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Non-fit Tested Respirators for Wildfire Smoke Protection in the Community Setting

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Highlights

- The main component of wildfire smoke is particulate matter ($PM_{2.5}$), which has been associated with adverse health effects. Measures to minimize these health risks include a variety of interventions to reduce exposures to wildfire smoke particulate matter outdoors, and managing indoor air quality.
- In addition, there is some evidence, varying in type, quality, and generalizability, that even without formal fit testing and training (as done in occupational settings), respirators will offer some protection from $PM_{2.5}$ to the wearer. Factors such as facial dimensions, activity, and model of respirator used, were identified as relevant factors affecting level of efficacy for members of the general public. Respirators are not designed to protect the wearer from exposure to gases.
- Education on fit and proper use (i.e., seal) of respirators may improve filtration efficacy and reduce exposure to wildfire smoke, when used by the general public.

Introduction

The severity of the wildfire season in 2023 Ontario and Canada in terms of area burned and resources required, prompted review of all the tools available to protect the public. Generally, a multi-pronged approach is required to reduce exposures to wildfire smoke by reducing time outdoors and managing indoor air quality. In addition, use of personal protective equipment (PPE) can be considered by individuals. In occupational settings, respirators (e.g., N95, CA-N95) are a commonly used type of PPE to protect wearers from certain inhalable exposures. The efficacy of protection is dependent upon a tight-fitting seal against the face, which is assessed using specialized testing, called fit testing, and health and safety training regarding care, use, and disposal of the respirators.

The purpose of this review is to scan the relevant scientific, peer-reviewed literature for evidence on particulate filter efficacy of respirators where fit testing and other occupational health and safety training are not available. This review is intended to inform public health recommendations on respirator use to reduce exposures to wildfire smoke as part of a broader public health strategy.

Background

A respirator is a device meant to be worn over the nose and mouth, that filters particulates in inhaled ambient air to protect an individual from pollutants.[1] While 'masks' and 'respirators' are terms that are often used interchangeably, there are important distinctions between the two. Respirators are designed and manufactured using specifications and standards for protection efficacy, selection, testing, and use, as provided by standard-setting agencies.[1] Masks are not intended or tested for their respiratory protection efficacy (only the mask materials are made to standards).[1,2]

In Canada, most approved respirators will conform either to standards developed by the United States National Institute for Occupational Safety and Health (NIOSH) or by the Canadian Standards Association (CSA).[2] Where respirators are intended for medical purposes, they are classified as medical devices and are regulated by Health Canada as Class I medical devices. Manufacturers, importers and distributors of medical respirators must hold a Medical Device Establishment Licence (MDEL) before they can import or sell in Canada. Health Canada takes regulatory action should any medical respirators be found to be non-compliant with Health Canada requirements.[2,3] Otherwise, respirator selection and use in workplaces is covered under occupational health and safety legislation.[4]

The most common type of respirator is a disposable filtering facepiece respirator (FFR) which is worn over the nose and mouth. FFRs are named according to the approval standard they are designed to meet. The most commonly known type is the N95 under NIOSH. CA-N95 respirators conform to specifications produced by the CSA. Other jurisdictions have their own design and performance standards, including Europe (FFP2), Korea (KF94) and China (KN95). Unless otherwise indicated in this document, the term "respirator" is used to indicate a FFR, however the term respirator technically includes other types of respiratory protection, e.g., supplied-air respirator.

Respirators are designed to protect the wearer from exposure to particulates that can be inhaled, and their number in the name (e.g. 95) generally signifies the maximum percentage of particles filtered (filtration efficiency) at the particle size that represents the "worst case challenge"; for N95s it is 0.3 micron aerosol particles.[1] The letter (e.g. N in N95) denotes the protection against oil-based aerosols, where "N" indicates non-oil proof, "R" indicates oil resistant, and "P" indicates oil proof.[1-3] Respirators (specifically FFRs) are not designed to protect the wearer from exposure to gases.

Fit testing is a formal procedure to ensure the specific respirator model is properly fitted for the tested individual.[5] It requires a trained technician to use either quantitative (using a machine to measure if test particles have leaked into the respirator) or qualitative (using a bitter tasting substance to alert the user to leakage) methods.[5] In the research setting, leakage into a respirator due to gaps along the edge is quantitatively measured as "Total Inward Leakage" (TIL), which is the fraction of a given substance inside versus outside the respirator (usually measured using sodium chloride (NaCl) and/or corn oil aerosols).[6] Filtration efficiencies assume perfect seal and thus in addition to a fit tested respirator model, depend on wearers to achieve a proper seal each time a respirator is donned, to ensure all respired air is forced through the filter. A seal check can be performed to confirm this by placing the hands over the respirator edges while exhaling or inhaling sharply, feeling for leakage around the edges.

