Reviewer's report

Title: Benefits and harms of the human papillomavirus (HPV) vaccines: comparison of trial data from clinical study reports with corresponding trial register entries and journal publications

Version: 0 Date: 26 Sep 2018

Reviewer: Bryony Dawkins

Reviewer's report:

The aim of this paper is to examine the impact of reporting bias between different documents which provide details on any given clinical trial. This was done through a systematic review of trial data relating to trials of human papillomavirus (HPV) vaccines. This is an important area and this article effectively draws attention to the practices of some organisations of selectively publishing results from trials which is potentially damaging to research initiatives but ultimately, and most importantly, can be damaging to patients.

The article is well written and the methods used for the analysis seem appropriate and are detailed appropriately within the manuscript, accounting for relevant nuances relating to best practices.

I would therefore recommend the article for publication. However, the following edits should be considered to improve clarity.

1. The main objective of the analysis conducted is to identify the importance of reporting bias between trial data reported in different documents which provide details of the same trial. However, the title of this article indicates that the paper may present results of a systematic review of the benefits and harms of HPV vaccines - which I believe is published elsewhere. While the analysis uses data from HPV vaccine trials the focus is actually on the comparison of trial documents. I would therefore recommend the authors consider altering the wording/word order of the title to make the purpose of the article clearer and so as not to mix the purpose of this paper with that of another.
2. Within the article the 'benefits' and 'harms' of HPV vaccines are referred to at various points. However, what exactly is meant by 'benefits' and 'harms' is not properly defined within the methods section. Instead, within the methods section the authors instead refer to their chosen 'outcomes' and these are listed without making reference to benefits or harms. It is, of course, clear with some understanding of this clinical data, and also with some reflection of how these outcomes are presented in the tables and figures, which are the benefits and which are the harms. Yet, for the benefit of any non-clinical reader, and also to help with clarity in general, I would recommend revising the text within this section of the methods to make clearer the definition of benefits and harms and be clear on which of the chosen outcomes are being reviewed as benefits and which as harms.

3. It seemed that some of the discussion points could have been made more strongly. For example, the point about clinical study reports being incomplete and that some data may have been left out. This is an important point and some evidence on how extensive this problem could be is given with the estimation of potentially 40,000 pages remaining undisclosed. However there is no discussion of the implications of this. Is there any indication of what might have been left out or what impact the missing information might have? I realise this is potentially difficult to comment on but nevertheless feel some effort could be made to indicate why this is a big problem.

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