Centre universitaire de santé McGill

McGill University Health Centre

Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC)

18 November 2024

Use of N95 respirators past their shelf life

Health Technology Assessment

Brief Repor

Report no. 9

Report prepared for the Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC)

by

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Mission Statement

The MUHC Health Technology Assessment Unit (TAU) advises hospital administrators and clinical teams in difficult resource allocation decisions. Using an approach based on independent, critical evaluations of the available scientific evidence and a transparent, fair decision-making process, novel and existing medical equipment, drugs and procedures used by healthcare professionals are prioritized on a continuous basis ensuring the best care for life with the best use of resources.

Brief Reports

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Declaration of Conflicts of Interest

Members of TAU's research staff and policy committee declare no conflicts of interest.

Suggested Citation

Almeida N. Use of N95 respirators past their shelf life. Montreal (Canada): Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC); Nov 18, 2023. Report no. 94. 27 pages

ACKNOWLEDGEMENTS

The expert assistance of the following individuals is gratefully acknowledged:

- Kim Tanguay, N. M.Ed., Nursing Practice Consultant, Nursing Directorate, McGill University Health Centre

REPORT REQUESTOR

This report was requested by Kim Tanguay, Nursing Practice Consultant, Nursing Directorate on November 10, 2023.

TYPES OF RECOMMENDATIONS ISSUED BY THE TAU COMMITTEE

Type of recommendation	Explanation
Approved	• Evidence for relevant decision criteria, including efficacy, safety, and cost, as well as context-specific factors such as feasibility, is sufficiently strong to justify a recommendation that the technology be accepted, used and funded through the institutional operating budget
Approved for evaluation	• There is a reasonable *probability* that relevant decision criteria, including efficacy, safety, and cost, as well as context-specific factors such as feasibility, are favorable but the evidence is not yet sufficiently strong to support a recommendation for permanent and routine approval. • The evidence is sufficiently strong to recommend a *temporary* approval in a restricted population for the purposes of evaluation, funded through the institutional operating budget.
Not approved	• There is insufficient evidence for the relevant decision criteria, including efficacy, safety, and cost; • The costs of any use of the technology (e.g. for research purposes) should not normally be covered by the institutional budget.

DISCLAIMER

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BACKGROUND

The COVID-19 pandemic necessitated the stockpiling of personal protective equipment (PPE) as a way to ensure the availability of necessary quantities during the public health emergency. As a consequence, healthcare establishments now have large stockpiled reserves of PPE, including N95 respirators, that have since exceeded their manufacture-designated shelf life.

The MUHC currently has a stockpile of 283,100 N95 Champak F550 respirators that have a manufacture-designated shelf life of 3 years, and that have recently expired or are due to expire in 2024. These masks were purchased by the MUHC at a cost of $228,654.

Given the need to balance the safety and effectiveness of expired N95 masks against the considerable procurement and storage costs of PPE, it is necessary to evaluate whether N95 respirators past their shelf life continue to be effective in protecting healthcare personnel.

This evaluation was therefore requested by Kim Tanguay, Nursing Practice Consultant, Nursing Directorate of the McGill University Health Centre (MUHC) on November 10, 2023.

OBJECTIVES

The objectives of this report are to:

1. Identify the evidence on the effectiveness of expired N95 respirators in terms of aerosol filtration efficiencies;
2. Identify guidance for the safe use of N95 respirators past their expiry date.

FINDINGS

Filtration performance of expired N95 respirators

- The best available evidence on the viability of expired N95 respirators comes from a large study (n=3,971 stockpiled N95 respirators manufactured between 2003 and 2013) conducted by The National Institute for Occupational Safety and Health (NIOSH) in the US. They reported that:
    - 98% (3,895 of 3,971) of the evaluated respirators **maintained their inhalation and exhalation resistance and filtration performance**, with the upper limit of the 99% confidence intervals well within the NIOSH minimum performance requirements. Filtration performance was based on Standard Test Procedures

that designate pass/fail criteria for Particulate Filter Efficiency for N95 to be ≥95%, i.e. N95 FFRs must have a particle penetration of less than 5.0%.
    - Storage conditions such as exposure to dust, moisture, sunlight and damage to pallets and cases are important factors that may impact respirator viability and should be carefully documented.
    - While these results are suggestive that the majority of evaluated N95 respirators stockpiled for long periods of time maintain their protective properties, NIOSH cautions that their results may not be applicable to other respirator models not included in this study or to stockpile facilities with various storage conditions. **The Champak F550 N95 respirators were not included in this study.**