Fit testing and proper training on donning, use, care, and disposal are part of a comprehensive respiratory protection program to help ensure that the respirator will function as designed, and are considered best practice in occupational health and safety.[1-3] Without proper fit testing and training, respirators may be worn incorrectly (increasing the risk of leakage around the edges) and will not filter as efficiently; this has been observed in both occupational and non-occupational settings.[1]

Wildfire smoke is a complex mixture of substances, and the composition will depend on variables such as fuel source, distance from fire, environmental conditions, and type of vegetation burned.[7] The most common substances found in wildfire smoke include particulates (e.g., $PM_{2.5}$ or fine particulate matter, mainly composed of organic and black carbon), gases (e.g. carbon monoxide or CO, nitrogen oxides or NOx, ozone, and sulfur dioxide or SO_2), water vapour, and certain chemicals (e.g. polycyclic aromatic hydrocarbons or PAHs, mercury, volatile organic compounds or VOCs).[7] $PM_{2.5}$ makes up approximately 90% of the total wildfire smoke mass in most cases, and is the most extensively reported component of wildfire smoke in population health studies.[7,8] Respiratory as well as cardiovascular health effects have been associated with wildfire smoke.[7,8] Since properly fitted respirators are designed to protect the wearer from particulate exposures, they could reduce exposures to a major component of wildfire smoke ($PM_{2.5}$).

Organizations such as Health Canada[9] and the United States Centers for Disease Control and Prevention (CDC)[10] have provided advice to the general public around the use of respirators for protection against wildfire smoke. However, as a public health intervention for wildfire smoke, their overall effectiveness, or the actual protection received from the use of respirators, is unclear. Loss of filtration from potential poor or loose fit (due to a lack of training or fit testing), the inability of respirators to filter gases, a false sense of security and the increased work of breathing are some concerns.[11] Thus, this rapid scoping review summarizes the available evidence on the efficacy of respirators in non-occupational settings.

Methods

A rapid literature search was performed by PHO Library Services on December 18, 2023, which used MEDLINE (all, 1946-date of search), Embase (all, 1974-date of search), and Environment Complete (all) with additional titles sourced from bibliographic review of selected relevant articles. This was supplemented with a review of the relevant grey literature. Search terms included (not limited to): fires, wildfires, smoke, particulate, air pollution, PM 2.5, PM 5, PM 10, respiratory protective devices, masks, N95, FFR, and respirator. Library search results (N=485) were assessed independently by two reviewers, and relevant titles and abstracts selected for full article review. A full search methodology is available upon request.

Results

A variety of study methodologies were identified in the literature search. These included general reviews, modelling studies, laboratory studies on manikin headforms, and experimental studies using volunteers. Each is summarized below:

Reviews on Respirators as a Public Health Intervention

The British Columbia Centre for Disease Control (BCCDC) did an evidence review in 2014 on the use of respirators for wildfires which noted that fit-tested respirators (e.g. N95s) are the most logical choice for respiratory protection against wildfires (particularly compared to surgical masks) because they filter particulate matter which is a key component of wildfire smoke, as well as their availability.[12] However, they also noted that fit testing is essential, citing one study that observed in a laboratory setting that up to 100% of sub-micron particles were measured inside a mask, via seal leakage.[12,13] They also noted that certain individuals (e.g., individuals with beards, abnormal facial dimensions) or groups (e.g., children, elderly) may have more difficulty acheiving a proper seal, and additionally, the increased resistance caused by flitration is associated with breathing discomfort in some individuals. They state that overall there is little evidence for respirator use as an individual-level mitigation approach in the context of wildfire smoke exposure.[12]

A general review of public health interventions for protection against wildfire smoke was published by the United States (US) Environmental Protection Agency (EPA) in 2021.[14] In the chapter on mask use, they note that given that respirators are available in multiple sizes, even without a fit test, they would be expected to provide at least some protection to users, although references are not provided.[14] They describe some basic principles on respirator selection, donning and seal checking.[14] They also note that surgical masks, dust masks, and other face coverings (e.g., cloth masks, bandanas) should not be relied upon for protection, consistent with BCCDC.[14]

