Face Mask Use in households and health care workers

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Background

• During an influenza pandemic, shortages of antivirals and delays in vaccine development mean that non pharmaceutical measures will play a major role.

• Many countries issue sweeping health guidelines on mask use in the absence of high level supporting evidence.

• Until recently, the only data supporting mask use are retrospective, observational data from outbreaks such as SARS.

• These data do not allow differentiation of the effect of other factors such as infection control, handwashing and social distancing.
• Health care workers – front line responders with repeated, multiple exposures.
• High priority for prevention
• Vulnerable due to delays in vaccine and shortages of/resistance to antivirals
• No level 1 evidence on N95 vs surgical masks
• Experimental evidence is not a substitute for clinical efficacy data
• In 2006, the CDC and WHO identified clinical efficacy evidence of PPE as a gap in knowledge required to inform pandemic planning.
Face Mask Use and Control of Respiratory Virus Transmission in Households

C. Reina MacIntyre, Simon Cauchemez, Dominic E. Dwyer, Holly Seale, Pamela Cheung, Gary Brown, Michael Fasheh, James Wood, Zhanhai Gao, Robert Booy, and Neil Ferguson

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Learning Objective

Upon completion of this activity, participants will be able to:

- Identify the role of masks used to control the spread of infectious respiratory pathogen transmission.
- Identify the most frequent clinical and laboratory features of common acute respiratory infections.
- Conduct a thorough risk assessment for individuals with severe pre-existing conditions.
- Discuss the critical role of mask use in preventing spread of infectious respiratory infections.

Editor

S. McMillan, Medscape, Inc.

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Many countries are stockpiling face masks for use as a non-pharmaceutical intervention to control virus transmission during an influenza pandemic. We conducted a prospective, cluster randomized trial comparing surgical masks, non-fitted P2 masks, and no mask in prevention of influenza-like illness (ILI) in households. Mask use adherence was self-reported. During the 2005 and 2007 winter seasons, 200 exposed adults from 143 households who had been exposed to a child with clinical respiratory illness were recruited. We found that adherence to mask use significantly reduced the risk for ILI-associated infection but <50% of participants wore masks most of the time. We concluded that household use of face masks is associated with low adherence and is ineffective for controlling seasonal respiratory diseases. However, during a severe pandemic when use of face masks might be greater, transmission in households might be reduced.

Self-reported. During the 2005 and 2007 winter seasons, 200 exposed adults from 143 households who had been exposed to a child with clinical respiratory illness were recruited. We found that adherence to mask use significantly reduced the risk for ILI-associated infection but <50% of participants wore masks most of the time. We concluded that household use of face masks is associated with low adherence and is ineffective for controlling seasonal respiratory diseases. However, during a severe pandemic when use of face masks might be greater, transmission in households might be reduced.

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Aims

• To determine the efficacy of surgical masks and P2 masks compared to control (no mask) in households on the interruption of transmission of influenza and other respiratory viruses.
Rationale

- Other respiratory viruses have similar mode of transmission
- Relying on influenza alone reduces the power of the study and subjects it more to seasonal variations that may occur
- Proof of principle
Study Design

• Prospective cluster randomized, controlled trial
• Families of index children with influenza like illness (ILI) were the unit of randomization.
• One index case within the household (the child).
• Random allocation of families to one of three groups: surgical, P2, and control groups.
• Measure incidence of ILI and lab confirmed RV infection per arm and efficacy of masks in prevention of RV infection.
Participants and Setting

• Sydney, winter/spring of 2006 and 2007

• Families of children presenting to the emergency department and general practice with ILI: a temp of >37.8 and at least one respiratory symptom.

• The child is the index case in the family.

• At least 2 well adults in household.
Recruitment of Participants

• A nose throat viral swab was obtained for PCR testing for influenza and other respiratory viruses.

