Author’s response to reviews

Title: An Evaluation of South Africa's Public-Private Partnership for the Localisation of Vaccine Research, Manufacture and Distribution

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Reviewers’ Comments (in Black) and Replies (in Magenta)

1. Letter from the Editor

Rosanna Gonzalez-Mcquire

Health Research Policy and Systems

Please include a point-by-point response within the 'Response to Reviewers' box in the submission system and highlight (with ‘tracked changes’/coloured/underlines/highlighted text) all changes made when revising the manuscript.

Completed as requested.

Please ensure you describe additional experiments that were carried out and include a detailed rebuttal of any criticisms or requested revisions that you disagreed with.

Experiments were not part of the study; the authors had no disagreements with the criticisms of the reviewers and have attended to all the suggestion and requested revisions.

Please also ensure that your revised manuscript conforms to the journal style, which can be found in the Submission Guidelines on the journal homepage.

Completed as requested.

The due date for submitting the revised version of your article is 24 Apr 2018. This deadline may be extended upon specific request.

This extension is not required.
By resubmitting your manuscript you confirm that all author details on the revised version are correct, that all authors have agreed to authorship and order of authorship for this manuscript and that all authors have the appropriate permissions and rights to the reported data.

Agreed.

2. Chief Editors' comments

Please extend the title to include something like ‘for the localisation of vaccine research, manufacture and distribution’ after ‘Partnership’.

Completed as requested. This title makes more sense and clearly indicates the unique contribution of the article to the PPP literature.

3. Reviewer #1

3.1. General Comments

This manuscript focused on an important subject, vaccines development for diseases with little economic incentives from the pharmaceutical industry. The author thoroughly reviews the Biovac Institute (BI) partnership, presenting a value for money and cost benefit analysis. The manuscript is very well written; it is easy to read and follow. The article is worth publishing in the journal after minor revisions.

Thank you for this review and the suggestions, which we have attempted to address as thoroughly as we were able.

3.2. Suggestions

i. In the introduction it would be interesting to describe further about the general "type" of these diseases targeted by such partnerships; the rationale for the Biovac Institute partnership to take place.

We have added this clause to the introductory paragraph “all of which are effectively and affordably controlled by the present vaccines and share the common characteristic of being highly contagious and having severe disease outcomes, especially for children.” We have also included a quote in the following paragraph from the EPI policy document itself and provided the reference for the interested reader.

The actual rationale for the establishment of the Biovac Institute is discussed in more detail in Section 2.3 and was not linked to the disease type, but rather to local manufacture.

ii. Introduction, line 51: change for "In this article, we describe the results of a value for money […]".
Completed; apologies for the typo!

iii. Figure 1: text is too small which makes it difficult to understand the figure

This figure has been simplified and revised to make the text easier to read. Apologies for this neglect in the original submission.

4. Reviewer #2

4.1. General

The paper addresses an interesting and important research area, investigating public-private partnerships. The authors draw on some prior studies, but a much more critical literature analysis is needed to strengthen the paper's argument and draw out the gaps they seek to address.

Thank you for this recommendation. We have expanded the literature analysis as indicated in 4.2 below. All suggested references have been included in the new text, plus other material. There are an additional 14 references, mostly covering the PPP literature of relevance to this paper.

Also, the paper needs to be present much stronger discussion and conclusion sections in order to offer value to the reader. Overall, the manuscript makes some interesting points and I realize that a lot of work went into this study. Nevertheless, I see significant room for improvement which will help to enhance clarity, readability, practical and theoretical contributions. The following paragraphs address each section of the paper in more detail and provide suggestions on how to revise the paper.

Agreed; we have strengthened the discussion and conclusion sections to indicate why the study is different, what it contributes to the literature (that is not already in the literature!), and what value it offers to the reader. We have also added material to the abstract which indicates the core contribution of the research. In our view, the gaps in the literature which we have attempted to fill are as follows:

- There has been no published review of the Biovac Institute despite its importance as a localisation initiative, and its use of public procurement, through a PPP, to effect localisation (technology transfer and establishment of local manufacturing in a high-tech industry)

- It is a longitudinal case study which has employed mixed methods to gain insight about the cost-benefit of the PPP

- It has presented a methodology for the evaluation of a manufacturing PPP (to our knowledge, there are no reports of similar PPPs in the literature)
It has discussed the dynamics of the governance structure, which was initially highly contractual but later became relational as the difficulty of the initial contractual targets became apparent and some flexibility in the interpretation thereof was required.

4.2. Introduction

While the authors establish some links to extant literature and argue for the importance of this piece of research, authors need to establish a more coherent framework for the overall paper. That means, the introduction should clearly indicate the need for this paper in relation to extant research studies, but also the importance of the research with regards to a practitioner/policy perspective. Which gap(s) are the authors trying to address here?