Guidance

- NIOSH acknowledges that managing stockpiled and expired respirators will be an ongoing consideration and that stockpile personnel require uniform guidance. They recommend:
    - The development of **an economically sustainable stockpile quality assurance process,** such that stockpiles from around the nation test and evaluate their respirator inventories using NIOSH's minimum performance requirements, and share their results with product manufacturers to optimize shelf life designations.
    - A national stockpile maintenance approach to purchase, store, and deploy respirators (e.g., rotate inventory) to ensure respirator availability and product usage within these optimized shelf lives.
- NIOSH developed a 4-step framework to guide stockpile managers to assess the performance of filtering facepiece respirators (FFR):
    1. Define the population of FFRs to be sampled;
    2. Use random sampling strategies to obtain a representative sample;
    3. Inspect and test the sampled units using standard testing procedures in accordance with government or Occupational Health and Safety norms and regulations;
    4. Compute results and extrapolate to the entire population to determine the probability of observing a similar failure rate in the whole population of FFRs.

CONCLUSIONS

- The best available evidence on the performance of expired or stockpiled N95 respirators is derived from a NIOSH evaluation of 3,971 stockpiled N95 respirators manufactured between 2003 and 2013, which found that 98% of the evaluated

respirators maintained their inhalation and exhalation resistance and filtration performance after their expiry date.

- Nonetheless, NIOSH cautions these results may not be applicable to other respirator models not included in this study or stockpile facilities with various storage conditions. The Champak F550 N95 respirators were not included in this study.
- Most regulatory bodies including Health Canada, the CDC and the WHO agree that respirators beyond their labelled shelf life, while no longer considered approved, may retain adequate filter performance if stored properly. However, because loss of elasticity in the bands or straps can impact a proper seal, they recommend that respirators be closely inspected for signs of damage and fit-tested before use.
- To guide stockpile personnel, NIOSH recommends the creation of a quality assurance process for stockpiled respirators to determine optimal shelf life designations.
- NIOSH has also developed a 4-step framework to guide stockpile managers in evaluating the performance of stockpiled respirators, such that a representative sample of respirators can undergo quality control to determine the probability of observing a similar failure rate in the whole population of respirators.

KEY FINDINGS AND RECOMMENDATIONS

- There is reasonable evidence to indicate that N95 respirators past their designated shelf life **retain adequate filter performance** if stored properly. NIOSH reported that 98% of almost 4000 evaluated N95 respirators past their expiry date maintained their protective properties. However, these results may not be generalizable to respirators not included in their analysis, including Champak F550 N95 respirators.
- Recommendations for the MUHC:
    - Stockpile managers should perform **quality assurance testing** on representative samples of Champak F550 N95 respirators from different lots and storage conditions, as described by NIOSH, so the viability of the complete stockpile can be ascertained. Representative sample testing allows extrapolation of findings to the population of respirators from which the sample was derived, allowing for a cost-effective solution;
    - The following factors should be evaluated:
        - Visual signs of damage to respirators and fit-testing before use
        - Filtration efficiency
        - Storage conditions
- Recommendations at the national/province level (NIOSH recommendation):
    - The creation of **an economically sustainable stockpile quality assurance process,** to ensure that stockpiles of respirator inventories across the province are evaluated using NIOSH's minimum performance requirements. Results should be shared with product manufacturers to optimize shelf life designations.
    - A stockpile maintenance approach at the national level to purchase, store, and deploy respirators (e.g., by rotating inventory) to ensure adequate respirator availability and product usage within these optimized shelf lives.

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CONTEXTE

La pandémie de COVID-19 a nécessité la constitution de stocks d'équipements de protection individuelle (EPI) afin de garantir la disponibilité des quantités nécessaires pendant l'urgence sanitaire. En conséquence, les établissements de santé disposent désormais d'importantes réserves d'EPI, notamment de respirateurs N95, qui ont depuis dépassé leur durée de conservation prévue par le fabricant.

Le CUSM dispose actuellement d'un stock de 283 100 respirateurs N95 Champak F550 dont la durée de conservation prévue par le fabricant est de 3 ans et qui ont récemment expiré ou doivent expirer en 2024. Ces masques ont été achetés par le CUSM au coût de 228 654 $.

