Author's response to reviews

Title: STOPFLU: Is it Possible to Reduce the Number of Days Off in Office Work by Improved Hand-Hygiene?

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Author's response to reviews:

Authors’ response to the points raised by the reviewers

Title: STOPFLU: Is it Possible to Reduce the Number of Days Off in Office Work by Improved Hand-Hygiene?

Version: 2 Date: 29 April 2010

Reviewer: Gordon Doig

Reviewer's report:

This is a very interesting undertaking. Congratulations. Could you please add the following details:

1. Please provide details regarding the actual process used to randomize and achieve balance. Were matched-clusters block randomised? Minimized? etc. Please reveal how the sequence was generated.

Details, including an equation of calculating the transmission risk score, regarding the cluster matching and randomization have been included in the text on chapter “Cluster matching and randomization” and highlighted with yellow. Also a reference has been added.
2. Please provide references to the appropriate cluster RCT methodological literature to support the selection of each statistical test identified as to be used for analysis of primary and secondary outcomes. After a thorough read of the literature, with a special focus on the text book by Donner and Klar (Donner A, Klar N. Design and Analysis of Cluster Randomization Trials in Health Research. New York, NY: Oxford University Press; 2000.) you may find a simple analytic approach that provides more power than a t-test comparing pooled event rates within clusters.

We are grateful for the referee for introducing a text book to us that has given valuable advice in strengthening the current manuscript and also for the further analysis of the study. We have described our choice of statistical methods in more detail in chapter “Study endpoints and outcome measures” and included references supporting our view.

3. Please provide an explicit list of all variables that will be assessed for baseline balance. For example, your 'predicted risk of infection' model might be decomposed into constituent parts (number of children etc) with each assessed for balance. Please provide explicit thresholds for determining a variable to be in imbalance and report what will be done when a variable is in imbalance.

A list of variables taken into account when matching the clusters has been provided in chapter “Cluster matching and randomization“ and Appendix 1. We feel that determining explicit thresholds for each variable would be artificial as it is not explicitly known, how much each of the variables actually affects the risk of infectious disease transmission. Furthermore, as the employees in any given working unit will show some extent of natural turnover, we prefer, instead of determining contrived thresholds, to assess the stability of the baseline balance with a repeated survey for contagion risks, as explained in the manuscript in chapter “Evaluation of matching and comparability between the arms”, and to describe the potentially discovered incongruities when analyzing the results. Again, because turnover as such is not the critical element but the "risk increment" is associated with individuals moving out from or into the cluster, we can judge the potential bias only afterwards.