

THE USE OF FACE MASKS DURING AN INFLUENZA PANDEMIC

SCIENTIFIC EVIDENCE BASE





Contents

Executive summary	3
Scope and purpose	4
Glossary and explanation of technical terms	4
Context and assumptions: avian versus pandemic influenza	5
Evidence about modes of transmission	6
Evidence about the effectiveness of face masks and respirators	8
Practical issues regarding use of face masks by the general public	10
International context/consensus on use of face masks and respirators	12
Interpretations in relation to specific settings	14
Possible future issues to be noted	16
References	17

Page

EXECUTIVE SUMMARY

- 1. In 2006 the Health Protection Agency (HPA) was tasked by the Department of Health Pandemic Influenza Scientific Advisory Group (SAG) to review the evidence base for the use of face masks during an influenza pandemic.
- 2. This paper is a comprehensive review of all the available literature and recommendations currently in the public domain. It has also taken account of the output from discussions at recent meetings, including the Scientific Working Meeting on Occupational Influenza Prevention and Control in Health Care Settings, Toronto, October 2006. It has since been reviewed by national and international experts as well as the Pandemic Influenza Scientific Advisory Group.
- 3. The Agency's views, shared by the Department of Health (DH), as to how this evidence base would translate into practical advice from a purely scientific point of view, are detailed in the section entitled: "Interpretations in relation to specific settings". Essentially these are:

• Health care settings

HPA continues to support the use of infection control procedures, including personal protective equipment (PPE) such as surgical face masks, consistent with interrupting droplet and contact transmission, except under specific circumstances where aerosols are likely to be generated, eg certain healthcare procedures, where FFP3 respirators are recommended.

o Surgical mask use by the general public

The specific evidence base regarding use of face masks by the general public is currently too uncertain and too limited to firmly support face masks for use by the public during an influenza pandemic. However, the evidence of harm from use by the general public is even more limited. The current evidence base is consistent with a permissive approach to voluntary mask use by the general public, but no recommendation or encouragement. As some members of the public are likely to choose to wear masks, it is important that guidelines on correct usage are provided to the general public.

• Surgical mask use by symptomatic persons outside the home

Some data exist to support masking of persons with symptoms as a means of containing respiratory secretions and reducing contamination of the immediate environment around the patient. This policy is already applied within NHS pandemic guidance for patients in public waiting areas. Whilst it is clearly more desirable for persons with symptoms to be masked in public places than unmasked, the main message to promulgate is voluntary self-isolation (staying at home until symptoms resolved) together with a package of basic hygiene measures. Therefore, from an efficacy point of view, this measure could be considered, but it is noted there would be significant communication, logistic and training issues to overcome.

Surgical mask use by symptomatic persons inside the home
 Some data exist to support masking of persons with symptoms as a means of containing respiratory secretions and reducing contamination of the immediate

environment around the patient. However the main message to promulgate is voluntary self-isolation (living in another room or part of the house until symptoms resolved) together with a package of basic hygiene measures. Therefore, from an efficacy point of view, this measure could be considered, but it is noted there would be significant communication, logistic and training issues to overcome.

 Surgical mask use by carers/lay attendants in home/household settings This situation is the most analogous to close contact between healthcare workers and their patients. It could be supported scientifically but carries with it major issues about training, logistics and safe mask use.

Scope and purpose

- 4. This paper is intended to:
 - Review the evidence base for use of face masks (surgical masks) in a variety of settings (healthcare and general public) for the prevention of transmission of human (as opposed to avian) influenza viruses. It excludes situations related to non-healthcare occupational settings, which are being addressed separately by the Health and Safety Executive (HSE).

Glossary and explanation of technical terms

- 5. In this paper, the term 'face mask' is used to describe a disposable mask of the type commonly worn by surgical staff in operating theatres (surgical face mask).
- 6. Surgical face masks were originally designed to prevent material from beneath the mask, ie originating from the wearer, contaminating the operating environment, ie the patient. However it is recognised that a correctly worn face mask, especially if manufactured from or coated with fluid repellent materials, will provide a physical barrier against splashes in both directions, ie some degree of protection is also offered to the wearer.
- 7. The paper also makes reference to studies involving 'simple paper masks' which are also known as 'procedure masks' in some settings. These are simple (usually flimsy) paper masks which attach to the wearer by small elastic ear loops.
- 8. The term 'respirator' is used to describe a device or equipment (eg filtering mask, helmet, hood, or other) which has been specifically designed to provide an element of filtration, not just a physical barrier, and whose purpose is primarily to protect the wearer from inhalation of particles of various sizes.
- 9. In the EU respirators are classified according to the level of protective filtration offered using the nomenclature FFP1, FFP2, FFP3, the latter being the highest.
- 10. An alternative classification is used in North America and other places: N95, N99 etc. The two rating scales are not interchangeable at a technical level. However, in broad conceptual terms only, N95 can be considered equivalent to FFP2, and N99 equivalent to FFP3.