Étant donné la nécessité d'équilibrer la sécurité et l'efficacité des masques N95 périmés par rapport aux coûts considérables d'approvisionnement et de stockage des EPI, il est nécessaire d'évaluer si les respirateurs N95 ayant dépassé leur durée de conservation continuent d'être efficaces pour protéger le personnel de santé.

Cette évaluation a donc été demandée par Kim Tanguay, conseillère en pratique infirmière, Direction des soins infirmiers du Centre universitaire de santé McGill (CUSM) le 10 novembre 2023.

OBJECTIFS

Les objectifs de ce rapport sont les suivants :

1. Identifier les preuves de l'efficacité des respirateurs N95 périmés en termes d'efficacité de filtration des aérosols ;
2. Identifier des lignes directrices pour une utilisation sûre des respirateurs N95 après leur date d'expiration.

RÉSULTATS

Performance de filtration des respirateurs N95 périmés

- Les meilleures preuves disponibles sur la viabilité des respirateurs N95 périmés proviennent d'une étude à grande échelle (n=3 971 respirateurs N95 fabriqués entre 2003 et 2013) menée par le National Institute for Occupational Safety and Health (NIOSH) aux États-Unis. Ils ont rapporté que :
    - 98 % (3 895 sur 3 971) des respirateurs évalués **ont conservé leur résistance à l'inhalation et à l'expiration et leurs performances de filtration**, la limite

supérieure des intervalles de confiance de 99 % se situant bien dans les exigences minimales de performance du NIOSH. Les performances de filtration étaient basées sur des procédures de test standard qui désignent les critères de réussite/échec pour l'efficacité du filtre à particules pour le N95 comme étant ≥ 95 %, c'est-à-dire que les FFR N95 doivent avoir une pénétration des particules inférieure à 5,0 %.

- Les conditions de stockage telles que l'exposition à la poussière, à l'humidité, à la lumière du soleil et les dommages aux palettes et aux caisses sont des facteurs importants qui peuvent avoir un impact sur la viabilité des respirateurs et doivent être soigneusement documentés.
- Bien que ces résultats suggèrent que la majorité des respirateurs N95 évalués stockés pendant de longues périodes conservent leurs propriétés protectrices, le NIOSH prévient que leurs résultats peuvent ne pas être applicables à d'autres modèles de respirateurs non inclus dans cette étude ou à des installations de stockage présentant diverses conditions de stockage. **Les respirateurs Champak F550 N95 n'ont pas été inclus dans cette étude.**

<u>Lignes directrices</u>

- Le NIOSH reconnaît que la gestion des respirateurs stockés et périmés sera une préoccupation constante et que le personnel chargé des stocks a besoin de directives uniformes. Il recommande :
  - Le développement **d'un processus d'assurance qualité des stocks économiquement durable**, de sorte que les gestionnaires de stocks de tout le pays testent et évaluent leurs inventaires de respirateurs en utilisant les exigences de performance minimales du NIOSH et partagent leurs résultats avec les fabricants de produits pour optimiser les désignations de durée de conservation.
  - Une approche nationale de maintenance des stocks pour acheter, stocker et déployer des respirateurs (par exemple, rotation des stocks) afin de garantir la disponibilité des respirateurs et l'utilisation des produits dans ces durées de conservation optimisées.
  - Le NIOSH a développé un cadre en 4 étapes pour guider les gestionnaires de stocks dans l'évaluation des performances des respirateurs à masque filtrant :
    1. Définir la population des respirateurs à échantillonner ;
    2. Utiliser des stratégies d'échantillonnage aléatoire pour obtenir un échantillon représentatif ;
    3. Inspecter et tester les unités échantillonnées en utilisant des procédures de test standard conformément aux normes et

règlementations gouvernementales ou en matière de santé et de sécurité au travail ;

4. Calculez les résultats et extrapolez-les à l'ensemble de la population pour déterminer la probabilité d'observer un taux de défaillance similaire dans l'ensemble de la population des respirateurs.

