Reviewer's report

Title: Monitoring vaccine and non-vaccine HPV type prevalence in the post-vaccination era in women living in the Basilicata region, Italy

Version: 0 Date: 18 Apr 2017

Reviewer: Dorothy Machalek

Reviewer's report:

The manuscript by Carozzi et al. evaluated the effect of HPV vaccination on the prevalence of vaccine and non-vaccine targeted HPV types among age eligible (18-30 year old) Italian women, in the post-vaccine era. The article also provides information on the age-specific prevalence of HPV among a broader cohort of women up to the age of 50 years. Overall the reported reductions in vaccine-targeted HPV genotypes among vaccinated women contribute important data on the population impact of the vaccination program in Italy. My comments are as follows:

Major

1. The manuscript could be improved by a clearer focus on the primary analysis comparing vaccinated and unvaccinated women in the 18-30 year age group, rather than describing everything without clear indication of relevance. Please reconsider including supplementary tables 1 and tables 2, in the main body of the manuscript, with Tables 1 to 3 moved to the supplementary section.

2. Further to the above, my main point of critique is in the merging of data from two sampling frames to present HPV prevalence rates across the entire 18-50 year old cohort (estimates presented in Tables 2 and 3). The potential bias of this on the reported estimates of HPV prevalence overall, is not acknowledged in the manuscript. The key issue is that women recruited from the community are likely to be significantly different in terms of HPV risk factors, to those recruited as they present for routine screening. The percentage testing positive measured from populations accessing testing (i.e. cervical cancer screening) cannot be extrapolated to the other populations as individuals tested tend to have different risks of infection than those who have not been tested. The authors try to account for this by comparing demographic characteristics of the study population to those of the general Italian population using ISTAT data, reporting little differences. However, I am not fully convinced that this justifies the approach.

3. The authors stated a very high participation rate (>98%) among women presenting for screening. What proportion of women access screening in the region? It would be valuable to add that information in the introduction.

4. The way the data is organised in Tables 4 and 5 is a little unclear. The primary analysis includes the full cohort of women eligible for the vaccine (i.e. women aged 18-30 years), while the analysis among 18-24 year olds is a sensitivity analysis among women recruited from the
community only. Is that correct? If so, this needs to be clarified in the methods. The authors could consider moving the results of the sensitivity analysis to the supplementary table.

5. The multivariable analysis presented in Table 5 includes all factors that were significantly associated (p<0.1) with HPV infection. The models should also be adjusted for sociodemographic characteristics that varied between vaccinated and unvaccinated women (those in the supplementary tables). Furthermore, results of both unadjusted and adjusted analyses should be included.

Minor
Line 218: please add the proportion with a high school diploma or higher that was expected in the younger age group (i.e. study: 87%; ISTAT: ?%)

All tables where relevant: Please add numerators and 95% confidence intervals for all prevalence estimates.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

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Please indicate the quality of language in the manuscript:

Acceptable
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