Context and assumptions: avian versus pandemic influenza

- 11. Currently, the World Health Organization (WHO) has declared pandemic alert level 3, characterised by threat from an influenza virus which produces human infections (with clinical illness) but which spreads hardly at all between humans.
- 12. Subsequent pre-pandemic alert levels (WHO Phases 4 and 5) reflect a virus which is acquiring the ability to transmit from person to person, but which is not yet doing so as efficiently as a pandemic virus.
- 13. WHO Phase 6 represents a pandemic itself when the virus has fully adapted to humans, to the extent that it now transmits efficiently from person to person, in the same way that 'normal' seasonal influenza does at present.
- 14. The influenza A/H5N1 virus isolated in Phase 3 is known to be a pure avian virus which is rightly classified as 'avian influenza' not pandemic influenza.
- 15. If H5N1 evolves such that WHO Phases 4 and then 5 are triggered, it is assumed that this will still be regarded as avian influenza at both these stages.
- 16. In the UK H5N1 avian influenza has already been considered by ACDP and classified as a dangerous pathogen (ACDP level 3, SAPO Level 4). See http://www.hse.gov.uk/aboutus/meetings/acdp/100505/influenzavirus.pdf and http://www.hse.gov.uk/biosafety/diseases/acdpflu.pdf
- 17. In turn, the HSE has issued guidance for workers who are at risk of exposure to H5N1 viruses, and other forms of avian influenza, available at http://www.hse.gov.uk/biosafety/diseases/avianflu.htm and http://www.hse.gov.uk/biosafety/diseases/aisuspected.pdf
- 18. In general, the approach specified by HSE is for high level PPE to be worn in these settings. The use of face masks or respirators for possible exposure to avian influenza viruses therefore lies outwith the scope of this paper.
- 19. In considering the later sections of the current paper, readers are asked to bear in mind throughout that HSE, DH and HPA have each recognised the change in context from avian to pandemic influenza. It cannot currently be known from which virus a future pandemic virus might derive. However, given the immunological naivety of the population to a pandemic virus, it is likely that morbidity and mortality will both be greater than observed for normal seasonal influenza.
- 20. The virus is likely to become ubiquitous across all areas of UK society within weeks of its introduction to the UK and the risks of exposure to symptomatic persons will be present in all areas of society (not least of which the family home or whilst using public transport) and certainly not limited to healthcare or occupational settings. This change in emphasis is currently reflected in HSE advice to employers, and Pandemic Infection Control Guidance for Healthcare Settings, issued jointly by DH and HPA, after consultation with HSE. http://www.hse.gov.uk/biosafety/diseases/pandemic.pdf and http://www.dh.gov.uk/assetRoot/04/12/17/54/04121754.pdf

- 21. Any policy decisions regarding the use of face masks in the UK need to be informed by:
 - evidence about the modes of transmission of influenza viruses and the relative importance of each mode;
 - o evidence about the protection afforded by masks;
 - o practical considerations in specific settings;
 - o international context;
 - o procurement and logistics;
 - o the availability of antiviral drugs and vaccines within the UK;
 - o emerging morbidity and mortality data relating to the new virus.
- 22. For planning purposes, it is assumed that a future pandemic influenza virus will have similar transmission parameters (modes, incubation period, period of communicability) to normal seasonal influenza. This is an area where certainty will only exist once epidemiological data on the pandemic virus begin to emerge.

Evidence about modes of transmission

23. The four possible transmission categories for an infectious respiratory agent such as influenza, are principally via droplets, but also via aerosols, direct contact (such as kissing) and indirect contact (fomites). The table below summarises the differences between aerosols and droplets. Note that although a 5µm upper limit has historically been accepted in infection control guidance and literature for aerosols, this is now regarded as a somewhat arbitrary threshold.

Features	Aerosol-transmission	Droplet-transmission
Definition	Infection via inhalation of pathogen-carrying aerosols or droplet nuclei	Infection via spraying droplets by coughing or sneezing onto conjunctiva or mucous membranes
Transmission vehicle	Aerosol or droplet nuclei	Droplet
Mean particle size (diameter) of transmission vehicle (16)	< 5 µm in diameter However, there is no true consensus on the exact size criterion of an aerosol	> 10 µm However, there is no true consensus on the size criterion of a droplet
Particle suspension time in the air	Sufficiently small to remain suspended in air for several minutes to hours	Do not stay suspended in the air, but settle out in seconds to minutes
Distance at which the virus can be spread	Can be disseminated by air currents in a room or through a facility; does not require face-to-face contact	Short distance (typically ≤1m); face-to-face contact important
Inoculation site	Lower respiratory tract (ie alveoli) is thought to be the main inoculation site	Mucous membranes (upper respiratory tract); particles below 50 μ m but >5 μ m will impact in the trachea, bronchi, or bronchioles; particles > 50 μ m will impact high in the respiratory tract
Dose of virus required to induce infection	Relatively low doses of virus may be sufficient (compared to droplets)	Relatively larger dose of virus seems to be needed (compared to aerosol transmission)
% of particles of this size emitted during cough or sneeze	Data limited and proportion of different size particles may change over time (5;12-14)	Data limited and proportion of different size particles may change over time (5;12-14)

Table: main features of aerosol-transmission versus droplet-transmission.