A narrative review focusing on wildfire smoke health effects and public health tools also looked at the use of masks and respirators to mitigate exposure.[15] They identified a number of studies that support that both surgical masks and respirators would reduce potential wildfire smoke exposure to a varying degree.[15] With respect to evidence of protection for respirators for the public, they identified a study on 18 respirator models from NIOSH that suggested that respirators may confer some protection (74% of users) even without fit testing but donned as per manufacturer's instructions with a seal check.[16] On the basis of their review, the authors support that respirators could be used for the general public (specifically children) as one of a suite of mitigating measures against wildfire smoke exposure.[15]

Modelling Studies

Generally, these types of studies use data derived from other sources as parameters in mathematical models to make predictions or test hypotheses. Two modelling studies were identified which attempted to estimate respirator protection from air pollution (a range of particulate diameters) when accounting for leakage.

The first modelled "real world" factors including mask leakage and inconsistent (non-continuous) use to estimate mask effectiveness through a mathematical model applied to estimate population-level health benefits from mask wearing using historical data from a wildfire season in Washington State in 2012. They observed significant filtration efficiency for N95 respirators (97% at 0.05 µm) compared to cotton fiber (21% at 0.6 µm), synthetic fiber (45% at 0.6 µm), and surgical masks (91% at 0.04 µm).[16] N95s similarly were estimated to be superior to the other 3 types when comparing filtration of different aerosol sources (urban, wildfire, dust) as well as better filtration efficiency even under typical use (non-continuous through the day) and with leakage. The authors' model estimated that widespread public use of N95 respirators could have potentially reduced exposure-related respiratory hospitalization by 22-39% in 2012 in Washington State, with uncertainty driven by percentage of the population using respirators, and for how much of the day.[17] The second study looked at estimated protection provided by various mask types and leakage scenarios with exposure to wildfire smoke, allergenic bioaerosols, and infectious particles.[18] The modelling predicted >70% filtration efficiency under all predicted fit conditions for particulates, and this finding was consistent with experimental data from the same study.[18]

Overall these studies model respirator filtration of particulates where leakage is assumed, and infer that even with leakage, respirators may provide some protection to the wearer.

Laboratory Studies – Headform (Manikin) Models

Manikin studies involve a physical model of a human head or body to simulate aspects of human physiology such as breathing and respirator fit and function. Two relevant laboratory-based manikin model studies were identified. The first study measured respirator leakage under varying conditions including different combustion fuels (wood, paper and plastic), air flow speeds to simulate breathing, and leakage conditions (e.g., "sealed", "partially sealed" or 30% of circumference open). The study observed 3 to 16% of particles penetrated the respirator (for all combustion fuels compared to <0.05% for sealed respirators and 0.05-0.7% in partially sealed respirators.[19] The second study was conducted in a similar fashion (by the same research group) and measured up to 17.9% particle penetration compared to 0.38% for nose-only sealed, 0.28% for nose and chin sealed, and 0.003% for fully sealed conditions.[20]

Overall these studies all observed some filtration of particulate (approximately 82-84%) in simulated settings, even when attempting to account for leakage suggesting use of non-fit tested respirators could be beneficial in reducing an individual's exposure to particulates compared to no respirator use. However, both studies observed differences in filtration based on the completeness of the seal.

Experimental Studies – Healthy Volunteers

a) Studies using fit tests to assess respirator leakage

Four small (N=10-56) volunteer studies were identified that measured leakage under certain conditions. The first observed between 0.26%-68% leakage, which varied by mask/respirator type and various activities while wearing the devices.[21] One specific model showed leakage of <10% under all conditions.[21] The second study of 10 respirator models in China observed that only two adequately fit the tested group, with fit test pass rates of 20% and 44.7%. The authors attributed this to the respirators not being designed for Chinese facial dimensions.[22] Another study in Latino farm workers also observed poor fit in most (59%) workers, and this observation was also attributed to facial differences between the study population and standard anthropomorphic models used by manufacturers.[23] The last study measured an average leakage of 9% of measured $PM_{2.5}$ using a non-fit tested respirator whilst performing simulated environmental clean-up activities.[24] This was better than surgical mask models, but participants reported discomfort with wearing the respirator.[24]

