American Red Cross Advisory Council on First Aid, Aquatics, Safety and Preparedness

ACFASP Scientific Review

Mask Usage for Influenza in Non-Healthcare Settings

Questions to be addressed:

Should members of the public wear face masks during influenza pandemics to reduce viral transmission?

Hypothesis: In members of the general public the use of surgical or procedure masks compared to not wearing a mask reduces the attack rate of influenza.

During the December 9, 2006 at its meeting in Washington, DC, the Council added the following sub-questions: When should masks be changed and can they be reused?

This scientific review was reviewed in November 2009.

Introduction/Overview:

Flu is a contagious respiratory illness caused by influenza viruses. It can cause mild to severe illness, and at times can lead to death.

Every year in the United States, on average:

- 5% to 20% of the population gets the flu;
- more than 200,000 people are hospitalized from flu complications, and;
- about 36,000 people die from flu.

Some people, such as older people, young children, and people with certain health conditions, are at high risk for serious flu complications.

Pandemic flu is virulent human flu that causes a global outbreak, or pandemic, of serious illness. Because there is little natural immunity, the disease can spread easily from person to person. Human influenza is transmitted from person to person primarily via virus-laden large droplets (particles >5 µm in diameter) that are generated when infected persons cough or sneeze; these large droplets can then be directly deposited onto the mucosal surfaces of the upper respiratory tract of susceptible persons who are near (i.e., within 3 feet) the droplet source. Transmission also may occur through direct and indirect contact with infectious respiratory secretions. The use of surgical or procedure masks by infectious patients may help contain their respiratory secretions and limit exposure to others.

Review Process and Literature Search Performed

We searched MEDLINE though PubMed with the following search strategy: ((“Influenza, Human"[Mesh]) OR (influenza*[TIAB]) OR ("flu"[TIAB])) AND ((masks[Mesh]) OR (mask*[TIAB])) AND (Therapy/Narrow[filter]).

We searched EMBASE with the following search strategy: 'influenza'/exp AND 'surgical mask'/exp AND ([controlled clinical trial]/lim OR [randomized controlled trial]/lim).

We reviewed the Cochrane Database with the terms MeSH descriptor **Influenza, Human** explode all trees AND MeSH descriptor **Masks** explode all trees.

We also reviewed additional publications found in the bibliographies of appropriate articles.

Inclusion criteria: articles that met search criteria.
Exclusion criteria: articles not dealing with the use of face masks, articles not evaluating influenza (e.g. we excluded articles dealing with mask use for SARS), and experimental studies without a control group.

We retrieved eighteen articles database searching and fourteen additional records through other sources. 29 articles were left after duplicates were removed. We screened these records and excluded eleven. This left eighteen full-text articles that we assessed for eligibility. We excluded five articles as being out-of-date, one article for dealing with SARS only, and one that was an experimental trial without a control group. This left eleven studies that we included in the qualitative synthesis.

Scientific Foundation:

The studies that give the best scientific evidence to help us answer the question are from Cowling 2009 and MacIntyre. These are both well-designed, blinded, randomized, controlled trials. The challenge is that they give opposite results. Cowling showed a small, but significant decrease in the spread of influenza in a household when both the patient and family contacts wore a surgical mask as much as possible, if the intervention was initiated within 36 hours of the first clinic visit. This was coupled with a home visit and encouragement to keep a log of mask use that the subjects returned at the completion of the study.

In contrast, the MacIntyre study issued the masks and provided instruction in the clinic. There was regular telephone follow-up, but home visits only occurred if a household member developed flu-like symptoms. In this study neither a surgical nor a P2 (N-95-type) mask had a significant reduction on the secondary attack rate, despite an adequate power.

Summary:

Recommendations and Strength (using table below):

Standards: None.

Guidelines: None.

Options: The use of surgical or procedure masks should be considered for people with influenza and their household contacts. (Class IV)

Class	Description	Implication	Level of Evidence
I	Convincingly justifiable on scientific evidence alone.	Usually supports Standard	One or more Level 1 studies are present (with rare exceptions). Study results consistently positive and compelling
II	Reasonably justifiable by scientific evidence and strongly supported by expert opinion.	Usually supports Guideline but if volume of evidence is great enough and support from expert opinions is clear may support standard	Most evidence is supportive of guideline. Level 1 studies are absent, or inconsistent, or lack power. Generally higher levels of evidence. Results are consistently supportive of guideline.
III	Adequate scientific evidence is lacking but widely supported by available data and expert opinion.	Usually supports Option.	Generally lower or intermediate levels of evidence. Generally, but not consistently results are supportive of opinion.
IV	No convincing scientific evidence available but supported by rational conjecture, expert opinion and/or non peer-reviewed publications	Usually does not support standard, guideline, or option. Statement may still me made which presents what data and opinion exists. In some cases and in conjunction with rational conjecture may support option.	Minimal evidence is available. Studies may be in progress. Results inconsistent, or contradictory.