• A diary card was given to each adult in the family to record temperature and level of compliance with mask use while in same room as index case.
Follow up

• Each family was then followed up by daily phone calls for a period of one week to ascertain if there were any secondary cases.
• In the case of secondary infection, the family was followed for an additional week.
• Secondary cases – nurse home visit, nose and throat swabs collected and PCR tested for influenza and other respiratory viruses.
• Several measures were used to measure adherence with mask use.
Outcomes Analysis

- An intention to treat analysis and subgroup analysis to look at the impact of masks.
Main outcomes

1. CRI and laboratory diagnosis of influenza or other respiratory viruses (as determined from nasopharyngeal swabs)

2. Impact on CRI/flu transmission in household
Results

145 Families (290 adults)

Surgical Group: 47 (94)
94 adults

P2 Group: 46 (92)
92 adults

Control Group: 52 (104)
104 adults
Table 1. Demographic characteristics of each household by arm of randomization in the study, Sydney, New South Wales, Australia, 2006 and 2007 winter influenza seasons.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control group, no. (%), n = 50</th>
<th>Surgical mask group, No. (%), n = 47</th>
<th>p value</th>
<th>P2 mask group, No. (%), n = 46</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Living arrangement</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reside in house</td>
<td>38 (76)</td>
<td>32 (68)</td>
<td>0.39</td>
<td>33 (72)</td>
<td>0.64</td>
</tr>
<tr>
<td>&gt;4 persons in house</td>
<td>13 (26)</td>
<td>18 (38)</td>
<td>0.20</td>
<td>19 (41)</td>
<td>0.11</td>
</tr>
<tr>
<td>≥3 adults in house</td>
<td>8 (16)</td>
<td>11 (23)</td>
<td>0.36</td>
<td>12 (26)</td>
<td>0.23</td>
</tr>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian race*</td>
<td>28 (56)</td>
<td>20 (43)</td>
<td>0.18</td>
<td>17 (37)</td>
<td>0.06</td>
</tr>
<tr>
<td>Both adults work</td>
<td>28 (56)</td>
<td>25 (53)</td>
<td>0.78</td>
<td>27 (59)</td>
<td>0.79</td>
</tr>
<tr>
<td>Smoker in house</td>
<td>12 (24)</td>
<td>12 (26)</td>
<td>0.86</td>
<td>4 (9)</td>
<td>0.046</td>
</tr>
<tr>
<td>Index child fully immunized</td>
<td>45 (90)</td>
<td>45 (96)</td>
<td>0.28</td>
<td>39 (85)</td>
<td>0.44</td>
</tr>
<tr>
<td>Index child attends childcare</td>
<td>37 (74)</td>
<td>34 (72)</td>
<td>0.85</td>
<td>27 (59)</td>
<td>0.11</td>
</tr>
<tr>
<td>Influenza vaccination</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Index child</td>
<td>1 (2)</td>
<td>1 (2)</td>
<td>0.97</td>
<td>0</td>
<td>0.34</td>
</tr>
<tr>
<td>1 adult vaccinated</td>
<td>2 (4)</td>
<td>2 (4)</td>
<td>0.95</td>
<td>0</td>
<td>0.17</td>
</tr>
<tr>
<td>Duration of child sickness†</td>
<td>4</td>
<td>5</td>
<td></td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Siblings reporting illness</td>
<td>3 (6)</td>
<td>1 (1)</td>
<td>0.34</td>
<td>0</td>
<td>0.09</td>
</tr>
</tbody>
</table>

*Information relates to the participating adult interviewed.
†Median no. days.
Results

145 Families (290 adults)

- Surgical Group: 47 (94)
  - 94 adults
    - 21 sick adults (22%)

- P2 Group: 46 (92)
  - 92 adults
    - 14 sick adults (14%)

- Control Group: 52 (104)
  - 104 adults
    - 16 sick adults (16%)

By ITT, no significant difference between the arms by families or individuals
On day one of mask use, 36/94 (38%) of surgical mask users and 42/90 (46%) of P2 mask users stated that they were wearing the mask “most or all” of the time.

remainder using it rarely or never.

Adherence dropped to 29/94 (31%) and 23/90 (25%) respectively by day 5 of mask use.