Overall these studies suggest that in the context of no fit testing, wearer activity (e.g., more activity may increase leakage), mask model, and wearer face shape may affect leakage, and hence, protection from particulates.

b) Fit test after education or instruction

A study measured fit test results in 21 healthy volunteers before, in-between, and after receiving respirator use instructions delivered in different modes (paper, video, and in-person).[25] They observed improvement in filtration efficiency from an average of 86.1% (baseline, no instruction) to 97.5% after video instruction, and 98.3% with staff intervention.[25] Interestingly, they observed no significant difference in baseline fitted filtration efficiency between individuals who had previous experience wearing respirators and those who did not.[25]

A few articles evaluated the efficiency of N95 filtration when only a seal check (i.e., without formal fit testing) was performed by the user.[26] One study (using three different 3M and Kimberly-Clark models of N95s on a group of nursing students) found that gross leakage was present in 31.0%-39.2% with the former, and 65.4%-65.8% with the latter brand respirators.[27] Subsequent fit testing found sensitivity and specificity of the user seal check for identifying actual gross leakage were approximately 27.7% and 75.5% for 3M-1860s, 22.1% and 80.5% for 3M-1862, and 26.9% and 80.2% for Kimberly-Clark model.[27] The authors conclude that seal checks should not supplant fit testing to identify leakage, but that such checks may enhance donning and fit where fit testing has been done.[27]

These studies suggest that education on fit and use, and/or the use of seal checks, may decrease leakage (and hence increase protection) to the wearer.

c) Health/physiologic outcome studies

Six studies were identified that measured physiologic outcomes in individuals exposed to particulates under conditions of respirator use. Some did not indicate whether fit testing was performed, and some indicated no fit testing. The first observed no significant difference in reported clinical respiratory tract infections between health care workers who used no masks, surgical masks, or fit-tested respirators.[28] The second measured changes in biomarker levels in 15 healthy volunteers exposed to elevated traffic-generated $PM_{2.5}$ at levels well above World Health Organization's 24 hour limits, and observed a statistically significant rise in inflammatory biomarkers only in the group who had non-functioning filtration valves.[29,30] The volunteers received instructions on how to don the respirators (but formal fit testing was not noted to have occurred).[29] Another study observed increased levels of blood manganese concentrations in welders who failed respirator fit testing.[31] Two studies compared physiologic cardiovascular parameters (e.g. blood pressure, heart rate) with and without respirator use during exposure to traffic-associated $PM_{2.5}$ and found some evidence for improvement in measured parameters associated with respirator use.[32,33] Another study measured exhaled CO levels (as a surrogate marker of traffic-related air pollution exposure) in individuals wearing respirators, and compared to surgical and charcoal-filter masks, and observed a reduction in exhaled CO levels, most prominently with N95 use, but also with surgical and charcoal containing masks (but not cloth masks).[34]

These studies suggest that even without fit testing, the use of respirators may reduce certain physiologic markers (e.g., inflammatory marker levels, reported respiratory infection) associated with exposures to particulates.

Limitations

The articles identified for this review were heterogeneous in terms of study methods in addition to being limited in overall number as they related to non-fit tested contexts. This makes it difficult to confidently draw conclusions around the effectiveness of non-fit-tested respirators in reducing the risk for adverse health outcomes for the public during wildfire exposure events.

Conclusion

A variety of studies were identified relevant to the question of respirator efficacy in non-fit-tested groups that used modelling, laboratory tests (e.g., simulated tests using manikin heads), and healthy volunteers (e.g., measuring particle concentrations inside the mask, measuring biomarkers of exposure/effect). Though limited in number, the studies generally suggest that the use of non-fit tested respirators could confer some reduction of exposure to inhalable particles. There was also some evidence that the use of non-fit tested respirators may reduce inflammatory markers in those exposed to $PM_{2.5}$, but whether this would translate into a reduction of adverse health outcomes is unclear.

Studies varied in the estimated magnitude of reduced risk, and examined several factors that affect leakage, indicating that actual respiratory protection to individuals will vary, i.e., based on facial dimensions, activity, model of respirator used, etc. As well, breathing discomfort with increased filtration was noted in some studies. However, there was also evidence to suggest that interventions to optimize fit (e.g., respirators designed for a wider variety of face shapes, instructional videos or other public-oriented educational materials) may improve filtration, and/or promote user knowledge and proper donning at each point of use.

Additional Resources

Additional Public Health Ontario wildfire resources are available on our website.

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