Author's response to reviews

Title: Implementation of a national school-based Human Papillomavirus (HPV) vaccine campaign in Fiji: knowledge, acceptability and information needs of parents

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Version: 3
Date: 15 November 2015

Author's response to reviews: see over
The Editor,
BMC Public Health

13 November 2015

Dear Editor

RE: Implementation of a national school-based Human Papillomavirus (HPV) vaccine campaign in Fiji: knowledge, acceptability and information needs of parents

I am pleased to submit for your review our revised manuscript and responses to reviewer comments (below).

We are very grateful to the reviewers for their insightful comments and queries, and believe the revisions have resulted in a stronger and more focused manuscript. We hope our responses satisfactorily address the reviewers’ concerns.

Thank you also for your willingness to extend the deadline for re-submission in the light of my current absence from work due to maternity leave.

I look forward to your response.

Yours sincerely

Dr Sophie La Vincente
Response to reviewer comments - Reviewer 1

Minor Essential Revisions

Abstract:

- Lines 55-56: Authors could delete the sentence “Almost universally...” because it is redundant and add a sentence about the reported reason of vaccine refusal

  Response: The sentence beginning “Almost universally..” has been deleted (line 59-60). A sentence about reported reason for vaccine refusal is already included in the abstract (line 65-67).

Background:

- Lines 78-86: Authors should also describe the role played by health care workers in vaccine uptake

  Response: With the significant reworking of the introduction and discussion in response to reviewer comments, we consider that the role played by health care workers in vaccine uptake is now best placed in the discussion, in the context of their role as a trusted source of health information and in light of the evidence of community influencers in supporting vaccine acceptance. This has been included (paragraph commencing line 398).

- Lines 88-97: Authors should also describe the burden of genital warts since the quadrivalent vaccine used in the immunization campaign protect also against this type of lesions

  Response: We agree that the potential for the vaccine to reduce the burden of genital warts is an important point. The section to which the reviewer refers is describing the burden of HPV and cervical cancer in Fiji, and to date there have been no studies of the burden of genital warts in Fiji. We have therefore instead included reference to HPV as a cause of genital warts early in the Introduction (lines 82-85), where we highlight the potential for HPV vaccination to reduce the burden of diseases other than cervical cancer.

- Lines 94-96: Authors should discuss the reasons of very low Pap-test screening uptake and highlight that the best preventive strategy include both Pap-test screening and vaccine

  Response: We have included a sentence on the reasons for the low uptake of Pap test screening in Fiji (lines 123-126); however, with little information available and no formal studies having been done on this, we are limited in what can be said on the issue. We have included in the discussion a comment regarding the importance of ongoing strengthening of cervical
screening, noting that the ideal strategy would include both cervical screening and HPV vaccination (line 471-474).

- Lines 112-115: Authors should clarify if the strategy has been concerted between teachers and health care workers

  Response: An additional sentence has been added to clarify the involvement and engagement of the Ministry of Education, schools and teachers (line 148-150).

- Line 130: Authors should add references about the sentence “parental acceptance of HPV vaccination remains a concern in many settings”

  Response: On review, we consider this sentence to be redundant and have thus deleted it (line 161).

Methods:

- Lines 143-145: Authors should clarify if the schools randomly selected were all kind of schools or only schools attended by students aged 9-12 years

  Response: Schools were primary schools. This has been clarified (line 174).

Results:

- Line 255: the “table 5” reference should be added

  Response: The analysis to which the reviewer refers has been removed (lines 252-256); however a reference to the relevant table has been included for the other analyses presented in this paragraph (line 251).

- Line 263: Authors should clarify if parents asked information about HPV and cervical cancer to their family physician

  Response: We have included the proportion of the survey sample that sought information from the community, including health workers (Table 1). In addition, given consultation with community members has previously been identified as an important factor in vaccine acceptance (Galagan et al., 2012), we also now explore this relationship in our data, by including discussion with community members, family members and involvement of the vaccine-eligible girl in univariate analyses looking at factors associated with vaccine consent (see lines 258-264; 302-307; 406-412).

- Line 265: Authors could clarify if parent’s who declined to participate to the survey and who decided not to adhere to vaccine campaign had daughters who attended schools which opposed to the vaccine campaign

  Response: Only a small number of respondents (n=7) reported that their daughter’s school was openly opposed to the vaccine campaign. We have
reported that the majority (n=6) of these 7 respondents still consented to vaccination for their daughter (lines 275-278). Only 20 of 313 (6.4%) parents invited to participate declined, and we do not have data on which schools the daughter of these parents attended.

- Lines 287-288: Authors could address the male vaccination issue in the discussion section, since the quadrivalent vaccine used in the vaccination campaign is indicated both in females and males

Response: We have included a sentence in the discussion section noting that many parents indicated they would be open to vaccination of boys, and this should be considered in targeting community education and sensitisation in future HPV vaccination in Fiji (lines 428-430). However, for the sake of keeping to an acceptable word count and given the issue of vaccination of boys is not a major focus of the study, we have not elaborated further to include, for example, a broader discussion of the literature on the acceptability or status of male vaccination in other settings.

