of a specific non-standard cycle can carry a risk of error.

A hydrogen peroxide vaporizer (room disinfection device) has the advantage of having a much higher performance yield than low- and high-temperature sterilizers. However, this technology is rarely found within Québec's health network, although some facilities now have access to it.

No technology based on UVC irradiation alone has been authorized in Canada to disinfect N95 FFRs. However, two technologies combining UVC irradiation with other processes (hydrogen peroxide, ozone, etc.) have been authorized by Health Canada (2021a). To our knowledge, these devices are not currently found in Québec health care facilities.

The results for disinfection of N95 FFRs reported in the literature derive from pilot scale tests. The results of N95 disinfection process testing allow for verification of the safety and feasibility criteria presented in this evaluation. Feasibility criteria may vary depending on the disinfection process and device used.

Recommendations

Health care facilities must comply with the MSSS guidelines for assessing the status of an N95 FFR shortage. In addition, they must verify that the technologies, at the time of their use, are still authorized by Health Canada under the Interim Order for COVID-19 (Health Canada, 2021a).

In the event of a shortage of N95 FFRs, the CERDM recommends following:

- The recommendations of the Comité sur les infections nosocomiales du Québec (CINQ), including that of optimizing the use of N95 FFRs and that concerning exceptional measures (INSPQ, 2020a, 2021b,c);
- The manufacturers' instructions for the technologies approved by Health Canada for disinfection of single-use N95 FFRs under the Interim Order applicable to COVID-19 (Health Canada, 2021a);
- Health Canada's recommendations regarding disinfection of N95 FFRs and concerning AGMPs (Santé Canada, 2021b);
- For low-temperature sterilizers, a minimum pre-treatment drying period of one hour, as well as a 24-hour aeration period following disinfection, to avoid the presence of hydrogen peroxide in the N95 FFR, based on the results of the study conducted by the IRSST (2020). This recommendation applies to the three manufacturers of low-temperature sterilizers (ASP, Steris, Stryker). The instructions of the manufacturer of the PureTech™ device also specify a 24-hour aeration period following disinfection;
- The CERDM's guidelines (INSPQ, 2021d), to develop an internal disinfection procedure for the facility, beginning with the collection of single-use N95 FFRs and continuing up to their storage.

Disinfection of single-use N95 FFRs represents a solution of last resort to be applied when there is an anticipated shortage in order to be able to distribute them to workers only during a real shortage and when all other strategies for addressing the shortage of N95 FFRs are insufficient.

Annex

Table A1 Processes for disinfecting N95 FFRs, based on various evaluation criteria

Hydrogen peroxide	Steam (moist heat)	Ultraviolet (UVC) combined with other technologies
Effectiveness of the process in eliminating pathogen burden		
Yes	Yes	▶ The system must be designed to allow exposure of all surfaces and eliminate shading (exposing all surfaces may be more difficult for some N95 FFR models (shapes)) ▶ Two technologies authorized by Health Canada: UVC combined either with microwaves, hydrogen peroxide and ozone or with hydrogen peroxide and ozone
FFR integrity after disinfection (adequate filtration and facepiece fit)		
Yes	Yes	Yes
Absence of chemical residual hazard - potentially hazardous to the worker's health - in the N95 FFR after disinfection		
Yes ▶ Observe the recommended aeration time to avoid retention of hydrogen peroxide in the N95 FFR	Yes	Yes
Availability of disinfection equipment		
▶ Low-temperature sterilizers present in MDRDs ▶ Few hydrogen peroxide vaporizers currently present in Québec facilities	▶ Steam sterilizers present in MDRDs (health care facilities and external clinics)	▶ Technology not present in Québec facilities
Duration of cycle		
▶ Low-temperature sterilizers: maximum cycle duration of one hour in the sterilizer (followed by an aeration period outside the sterilizer) ▶ Hydrogen peroxide vaporizers: several hours (including an aeration period)	▶ 30 minutes	▶ A few minutes (followed by an aeration period)
Performance (number of FFRs per disinfection cycle)		
▶ Low-temperature sterilizers: Variable depending on the device used ▶ Hydrogen peroxide vaporizers: could yield a higher performance than low-temperature sterilizers	▶ Up to 180 N95 FFRs per cycle depending on the model	▶ Highly variable (1 for PureTech™ or 800 for Clean Flow Mini)
Process requirements		
▶ Low-temperature sterilizers: ideally devoted to the disinfection of N95 FFRs and installed in a dedicated room ▶ Hydrogen peroxide vaporizers: empty room required for disinfection	▶ Availability of steam sterilizers and programming of a specific non-standard cycle by the manufacturer	▶ Dependent on the technology used

