

## AT A GLANCE

# Community use of Medical Masks for SARS-CoV-2

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#### Introduction

The type of face masks used by the general public in the Coronavirus Disease 2019 (COVID-19) pandemic varies across jurisdictions globally. While medical masks have been recommended for health care settings largely related to concerns about supply, there is an interest in the use of medical masks in community settings to reduce transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in the context of ongoing COVID-19 resurgence. This brief review provides background information about medical mask standards in Canada and summarizes recommendations for community use of medical masks from select jurisdictions either affected or close to areas affected by SARS-CoV-2 variants. Finally, a few notable studies comparing medical masks to non-medical masks are briefly described.

### Medical Mask Terminology, Approval and Standards in Canada

In Canada, medical masks may be referred to as procedure masks, isolation masks, fluid-resistant masks or surgical masks. Procedure masks and isolation masks may not be rated for fluid or water resistance; however, fluid-resistant and surgical masks meet standards for heavy exposure to droplets or bodily fluids. Health Canada considers medical masks to be class I medical devices and that they are tested against standards. Health Canada approval for the import and sale of medical masks encompasses if: the manufacturer or importer holds a Medical Device Establishment Licence (MDEL); the device is included in the list of authorized medical devices other than testing devices; the device is included in the list of medical devices for expanded use in relation to COVID-19; or, the device is included in the list of medical devices for exceptional importation and sale.

Similar to the United States Food and Drugs Administration, Health Canada does not perform testing on products and relies on device data submitted for approval. For a face mask to be labelled for medical use and to have a fluid resistance rating, it should meet specifications of American Society for Testing and Materials (ASTM) F2100 (level 1 to 3) or European Norm (EN) 14683 (Type IIR).<sup>4</sup> Masks marketed as non-medical may not be used as personal protective equipment (PPE) for respiratory infections. Non-medical masks is a term that may be used to describe masks that have a similar appearance and construction as medical masks but do not meet the appropriate standards, or may refer to masks made from cloth or other fabrics (often called reusable face masks).

#### Jurisdictional Scan for Medical Mask Use in the General Public

• The Public Health Agency of Canada (PHAC), Ontario, Ireland, the Netherlands, and the World Health Organization (WHO) recommend that medical masks be reserved for health care

providers and others providing direct care to COVID-19 patients.<sup>5-9</sup> PHAC suggests that workplaces consult occupational health and safety resources or their local public health authority for advice on devising mask-wearing policies, including whether to use medical or non-medical masks in relation to the particular working conditions or environment.<sup>10</sup> Ontario's guidance for workplaces is aligned with PHAC.<sup>11</sup>

- The United States Centers for Disease Control and Prevention (CDC) recommends either medical masks or high-quality non-medical masks. Recently, guidance recommends wearing a cloth mask over a medical mask, termed 'double-masking', as a means to improve fit (and filtration), or to perform a 'knot and tuck' method on medical masks to improve their fit.<sup>12</sup> The 'knot and tuck' method may not be an option for individuals with larger faces because this method reduces the surface area that the modified medical mask covers.
- The European Centre for Disease Prevention and Control (ECDC) notes insufficient evidence to recommend medical masks compared to non-medical masks use in the general public.<sup>13</sup>
- Denmark predominantly recommends Type I medical masks (EN 14683 standard) for community use, particularly for high-risk populations and scenarios. High-quality non-medical masks are also accepted. Type II medical masks, which have a higher bacterial filtration efficiency requirement than Type I, are recommended to be reserved for health care.
- Recently, Austria and Germany changed recommendations for medical masks or respirators for community use. 15,16 France now requires higher quality non-medical masks rated for at least 90% minimum filtration (category 1 standards) or medical masks. 17 Changes were based on mitigating the risk from new variants of concern, with the assumption that better filtration ability of medical masks compared to cloth masks demonstrated in simulation experiments would lead to reduced transmission amongst populations. 18
- Other jurisdictions such as Belgium, England, Israel and South Africa do not have recommendations for medical mask use by the general public.<sup>7,19-23</sup>

## Jurisdictional Scan for Medical Mask Use in High-risk Populations and Scenarios

- Populations at higher risk of severe illness (e.g., older age, underlying medical conditions) or source control scenarios where the risk is higher (e.g., when positive for SARS-CoV-2 or when visiting an individual at higher risk of severe illness) are in some jurisdictions highlighted as special cases where the recommended type of respiratory protective equipment may differ.
- Scenarios considered to be high-risk and when it is advised by PHAC to wear a medical mask include: if an individual diagnosed with or having symptoms of COVID-19 is required to leave an isolation location (e.g., to seek medical attention); are in a shared space; or may come into contact with others.<sup>10</sup> PHAC also recommends that individuals providing care to someone who has been diagnosed, or has symptoms of COVID-19, should wear a medical mask. In either scenario, in lieu of a medical mask, a non-medical mask that meets material and fit parameters can be used.<sup>10</sup>