Discussion:
- Lines 301-302: Authors should add references at the end of the sentence –

Response – this sentence has been removed from the reworked Discussion section (line 355-356)

Lines 308-311: Authors could discuss obtained vaccination coverage

Response – Discussion has been included (lines 365-370)

- Lines 356-358: this observation has not been cited in the section Results

Response - This sentence is no longer included in the revised Discussion section (lines 458-460)

Table 2 is redundant: it contains data yet described in the text

Response: Table 2 has been deleted.

Figures are not clearly readable

Response: Figures have been redone with higher resolution
Response to reviewer comments – Reviewer 2

1. The definition of satisfaction is crude and not operational. Despite the absence of definition regarding “parents satisfaction” presented in the section methods, I understand that satisfaction is a binary variable “yes or not”. Because satisfaction measure is a key point of the paper, other approaches of satisfaction should have been be used (e.g. using a 4 or 5 points Lickert scale, etc.). Similarly, there is the same main methodological difficulty with the definition of “access to sufficient” information.

Response: We thank the reviewer for this comment and agree in hindsight that a more specific measure of satisfaction would have been preferable, rather than a binary response. We have raised this as a limitation in the discussion (lines 494-499) and also in response to the reviewer’s question on limitations.

2. The representativeness of the results remains a critical key point. Only 52% of the parents agreed to participate in the study. I suppose and the results demonstrate this fact, that satisfaction level is very high in the included population, but this bias generates important methodological limitations and generalization of the results. Unfortunately, this key limitation is not discussed. In addition, this point could potentially impact the sample size calculation and is certainly a major selection bias.

Response: Among the 560 vaccine-eligible girls from the randomly selected schools, the research team was unable to contact 247 families due to incorrect or missing phone number. Of the 313 parents who were contacted and invited to participate, the large majority agreed (293/313, 93.6%). We have amended the text to make this clearer and avoid misinterpretation (lines 52-54; 218-224). We do not consider there is a high likelihood of sampling bias as described, with most of the parents given the opportunity to participate agreeing to do so. However, we do recognise that there is a potential bias introduced by opting for a phone survey, regarding the issue of whether those parents with access to a phone are representative of the broader population. This is discussed as a limitation of the study (see paragraph beginning line 476).

3. The number of information collected and tested in the paper remains low and insufficient (education level of parents, household income, region in the Fiji). Other interesting information, actually public health challenging, were not collected (e.g. Key sensitization messages, girl follow-up strategies role of communities, Community involvement actions, etc.)

Response: We recognise that collecting data across a broader range of issues would have been ideal. In developing the survey we were guided by partners from the Fiji Ministry of Health regarding the key issues they wanted to address in the survey, while also balancing the length of questionnaire that our Fijian team considered reasonable to ensure a representative sample would be willing to participate, and the resources available for the study.
4. References are old, less or equal 2012/2013. Many articles were published in 2014 and 2015, and must be cited in the paper, especially about HPV vaccination programs implementation and vaccine acceptability in low and middle-income countries (Peru, Brazil, Cameroon, Kenya, Lesotho, etc.). In addition, references are not presented according to the international standards.

Response: We agree that referencing should have been updated. We have substantially reworked the introduction (lines 97-112) and discussion (lines 387-443) recognising the rapidly growing body of literature that has recently emerged from low and middle-income countries. The references have been presented in the style specified by the journal (SpringerVancouverNumber).

5. Statistical tests used in univariate analysis are not presented in the section methods.

Response: Generalised Estimating Equation has been used for the univariate analysis. This is presented in the methods section, lines 200-201.

6. Vaccine acceptance was defined as self-reported of consent. This approach generates certainly a miss-classification (vaccine acceptance is usually defined as vaccination performed).

Response: We have discussed this as a limitation of the study (lines 501-510): noting that given a relatively small proportion of consenting parents reported that their daughter had not had all three doses and that few consenting parents reported having concerns about their decision to consent, we consider it unlikely to have had a major impact on findings.

Minor Essential Revisions

7. Educational level presented in univariate analysis in table 3 (p value=0.22) is certainly a potential confounding factor and should be introduced (at least tested) in multivariate analysis.

Response: Educational level has been included in multivariate analysis (lines 317-329, and tables).

8. In the variable “access to sufficient” information”, responses “no” could be not pooled with the responses “don’t know”. “No” and “don’t know” definitions are different.

Response: The analyses have been redone with separate categories for “No” and “Don’t know” responses for all variables

9. Table 2 and figure 2 are not useful.
Response: Both have been deleted

10. The limitations of the study in the discussion must be reinforced.

Response: We have expanded the discussion on limitations, as outlined in the response to the queries 1 and 2, above.

11. In the table 3, age seems to be presented as a mean, it is impossible to calculate crude odds ratio for mean values.

Response: Age is presented as median and interquartile range. We used Generalised Estimating Equation (GEE) to explore the relationship between age (continuous variable) and vaccine consent (binary variable). Using GEE does permit calculation of a crude odds ratio. In this case an OR of 0.99 indicates that that odds of consent reduces by 1% for each one year increase in age.

12. In table 3 (univariate analysis) the variable “access to sufficient information” (table 4, multivariate analysis) is “satisfied with access to information”: “access to information” or “satisfied with access”? There is gap between the interpretation of these two approaches.

Response: This is an oversight in relation to inconsistency with wording used, and has been corrected. The variable is “satisfaction with access to information” (see Tables)