24. There are further important considerations about particle size in relation to their ultimate infectivity; airborne microbes are rarely the size of the pathogen itself, but instead are usually carried within a larger particle; aqueous particles change in size as they dry and become smaller.

- 25. Size largely determines how rapidly a particle will settle and where it will be deposited into the respiratory tree.
- 26. Several other factors apart from size also influence a particle's infectivity including:
 - host factors (eg immune status, stage in illness affects viral load);
 - o pathogen factors (eg concentration of organisms and dilution of the inoculum);
 - environmental factors (eg temperature and humidity) which affect the duration of survival of the organism within the particle;
 - particle size -- the larger the particle, the greater the number of potentially infectious organisms it is likely to contain.
- 27. A literature review on transmission and communicability of influenza virus was performed when writing the Pandemic Infection Control Guidance for Healthcare Settings in October 2005. This review concluded that there is simply not enough evidence with which to establish beyond doubt a clear hierarchy for the various modes of transmission. However it was possible to say that although all four modes of transmission seem to have been described for influenza, the patterns of transmission observed during 'real-life' nosocomial outbreaks most often pointed to short-range transmission. This probably suggests that droplet and contact transmission are the most important and most likely routes. However it has also been hypothesized by some researchers that "*in cases in which the source produces a low concentration of infectious particles, the aerosol becomes so dilute as it travels away from the source that most secondary infections occur in the immediate vicinity of the index patient. Therefore, the epidemiologic pattern associated with a dilute aerosol mimics that expected with large-droplet sprays or surface contact (<i>ie face-to-face contact*)" (15). This is an alternative explanation.
- 28. Since the time when the literature review was performed, no real new evidence has been presented in the scientific literature. A review by Tellier, which aimed to answer the question of whether aerosol transmission took place at all, concluded that aerosol transmission of influenza is significant (18). Another recent review attempts to determine the relative importance of the different modes. Reviewing basically the same evidence, it arrives at the conclusion that the data are limited, but what data there are gives greater significance to transmission at close range rather than over long distances. They therefore conclude that aerosol transmission is unlikely to be of significance in most clinical settings (2). Indeed, many of the publications reviewed in the article have been previously cited by other reviewers (including HPA) as supporting the case for predominantly droplet transmission.
- 29. At the Scientific Working Meeting on Occupational Influenza Prevention and Control in Health Care Settings, Toronto, October 2006 (attended by 125 occupational health, infectious diseases and public health professionals including one HPA delegate), two Canadian groups presented two further reviews (one of which is referenced above). Essentially both groups concluded that that the available data are insufficient to draw any firm conclusions about the relative importance and frequency of the various modes of transmission. Both groups did however agree that most transmission seemed to occur at short range. No consensus was reached.
- 30. Thus HPA maintains its original position that the data upon which to base any judgment about modes of transmission of influenza virus present multiple competing hypotheses, lack

reproducible findings and frequently extrapolate from experimental and animal models. As such they are insufficient to draw firm conclusions. **Nevertheless, most data point towards short-range transmission in real-life settings (nosocomial outbreaks of influenza).** This pattern of transmission is known to be associated with spread by droplets and contact transmission. But at present, there are insufficient data to determine any additional role which may or may not be played by aerosol spread.

31. Definitive new studies are needed which will help: a) disentangle the scientific uncertainty about modes of transmission of influenza virus; and, b) establish a hierarchy of risk for aerosol-generating procedures.

