Reviewer's report

Title: The role of facemasks and hand hygiene in the prevention of influenza transmission in households: results from a cluster randomised trial; Berlin, Germany, 2009-2011.

Version: 1 Date: 28 November 2011

Reviewer: Holly Seale

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Minor Essential Revisions

This study aims to investigate the efficacy, acceptability and tolerability of NPI in households with influenza index patients. While the study employs the same methodologies previously used in a number of studies, the body of literature around this subject is still not comprehensive- so is very useful.

Background

1. It might be worth highlighting that other groups have recently highlighted the need for more research in this area including the Institute of Medicine of the National Academies (Committee on Personal Protective Equipment for Healthcare Workers During an Influenza Pandemic, 2010)

2. When referring to the studies conducted to date, I think it is important to include a sentence which outlines that the study designs have been different and that only one study has compared masks/respirators while the other studies have focused on comparing different interventions.

3. In regards to the following sentence (‘In all publications, it was hypothesised that the effect…’) could you include some of the data from the observational studies which examine the use of the interventions (especially mask use) during SARs or pandemic H1N1.

Methods

4. How many recruitment sites were included in the study and who was responsible for recruitment?

5. How were you able to blind the physicians in the randomisation process? Did they not need to distribute the masks/hand rub out to the parents?

6. Who determined the fit of the mask for the child? Was this done at recruitment? Or was it during the follow up visit?

7. In each of the households, were there a maximum number of people who could participate? If there were not present at the initial recruitment visit, how were they consented?
8. How many masks were participants provided with on a daily basis? When were they instructed to change them?

9. Can you please clarify what you mean in the following sentence: 'When household members developed fever…..they were asked to adopt the same preventative behaviour…'

10. Can the authors please revise the paragraph at the bottom on page 8. It is currently a series of short sentences. Also, can you please provide further information about the use of antiviral therapy- was this provided to the index case or to the families? If it was provided to the families- information about the impact of its use should be included in the results (beyond the table).

11. Did the participants know about the reimbursement at the time of recruitment? Especially as it is quite a large reimbursement.

12. Did you specify the times where participants were not required to wear their masks (if any)? Previous studies have stated meal times, when sleeping or when the index case was away from the residence.

13. Have you tested whether there was any differences in quality and efficacy (in lab controlled conditions) between the two brands of masks used in the study? Why did you decide to use two different brands?

14. Can you please provide the reference for the WHO definition of ILI

15. It would be useful if the authors used some more headings in the methods section: objectives, outcomes, randomisation, blinding, statistical methods etc. Also, a table outlining the components of the different arms would also be useful.

Results

16. It would be better if the information regarding the virus transmission was reported separately and that the first paragraph was dedicated to report the statistically significant differences between the arms.

17. Can you please comment on symptom onset to randomisation- what was the range in time/median etc.

Discussion

18. In regards to your statement about influenza B transmission (page 30)- has there been any studies to support this?

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, but I do not feel adequately qualified to assess the
statistics.

**Declaration of competing interests:**

'I declare that I have no competing interests'