

A review of medical masks and respirators for use during an influenza pandemic

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To the editor:

On 11 June 2009, the World Health Organisation (WHO) raised the influenza pandemic alert to Level 6 (defined as 'sustained community level outbreaks in at least one other country in another WHO region') because of the emergence of a novel influenza A/H1N1 subtype.¹ Australia's first laboratory confirmed case of pandemic (H1N1) 2009 virus, a NSW woman who had visited Los Angeles, was reported in the second week of May 2009. Within a month, 1336 laboratory confirmed cases had been identified, the majority of them in Victoria, rising to nearly 20 000 Australia-wide by the end of July.

Given the lack of a specific vaccine against the pandemic (H1N1) 2009 virus, mitigation measures in Australia have so far focused on identifying, treating, and isolating people who have the disease, and educating the public about the steps that individuals can take to reduce transmission. Antiviral medications have been deployed as both treatment and prophylaxis. Clinical trials of the pandemic (H1N1) 2009 vaccine are currently underway; however, it is unclear when and to whom the vaccine will be made available. Healthcare workers (HCWs) and those on the 'front line' will be the first to be vaccinated; there will be a lag time for members of the general public.

Non-pharmacological public health interventions including use of face masks are therefore likely to play a vital role in mitigating disease spread, particularly in developing countries. Medical masks are unfitted devices worn by an infected person, HCW or member of the public to reduce transfer of potentially infectious respiratory tract material between individuals. They are designed to be disposable. Surgical masks are specifically designed to protect patients from contamination of wounds during surgical procedures. In contrast, a respirator is a fitted device that protects the

wearer against inhalation of harmful contaminated material. Respirators can be disposable or reusable and are recommended for use in high-risk activities (e.g. aerosol-generating procedures) in healthcare settings. The National Institute for Occupational Safety and Health (NIOSH) regulates the testing and certification of respiratory protection equipment.² The NIOSH tests filters for the effects of loading (particle burden), temperature, and relative humidity and requires a minimum filtration efficiency of 95%, 99% or 99.97% using neutralized 0.075-mm count median diameter solid aerosols at 85 l/min. Filters can be certified for a range of efficiency classes (e.g. 95%, 99% or 100%) as well as for their ability to withstand degradation as a result of loading or oil mist exposures. N95 filters are not permitted to have more than 5% of the challenge aerosol concentration penetrate the filter, and would be expected to have less aerosol penetration with either larger or smaller particles than the size used in certification testing.

In 1973, a letter to the editor of the *New England Journal of Medicine* from Jack Resnick, MD,³ suggested '...perhaps the ancient oriental custom of wearing gauze or cloth, surgical-type masks during a cold has some merit? Perhaps Western society has another lesson to learn by observing the oriental customs besides acupuncture.' He proposed that this matter be studied in a rigorous manner. Since then, there have been many studies on the filtration efficiency under controlled laboratory settings, but until recently there has been limited study as to whether masks or respirators will provide clinically relevant protection in healthcare settings. Most data have been derived from at best observational settings and frequently has been based on anecdotal rather than controlled trials evidence.⁴⁻⁶ Jefferson summarized these data in his systematic review of the literature in 2007;⁷ two papers were included which

focused specifically on N95 masks.^{8,9} Although the authors concluded from the pooled estimate of effect that the intervention effectiveness was 91%, this evidence was thin as the studies included showed inconsistencies and failed to adequately describe the use of controls. Jefferson and colleagues concluded that more experimental studies were needed to identify the effectiveness of wearing face masks or respirators in reducing exhaled infectious viral particles.⁷

In 2009, we reported the first prospective cluster-randomized trial comparing surgical masks, non-fit-tested P2 masks (N95 equivalent) and no masks in prevention of influenza-like illness (ILI) in households.¹⁰ Intention to treat analysis showed no significant difference in the relative risk of ILI in the mask groups compared with the control group. However, less than half of the subjects wore masks 'most of the time'. Adherence to mask use significantly reduced the risk of ILI-associated infection, with a hazard ratio of 0.26 (95% CI 0.09–0.77; $P = 0.015$). A recently reported randomized trial showed a significant benefit of both hand hygiene and face masks (worn by the index case and contacts) in preventing influenza transmission in households, although adherence to the face mask intervention was low among household contacts.¹¹

Surgical masks and N95 respirators have been recognized as an important non-invasive technology to use during this new pandemic period. However, there are many factors which may compromise the overall effectiveness of these measures. Poor training, lack of guidance and consistency in the use of masks, improper use and for N95 respirators, the need for fit-testing, may limit their usefulness. Data from the SARS experience in Toronto illustrated the need for training and monitoring; Loeb and colleagues (2004) found that nine of 32 (28%) nurses entering a SARS patient's room did not consistently wear appropriate respiratory protection.¹² There is also the problem of workplace acceptance. In a logistics exercise undertaken during the peak of seasonal influenza activity in 2007 in Australia, compliance by emergency department staff, with N95 mask wearing was found to be low, with only 36.1% of participants wearing the mask 'occasionally' in week one and only 18.8% by week four. Many staff reported that they found the mask hot and hard to breathe through, and others reported that they had problems both communicating with patients and storing the mask between uses.¹³

Much time and effort has been devoted to developing an optimal strategy for the use of pandemic vaccines and antivirals, in addition to non-pharmaceutical measures. However, comprehensive assessments of the literature to date recognize the generally poor quality of evidence on which to base non-pharmaceutical pandemic planning decisions. Despite the lack of high level evidence, recommendations on the use of face masks and respirators for HCWs are

made by many health authorities. To ensure that HCWs wear face masks to protect themselves during this time, cultural attitudes and the physical discomfort and mechanical issues associated with long-term respirator use must be addressed. Other factors that affect the use of personal protective equipment, such as staff and management attitudes about the value of respirator use, fatigue and the availability of replacement masks, also need to be considered.

Author's contributions

All authors contributed to the writing and revising of the text.

Conflict of interest statement

There are no conflicts of interest.

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