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N95 mask reuse in a major urban hospital: COVID-19 response process and procedure

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SUMMARY

Background: The shortage of single-use N95 respirator masks (NRMs) during the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has prompted consideration of NRM recycling to extend limited stocks by healthcare providers and facilities.
Aim: To assess potential reuse via autoclaving of NRMs worn daily in a major urban Canadian hospital.
Methods: NRM reusability was assessed following collection from volunteer staff after 2–8 h use, sterilization by autoclaving and PortaCount fit testing. A workflow was developed for reprocessing hundreds of NRMs daily.
Findings: Used NRMs passed fit testing after autoclaving once, with 86% passing a second reuse/autoclave cycle. A separate cohort of used masks pre-warmed before autoclaving passed fit testing. To recycle 200–1000 NRMs daily, procedures for collection, sterilization and re-distribution were developed to minimize particle aerosolization risk during NRM handling, to reject NRM showing obvious wear, and to promote adoption by staff. NRM recovery ranged from 49% to 80% across 12 collection cycles.
Conclusion: Reuse of NRMs is feasible in major hospitals and other healthcare facilities. In sharp contrast to studies of unused NRMs passing fit testing after 10 autoclave cycles, we show that daily wear substantially reduces NRM fit, limiting reuse to a single cycle, but still increasing NRM stocks by ~66%. Such reuse requires development of a comprehensive plan that includes communication across staffing levels, from front-line workers to hospital administration, to increase the collection, acceptance of and adherence to sterilization processes for NRM recovery.
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Introduction

The coronavirus disease 2019 (COVID-19) pandemic represents a unique dual challenge to both patient management and the distribution and deployment of personal protective equipment (PPE) required to protect healthcare workers. The rapid increase in infected patients and global reach of the outbreak has strained supply chains not only for equipment such as ventilators, but also for disposable PPE used in the management of these patients, especially single-use N95 respirator masks (NRMs). Assessing the potential reuse of NRMs is thus a rapidly emerging critical issue.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is primarily spread via respired airborne droplets [1]. Its lipid-rich envelope is critical for viral propagation, but may be removed via physical or chemical means [2]. Airborne virus-containing droplets have been detected on a variety of surfaces up to three days following exposure, with indications of a half-life of several hours [3,4]. Various disinfecting approaches are effective against coronavirus generally, and SARS-CoV-2 specifically. The Centers for Disease Control and Prevention (CDC) and Environmental Protection Agency maintain lists of effective approaches for surface cleaning including solutions with alcohol concentrations >70% and bleach [5,6]. In contrast to physical spaces and fixtures, NRMs are typically made for single exposure applications without regard for disinfection and reuse.

Given global shortages and rapidly declining stockpiles of NRMs at healthcare facilities, the reuse of NRMs following autoclaving was explored in the context of the demands of a large tertiary care hospital in a major Canadian city. Several groups recently explored various options for sterilizing NRMs and/or swatches of the meltblown polypropylene filter material that comprises the key electrostatically charged physical filter, including ethylene oxide gas, microwave-generated steam, ionized hydrogen peroxide, vaporized hydrogen peroxide, ultraviolet light, warm air exposure, and autoclaving [7—9]. Most such approaches appear capable of sterilizing masks or filter material, but with key caveats [10]. In some studies, only single rounds of sterilization were employed, thus the effect of repeated cycles remains unclear. Several studies reported damage to the filter material or components such as straps, resulting in failed fit testing. These studies largely agree with earlier data released by the 3M company, which manufactures the N95 filter material [11]. A recent study stated that up to 10 resterilization procedures could be carried out without altering mask integrity [12]. However, these were new masks. No study has yet been done with NRMs that have actually been worn by workers in clinical environments and sterilized by autoclaving. Our report describes both the sterilization of masks and the logistical plan for collection and deployment. The approaches employed will provide useful guidance for healthcare agencies facing an influx of COVID-19 patients and NRM shortages.

Methods

Collection of contaminated masks

Given the transmissibility of SARS-CoV-2 by respired droplets and a potentially long half-life, minimizing the potential for aerosolization of particles and self-contamination was necessary for handling NRMs prior to sterilization. Doffing NRMs may generate aerosols and increase exposure; therefore we limited the number of doffing locations [13].

