Author's response to reviews

Title: Protocol for a randomised controlled trial to compare opt-in and opt-out parental consent for childhood vaccine safety surveillance using data linkage

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Author's response to reviews: see over
Dear Editor,

RE: MS: 5821322344488407. Changes required: Due 9 November 2010

We thank you for your review. Please find attached our revised manuscript submitted with our revisions documented below.

Your email on 26 October 2010 required three changes:

1. I am puzzled by the projected 25% missing in “opt-in” – I would assume that people who did not opt-in have by not responding effectively said “no”. Perhaps I misunderstood what the authors were saying, but I would recommend that they clarify what they mean by missing.

We confirm that the sample size estimation for the primary outcome has an error in the calculation for the opt-in arm only. As you rightly observed, there is no need to further inflate the sample size in the opt-in arm to allow for non-response since such people will simply not opt-in and this will be reflected in the participation rate. We have checked (and are reassured) that the sample size estimation for the secondary outcome, which was used to set our recruitment goal, is correct. In terms of text corrections, we have deleted the sentence ‘We further allowed for 25% non-response in the opt-in arm…’ and altered a following sentence to ‘Thus, the sample size for the primary outcome required 344 participants in each arm: a total of 688 participants.’

2. They plan to use multiple imputation for some of the missing data – they need to be more specific.

We have included three new sentences detailing the analysis plan for missing data. ‘Missing data are likely… A total of 50 imputed datasets will be generated using the package mi in Stata statistical software [36]. Depending on the pattern of missing values, we will use sequential univariate conditional distributions or a multivariate normal method, using socio-demographic and other background variables as predictors. The quality of the imputations will be evaluated by checking how reasonable the imputed data are and testing the fit of the missing-data models.’

3. The writing is clear. In some places, however, pronouns and their antecedents do not match and in some places the punctuation is off.

The paper has been edited to improve the grammar and punctuation, as indicated by track changes. Figure 1 has been formatted to achieve symmetry and its text been changed to the past tense. Also, the Chief Investigator has requested to be last in the authorship list.

We look forward to a decision on the manuscript in due course. Please contact me if any further amendments are required.

Yours sincerely
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