Evidence about the effectiveness of face masks and respirators

- 32. The current Pandemic Infection Control Guidance for Healthcare Settings (http://www.dh.gov.uk/assetRoot/04/12/17/54/04121754.pdf) recommends the use of highlevel respiratory protection (FFP3 standard) for healthcare workers engaged in aerosol generating procedures. Two recent studies compared face masks against respirators (N95 standard) for the protection afforded against small sub-micron sized particles. The data are conclusive that respirators offer vastly superior protection than masks against small particles, but even N95 standard filtration may not be sufficient (1;9). This finding is unsurprising, but nevertheless supports the use of high-level respiratory protection when aerosols are likely to be generated during specific healthcare interventions.
- 33. The current Pandemic Infection Control Guidance for Healthcare Settings recommends that, where possible, patients with pandemic influenza wear masks in certain settings to the extent that they can tolerate to do so (eg public waiting areas in GP surgeries, A&E Departments, in transit within a hospital to the X-ray Department or similar). Although a policy decision has already been made to advise persons with symptoms of pandemic influenza to stay at home until recovered, it is under consideration whether such persons who are obliged to enter a public space should be advised to wear a mask for the protection of others; and whether such persons should be advised to wear masks in the home for the protection of family members. Japanese researchers have recently examined the effect of surgical masks on the coughing patient and noted a 90% reduction in airflow velocity achieved by surgical mask use. These data support the masking of symptomatic patients as a means of reducing pandemic influenza transmission (7).
- 34. HPA has already provided to DH two preliminary reviews on the effectiveness of face masks for the general public, in November 2005 and again in October 2006. From these earlier reviews the main messages were that:
 - the evidence base was limited; all three major studies examined a range of other public health interventions in addition to masks (8;10;19);.
 - \circ in one study the effects of any single intervention were difficult to disentangle (7);
 - o all three major studies might have been open to significant recall bias;
 - all three major studies were performed in the context of SARS in SE Asia, and only one (the weakest) specifically examined the relationship with other respiratory viruses including influenza (10);
 - nevertheless, protective effects against clinically diagnosed SARS were observed in two papers (8;19),and against the laboratory confirmed incidence of influenza in another (10);
 - o appreciable concerns remained about the safe use of masks by the public;

- international consensus currently leans against advising face masks for use by the asymptomatic general public.
- 35. A further literature search has now been performed, revealing only one further study relating to mask/respirator use by the general public. In this survey the respirator donning by the general public involved in mould remediation in the aftermath of a hurricane in New Orleans was evaluated. Only 24% (129 / 538 participants) demonstrated proper donning (3).
- 36. Four further studies have been identified which contribute data on the use of face masks by health professionals (4;6;11;17).
 - <u>Davies et al (4)</u>: Comparison study of dentists versus controls. Measured seropositivity to respiratory viruses. Data on wearing of masks and eye protection open to recall bias. Protective effect of mask wearing (type unspecified) against influenza and RSV infections: not measurable for influenza A since dentists were 100% seropositive; some suggestion that masks may have a small protective effect for influenza B and RSV.
 - <u>Seto et al</u> (17): Retrospective case-control study from Hong Kong SARS epidemic. The use of 'masks' (surgical or N95 respirator) by healthcare workers was significantly and strongly associated with non-infection with SARS (OR = 0.08). Simple paper masks were ineffective. Study open to recall bias.
 - Loeb et al (11): Retrospective cohort study performed in two critical care units in Toronto during SARS epidemic. Unclear if data collection on mask use was obtained from health care records or interviews (latter open to recall bias). Consistent 'mask' wearing (surgical or N95 respirators) offered significant protection against SARS (OR = 0.23, 95% CI: 0.07-0.78). N95 respirators appeared more effective than surgical masks. Small numbers in the study led to extremely wide confidence intervals for estimates of protection.
 - <u>Hall and Douglas</u> (6): Intervention study. Paediatric wards assigned to 'no face masks and no gowns' for a period of 4 weeks followed by 'face masks and gowns' for 4 weeks, during known community respiratory syncytial virus (RSV) outbreak. Nosocomial secondary attack rate measured (32% vs 41%). Use of 'face masks and gowns' appeared to have no incremental effect over and above other infection control procedures such as hand washing.
- 37. Two of these four additional studies support (at least to some extent) the use of face masks and/or respirators by healthcare professionals when in close contact with patients with pandemic influenza. However, there are difficulties in generalising the estimates of protection described by Seto et al (17) and Loeb et al (11) to mask wearing by the general public, as these observations were made in the context of close healthcare contact with seriously ill patients.
- 38. In summary, whilst each of the studies' methodological approaches preclude firm establishment of a causal relationship between mask use and protection against respiratory illness, an overall impression does emerge, from those studies that examined multiple interventions, that increased utilisation of hygiene measures, such as handwashing, surface cleaning and mask wearing, may reduce the risk of acquiring a respiratory viral infection. However, the evidence base specifically regarding use of face masks by the general public still appears too uncertain and too limited to support a national policy (with far reaching financial and logistic consequences) which firmly recommends, or which recommends and

provides, face masks for use by the public during an influenza pandemic. A permissive approach is recommended since a lack of evidence is not negative evidence, and common sense dictates masks worn by the general public might do some good on an individual level.

- 39. Given that the masking (where possible) of symptomatic patients in public areas of NHS premises (other than on dedicated 'flu wards') is already recommended in pandemic infection control guidance, there is a clearer rationale to support more limited use of face masks by ill members of the public in analogous situations, namely:
 - if they cannot stay at home and are compelled to enter a public space whilst experiencing symptoms of influenza (eg whilst travelling to a healthcare facility by public transport);
 - if they live with other persons and wish to take measures which might reduce transmission in the home. (*N.B. masking in the home could not easily be applied to small children*)
- 40. However the evidence base is still extremely limited and any recommendations for such actions should be carefully positioned so as not to detract from, or complicate, the main public health messages which will be:
 - o to stay at home when symptomatic;
 - as far as is possible, to avoid other family/household members when symptomatic by living in separate rooms of the house.
- 41. Surgical masks could also be considered for family members caring for a relative who had pandemic influenza. Such use would be consistent with the policy of providing face masks to healthcare workers in contact with pandemic flu. However inevitable concerns would exist about practical issues of training, safe use and the logistics of distribution (see section entitled "Practical issues regarding use of face masks by the general public" below).