Summary of Key Articles/Literature Found and Level of Evidence:

Author(s)	Full Citation	Summary of Article (provide a brief summary of what the article adds to this review)	Level of Evidence (Using table below)
Aledort	Aledort, J. E., Lurie, N., *et al.* (2007). Non-pharmaceutical public health interventions for pandemic influenza: An evaluation of the evidence base. *BMC Public Health,* **7**, 208.	This article from the RAND Center for Domestic and International Health Security reports a systematic review of 168 manuscripts selected according to pre-defined criteria after identifying 2,556 titles from a database search. They followed this with an expert consensus conference in Alexandria, VA in January 2006. They were not able to identify any evidence supporting mask use by the public. There was disagreement among the experts on the appropriateness of this intervention during the early localized and advanced stages of a pandemic. The article did not identify the member of individuals on the expert consensus panel, nor did it describe how they selected these individuals for participation.	5
CDC	CDC. Experiences with Influenza-Like Illness and Attitudes Regarding Influenza Prevention --- United States, 2003--04 Influenza Season. MMWR. 53(49);1156-1158	A 2004 survey using random digit dialing of 2,231 non-institutionalized individuals across the United States found that 59% of the individuals questioned agreed with the statement “people who are sick and able to spread germs should wear a mask in public."	5

Chen	Chen, S. C. and Liao, C. M. (2007). Modelling control measures to reduce the impact of pandemic influenza among schoolchildren. *Epidemiol Infect*, 1-11.	This mathematical study combined the Wells-Riley equation and the susceptible-exposed-infected-recovery model to evaluate the impact of increased indoor ventilation and mask use on reducing influenza transmission in a public school. This model did not factor mask use to protect the individual using the mask. Instead, it estimated the effectiveness of masks at reducing the burden of influenza virus particles in the indoor air environment. The model showed an improvement in the reproduction number, a measure of the transmission potential of a disease, in a shared indoor airspace. Interestingly, the improvement in reproduction number is more significant in children than in adults.	4
Cowling 2008	Cowling BJ, Fung RO, Cheng CK, Fang VJ, Chan KH, Seto WH, et al. Preliminary findings of a randomized trial of non-pharmaceutical interventions to prevent influenza transmission in households. PLoS One. 2008;3(5):e2101	This is a study of good quality that was designed as the pilot study to Cowling's paper of 2009. The population under study and the methods are generally similar, although this paper was not adequately funded to test the hypothesis. This study was funded by CDC, the government of the Hong Kong SAR, and Hong Kong University.	1b

Cowling 2009	Cowling BJ, Chan KH, Fang VJ, Cheng CK, Fung RO, Wai W, et al. Facemasks and hand hygiene to prevent influenza transmission in households: a cluster randomized trial. Ann Intern Med. 2009 Oct 6;151(7):437-46	This trial is supports the hypothesis. The quality of the data is good in that the assignment of subjects to treatment was randomized, the randomization list was concealed to the extent possible, all subjects that entered the trial were accounted for at its conclusion, the subjects were analyzed in the groups to which they were randomized, the clinicians (although not the patients) were "blinded" to the treatment being received, aside from the experimental intervention, the groups were treated equally, and the groups were similar at the start of the trial. This study was funded by CDC, the government of the Hong Kong SAR, and Hong Kong University. This was a study of 794 household members in 259 households who were contacts of 407 people presenting to outpatient clinics with influenza-like illness who were positive for influenza by rapid testing. The case patient and family were randomized to either lifestyle education (control) or hand hygiene or hand hygiene and face mask supply and education. All subjects received home-visits. For those households where intervention was initiated with 36 hours of the first clinic visit, there was a statistical decrease in the secondary spread of influenza as confirmed by RT-PCR. This study had a limitation of very close follow-up and home visits to initiate the intervention.	1b
Derrick	Derrick, J. L. and Gomersall, C. D. (2005). Protecting healthcare staff from severe acute respiratory syndrome: Filtration capacity of multiple surgical masks. *J Hosp Infect,* **59**(4), 365-8.	This very small study used a Portacount and determined that multiple rectangular pleated surgical masks, even up to five, were not as effective as an N-95 mask. It was a prospective cohort study with a cross-over design. There was a high risk of bias.	2a