Two paragraphs have been added to the introduction explaining what gaps the article is intended to address, its importance to the policy/practitioner audience and its general importance, as follows:

“In this article, we describe the results of a ViM, or cost benefit analysis, of the BI-PPP. There are already in the literature several hundred publications on PPPs, covering a range of sectors and types of partnerships. However, very few deal with manufacturing and, as far as the authors are aware, there are no reports of PPPs covering vaccine procurement, distribution and supply. Other gaps in the present literature include the limited use of longitudinal studies or research approaches other than case studies, the limited application of surveys for data acquisition, and a narrow scope of PPP evaluation, which tends to be restricted to cost benefit analysis and ignores other factors such as social return on investment and employee satisfaction [11]. The latter are important since PPPs are also social constructs in which two parties from different sectors, cultures and perspectives agree on the partial or complete privatization of a specific service previously supplied by the public sector. The impact of this decision on workers and the broader public is infrequently studied and reported [12].

This study has attempted to address at least some of these gaps in the literature. It has followed a concurrent mixed methods approach with a qualitative arm adopting a survey approach to assess stakeholder perceptions of BI’s contribution to public health; it has followed a longitudinal approach to the collection of quantitative data; and it deals with a previously unreported application of PPPs, namely the use of the PPP structure to support the transfer and localization of vaccine manufacturing technology. The use of public procurement as a means of stimulating innovation, employment and economic growth is particularly relevant to developing countries, given the opportunity that demand side measures offer in this respect, but the general difficulty in translating this opportunity into real outcomes [13-15].

Here you need to clearly link to extant PPP literature (e.g. please see the work by Barlow, Caldwell Mahoney and Kivleniece).

All these references have been added to the overview section and further discussed. Thank you for this suggestion.
Vaccines and the use of PPP will then give you a very interesting research context in which to ground your study.

Agreed; hopefully this grounding is more evident in the discussion following our revisions.

4.3. Conceptual Background and Theoretical Development

The authors need to establish some clearer links to extant literature (e.g. the author(s) may find works by Barlow, Caldwell and Zheng relevant - please see suggested references below).

The Introduction and Overview have been extended. All five references included below have been added to the document (unfortunately these changes are not highlighted by Word’s Track Changes feature in the actual reference list but are apparent in the text itself). In addition, other references have been added including Marks, Fombad, Edler, Aschhoff, Bolton, Lonsdale and others.

The author(s) should clearly draw out the benefits and limitations (e.g. Zheng et al. (2008) discusses the importance and interplay of contracts and trust in long-term PPP arrangements) of PPPs and issues around the management of such long-term relationships.

This is a valid request but is a little difficult to address retrospectively since it requires a different set of research questions to those that were asked in this study. For instance, in the qualitative survey, it would have been important to ask each respondent about the nature and effectiveness of the governance structure for the Biovac Institute.

However, we have included some discussion of this topic (forms of governance) in Sections 2.1, 2.3 and 5. It is noted, for instance that although the initial governance structure was highly contractual, over time this shifted to a more relational structure, mainly as a result of the unrealistic targets of the SEP obligations and hence the need for some flexibility in the expectations of the Department of Health.

This should then be linked to discussions around value for money, and risks (e.g. Roehrich et al., 2014 and similar).

The VfM discussion has been expanded to include some reflection on how the governance approach shifted, and that notwithstanding the failure to achieve the manufacturing obligation, the PPP still delivered a positive VfM.

Then, the author(s) can follow up by discussing key extant studies around evaluation of partnerships. This would then help to draw out the gaps in prior studies this study seeks to address.

A final paragraph in the discussion section has been added to address this request.

4.4. Methods and Analysis
Overall, this section is well written and addresses key methodological implications and key findings. Please clearly describe how interviewees were sampled and data were coded.

The sampling strategy and the data coding is described in Section 3.2 of the paper. Some additions have been made but the sampling strategy has already been described.

What were the key differences with regards to your key concepts across the different research methods? You need to further motivate the need to not only use one research methods but to combine multiple methods.

Such motivation is provided in Section 3.2 – “qualitative data can provide a more informed and detailed understanding of initiatives such as BI-PPP, thereby generating new ideas and suggestions for improvements”.

4.5. Discussions and Conclusions

Derived from a conceptual background section which did not clearly draw out the gaps the paper seeks to address, the discussion and conclusion sections do offer only some additional value to the reader as it stands. The authors need to offer more fine-grained results here and discuss what they intended to find out in the introduction section (link to research question; overall aim of the paper).

The discussion section has been expanded as noted earlier (see 4.1 and 4.3 of this document). The overall objective has been to link more clearly to the extant literature and then indicate what lessons can be extracted from the study which have not already been covered by previous articles.

Overall, the authors need to clearly draw out what the theoretical contributions are and how they add to the existing body of knowledge. This section also needs to clear link back to extant studies (PPP, value, evaluation) to offer some clear value to the reader. Please also offer some clear policy implications derived from your study.

The previous answer also refers. Two specific policy recommendations have been made, the first covering the importance of an incremental approach to complex PPP goals and the second dealing with the weakness of relational governance within a context of difficult outcomes (and hence the need for stronger contractual terms).

Good luck with your revisions.

Thank you and we hope that you are satisfied with the revisions. We are most grateful for your guidance and particularly for your insistence on locating the work more clearly within the theory of PPPs. Although this paper was intended mainly as a report on a rather unusual PPP, we agree that we did not focus sufficiently on PPP theory, and how this could be supplemented, with the results of our study.

4.6. Useful References