CONCLUSIONS

- Les meilleures données disponibles sur la performance des respirateurs N95 périmés proviennent d'une évaluation du NIOSH portant sur 3 971 respirateurs N95 stockés fabriqués entre 2003 et 2013, qui a révélé que 98 % des respirateurs évalués conservaient leur résistance à l'inhalation et à l'expiration et leur performance de filtration après leur date de péremption.
- Néanmoins, le NIOSH prévient que ces résultats peuvent ne pas s'appliquer à d'autres modèles de respirateurs non inclus dans cette étude ou à des installations de stockage avec diverses conditions de stockage. Les respirateurs Champak F550 N95 n'ont pas été inclus dans cette étude.
- La plupart des organismes de règlementation, dont Santé Canada, les CDC et l'OMS, conviennent que les respirateurs au-delà de leur durée de conservation indiquée sur l'étiquette, bien qu'ils ne soient plus considérés comme approuvés, peuvent conserver une performance de filtration adéquate s'ils sont stockés correctement. Cependant, comme la perte d'élasticité des bandes ou des sangles peut avoir un impact sur une bonne étanchéité, ils recommandent que les respirateurs soient inspectés de près pour détecter tout signe de dommage et testés avant utilisation.
- Pour guider le personnel chargé des stocks, le NIOSH recommande la création d'un processus d'assurance qualité pour les respirateurs stockés afin de déterminer les durées de conservation optimales.
- Le NIOSH a également développé un cadre en 4 étapes pour guider les gestionnaires de stocks dans l'évaluation des performances des respirateurs stockés, de sorte qu'un échantillon représentatif de respirateurs puisse subir un contrôle qualité pour déterminer la probabilité d'observer un taux de défaillance similaire dans l'ensemble de la population de respirateurs.

PRINCIPALES CONCLUSIONS ET RECOMMANDATIONS

- Il existe des preuves raisonnables indiquant que les respirateurs N95 ayant dépassé leur durée de conservation prévue **conservent une performance de filtration adéquate** s'ils sont stockés correctement. Le NIOSH a signalé que 98 % des près de 4 000 respirateurs N95 évalués ayant dépassé leur date de péremption ont conservé leurs propriétés protectrices. Cependant, ces résultats peuvent ne pas être généralisables aux respirateurs non inclus dans leur analyse, y compris les respirateurs Champak F550 N95.

- Recommandations pour le CUSM :

    - Les gestionnaires de stocks doivent effectuer **des tests d'assurance qualité** sur des échantillons représentatifs de respirateurs Champak F550 N95 provenant de différents lots et conditions de stockage, comme décrit par le NIOSH, afin que la viabilité de l'ensemble du stock puisse être déterminée. Les tests d'échantillons représentatifs permettent d'extrapoler les résultats à la population de respirateurs à partir de laquelle l'échantillon a été dérivé, ce qui permet une solution rentable ;

    - Les facteurs suivants doivent être évalués :
        - Signes visuels de dommages aux respirateurs et essai d'ajustement avant utilisation
        - Efficacité de filtration
        - Conditions d'entreposage

- Recommandations à l'échelle nationale/provinciale (recommandation du NIOSH) :

    - La création d'un **processus d'assurance qualité des stocks économiquement durable**, afin de garantir que les stocks de respirateurs de la province sont évalués à l'aide des exigences minimales de performance du NIOSH. Les résultats doivent être partagés avec les fabricants de masques afin d'optimiser les désignations de durée de conservation.

    - Une approche de maintenance des stocks à l'échelle nationale pour acheter, entreposer et déployer des respirateurs (p. ex., en faisant tourner les stocks) afin de garantir une disponibilité adéquate des respirateurs et une utilisation adéquate des produits dans le cadre de ces durées de conservation optimisées.

LIST OF ABBREVIATIONS

CADTH	Canadian Agency for Drugs and Technologies in Health
CDC	Centres for Disease Control and Prevention, US
FDA	Food and Drug, US
FFR	Filtering facepiece respirator
INESSS	Institut national d'excellence en santé et services sociaux, QC
PPE	Personal protective equipment
NICE	National Institute for Health and Care Excellence, UK
NIOSH	National Institute for Occupational Safety and Health, US
WHO	World Health Organization

USE OF N95 RESPIRATORS PAST THEIR SHELF LIFE

1. BACKGROUND

The COVID-19 pandemic necessitated the stockpiling of personal protective equipment (PPE) as a way to ensure the availability of necessary quantities during the public health emergency. Although The National Institute for Occupational Safety and Health (NIOSH) does not require manufacturers of filtering facepiece respirators (FFR) to assign an expiry date for certification purposes, most FFR manufacturers designate a 5-year shelf life. During and following the pandemic, healthcare establishments developed stockpiled reserves of PPE, including N95 respirators, that have since exceeded their manufacture-designated shelf life.

The main objective of N95 masks is to protect healthcare personnel from infection with airborne pathogens by preventing aerosol transmission, which raises important questions about the continued effectiveness of expired masks. Given the considerable procurement and storage costs of PPE and the potential need for such equipment in future public health crises, the destruction of large quantities of potentially effective respirators may not be fiscally responsible.