Practical issues regarding use of face masks by the general public

42. HPA has already expressed a number concerns about the practical implementation of any policy relating to mask use by the general public. These are best highlighted by reference to the use of masks in healthcare settings.

Factor	Healthcare setting	General public
Training	 Specific training in correct use provided. 	 General advice could be provided, but not formal training.
Usage	 Safe use depends on ready access to hand hygiene facilities before donning and after removal and receptacles for safe disposal. Must be worn and then disposed of not hung around the neck etc. Masks become inefficient when moist and must be changed regularly. 	 Performance of hand hygiene and access to receptacles may be limited and inconsistent. Failure to perform hand hygiene, especially after removal might increase risk of self-contamination. Neck wearing and re-use likely. Less likely to be changed regularly.
Indication	 Close (≤1m) contact with influenza 	 Since contact with infectious

Table – Comparison of surgical mask use in healthcare and community settings

for use	 patients. Would NOT be worn in non- influenza areas of hospital/clinic or when caring for non-influenza patients unless splashes/contact with blood/body fluids, etc. anticipated. 	 persons in public venues would be random and unpredictable, masks might be worn for prolonged periods. Might be worn to conceal respiratory symptoms rather than stay at home if ill.
Risk of exposure to respiratory droplets	 Increased due to: Close contact with large numbers of clinically ill, symptomatic patients. Contact for long periods of time (eg >=8-hrs/day throughout pandemic). Concentration of patients in small, segregated spaces. Exposure to respiratory secretions via extra-ordinary procedures (eg suctioning, mechanical ventilation). 	 Not increased above community average, although crowded settings likely to increase risk of exposure. Contact with infectious persons in public venues would be random and unpredictable. Contact with ill family members is more predictable.
Quality of mask	 Good; meets required standards; establish supplies from reputable manufacturers. 	 Variable; potential for poor quality.

- 43. HPA believes that the practical issues for public use as laid out above, coupled with the reduced likelihood, intensity and duration of exposure (compared with healthcare settings), the risk of diluting or complicating messages about home self-isolation, the risks of engendering a false sense of security (eg overemphasis on masks as means of protection compared with hand washing) increase the likelihood that masks worn widely by the public would provide little benefit.
- 44. Availability and supply are further issues that government will need to consider, but lie outside the scope of this paper.
- 45. HPA has recently completed two pandemic simulation studies in healthcare settings. The first of these took place on an Intensive Care Unit over a period of 48 hours, and was aimed primarily at assessing the use of respirators. A second simulation took place on a general medical ward over 24 hours; this was a setting where surgical face masks were predominantly used. It should be noted that medical and nursing staff:
 - o used large quantities of surgical masks
 - o were unsure about infection control procedures relating to donning and removal
 - encountered storage issues
 - o encountered issues with the volume of clinical waste generated
 - o took substantially longer to perform basic tasks
 - o experienced discomfort and dehydration.

These aspects of practical implementation might be expected to carry over into public use and might seriously affect compliance.

46. Nonetheless, it can be expected that during a pandemic the public will have considerable interest in procuring and wearing masks which would be expected to prevent some

exposures if used correctly.

International context/consensus on use of face masks and respirators

Healthcare workers:

- 47. WHO issued interim guidelines in June 2007 for Infection prevention and control of epidemic- and pandemic-prone acute respiratory diseases in health care (<u>http://www.who.int/csr/resources/publications/WHO_CD_EPR_2007_6/en/index.html</u>). Standard and Droplet Precautions are recommended when caring for patients with an "influenza virus with sustained human-to-human transmission (eg seasonal influenza and pandemic influenza)" including medical masks for healthcare workers and caregivers; particulate respirators are advised for aerosol-generating procedures.
- 48. At an EU conference about pandemic preparedness organised in July 2007 by the UK Government (http://www.dh.gov.uk/en/PandemicFlu/DH_076566), the current position being taken by several countries was reviewed on recommendations for use of face masks and respirators for healthcare workers. In summary:
 - Canada: surgical mask for close contact; N95 respirator for aerosol generating procedures; recommendations for healthcare settings under review currently and expected to be released in late 2007;
 - France: FFP2 respirators for all close contact and aerosol generating procedures;
 - Austria: FFP3 for healthcare workers in direct contact with pandemic flu patients;
 - Japan: surgical mask for close contact; N95 respirator or surgical mask being debated for aerosol generating procedures, but initial experience indicates it hinders effective communication and induced dehydration and fatigue in staff;
 - USA: N95 respirator "prudent" for close patient contact; N95 respirator recommended for aerosol generating procedures.