- The ECDC suggests the use of medical masks for individuals at higher risk of severe illness, for individuals diagnosed with or having symptoms of COVID-19 and those sharing their household.<sup>13</sup>
- Populations at higher risk of exposure or more severe disease or outcomes are also advised to wear a medical mask by PHAC.<sup>10</sup> WHO recommendations align with PHAC.<sup>9</sup>
- CDC recommends medical masks with modifications to improve fit (e.g., 'double-masking' or 'knot and tuck', mask fitter or brace) or cloth masks with modifications to improve fit (e.g., mask fitter or brace) in scenarios that involve multiple exposures or prolonged close contact exposures.<sup>12</sup> CDC also suggests KN95 respirators as an option for high-risk populations and scenarios including prolonged close contact in crowded locations such as public transit.<sup>12</sup>

## Key Evidence on Efficacy of Medical Masks in the Community

A recently updated review of non-medical masks (search conducted December 2, 2020) from PHAC included studies comparing medical and non-medical masks. The review found that medical masks were slightly more effective than non-medical masks made of high quality fabrics with multiple layers that fit snugly around the mouth and nose to reduce spread of and exposure to SARS-CoV-2.<sup>18</sup> The majority of studies included were simulation experiments that evaluated blocking/filtration efficiency, breathability and fit. Thus, the extrapolation to real-world conditions is limited.

CDC modified recommendations to include 'double-masking' and 'knot and tuck' as improved community-based respiratory protection methods.<sup>12</sup> 'Double-masking' involves wearing a tight-fitting three-layer cloth mask over a medical mask. 'Knot and tuck' involves modifying the ear loops and mask filter layers to improve facial fitting characteristics of a medical mask.<sup>24</sup> Data to inform the recommendation change comes from an experimental simulation study using masked dummy headforms. No testing was done to improve fitting for non-medical masks (e.g., using mask fitters or braces). Without fitting adjustments, medical masks and cloth masks provided equal reduction of exposure in the study of Brooks et al.<sup>24</sup> Nonetheless, this experimental study highlights advantages of proper mask fit to increase the amount of air that is filtered in reducing exposure to aerosols. A previous study using 'knot and tuck' and other means to improve the fit of a medical mask also reported improved exposure reduction.<sup>25</sup>

One unblinded randomized controlled trial from Denmark did not demonstrate a significant protective effect afforded by surgical mask use compared to no mask use in a community setting. <sup>26</sup> However, this study had some limitations including that it was powered to detect a 50% protective effect. This study could not exclude a smaller effect size and it did not evaluate the benefit of surgical mask use for source control.

Ecological studies are limited due to the variation in types of masks used in communities studied and application of multiple public health measures at the same time as community masking policies. However, multiple ecological studies have demonstrated that community masking, regardless of consideration of type of mask, is associated with reduced COVID-19 transmission.<sup>27</sup>

#### Other Considerations

Implementation considerations are expected to also be important related to the use of medical masks in the community. Disposable non-medical masks are difficult to distinguish from medical masks, given their similar appearance and construction and the existence of counterfeit products available in online

marketplaces.<sup>28</sup> A nationally or provincially coordinated distribution plan would be important to ensure supplies for healthcare use are not impacted, as well as availability and appropriate selection of approved medical masks by the community. The cost of disposable masks may be prohibitive to some people or populations. Subsidized or free access to medical masks would be required to reduce health inequities.

A recommendation to use disposable medical masks as a minimum standard would also have environmental impacts due to the increase in waste. 10

#### Conclusions

Ecological data have demonstrated an association between non-medical mask-wearing in the community and a reduction in COVID-19 cases. The evidence base for the benefits of medical masks compared to non-medical masks in the community is evolving, but is still small and derived from simulation experiments. No real-world trials have compared medical and non-medical masks for reducing transmission of SARS-CoV-2. PHAC, CDC and WHO have incorporated recommendations for medical masks for high-risk individuals and scenarios. In addition, some jurisdictions have recommended the use of medical masks more broadly in community settings based on mitigating the risk from more transmissible variants of concern. Recent studies demonstrate the importance of a mask, whether non-medical or medical, covering the nose and mouth completely and remaining in place without the need for adjustment during routine use, while minimizing gaps between the face and mask.

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## At a Glance

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