It is therefore important to evaluate whether N95 respirators past their shelf life continue to be safe and effective in protecting healthcare personnel.

1.1 Reason for Brief Report

The MUHC currently has a stockpile of 286,100 N95 Champak F550 respirators that have recently expired or are due to expire in 2024. **T**hese masks were purchased by the MUHC at a cost of $228,654.

This stockpile resulted due to a confluence of factors:

- A transition from Champak F550 respirators to Medicom masks in 2022
- Offloading of Champak F550 respirators from the MSSS to deplete their inventory

The Champak F550 masks are NIOSH approved, were deemed safe by an evaluation of the Occupation Health and Safety department of the MUHC, and underwent extensive fit testing. Given the considerable acquisition, storage and disposal costs, as well as potential safety risks to healthcare personnel, there is a need to evaluate the risks and benefits of using N95 respirators past their expiration date.

Therefore, this evaluation was requested by Kim Tanguay, Nursing Practice Consultant, Directorate of Nursing at the McGill University Health Centre (MUHC) on November 10, 2023.

2. POLICY AND EVALUATION QUESTIONS

2.1 Policy Question

Can the MUHC continue to use N95 respirators past their expiration date?

2.2 Evaluation Questions (Objective of this report)

- What is the evidence on the safety and effectiveness of expired N95 respirators in terms of aerosol filtration efficiencies?
- Is there guidance for the safe use of N95 respirators past their expiry date?

3. METHODS

3.1 Literature search

We conducted a literature search of PubMed, health technology assessment (HTA) databases (CADTH, INESSS, NICE) and regulatory bodies (WHO, CDC, Health Canada) for studies on effectiveness of and guidance for expired N95 respirators. The most recent search was conducted on November 17, 2023. The following key words were used in PubMed: (N95) AND ((expired) OR (stockpile) OR (shelf life)).

4. EVIDENCE FROM SCIENTIFIC LITERATURE

4.1 Results of the literature search

We identified three studies that evaluated the filtration performance of expired N95 respirators, one framework for evaluating stockpiled N95 respirators, and several guidance documents from regulatory bodies relating to the use of expired respirators in times of low supply.

4.2 Factors that determine N95 respirator performance

4.2.1 Aerosol filtration efficiencies

Filtration performance of N95 respirators is based on NIOSH Standard Test Procedures. The Pass/Fail criteria for Particulate Filter Efficiency for N95 is ≥95%, i.e**. N95 FFRs must have a particle penetration of less than 5.0%.**

- The largest study to date to evaluate the filtration performance of stockpiled N95 respirators was conducted by **NIOSH** between 2017 and 2019 to understand the viability of respirators that have undergone long-term storage.[1] They evaluated 11 types of N95 filtering facepiece respirators manufactured between 2003 and 2013, for a total of 3,971 respirators sampled from 91 manufacturing lots. The models included were from the following manufacturers: 3M, Gerson, Kimberly Clark, Medline/Alpha Protech and Moldex. The expired respirators were compared to a control group of new respirators of the same model and evaluated for inhalation and exhalation resistance and filtration performance, based on NIOSH Standard Test Procedures.

  Findings: NIOSH found that 98% (3,895 out of the 3,971) of the evaluated respirators maintained their inhalation and exhalation resistance and filtration performance, with the upper limit of the 99% confidence intervals well within the NIOSH minimum performance requirements.

- In a small quality improvement study by **Sickbert-Bennett et al.** in 2020 that tested 29 fitted face mask models, the authors report that N95 respirators from the company 3M that were 9 and 11 years past their expiry date had fitted filtration efficiencies of 98.5% and 97%, respectively.[2]

  Findings: The authors conclude that expired N95 respirators with intact elastic bands continue to provide effective protection against submicron particle penetration. However, this conclusion was drawn on the basis of testing only 3 masks of each model (3M 8210 and 3M 1816) on a single male participant.

- An older study by **Viscusi et al.** in 2009 evaluated the filtration performance of 63 masks from 21 different N95 respirator models that had been stored in their original packaging for an average of 7.3 years at temperatures ranging between 15°C and 32°C and relative humidity between 20% and 80%.[3]

  Findings: 19 of 21 models passed the NIOSH Standard Test Procedure and had particle penetration of less than 5.0%; 2 models failed the test by less than 1.0%.