General public:

- 49. Following an international consultation on priority public health interventions before and during an influenza pandemic, WHO has made the following recommendations:
 - Masks in public places not recommended; "not known to be effective; permitted but not encouraged" and
 - Masks for symptomatic persons recommended, but "*logistics need to be considered*" <u>http://www.who.int/csr/disease/avian_influenza/final.pdf</u>
 - Persons with an acute febrile respiratory illness should be masked upon entry to emergency and outpatient care, if possible (<u>http://www.who.int/csr/resources/publications/WHO_CD_EPR_2007_6/en/index.</u> <u>html</u>).
- 50. A WHO writing group has also published the following statement :

"WHO has recommended that mask use by the public should be based on risk, including frequency of exposure and closeness of contact with potentially infectious persons; routine mask use in public places should be permitted but not required. This recommendation might be interpreted, for example, as supporting mask use in crowded settings such as public transport." http://www.cdc.gov/ncidod/EID/vol12no01/05-1371.htm

51. The European Centre for Disease Prevention and Control (ECDC) in October 2006 recommended:

"The issue of **general mask wearing by the public** is probably the most difficult issue to give evidence-based advice upon. The aim being to reduce the risk of acquiring infection in mask wearers. This is because there is scarcely any evidence. Mask-wearing is standard during the influenza season in a number of countries, notably in the Far East though there is no evidence whether or not this reduces influenza transmission there below rates seen in non-mask wearing countries. Contrary arguments were presented to ECDC that general mask-wearing might either reduce <u>or</u> increase risk to wearers and to others. There is some weak observational evidence that mask-wearing was protective to wearers during SARS outbreaks. However apart from that there is no firm evidence for general mask wearing by the public being protective or not for influenza any other respiratory infection. Some European authorities suggested that a person who was developing influenza might be tempted to wear a mask and take medication and continue working rather than go home. Or that poor use of a wet mask by an infectious person would be more dangerous than good use of disposable tissues.

Given the lack of evidence and the diverging views the ECDC position is neutral but permissive. This is the same position as that adopted by WHO following the Reviews in the Annex to its Pandemic Plan. ie based on the scientific and public health evidence ECDC cannot recommend countries or EU citizens to adopt general mask-wearing. Equally when influenza is circulating locally if people wish to wear simple masks ECDC would not say that there is any evidence that they should not be allowed to do so, especially if individuals see themselves as being at higher risk, for example from travelling in crowded transport or in having face to face contact with the public. Simple masks if used should be worn properly and changed and disposed of safely (like tissues) when they become wet. Mask wearing must not be seen as an alternative to early self-isolation though mask-wearing or covering the mouth and nose is recommended for symptomatic people on their way home to bed."

- 52. The EU conference on pandemic preparedness organised by the UK in July 2007 reviewed the current position being taken by several countries on recommendations for use of face masks by the public which are:
 - Canada: surgical mask for ill persons in public and surgical mask with eye protection for household carers in direct contact;
 - France: surgical mask for ill persons in public; further recommendations are under discussion; FFP2 respirators for household carers in direct contact;
 - Austria: FFP1 masks are being made available to everyone at a reduced price for use by the general public;
 - Japan: surgical mask for the well public in public where infection has been observed;
 - USA: Facemasks should be considered for use by persons who enter crowded settings, both to protect their nose and mouth from other people's coughs and to reduce the wearers' likelihood of coughing on others. Respirators should be considered for use by persons for whom close contact with an infectious person is unavoidable including those who must take care of a sick person (eg family member with a respiratory infection) at home;
 - Germany: surgical masks for household carers in direct contact; no support for mask use for the well public.
- 53. HPA conducted a review in 2006 of published national pandemic plans to determine the extent to which the use of face masks by the general public is being considered elsewhere. In addition to the information on countries noted in the preceding paragraph, during that

review 8 national pandemic plans were found in English of which one (Slovakia) explicitly mentions that the public will be advised to wear masks when using communal transport. One country's plan (Italy) explicitly mentions that masks are not recommended for asymptomatic persons in public places.