Table A2 Health Canada authorizations for the disinfection of N95 FFRs

Disinfection device	Manufacturer (models)	Date of authorization (Health Canada, 2020a)	Characteristics
Low-temperature sterilizer (vaporized hydrogen peroxide and ozone)	Stryker (Sterizone VP4)	April 5, 2020	▶ Single wearer ▶ 2 disinfections allowed ▶ Not compatible with N95 FFRs containing cellulose, paper, natural rubber or latex (Stryker, 2020 a,b)
Low-temperature sterilizer (hydrogen peroxide plasma)	ASP (STERRAD 100S, STERRAD NX, STERRAD 100NX)	April 9, 2020	▶ Single wearer ▶ 2 disinfections allowed ▶ Not compatible with N95 FFRs ▶ containing cellulose or paper ▶ with exhalation valves ▶ duckbill shaped ▶ autorized under the emergency use authorization for disposable filtering respirators not certified by NIOSH or manufactured in China (ASP, 2021) ▶ Up to 480 FFRs per day depending on the model (FDA, 2020a)
Low-temperature sterilizer (vaporized hydrogen peroxide)	Steris (V-PRO 1 Plus, V-PRO MAX, PRO MAX2, V-PRO S2)	April 15, 2020 (V-PRO 1 Plus, V-PRO MAX, PRO MAX2) September 16, 2020 (V-PRO S2)	▶ Single wearer ▶ 10 disinfections allowed ▶ Not compatible with N95 FFRs containing cellulose or paper (Steris, 2020a)
Hydrogen peroxide vaporizer (room disinfection device)	Bioquell (BQ50, L4, PROTEQ, Q10)	April 20, 2020	▶ Single wearer ▶ 20 disinfections allowed ▶ Not compatible with N95 FFRs containing cellulose or paper ▶ 400 N95 FFRs authorized (approximately 1000 N95 FFRs per cycle, tested and validated, with the possibility of validating greater quantities) (Bioquell, 2020a,b)

Table A2 Health Canada authorizations for the disinfection of N95 FFRs (continued)

Disinfection device	Manufacturer (models)	Date of authorization (Health Canada, 2020a)	Characteristics
High-temperature sterilizer (moist heat: steam sterilizer)	Steris (AMSCO 400, AMSCO Century Medium)	July 23, 2020	▶ Single wearer ▶ 10 disinfections allowed ▶ Compatible with some N95 FFRs containing cellulose ▶ Compatible with the following N95 FFRs from 3M: 1860, 1860S, 1804, 1804S, 8110S, 1805, 1805S, 1870+ and 9210+ ▶ Up to 180 FFRs/cycle depending on the model ▶ Non standard cycle (65 °C 30 minutes) must be programmed specifically for N95 FFRs (Steris, 2020b,c)
High-temperature sterilizer (moist heat: steam sterilizer)	SciCan Ltd. (BRAVO 17V, BRAVO 21V)	January 21, 2021	▶ Single wearer ▶ 10 disinfections allowed ▶ Compatible with the following N95 FFRs from 3M: 1870+ and 9210+ ▶ Up to 5 FFRs/cycle (SciCan, 2021)
Disinfection device combining several technologies (UVC, vaporized hydrogen peroxide and ozone)	Clean Works Medical (Clean Flow Health Care Mini)	April 13, 2020	▶ Single wearer recommended ▶ 10 disinfections allowed ▶ Not compatible with N95 FFRs containing cellulose, natural rubber or latex ▶ Up to 800 FFRs/hour (Clean Works, 2020a,b)
Disinfection device combining several technologies (UVC, microwaves, hydrogen peroxide and ozone)	Medera Technologies Inc. (PureTech™ disinfection device)	May 5, 2021	▶ Single wearer ▶ 10 disinfections allowed ▶ 1 FFR/cycle ▶ Compatible with N95 FFR models in the Moldex series 1500 N95 ▶ Requires a ventilation hood with direct evacuation and the Hamilton Beach EM031MFW microwave oven (PureTech™, 2021)