The authors report that there did not appear to be any correlation between the length of storage and failure to pass the initial penetration test, with models stored for approximately 10 years still achieving very good filtration performance.

4.2.2 Respirator strap performance

A study by **Rottach et al.** examined the degradation of polyisoprene (synthetic rubber) elastomer straps taken from a sample of two N95 FFR models (n=54) of various ages (1-10 years).[4] The masks were stored in poor conditions, and factors like high heat can deform strap stability.

Findings: The authors report that the tension of the straps from one model were found to differ according to age, while the second model showed no correlation with time. They also note that minor variations in strap tensile properties may not result in significant differences in respirator seal quality. Based on this small study in 2 respirator models, they conclude that prolonged storage may affect the tensile properties of headstraps for some models of N95.

4.2.3 Storage conditions

There is consensus from regulatory bodies that the following storage conditions could affect the protective ability of N95 respirators:[5]

- Length of storage time beyond its shelf life;
- Storage conditions such as temperature, humidity and exposure to dust, moisture, sunlight and direct light, proximity to fans, windows, doors, and ventilation systems, and presence of mould;[1]
- Damage to pallets, cases, boxes and individual masks, which could result in damage of nose bridge, nose foam, filter media or straps;[1]
- Tensile properties of straps after prolonged storage.

4.3 Summary of NIOSH findings

- NIOSH acknowledges that shelf life issues will be an ongoing consideration for managing stockpiled respirators.[1]
- Results of their large study provide important information on the levels of protection that may be provided by respirators stored for long periods in U.S.

stockpiles. Nonetheless, the results may not be applicable to other respirator models or stockpile facilities.[1]

- They report that the majority of respirators evaluated would be protective across a variety of storage conditions, but important variability was observed.
- NIOSH does not have enough information to definitively know the level of protection that may be provided by all respirators that 1) are stored for prolonged periods of times; 2) are stored under various storage conditions; or 3) have exceeded the approval holder's designated shelf life.[1]

5. SOLUTIONS FOR STOCKPILED RESPIRATORS

5.1 NIOSH recommendations for stockpiled respirators

- Given the current reality that most US facilities have stockpiles of respirators and other PPE stored past their designated shelf life, there is need for uniform guidance related to inventory management for expired respirators.[1]
- **One solution is the development of an economically sustainable stockpile quality assurance process, such that stockpiles from across the nation test their respirator inventories using NIOSH's minimum performance requirements, and share their results with product manufacturers to optimize shelf life designations.**[1]
- In addition to optimizing shelf life designations, NIOSH recommends a national stockpile maintenance approach to purchase, store, and deploy respirators, for example by rotating inventory, to ensure adequate respirator availability and usage within these optimized shelf lives.[1]

5.2 A framework for evaluating and testing stockpiled FFRs

Yoon et al. developed a 4-step process aimed at stockpile managers and policy-makers for evaluating the performance viability of N95 FFRs:[6]

1. Define the population of FFRs to be sampled: "If quality information is desired for a single FFR model with a few lots, designing a study that allows for quality inferences to be made to the entire FFR model (i.e., the study population) could be easily accomplished by randomly sampling FFRs from each lot."

2. Sampling strategies: Once the population is defined, a random sampling process should be used to ensure that each unit within a lot has an equal probability of being selected for testing. When lot information is available and large quantities of FFRs are stored, testing and evaluation may use the Lot Quality Assurance Sampling (LQAS) technique. This is a stratified random sampling design developed to facilitate decisions to accept or reject the entire lot, by allowing generalization of the results from sample data to the wider population from which the sample was drawn (Appendix Figure 1)

3. Inspecting and testing the sample: Samples should be tested for:

    - Visual inspection: For visible damage, deformation or presence of dust or mould (see example visual checklist in Appendix Figure 2)

    - Standard Testing Procedures (STP): STPs should be evaluated in accordance with government or Occupational Health and Safety norms and regulations. NIOSH STP-0059 to determine Particulate Filter Efficiency Level should be considered the primary performance test to evaluate the viability of the FFRs being tested. For N95 FFRs, particulate penetration is required to be at or below 5.0%.

4. Evaluating the test results: The number of units per sample that fail the above criteria can be tabulated and then extrapolated to the entire population to determine the probability of observing a similar failure rate in the whole population of FFRs.