Interpretations in relation to specific settings

- 54. Healthcare settings: Most data point towards short-range transmission of influenza. This pattern of transmission is known to be associated with spread by droplets and by contact transmission. At present, there are insufficient data to determine any additional role which may or may not be played by aerosol spread. Pending any new scientific evidence to the contrary and an assessment of the transmission characteristics of the pandemic virus when it emerges, HPA continues to support the use of infection control procedures, including PPE, consistent with interrupting droplet and contact transmission (surgical mask), except under specific circumstances where aerosols are likely to be generated and an FFP3 respirator should be used. There is no compelling or conclusive scientific rationale to amend the overall strategy within the current Pandemic Infection Control Guidance for Healthcare Settings, as the measures described in this document need to be viewed in the context of the UK having a large stockpile of antiviral drugs (to which healthcare workers would have priority access for treatment) and a stockpile of H5N1 vaccine which might be offered to healthcare workers if the risk of an H5N1 derived pandemic increased. However it is nevertheless acknowledged that the evidence might change (qualitatively and quantitatively) in the future, and policy must therefore be kept under review. Significant practical issues exist with regard to implementing current guidance across NHS (logistics and training). There is an urgent need for R&D to resolve mode of transmission. In conclusion:
 - o support existing DH/HPA/HSE infection control guidance
 - keep evidence base under review
 - o support definitive R&D on influenza transmission
 - o acknowledge challenging communication issues given:
 - queries received about existing DH pandemic healthcare mask guidance;
 - incomplete data regarding influenza transmission routes;
 - expected elevated morbidity and mortality during a pandemic;
 - that faced with same inadequate evidence, some countries have already adopted a more risk averse approach and made recommendations for respirator use in all close healthcare contacts.
- 55. With regard to which healthcare procedures are truly aerosol generating, revised WHO infection control guidance regarding high-risk aerosol-generating procedures should be consulted (Annex A of *Infection prevention and control of epidemic- and pandemic-prone acute respiratory diseases in health care* http://www.who.int/csr/resources/publications/WHO_CD_EPR_2007_6/en/index.html).
- 56. **Surgical mask use by general public:** Extremely limited data available and none which lend concrete support to this intervention. An overall impression does emerge, from those studies that examined multiple interventions, that increased utilisation of hygiene measures, such as handwashing, surface cleaning and mask wearing, may reduce the risk of acquiring a respiratory viral infection. Although the specific evidence base regarding use of face masks by the general public is too uncertain and too limited to firmly support face masks for use by the public during an influenza pandemic, a protective effect cannot be

excluded and a permissive approach is recommended. Very significant issues remain in relation to logistics, safe use by the public, communication and engendering a false sense of security. ECDC and WHO do not support the use of masks by the general public, but both acknowledge that it will happen and adopt permissive stances. In conclusion:

- o permissive approach to voluntary mask use by public
- but no recommendation or encouragement; however, information would need to be provided about correct usage if public chooses to wear
- maintain strong communication strategy around voluntary self isolation, respiratory etiquette, hand hygiene and household surface cleaning, as package of measures
- acknowledge challenging communication issues, given that some workers in public settings (eg transit, retail) may be wearing masks provided by employers.
- 57. **Surgical mask use by symptomatic persons outside the home:** Some data exist to support masking of persons with symptoms as a means of containing respiratory secretions, thereby reducing environmental contamination and onward transmission. This policy is already applied within the Pandemic Infection Control Guidance for Healthcare Settings for patients in public waiting areas. It is clearly more desirable for persons with symptoms to be masked in public places than unmasked. However the desirability of this needs to be weighed carefully against the communication difficulties and logistic obstacles that might be encountered. In conclusion:
 - policy could be justified on scientific grounds and conceptual similarity to healthcare settings
 - o risk of undermining main message about voluntary self isolation
 - needs to be careful weighed against communication difficulties and logistic obstacles.
- 58. **Surgical mask use by symptomatic persons inside the home:** Some data exist to support masking of persons with symptoms as a means of containing respiratory secretions, thereby reducing environmental contamination and onward transmission. This policy is already applied within the Pandemic Infection Control Guidance for Healthcare Settings for patients in public waiting areas. WHO interim guidelines (Annex K) recommend that when close contact care must be provided with an ill person in the home setting, the ill person should cover their mouth/nose with hands or other materials (eg tissues, handkerchiefs, or if available, a cloth or medical mask)

<u>http://www.who.int/csr/resources/publications/WHO_CD_EPR_2007_6/en/index.html</u>) Communication and logistics could be problematic, as the main message is voluntary selfisolation (living in another room or part of the house until symptoms resolved). Almost impossible to apply to children. In conclusion:

- policy could be justified on scientific grounds and conceptual similarity to healthcare settings
- needs to be careful weighed against communication difficulties and logistic obstacles
- o physical isolation more important than masking
- masking would be advocated for face-to-face contact situations but not for continuous wear in the home.
- 59. **Surgical mask use by carers/lay attendants in home/household settings:** This situation is the most analogous to close contact between healthcare workers and their

patients. Annex K of the WHO interim guidelines recommend that if available, caregivers should wear a medical mask or the best available protection against respiratory droplets when in close contact with the ill person in the home setting

(http://www.who.int/csr/resources/publications/WHO_CD_EPR_2007_6/en/index.html)

However there are significant training and logistic issues and concerns about safe use by untrained carers, engendering a false sense of security and diverting attention away from hand washing, respiratory etiquette and surface cleaning. Nevertheless there are other relevant considerations for this option:

- It would be an alternative for parents who could not mask their symptomatic children;
- It might encourage home care of non-critically ill persons at home rather than hospitals;
- It might be appropriate for households known to contain high-risk persons who have to act as carers;
- It acknowledges that there is a legitimate role for masks in preventing exposure in some situations but not in others.