NRM collection was initiated in the emergency department (ED) prior to scale-up and a rolling introduction in other hospital units. An unlined 75 L Rubbermaid tote with snap-on lid capable of being disinfected was provided to transport used NRMs from the unit to medical device reprocessing (MDR). The tote was marked clearly for NRM collection and deployed in a single location in the ED determined as optimal in consultation with unit staff (Figures 1 and 2). NRM collection instructions were provided to unit staff, with accompanying signage noting that only Pleats Plus NRMs (Aearo Co., Indianapolis, IN, USA) were being collected (Appendix A). Contact information was provided for reporting problems or requesting tote pick-up, with a primary contact established for the entire hospital to ensure uniform responses. In consultation with infection, prevention and control (IP&C) practitioners, units/departments could elect to use additional plastic-lined receptacles to collect used NRMs from staff with consideration of the size and physical layout of each clinical area, and the usual number of doffing locations. If receptacles were used, unit/department staff were informed that compressing such bags may lead to aerosolization of contents and were advised to avoid such handling. Unit staff were responsible to collect bags and deposit in the MDR tote prior to pick-up. The number of totes and frequency of MDR exchanges was subject to adjustment based upon unit/department usage of NRMs.

Masks that were visibly soiled, exposed to hazardous agents (e.g. chemotherapeutics), used in conjunction with tuberculosis patients, or damaged/torn were not accepted for processing and disposed via normal protocols for infectious items. NRMs soiled by make-up may exhibit altered filtration characteristics, and may subsequently be refused by staff following sterilization, which does not remove stains. Staff were thus instructed not to wear make-up.

Figure 1. Collection tote design and placement. Rubbermaid 75 L totes with lids were marked with red tape and instructions on mask recycling (left). Totes were placed at key sites in participating units in consultation with unit staff (right).

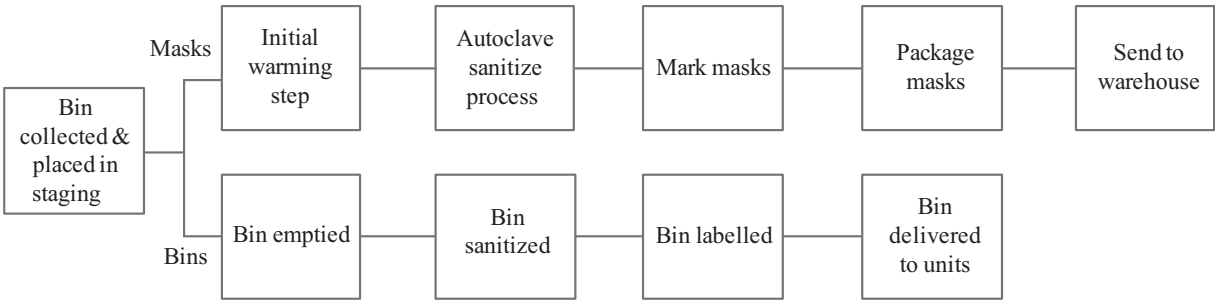

Figure 2. Process flow of N95 respirator masks and collection totes.

Handling of contaminated masks

Totes containing masks were picked up by MDR staff using a wheeled cart to facilitate transfer and minimize risk of spilling, and exchanged with a clean replacement tote. Totes containing contaminated NRMs were transported to the MDR-Main facility, pre-sorted to remove visibly soiled or damaged masks, and placed into an Olympic dryer (45–55°C, up to 66 h) to provide an initial round of sanitation, with the aim of reducing viral load and exposure of workers that subsequently load the autoclave (Figure 2) [14].

Following the initial warm air step, NRMs were carefully unloaded to minimize potential aerosol generation, bloomed to maximize surface area, and sorted per the above criteria prior to being arranged in the autoclave. NRMs were suspended by their straps via a string and attached to the autoclave racks to eliminate contact of the mask with metal surfaces, which may adversely affect mask materials (Figure 3) [8]. Used totes with their lids were decontaminated in a cart washer including a thermal disinfection at 90°C for 1 min prior to subsequent return to collection sites (Figure 2).

Sterilization of N95 respirator masks

Approximately 90% of the NRMs used in our hospital are AO Safety 1054S Pleats Plus, thus we focused on their sterilization and reuse. Autoclaving, typically available in most healthcare facilities of various sizes, may effectively sterilize NRMs while maintaining filtering characteristics and minimizing adverse effects on mask structure across multiple cycles of sterilization. A recent preliminary report indicated that Pleats Plus masks inoculated with ~5.0 $\log_{10}$ $TCID_{50}$ (fifty-percent tissue culture infective dose) viral suspension of SARS-CoV-2 and subjected to autoclaving at 121°C for 15 min yielded no recoverable virus [12]. Notably, these masks passed PortaCount (Shoreview, MN, USA) fit testing after 10 rounds of autoclaving.