6. GUIDANCE FOR EXPIRED N95 RESPIRATORS

Most regulatory bodies including Health Canada and the WHO agree that respirators beyond their labelled shelf life, while no longer considered approved, may retain adequate filter performance if stored properly.[5] However, because loss of elasticity in the bands or straps can impact a proper seal, they recommend that respirators be closely inspected for signs of damage and fit-tested before use.

6.1 Health Canada guidance[7]

- An expired mask can still be effective at protecting the health care provider if:
    - The straps are intact
    - There are no visible signs of damage

- They can be fit-tested

- Health care providers should inspect the mask and perform a seal check

- There is no specific timeframe beyond the expiry dates for N95 respirators at which they would no longer be considered suitable for use.

6.2 WHO guidance

The WHO issued guidance on the use of PPE beyond the manufacturer-designated shelf life or expiration date in times of PPE shortages.[8] Although respirators past their designated shelf life are no longer considered approved in accordance with their associated regional/international standards, the WHO recommends that:

- Such items may still be effective and should be inspected before use to verify equipment is in good condition with no degradation that could affect performance. Specifically, a respirator may still be effective if

  - It has been appropriately stored to avoid the effects of moisture or contamination,

  - The straps have remained intact,

  - There are no visible signs of damage and

  - A self-fit test/seal check can be performed successfully by the wearer before use.

7. CONCLUSIONS

- The best available evidence on the performance of expired or stockpiled N95 respirators is derived from a NIOSH evaluation of 3,971 stockpiled N95 respirators manufactured between 2003 and 2013, which found that 98% of the evaluated respirators maintained their inhalation and exhalation resistance and filtration performance after their expiry date.

- Nonetheless, NIOSH cautions these results may not be applicable to other respirator models not included in this study or stockpile facilities with various storage conditions. The Champak F550 N95 respirators were not included in this study.

- Most regulatory bodies including Health Canada, the FDA and the WHO agree that respirators beyond their labelled shelf life, while no longer considered approved,

may retain adequate filter performance if stored properly. However, because loss of elasticity in the bands or straps can impact a proper seal, they recommend that respirators be closely inspected for signs of damage and fit-tested before use.

- To guide stockpile personnel, NIOSH recommends the creation of a quality assurance process for stockpiled respirators to determine optimal shelf life designations.

- NIOSH has also developed a 4-step framework to guide stockpile managers in evaluating the performance of stockpiled respirators, such that a representative sample of respirators can undergo quality control to determine the probability of observing a similar failure rate in the whole population of FFRs.

8. KEY FINDINDS AND RECOMMENDATIONS

- There is reasonable evidence to indicate that N95 respirators past their designated shelf life retain adequate filter performance if stored properly. NIOSH reported that 98% of almost 4000 evaluated N95 respirators past their expiry date maintained their protective properties. However, these results may not be generalizable to respirators not included in their analysis, including Champak F550 N95 respirators.

Recommendations for the MUHC:

- Stockpile managers should perform quality assurance testing on representative samples of Champak F550 N95 respirators from different lots and storage conditions, as described by NIOSH, so the viability of the complete stockpile can be ascertained. Representative sample testing allows extrapolation of findings to the population of respirators from which the sample was derived, allowing for a cost-effective solution;

- The following factors should be evaluated:
    - Visual signs of damage to respirators and fit-testing before use
    - Filtration efficiency
    - Storage conditions

Recommendations at the national/province level (NIOSH recommendation):

- The creation of **an economically sustainable stockpile quality assurance process,** to ensure that stockpiles of respirator inventories across the province are

evaluated using NIOSH's minimum performance requirements. Results should be shared with product manufacturers to optimize shelf life designations.

- A stockpile maintenance approach at the national level to purchase, store, and deploy respirators (e.g., by rotating inventory) to ensure adequate respirator availability and product usage within these optimized shelf lives.