In conclusion:

- o conceptual similarity to healthcare settings
- needs to be weighed against communication, training, and logistic difficulties
- maintain strong communication strategy around voluntary self isolation, respiratory etiquette, hand hygiene and household surface cleaning as package of measures in the home
- masking would be advocated for face-to-face contact situations but not for continuous wear in the home.

Possible future issues to be noted:

- 60. HPA has not raised the issue of the use of respirators (as opposed to surgical masks) by the public at this time firstly, because it is unlikely that the public would be exposed to aerosol generating procedures and secondly, given the significant issues already apparent within the NHS regarding availability, training and fit-testing of respirators, such an approach would raise major feasibility issues.
- 61. It should finally be noted that some experts have advocated that "immunocompromised persons", persons with chronic conditions or other factors that increase likelihood of elevated risk of morbidity and mortality (ie groups for whom seasonal flu vaccine is recommended) might wish to consider use of masks in public places whilst asymptomatic, even if more widespread general use is not supported.

References

- 1. Balazy A, Toivola M, Adhikari A, Sivasubramani SK, Reponen T, Grinshpun SA. Do N95 respirators provide 95% protection level against airborne viruses, and how adequate are surgical masks? Am J Infect Control 2006;34 (2):51-7.
- 2. Brankston G, Gitterman L, Hirji Z, Lemieux C, Gardam M. Transmission of influenza A in human beings. Lancet Infect Dis 2007;7(4):257-65.
- 3. Cummings KJ, Cox-Ganser J, Riggs MA. Respirator donning in post-hurricane New Orleans. Emerg Infect Dis [serial on the Internet] 2007;13(5).
- 4. Davies KJ, Herbert AM, Westmoreland D, Bagg J. Seroepidemiological study of respiratory virus infections among dental surgeons. Br Dent J 1994;176(7):262-5.
- 5. Duguid JP. The size and duration of air-carriage of respiratory droplets and droplet nuclei. J Hyg 1946;4:471-80.
- 6. Hall CB, Douglas RG Jr. Nosocomial respiratory syncytial viral infections. Should gowns and masks be used? Am J Dis Child 1981;135(6):512-5.
- 7. Inouye S, Matsudaira Y, Sugihara Y. Masks for influenza patients: measurement of airflow from the mouth. Jpn J Infect Dis 2006;59(3):179-81.
- 8. Lau JT, Tsui H, Lau M, Yang X. SARS transmission, risk factors, and prevention in Hong Kong. Emerg Infect Dis 2004;10(4):587-92.
- 9. Lawrence RB, Duling MG, Calvert CA, Coffey CC. Comparison of performance of three different types of respiratory protection devices. J Occup Environ Hyg 2006;3(9):465-74.
- 10. Lo JY, Tsang TH, Leung YH, Yeung EY, Wu T, Lim WW. Respiratory infections during SARS outbreak, Hong Kong, 2003. Emerg Infect Dis 2005;11(11):1738-41.
- 11. Loeb M, McGeer A, Henry B, Ofner M, Rose D, Hlywka T et al. SARS among critical care nurses, Toronto. Emerg Infect Dis 2004;10(2):251-5.
- 12. Loudon RG, Roberts RM. Droplet expulsion from the respiratory tract. Am Rev Respir Dis 1967;95(3):435-42.
- 13. Nicas M, Nazaroff WW, Hubbard A. Toward understanding the risk of secondary airborne infection: emission of respirable pathogens. J Occup Environ Hyg 2005;2(3):143-54.
- 14. Papineni RS, Rosenthal FS. The size distribution of droplets in the exhaled breath of healthy human subjects. J Aerosol Med 1997;10(2):105-16.
- 15. Roy CJ, Milton DK. Airborne transmission of communicable infection--the elusive pathway. N Engl J Med 2004;350(17):1710-2.
- 16. Salgado CD, Farr BM, Hall KK, Hayden FG. Influenza in the acute hospital setting. Lancet Infect Dis 2002;2(3):145-55.

- 17. Seto WH, Tsang D, Yung RW, Ching TY, Ng TK, Ho M et al. Effectiveness of precautions against droplets and contact in prevention of nosocomial transmission of severe acute respiratory syndrome (SARS). Lancet 2003;361(9368):1519-20.
- 18. Tellier R. Review of aerosol transmission of influenza A virus. Emerg Infect Dis 2006;12(11):1657-62.
- 19. Wu J, Xu F, Zhou W, Feikin DR, Lin CY, He X et al. Risk factors for SARS among persons without known contact with SARS patients, Beijing, China. Emerg Infect Dis 2004;10(2):210-6.