In our study, NRMs worn by volunteer Animal Care Centre laboratory workers for 2–8 h were collected and autoclaved at 121°C for 30 min plus 15 min drying time (total cycle length 48 min) in a Steris Amsco 400 Series Prevacuum Steam Sterilizer Model 20 (Steris Corp., Mentor, OH, USA). Biological indicators (Attest 1292) were included in each autoclave cycle to confirm sterilization. Quantitative fit testing was performed using a PortaCount PRO+ 8038 to evaluate respirator facial seal during seven work-simulating exercises (60 s each): normal breathing, deep breathing, side-to-side head turning, head nodding up and down, talking out loud, bending over, and a second round of normal breathing. Fit factor scores were assigned for each exercise according to protocol CSA Z94.4–2011; respirator masks yielding an average fit factor <100 failed fit testing and were discarded [15]. An updated version of this standard, CSA Z94.4–2018, has been released that provides additional clarification, guidance and informative annexes; however, fit testing guidelines remain unaltered (a summary of changes can be found online [16]). Staff operating the autoclave were equipped with PPE including NRMs, head coverings, isolation gowns, and gloves.

Figure 3. Racking of masks for autoclaving. N95 respirator masks were bloomed, then suspended by strings through their straps to avoid contact with metal racks prior to autoclaving.

Distribution of sterilized masks

Following autoclaving, a tally mark was applied to the seam of sterilized NRMs using a permanent marker to indicate that they had been sterilized. Masks bearing the tally mark are discarded after one reuse. After autoclaving, NRMs were assorted by size, enclosed in plastic bags (10 per bag) and delivered by MDR staff to a central storage area. Printed instructions for reuse were included for staff to complete the following steps: (i) sanitize hands before and after touching or adjusting a mask; (ii) visually inspect the mask for defects/shape/form; (iii) check components such as the straps or nose bridge for degradation; and (iv) perform a fit-seal check immediately after donning. Units requiring NRMs were instructed to order them using standard hospital processes.

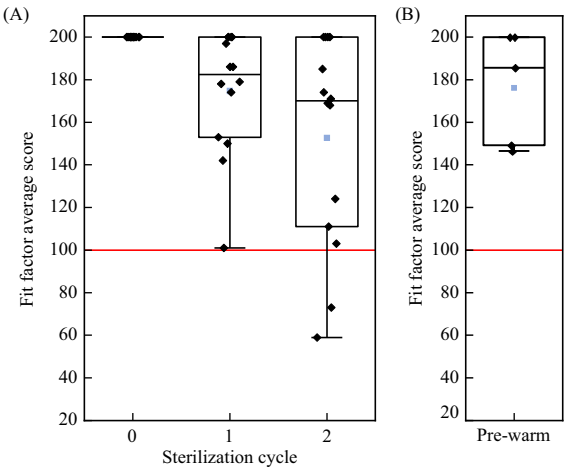

Figure 4. N95 respirator mask fit testing results. (A) Box-and-whisker plots showing the average fit factor results of new N95 Pleats Plus respirator masks, or following one or two wear and sterilization cycles. Masks scoring <100 (red line) are deemed to have failed fit testing. The average fit factor at each cycle is indicated by the blue square. (B) Average fit factor results following a combined pre-warming step (66 h at 45—55°C) and single sterilization cycle.

Results

A trial cohort of 14 NRMs was used by volunteer staff from the Animal Care Centre on our hospital campus for several hours during their normal work day, then collected for autoclave sterilization and fit testing using a PortaCount. Kumar *et al.* reported that masks could be autoclaved and pass fit testing for at least 10 cycles of 15 min at 121°C [12]. Notably, that study did not subject masks to real-world wear conditions. In contrast, an earlier study reported that autoclaved NRM failed a sodium chloride aerosol penetration test, but did not disclose the model or manufacturer of the NRM, and notably enclosed NRM in autoclave bags rather than minimizing surface contact via racking as in our study [17]. Our investigation revealed that, whereas all NRMs passed fit testing after a single round of sterilization by autoclave, masks started failing after a second round of wear and sterilization (Figure 4A). Although this number was relatively small — two masks out of 14 failed fit testing (14% failure rate) — this failure necessitated that the entire lot be discarded.

