Author’s response to reviews

Title: Benefits and harms of the human papillomavirus (HPV) vaccines: systematic review with meta-analyses of trial data from clinical study reports

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Author’s response to reviews:

Dear Dr. Jørgensen,

Thank you for the clarifications and the changes that you have made to the manuscript and please accept my apologies for the delay in responding to you. Because of the novel approach used in your review (i.e. basing the findings only on trials for which clinical study reports were available), I felt it was important to seek a second opinion from the journal's senior editors. Whilst this has inevitably led to delay, I felt that it was necessary to ensure the highest reporting standards.

LJ: Thank you very much.

The senior editors and I agree that because of the novel approach used, your manuscript needs to be very clear about what it has NOT included in the analyses. We would therefore request that you include an explicit statement in the methods section stating that in the event of no CSR being available (for an otherwise eligible trial), you did not plan to include data from the trial publication.

LJ: Thank you - we have inserted an explicit statement in the methods section stating that in the event of no CSR being available (for an otherwise eligible trial), you did not plan to include data from the trial publication.

Furthermore, in the results section, the senior editors suggest the addition of a statement along the following lines: "There were X published trials identified in the literature searches, which included a total of Y participants (z% of the total randomised participants) that did not have a corresponding CSR. These trials were not included in the review or analyses." (This would be similar to your very clear statement that ~20% of data are not included on account of not using CSRs for which a data sharing agreement was required). Please also state the % of the total randomised participants on which your analyses are based (i.e. including all eligible trials in your baseline).
LJ: We have inserted the requested numbers.

One final request, which the senior editors have reiterated, is to amend the COI statement to include the full name, not just the abbreviation, for the IFICA (International Federation for Injured Children and Adults) and the associated URL (www.ificaeurope.org).

LJ: We have amended the COI statement.

Assuming you are able to make these minor additions or edits, as suggested by the senior editors, I see no reason for the manuscript not to proceed to publication.

LJ: Thank you very much.