No significant difference between surgical and P2.
Compliance with mask use by day over 5 consecutive days

Day of mask wearing

Day 1
Day 2
Day 3
Day 4
Day 5

% compliant

Surgical
P2
Table 2. Characteristics of adherent versus nonadherent mask wearers in the study, Sydney, New South Wales, Australia, 2006 and 2007 winter influenza seasons.*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Fully adherent mask users, no. (%)</th>
<th>Nonadherent mask users, no. (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Living arrangement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reside in house</td>
<td>22 (73)</td>
<td>108 (69)</td>
<td>0.66</td>
</tr>
<tr>
<td>&gt;4 persons in house</td>
<td>11 (37)</td>
<td>64 (41)</td>
<td>0.66</td>
</tr>
<tr>
<td>≥3 adults in house</td>
<td>3 (10)</td>
<td>43 (28)</td>
<td>0.04</td>
</tr>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian race†</td>
<td>10 (33)</td>
<td>29 (19)</td>
<td>0.07</td>
</tr>
<tr>
<td>Working adult</td>
<td>22 (73)</td>
<td>118 (76)</td>
<td></td>
</tr>
<tr>
<td>Smoker in house</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily handwashing</td>
<td>14 (45)</td>
<td>54 (34)</td>
<td>0.21</td>
</tr>
<tr>
<td>Use of soap when handwashing</td>
<td>13 (43)</td>
<td>65 (42)</td>
<td>0.87</td>
</tr>
<tr>
<td>Index child fully immunized</td>
<td>15 (50)</td>
<td>69 (44)</td>
<td>0.56</td>
</tr>
<tr>
<td>Index child attends childcare</td>
<td>6 (20)</td>
<td>51 (33)</td>
<td>0.17</td>
</tr>
<tr>
<td>Influenza vaccination</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Index child</td>
<td>0</td>
<td>1 (0.5)</td>
<td>0.66</td>
</tr>
<tr>
<td>Adult 1</td>
<td>0</td>
<td>2 (1)</td>
<td>0.53</td>
</tr>
<tr>
<td>Adult 2</td>
<td>0</td>
<td>2 (1%)</td>
<td>0.53</td>
</tr>
<tr>
<td>Median days of child sickness</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Siblings reporting illness</td>
<td>0</td>
<td>1 (0.5)</td>
<td>0.66</td>
</tr>
</tbody>
</table>

*Adherence to mask use and handwashing measured by daily self-reports and exit interviews.
†Information relates to the participating adult interviewed.
Incidence of respiratory illness by arm of randomisation by intention-to-treat and by compliance
Table 5. Estimates of hazard ratios for ILI in the study*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Global effect of mask use</th>
<th>Effect per mask type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hazard ratio (95% CI)</td>
<td>p value</td>
</tr>
<tr>
<td>1-d incubation period</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adherence to use of surgical or P2 mask†</td>
<td>0.26 (0.09–0.77)</td>
<td>0.015‡</td>
</tr>
<tr>
<td>Adherence to use of surgical mask†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adherence to use of P2 mask†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. adults</td>
<td>1.07 (0.66–1.71)</td>
<td>0.80</td>
</tr>
<tr>
<td>No. siblings</td>
<td>0.86 (0.55–1.35)</td>
<td>0.52</td>
</tr>
<tr>
<td>Index patient &lt;5 y of age</td>
<td>0.88 (0.41–1.89)</td>
<td>0.75</td>
</tr>
<tr>
<td>Fraility§</td>
<td>0.005‡</td>
<td></td>
</tr>
<tr>
<td>2-d incubation period</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adherence to use of surgical or P2 mask†</td>
<td>0.32 (0.11–0.98)</td>
<td>0.046‡</td>
</tr>
<tr>
<td>Adherence to use of surgical mask†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adherence to use of P2 mask†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. adults</td>
<td>1.13 (0.71–1.81)</td>
<td>0.60</td>
</tr>
<tr>
<td>No. siblings</td>
<td>0.80 (0.51–1.27)</td>
<td>0.34</td>
</tr>
<tr>
<td>Index patient &lt;5 y of age</td>
<td>1.02 (0.46–2.24)</td>
<td>0.96</td>
</tr>
</tbody>
</table>

*ILI, influenza-like illness; CI, confidence interval.
†Time-dependent variable.
‡p < 0.05 significant (indicates that the outcome for 1 person is correlated with the outcome of other persons in the household).
§This term measures if the clustering of subjects in households is relevant to quantify the risk of ILI infection.
### Adjusted analysis of mask users by level of compliance, outcomes ILI.