As noted above, we included a pre-warming step at 45—55°C for at least one overnight period to initiate a reduction of the initial viral load prior to handling of NRMs by autoclave staff. In a test cohort, five NRMs were subjected to a combined procedure of 66 h of pre-warming, followed by autoclaving and fit testing. All five masks passed fit testing with similar fit factor score distribution and mean as for non-pre-warmed masks (Figure 4B), indicating that the pre-warming step does not

Table I
N95 respirator mask (NRM) recovery analysis

Load	Collected	Pre-sterilization reject	Post-sterilization reject	Packaged	Notes
1	24	3 S/M 6 M/L	0	15 (62.5%)	5 miscellaneous 6 other N95
2	90	14 S/M 2 M/L	9 S/M 3 M/L	62 (68.9%)	
3	160	16 S/M 3 M/L	10 S/M 11 M/L	120 (75%)	1 miscellaneous 7 other N95
4	224	31 S/M 12 M/L	3 S/M 11 M/L	167 (74.6%)	5 other N95
5	227	35 S/M 13 M/L	6 S/M 7 M/L	166 (73.1%)	3 miscellaneous 5 other N95
6	54	3 S/M 2 M/L	2 S/M 4 M/L	43 (79.6%)	
7	108	12 S/M 11 M/L	3 S/M 7 M/L	75 (69.4%)	
8	224	26 S/M 11 M/L	18 S/M 37 M/L	132 (58.9%)	1 other N95
9	77	7 S/M 10 M/L	3 S/M 3 M/L	54 (70.1%)	
10	224	27 S/M 17 M/L	20 S/M 37 M/L	123 (54.9%)	2 miscellaneous
11	295	32 S/M 27 M/L	36 S/M 56 M/L	144 (48.8%)	19 other N95
12	269	25 S/M 11 M/L	21 S/M 32 M/L	180 (66.9%)	3 other N95

The results of NRM collection activities are shown across 12 collection loads, each obtained on a different day as collection was introduced in more units. The total NRMs collected are shown, as well as the total rejected pre-sterilization according to mask size (small/medium, S/M; medium/large, M/L), the total rejected after sterilization, and the final number of masks packaged for redistribution (including the percentage ultimately available for reuse from those initially collected). Some collections included miscellaneous items such as hairnets or other personal protective equipment, or NRMs other than Pleats Plus, which were discarded and not included in the collection or packaged counts.

adversely affect mask wear characteristics consistent with other reports employing higher temperatures but for shorter times [18].

To estimate the efficiency of NRM recovery in our hospital, we analysed reprocessing data over 12 collections of masks as we expanded collection from the ED alone to three additional units (intensive care medicine/surgery, operating room, and labour and delivery). The individual lots collected ranged from 24 to nearly 300 masks (Table I). NRMs were rejected both prior and subsequent to autoclaving, almost universally due to visible make-up contamination. The inclusion of items other than Pleats Plus masks occurred with low frequency, which we attributed to the signage warning against this on the bins and communications with staff (Appendix A). Reprocessing rates, i.e. the percentage of NRMs collected that were made available for reuse after sterilization, ranged from 48.8% to 79.6% (Table I).

Discussion

St Boniface Hospital, a leading tertiary care centre in Winnipeg, Canada with ~4000 staff, treats 29,000 inpatients and 52,000 outpatients annually, serving a population of >800,000 citizens. NRM reuse at sufficient scale required both a sterilization mechanism that maintained protection and development of a logistical collection and redistribution process (Figure 2). Process development required collaboration between hospital senior administration and operational staff. A subcommittee, chaired by a senior administrator reporting to the hospital President/CEO, comprised representatives from MDR, IP&C, operations, nursing, workplace safety and health, and clinical engineering. The resulting workflow and sterilization process aligned with provincial and federal healthcare requirements, and with CDC policy [19,20].