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APPENDIX

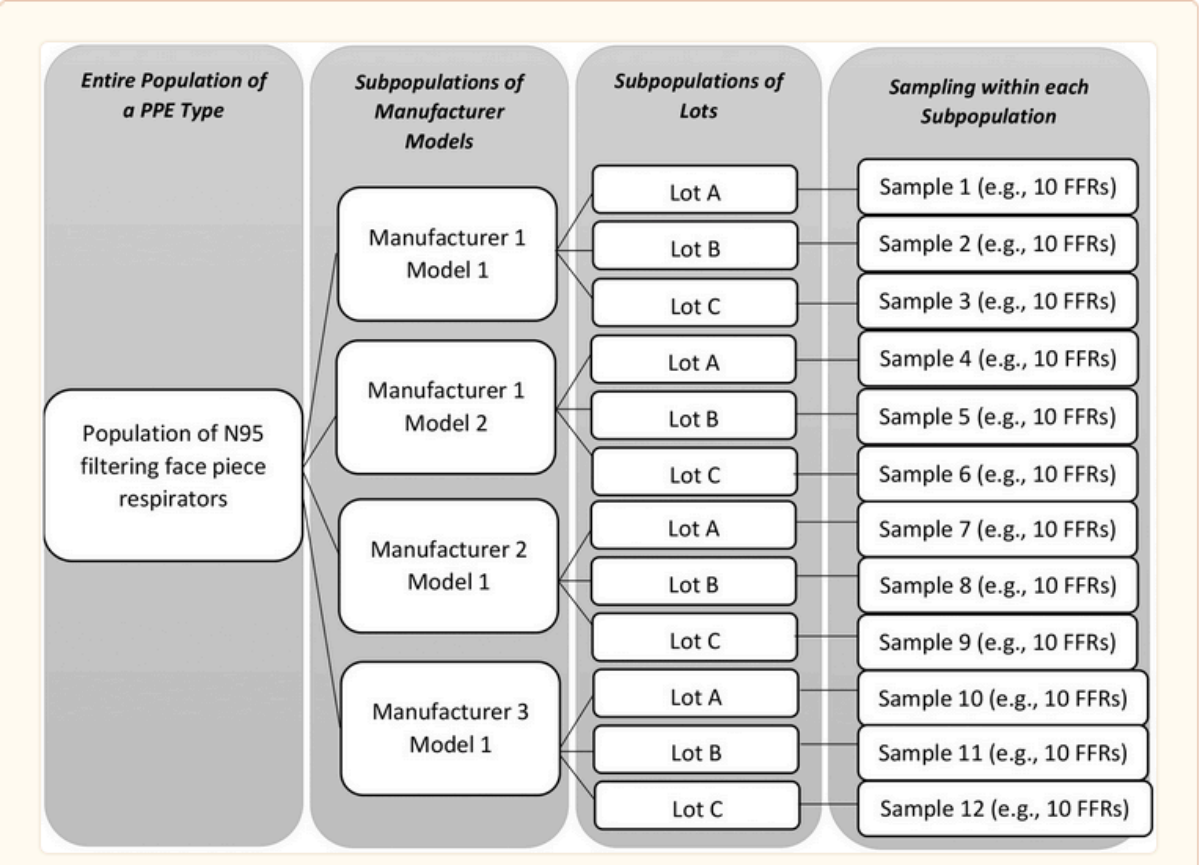

Figure 1: Hypothetical stratified random sampling design for N95 FFRs

Source: Yoon, K. N., Greenawald, L. A., Rottach, D. R., Pollard, J. P., & Yorio, P. L. (2020). A General Framework to Test and Evaluate Filtering Facepiece Respirators Considered for Crisis Capacity Use as a Strategy to Optimize Supply. *Journal of the International Society for Respiratory Protection*, *36*(1), 36–51.

Visual Inspection Items	Evaluation
1. Does the **packaging** have any signs of **damage?**	□ YES □ NO □ NA
2. Does the respirator have an **odor?**	□ YES □ NO □ NA
3. Does the respirator have a presence of **dust?**	□ YES □ NO □ NA
4. Is the respirator **deformed in any way?**	□ YES □ NO □ NA
5. **Is** the **nose clip cracked, corroded, or detached?**	□ YES □ NO □ NA
6. **Is** the **nose foam flaking, or does it appear damaged?**	□ YES □ NO □ NA
7. Does the **respirator appear moldy?**	□ YES □ NO □ NA
8. If applicable, are the **staples** attaching the straps **cracked, corroded, or rusty?**	□ YES □ NO □ NA
9. Are the straps **detached** from the respirator?	□ YES □ NO □ NA
10. Are the straps **damaged** in any way?	□ YES □ NO □ NA

Figure 2. Example Respirator Visual Inspection Checklist

Source: Yoon, K. N., Greenawald, L. A., Rottach, D. R., Pollard, J. P., & Yorio, P. L. (2020). A General Framework to Test and Evaluate Filtering Facepiece Respirators Considered for Crisis Capacity Use as a Strategy to Optimize Supply. *Journal of the International Society for Respiratory Protection*, *36*(1), 36–51.