<table>
<thead>
<tr>
<th>Reported mask use</th>
<th>Total no. of adults</th>
<th>No of sick adults</th>
<th>RR</th>
<th>Lower</th>
<th>Upper</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All mask, fully compliant</td>
<td>29</td>
<td>1</td>
<td>0.16</td>
<td>0.02</td>
<td>1.12</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>All masks, compliant 4/5 days</td>
<td>42</td>
<td>1</td>
<td>0.11</td>
<td>0.02</td>
<td>0.81</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>All masks, compliant 3/5 days</td>
<td>50</td>
<td>2</td>
<td>0.19</td>
<td>0.05</td>
<td>0.77</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>All masks, compliant day 1</td>
<td>86</td>
<td>9</td>
<td>0.5</td>
<td>0.26</td>
<td>0.99</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Control group</td>
<td>202</td>
<td>42</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Reported problems using masks

Table 3. Problems with face use reported by participants in the study, Sydney, New South Wales, Australia, 2006 and 2007 winter influenza seasons.

<table>
<thead>
<tr>
<th>Reported problem</th>
<th>Surgical mask users, no. (%)</th>
<th>P2 mask users, no. (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>46 (49)</td>
<td>42 (46)</td>
<td>0.66</td>
</tr>
<tr>
<td>Uncomfortable</td>
<td>16 (17)</td>
<td>14 (15)</td>
<td>0.74</td>
</tr>
<tr>
<td>Forgot to wear it</td>
<td>8 (9)</td>
<td>8 (9)</td>
<td>0.96</td>
</tr>
<tr>
<td>Child did not like it</td>
<td>6 (6)</td>
<td>8 (9)</td>
<td>0.55</td>
</tr>
<tr>
<td>Other</td>
<td>18 (19)</td>
<td>20 (22)</td>
<td>0.66</td>
</tr>
</tbody>
</table>
Conclusion

• No statistically significant difference between any of the 3 arms by ITT
• No difference in compliance or reported adverse events between surgical and P2
• Non-fit tested P2 and surgical masks protective in compliant users - compliant users 4 times more likely to be protected against RVs
• Difference between P2 and surgical?
• Efficacy may be better with proven infections
• In a pandemic or EID, compliance would be expected to improve and masks may provide benefit to the community.
• First RCT to show a positive effect of masks
The first trial of surgical masks versus fit and non-fit tested N95 masks in the prevention of respiratory virus infection in hospital workers in China

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2. The Beijing Centers for Disease Control and Prevention, Beijing, China.
3. MRC Center for Outbreak Analysis and Modelling, Department of Infectious Disease Epidemiology, Imperial College London, London, United Kingdom.
4. Institute for Clinical Pathology and Medical Research, Westmead Hospital, Sydney, Australia.
• No published randomized clinical trials (RCTs) comparing the efficacy of surgical and N95 masks
• Hospital health care workers (HCWs) are key to effective pandemic response and the capacity of health care systems
• Face masks are one of the key non-pharmaceutical interventions for protection of HCWs.
- HCW protection
- Protection of vulnerable patients
Aims

- To compare the efficacy of surgical masks, N95 masks (fit tested) and N95 masks (non fit tested), compared to controls (no mask) in health care workers.
Methods


- **Intervention:** Participants wore masks for 4 weeks during the winter and were followed for development of respiratory illness for 5 weeks. Symptomatic participants underwent testing for respiratory viruses including influenza.
• Arm 1: Fit tested N95 masks
• Arm 2: Non-fit tested N95 masks
• Arm 3: Surgical masks
• (arms 1-3 cluster randomised)
• Arm 4: Control (convenience)
Beijing

- Pilot work identified that Australian HCWs have very low adherence to masks (10%*)
- Required numbers for adequate power, given low adherence rates, unfeasible
- High adherence in China made Beijing a suitable setting to conduct this trial
- Collaboration with Beijing CDC
• **Main outcome measures:** Included clinical respiratory illness (CRI), influenza-like illness (ILI), laboratory confirmed respiratory virus infection, and laboratory-confirmed influenza.
• Full results to be presented at Interscience Conference on Antimicrobial Chemotherapy (ICAAC) Sept 12-15th 2009