Author's response to reviews

Title: Publication practices and standards: recommendations from GlaxoSmithKline Vaccines' author survey

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Version: 3 Date: 15 September 2014

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SUBMISSION TO TRIALS: RESPONSES TO REVIEWER’S COMMENTS

Ms. Ref. No.: 1222622511121910

Publication practices and standards: recommendations from GlaxoSmithKline Vaccines' author survey. Isabelle Camby, Véronique Delpire, Laurence Rouxhet, Thomas Morel, Christine Vanderlinden, Nancy Van Driessche and Tatjana Poplazarova

Reviewer’s report:

Major compulsory revisions: None

Minor essential revisions:

1. The publication mentions that there was a protocol for the study, but the protocol is not provided. Good practice would dictate making it available as supplementary material.

Response: As stated at the end of the Methods section, this manuscript presents the results of a voluntary survey and did not involve experimental research on human subjects. Therefore, development of a full study protocol according to Good Clinical Practice was not required. An initial proposal for study conduct was developed following discussions between Deloitte and GSK Vaccines, which is provided in the Appendix to this cover letter. Deloitte have agreed that this document can be provided to readers upon request. Wording to this effect has been added to the first paragraph under Methods/’The survey questionnaire’:

‘The initial proposal document for conduct of the study can be provided upon request.’

2. Not all questions from the questionnaire have been reported (eg questions 35-38). Either all questions should be reported, or some explanation should be given of why the authors feel only partial reporting is appropriate.

Response: Not all questions from the questionnaire were included for various reasons. As explained in the second paragraph of the Methods section ‘The survey questionnaire’, seven open-ended questions (questions 14, 17, 20, 29, 41, 44, 49) that related to publication practices were not included. These aimed to obtain opinions on topics such as ways to improve specific publication practices. Since the responses were qualitative and diverse in nature, we felt that their inclusion would not be of benefit to readers. Other questions were not included for similar reasons; questions 35 to 38 related to specific issues associated with user satisfaction with
Datavision and again we felt that their inclusion would be of limited interest. We made the decision to not include responses to six questions that related to congress-related activities (questions 24 to 29) in order to focus on publication practices. To clarify the exclusion of these questions, the following text has been added to the end of the paragraph:

‘Four questions that aimed to obtain further information on user satisfaction with Datavision™ and, in order to focus solely on publication practices, six questions on congress-related activities were not included.’

3. The explanation of the sample size in the first paragraph of "Survey participants and conduct" section is confusing. It makes it sound as if some calculation was done which required 15% of 1300 authors for a large enough sample. However, it is not clear that that calculation was done. If it was done, it should be presented. If there was another reason for choosing 1300 authors as the sample size (for example if that was the entire population of authors that GSK Vaccines had worked with during the relevant period), then that should be stated explicitly.

Response: We accept that the wording was confusing and have therefore amended the text in the first paragraph under Methods/'Survey participants and conduct’ to clarify the sample size, as follows:

‘All investigators/researchers who had authored at least one publication reporting GlaxoSmithKline Vaccines-sponsored human subject research since 2007 were invited to participate. Around 1,300 external authors had worked with the company during this period and the aim was to achieve a minimum response rate of 15%.’

4. The second paragraph of that section says "data were anonymised (apart from the respondents’ email address)", which is contradictory. Data including email addresses cannot be considered anonymised. Presumably the authors mean that the data were kept confidential. This should be corrected, and methods for ensuring confidentiality should be described.

Response: We acknowledge that further clarity is required regarding the use of personal-identifying information in the study. Email addresses were only used for initial contact; no personal-identifying information was required for survey conduct or was used during data analysis. The text at the end of the second paragraph under Methods/'Survey participants and conduct’ has therefore been amended, as follows:
‘Data were kept confidential and stored in a global database; personal-identifying information (including respondents’ email addresses) was excluded from survey and data analysis procedures.’

5. The section in the results entitled "Use of a secure web-based publication tracking tool" reads as if it has been copied directly from a sales brochure for the software. A more neutral description should be given.

Response: The wording of the sub-heading and text of this Results section have been amended, as suggested.

6. The second paragraph of the discussion section discusses the response rate. Although it is true that it is within the norms for online surveys (and higher than many) it is still low enough that response bias is a serious risk, and this should be acknowledged more frankly.

Response: We accept the reviewer’s comment and have added the following wording (in bold) to the second paragraph of the Discussion:

‘The response rate for the survey was 32.6%, which might have led to response bias but is in line with . . .’

Discretionary revisions:

1. The results section is very long. Readability could be greatly improved by cutting the text substantially and simply referring to the data presentations in the figures.

Response: Text in the Results section has been reduced, as indicated in ‘track changes’. The majority of cuts relate to data also presented in the Figures. Regarding data presented in the text only, we felt that it was important to present these in a consistent manner that ensured readers understood the percentage values recorded in different response categories. Therefore, for clarity and comprehensiveness, data presentation in these sections has not been reduced.

Other changes

The authors noted the publication of several key papers since submission. The following amends have therefore been made to the reference list:

• New reference 34. Nylenna M, et al. Authorship: attitudes and practice among Norwegian researchers. BMC Med Ethics 2014, 15:53. The results of this questionnaire reinforce the need to investigate the clarity of the ICMJE authorship criteria to potential authors. A sentence has been added to the fourth paragraph of the Discussion:

‘The results of a recent survey conducted in Norway suggest this is particularly important for less experienced researchers [34].’

• References 45 (Marchington J & Burd GP 2014) and 50 (Stretton 2014). Previous conference abstract citations have been replaced with full publication citations.

APPENDIX

Proposal prepared by Deloitte Health Economics Outcome Research Group regarding the conduct of the web-based survey for GSK Vaccines. Deloitte have agreed that this document can be provided to readers upon request.