Inouye	Inouye S, Matsudaira Y, Sugihara Y. Masks for influenza patients: measurement of airflow from the mouth. Jpn J Infect Dis. 2006 Jun;59(3):179-81	The investigators placed subjects in three surgical masks and measured airspeed of expired air compared to the airspeed of expired air without masks. All masks reduced airspeed during either blowing or coughing by a factor of 10. The study did not report the number of subjects tested, and, may have been an n of 1 study. Their conclusion is that wearing masks may reduce transmission of droplet nuclei to healthy individuals.	2a
Jefferson	Jefferson, T., Foxlee, R., *et al.* (2007). Interventions for the interruption or reduction of the spread of respiratory viruses. *Cochrane Database Syst Rev,*(4), CD006207.	A Cochrane review of interventions to reduce the spread of respiratory viruses. Most of the studies reviewed were for SARS or some other respiratory virus other than influenza. The data suggests, with moderate strength, that surgical mask use will reduce the spread of influenza. It also suggests that N95 mask use is no more effective for the public than less expensive and more comfortable surgical masks.	1b
Kerneis	Kerneis, S., Grais, R. F., *et al.* (2008). Does the effectiveness of control measures depend on the influenza pandemic profile? *PLoS ONE,* **3**(1), e1478.	A mathematical model of various pandemic influenza profiles, suggesting that early introduction of masks to the public will correlate strongly with pandemic outcomes. The mathematical model is of uncertain validity.	4
Lau	Lau, J. T., Kim, J. H., *et al.* (2007). Anticipated and current preventive behaviors in response to an anticipated human-to-human H5N1 epidemic in the Hong Kong Chinese general population. *BMC Infect Dis,* **7**, 18.	This telephone survey conducted in Hong Kong found that 74% of respondents were likely to use face masks in public venues during a pandemic influenza outbreak. There is a high possibility of bias because of the low (57%) response rate and the results may not be generalizable to other countries.	3a

MacIntyre	MacIntyre CR, Cauchemez S, Dwyer DE, Seale H, Cheung P, Browne G, et al. Face mask use and control of respiratory virus transmission in households. Emerg Infect Dis. 2009 Feb;15(2):233-41	This trial opposes the hypothesis. The quality of the data is good in that the assignment of subjects to treatment was randomized, the randomization list was concealed to the extent possible, all subjects that entered the trial were accounted for at its conclusion, the subjects were analyzed in the groups to which they were randomized, the clinicians (although not the patients) were "blinded" to the treatment being received, aside from the experimental intervention, the groups were treated equally, and the groups were similar at the start of the trial. This study was funded by The Office of Health Protection, Department of Health and Ageing, Australia, 3M Australia, and Medical Research Council (UK). In this study the investigators analyzed data on 286 adults from 143 families that were exposed to a family member with influenza. The families were randomized to either control (no intervention), a surgical mask, or a P2 mask without fit testing. In this study there was no significant reduction in the secondary spread of influenza, regardless of the type of mask used.	1b

Level of Evidence	Definitions **(See manuscript for full details)**
Level 1a	Population based studies, randomized prospective studies or meta-analyses of multiple studies with substantial effects
Level 1b	Large non-population based epidemiological studies or randomized prospective studies with smaller or less significant effects
Level 2a	Prospective, controlled, non-randomized, cohort or case-control studies
Level 2b	Historic, non-randomized, cohort or case-control studies
Level 2c	Case series: convenience sample epidemiological studies
Level 3a	Large observational studies
Level 3b	Smaller observational studies
Level 4	Animal studies or mechanical model studies
Level 5	Peer-reviewed, state of the art articles, review articles, organizational statements or guidelines, editorials, or consensus statements
Level 6	Non-peer reviewed published opinions, such as textbook statements, official organizational publications, guidelines and policy statements which are not peer reviewed and consensus statements
Level 7	Rational conjecture (common sense); common practices accepted before evidence-based guidelines
Level 1-6E	Extrapolations from existing data collected for other purposes, theoretical analyses which is on-point with question being asked. Modifier E applied because extrapolated but ranked based on type of study.