Reviewer's report

Title: Impact of human papillomavirus-related genital diseases on psychosocial wellbeing: results of an observational, health-related quality of life study in the UK

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Reviewer: Sarah Woodhall

Reviewer's report:

General comments

This is a well written article, and is presented as one of two companion papers that have been simultaneously submitted. Where my comments relate to the study overall, and therefore apply to both papers, I have provided the detail in this review, and have provided a cross reference to these comments in the review of the second paper (Dominiak-Felden et al).

The paper reports on a study of HPV-related genital diseases, where participants were asked to complete several validated questionnaires in order to measure psychosocial wellbeing and health-related quality of life (HRQoL, covered in the companion paper). The findings reported in the two papers together demonstrate the impact of HPV-related diseases on wellbeing and HRQoL.

Major Compulsory Revisions

1. Content of the two papers

There is substantial duplication between the two companion papers, particularly in the introduction and methods sections. In addition, there are several points where the discussion of the impact of genital warts (GW) and vulval intraepithelial neoplasia (VIN2/3), which were covered in both the papers, would be strengthened by considering all of the applied instruments together. I suggest that the authors combine the papers into a single manuscript in order to provide a fuller picture of the conditions that are reported in both, and to avoid duplication.

2. Recruitment of participants with a history of GW

The authors state that those with a history of GW, but no recurrence within >6 months (Methods: Participants). Please can the authors clarify this? Should this be no recurrence within 6 months previous to recruitment and baseline measurement, which would be?

In addition, please clarify the reasons why those with a history of GW were attending the stated healthcare services. If participants were attending for another non-HPV related condition, then it is possible that their HRQoL and psychosocial wellbeing would have been affected. What implications does this have for the use of this group as a control?

3. Differences in age and sociodemographic characteristics between groups
The age of participants varied by disease group, as would be expected given the different age-specific risks for these conditions. The impact of these different age distributions on the comparisons made in the paper is not fully dealt with, and requires further attention.

For example, sexual functioning assessment scores (using the CSFQ instrument), are presented in the main body of the paper without any adjustment for differences in age or other sociodemographic factors between analysis groups (Results; Tables 2a,2b; Figures 2a,2b). As sexual functioning is likely to vary by age, it is reasonable to expect that any differences between disease groups may be confounded by age. For example the finding that the VIN2/3 group had significantly reduced sexual functioning than the other groups is likely to be partly related to age, as they were older than women in the other groups (as the authors themselves acknowledge in the discussion (paragraph 3). However the authors state in the results section that “Similar results were observed when adjustments were made for sociodemographic characteristics (Appendix B)”. This appears to be contradictory with the discussion and it is not clear how this statement is supported by the data in the appendix (see comment 5). It is also feasible that age may be a factor in other comparisons. For example participants with GW or a history of GW were substantially lower than the other groups or the control group (women with a normal cytology result), thus might be expected to have a different sexual functioning to the control group.

4. The authors state that the greater reduction in HIP scores seen among women with CIN2/3 compared to CIN1 indicated that “psychosocial burden of CIN1 was more persistent than that of CIN2/3 over time” (Results, Psychosocial burned assessment, Longitudinal analysis). Is it possible that women were recruited at different times since their diagnosis? If so, the difference in HIP change over the follow up period may be related to time since diagnosis rather than time since recruitment.

5. Appendices A, B and C: The tables presented in the appendices do not clearly present the adjusted analyses, and these are very difficult to interpret in relation to the results presented in the main body of the paper. These appear to be tables showing p values, but the relationship between this and the outcome of a model adjusting for these factors is not clear. Please provide both the coefficients/adjusted estimates of the outcome measures as well as p values for the adjusted analyses.

6. Please provide a comment on the potential impact of loss to follow up in the longitudinal analyses. It is feasible that those who completed a follow up questionnaire were either more or less affected by their HPV-related condition than those who did not complete the follow up survey.

7. Please clarify in the methods and/or tables that the longitudinal analysis was based on a mean of the change, not a change in the mean scores between baseline and follow up.
Minor Essential Revisions

Methods: Study design and procedures:
8. Please clarify the clinic settings in terms of the numbers of general practitioner and family planning clinics.
9. Please provide a reference for the ‘Good Epidemiological Practice guidelines’
10. Please state the study objectives that the power calculations were based on. What differences between HIP estimates did the proposed sample size provide power for?
11. Please provide a reference for the estimation of 24 weeks as the “estimated mean time for successful treatment of GW in the UK”.

Discretionary Revisions
12. Tables 2 and 2a are very difficult to read due to their layout. Please consider revising the layout to make these easier to read, for example by having separate columns for the different follow up periods, so the comparable figures are next to each other rather than separated by several rows.
13. Figure 1 does not add a great deal to the paper if fewer tables or figures are needed.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests