Reviewer’s report

Title: Public health value of vaccines beyond efficacy: methods, measures and outcomes

Version: 0 Date: 27 Apr 2017

Reviewer: Pier Lopalco

Reviewer’s report:

The paper suggest innovative ways to assess vaccination impact both in pre- and post- marketing phase. Including indirect effects of vaccination is quite ambitious but worth to be highlighted.

- Pre-licensure: the Author support the cRCT design to be used for registration purposes; whilst it is clear the advantages of such study design for specific settings/vaccines, it should be commented the level of risk of bias, since this is particularly relevant for registration purposes

- Post-licensure: the Authors should comment on the costs of post-licensure evaluation and on who should cover such costs: public health? industry? Under this respect, some comment on complexity/costs of the proposed studies/study design should be provided. In my personal view, the lower the cost is the higher is the probability such studies are implemented.

- Overall, the paper is mostly focusing on positive outcomes of vaccines. Vaccine opponents are more and more vocal on unexpected AEFI. The role of post-licensure studies to investigate such AEFIs should be better highlighted

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

Yes

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

**Quality of written English**
Please indicate the quality of language in the manuscript:

Acceptable

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