Table A3 Use of moist heat for disinfection of single-use N95 FFRs, with regard to worker safety criteria (taken from version 2.1 dated May 21, 2020)

References	Conditions	Worker safety criteria[A]		
		Effectiveness in reducing pathogen burden	Filtration efficiency	FFR integrity (shape and facepiece fit)
Bergman, 2011	▶ 60 °C, 80 % relative humidity (RH), for 30 minutes, followed by air drying for 1 night (3 cycles)	Untested	Yes	Yes For 3 N95 models, but deformation for 2/3 of the SN95 models (surgical masks)
Viscusi, 2009	▶ 60 °C, 80 % RH, for 30 minutes, followed by air drying for 1 night	Untested	Yes	Possibility of post-treatment odour
Price & Chu, 2020	▶ Hot air at 70 °C for 30 minutes ▶ Hot water vapour from boiling water for 10 minutes	*E. Coli*	Yes	Untested
3M, 2020	▶ 65±5 °C, 50-80 % RH for 30 minutes (10 cycles) ▶ Hot water vapour from boiling water for 10 minutes	Untested	Yes	Yes
N95Decon, 2020	▶ According to a review of the literature: 65 to 80°C, 50 to 85% RH, for 30 minutes	SARS-CoV-1, H1N1 and H5N1	Yes	Acceptable facepiece fit (deformation mainly affecting SN95 masks)

[A] Yes: Criterion met in the study referenced.

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Record of modifications

Version	Date	Pages	Modifications
4.0	2021-09-30	1 2 4-11 6 6 to 9 9-14	▶ Clarifications made to the note of warning ▶ Clarifications made to the Context section: revocation of FDA authorizations ▶ Health Canada recommendations concerning the disinfection of N95 FFRs and for AGMPs ▶ Revision of the instructions for Canada for low-temperature sterilization of N95 FFRs by the manufacturer ASP ▶ Addition of devices authorized by Health Canada in their respective subsection of the Disinfection processes section ▶ Updating of technologies and equipment approved by Health Canada (SciCan Ltd and Medera Technologies Inc.)
3.0	2020-12-07	1 2 3 4-13 5-13 6-7-11-12 6-7-9 7 13 1 to 20	▶ Clarifications made to the Context section ▶ Clarifications regarding the level of sterility assurance required by Health Canada in the Method section ▶ Amendment of the considerations related to the notion of a single wearer, in the Precautions to be considered section ▶ Additional information concerning the number of disinfection cycles ▶ Essential elements for low-temperature sterilizers ▶ Updating of equipment approved by Health Canada (addition of steam sterilizers) ▶ Updating of processes (moist heat and dry heat) ▶ Additional information in the Ultraviolet section ▶ Addition of recommendations ▶ Harmonization of nomenclature (filtering facepiece respirators vs masks) throughout the document
2.1	2020-05-21		▶ Definition of the term disinfection in the section entitled Foreword ▶ Additional information in the section entitled Method ▶ Clarifications in the acknowledgements
2.0 (In French only)	2020-04-28		▶ Update related to new publications ▶ Health Canada authorizations
1.0 (In French only)	2020-04-01		▶ Evaluation of disinfection options for N95 masks

COVID-19: Evaluation of Disinfection Options for N95 Filtering Facepiece Respirators in the Context of the Pandemic

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The French version, entitled *COVID-19 : Évaluation des options de désinfection des appareils de protection respiratoire N95 dans le contexte de la pandémie*, is also available on the website of the Institut national de santé publique du Québec at: https://www.inspq.qc.ca/publications/2971

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