Regular communication between the subcommittee chair and the hospital CEO ensured that the process aligned with facility needs. The reprocessing strategy was introduced in stages — initially in the ED, with progressive introduction to other units over several weeks. Unit staff were continually provided with information detailing why NRM reprocessing was being conducted, the process and logistics, and unit-specific go-live dates. Sterilization testing results were shared with staff, emphasizing evidence of successful mask sterilization (biological indicators) and fit testing. Such engagement with unit leadership was critical for widespread process adoption by staff. During roll-out, signage (Appendix A) clearly indicated the specific NRMs to be collected, with an FAQ (Appendix B) to address common concerns. Communication between unit and MDR staff ensured that the collection process was mutually understood, and that collection totes were not neglected. Involvement of unit staff in determining collection locations further ensured process adoption. Updates from senior leadership provided additional context to the need to reprocess NRMs. During collection, units were updated on the number of NRMs collected, the number rejected at initial inspection, and numbers of non-mask items in the collection totes; such feedback reduced the number of inappropriate items in totes, and sustained reprocessing rates from 49% to 80%, averaging 66% (Table I).

Previous studies of NRM resterilization employed masks/materials that were unworn. Conversely, we examined the efficacy of resterilization of masks worn by staff for many hours under working conditions. Our results demonstrate that the process outlined here results in effective NRM sterilization while maintaining usability for a single cycle but not additional cycles. The method we used — autoclaving — is widely available even in small facilities and offices. In contrast, approaches such as vaporized hydrogen peroxide are effective but limited by unique equipment availability, and by potential exposure of staff to toxic substances. Our hospital uses ~400 NRMs daily; our autoclave-dependent process can sterilize ~800 masks daily, or many more with additional autoclaves. Our use of biological indicators confirmed sterilization, and formal fit testing confirmed that masks could be safely reused while also providing data on failure rates. We found that only a single round of sterilization of NRMs is possible without fit testing failures, in sharp contrast to studies with unused masks or N95 swatches indicating up to ten uses [12]. Thus, excluding testing of masks actually worn under working conditions gives the illusion of mask capacity for reuse without actually providing protection. Another study employed real-world testing, but only for 2 h of use and without assessing autoclaving, instead using 70°C dry heat to maintain mask integrity for up to two cycles [18]. Our results suggest that, whereas the mask material itself can likely tolerate additional sterilization cycles, real-world use severely reduces this number, an effect that we attribute to issues such as mask shaping to facial contours and sweating occurring during NRM usage (Figure 4). Interviews with staff did not reveal any reduced ability to breathe while wearing NRMs that had been autoclaved once, although comments from users noted a slight change in respirator odour, less elasticity in the straps, and a 'softer' texture to the mask material, suggesting that physical changes to the NRM had occurred, which may explain why fit failures commenced starting in the second round of autoclaving.

Our study has several limitations for consideration. We did not assess the elimination of SARS-CoV-2 by autoclaving, instead relying on biological indicators to demonstrate sterilization. However, a recent unpublished but robust study reported that one cycle of sterilization (15 min at 121°C) eliminated SARS-CoV-2 [12]. We also limited our process specifically to AO Safety Pleats Plus NRMs. These masks remain in widespread use, including in our facility. Others have reported that three varieties of 3M masks performed as well as the Pleats Plus after resterilization. We thus anticipate that our process can be used for other widely used respirators, although site-specific testing is required to confirm efficacy and evaluate whether additional sterilization cycles may be possible. Although we observed that only two out of 14 respirators tested failed after a second autoclave cycle, it is necessary to fail the entire lot in the absence of individual respirator fit testing since the specific failed units would not be known. Fit testing of every respirator is unlikely to be tenable in large healthcare facilities; however, in smaller facilities or offices, should such individual fit tests be completed, it may be possible to salvage additional masks for reuse beyond a single sterilization cycle — but such a comprehensive testing regime would be strictly required to avoid using potentially compromised respirators. Finally, we noted that staff were reticent to use reprocessed masks derived from a communal pool, i.e. when individual staff did not receive their own mask after sterilization. It may thus be necessary to individually identify and track NRMs. Should NRM supplies become seriously depleted, however, communal

pooling of sterilized masks would nonetheless provide an invaluable safety resource.

In conclusion, we describe here an NRM sterilization process for reuse at scale, as well as the logistics of collection and redistribution, and note important considerations for facilities considering adopting similar processes, including the importance of communication across administrative and operational levels. This study may guide other facilities, from single offices to large urban hospitals, to create robust processes that maintain user safety while extending limited NRM supplies during a global healthcare emergency. Resterilization of NRM, however, can only be achieved once in order to maintain safe working conditions for staff.

Conflict of interest statement
None declared.

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Appendix A. Supplementary data

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