

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Impact of a school- and primary care-based multicomponent intervention on HPV vaccination coverage among French adolescents: a cluster randomised controlled trial protocol (the PrevHPV study)
<b>AUTHORS</b>	Bocquier, Aurélie; Michel, Morgane; Giraudeau, Bruno; Bonnay, Stéphanie; Gagneux-Brunon, Amandine; Gauchet, Aurélie; Gilberg, Serge; Le Duc-Banaszuk, Anne-Sophie; Mueller, Judith; Chevreur, Karine; Thilly, Nathalie; /, the PrevHPV Study Group

### VERSION 1 – REVIEW

<b>REVIEWER</b>	LOMBRAIL, Pierre Sorbonne North Paris University - Bobigny Campus, Health Education and Practices Laboratory (LEPS UR 3412)
<b>REVIEW RETURNED</b>	08-Dec-2021

<b>GENERAL COMMENTS</b>	<p>This is a nice protocol, highly cooperative and pluridisciplinary on a vexing public health problem in France. It takes advantage of the potentials of an existing national system of health data. It relies on a very elegant statistical design. The authors plan an exploratory study of the equity dimension of the problem based on ecological perspective. The selection biases are acknowledged but this does not deny interest to this protocol; generalizability should be explored further if the results prove to be promising in this context. A checklist for the validity (SPIRIT) is used and confer a high robustness to the protocol.</p> <p>For an even better understanding of its interest, the authors should explain what are the "financial and organisational barriers to HPV vaccination as usual pathway to access vaccination" in France": do the parents have to pay for HPV vaccination in the usual life and how to disentangle for example the role of free of charge vaccination during intervention versus paying for in the "usual pathway"?</p> <p>The "health gains" taken into account in the economic analysis should also be explicitly described.</p> <p>The rest of the comments are just informative as the results will be very informative. To study implementation through an on-line survey appears limited. A qualitative on-site exploration would be an useful complement. For example, the "implementation gaps" could be useful adaptations to a local context rather than (or not only) a lack of fidelity".</p> <p>Looking for the results!</p>
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## VERSION 1 – AUTHOR RESPONSE

### Reviewer's Comments

6. This is a nice protocol, highly cooperative and pluridisciplinary on a vexing public health problem in France. It takes advantage of the potentials of an existing national system of health data. It relies on a very elegant statistical design. The authors plan an exploratory study of the equity dimension of the problem based on ecological perspective. The selection biases are acknowledged but this does not deny interest to this protocol; generalizability should be explored further if the results prove to be promising in this context. A checklist for the validity (SPIRIT) is used and confer a high robustness to the protocol.

Response: We thank the reviewer for his kind words.

7. For an even better understanding of its interest, the authors should explain what are the "financial and organisational barriers to HPV vaccination as usual pathway to access vaccination" in France": do the parents have to pay for HPV vaccination in the usual life and how to disentangle for example the role of free of charge vaccination during intervention versus paying for in the "usual pathway"?

Response: As suggested by the reviewer, we have provided additional information on the French context (see revised version with tracked changes, page 13, lines 10-16): "They [adolescents and parents] may also face financial and organisational barriers to HPV vaccination as usual pathway to access vaccination in France is rather complex.[14] In general, adolescents and their parents have to take an appointment with a physician to get the vaccine prescription, then go to a community pharmacy to obtain the vaccine, and finally take another appointment with their physician for its administration. Occasionally, individuals may also benefit from vaccination going to hospital vaccination centres, but their geographical accessibility can be difficult. Besides, HPV vaccine is only partially reimbursed by the French national Health Insurance, and some patients may be charged out-of-pocket costs.[14]"

8. The "health gains" taken into account in the economic analysis should also be explicitly described.

Response: We have completed the manuscript as follows:

- Statistical analysis section (see revised version with tracked changes, page 21, lines 5-8): "A budgetary impact analysis will then assess the costs associated with generalising effective component(s) at 1 and 5 years, which will be compared to the corresponding health gains in terms of size of the vaccinated population (1 and 2 doses). The time horizon will be too short to assess the impact on cancers and deaths prevented."

- Table 1 (see revised version with tracked changes, pages 12), "Annual cost and health gains of generalising the component(s) at the national level\*\*": "\*\*Costs associated with generalising effective component(s) at 1 and 5 years will be compared to the corresponding health gains in terms of size of the vaccinated population (1 and 2 doses)."

9. The rest of the comments are just informative as the results will be very informative. To study implementation through an on-line survey appears limited. A qualitative on-site exploration would be an useful complement. For example, the "implementation gaps" could be useful adaptations to a local context rather than (or not only) a lack of fidelity".

Response: We thank the reviewer for this remark that would be interesting to discuss in light of the results on the intervention components' implementation in an upcoming paper.