Author's response to reviews

Title: Are vaccination programmes delivered by lay health workers cost-effective? A systematic review

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Author's response to reviews: see over
Reviewer: Stephen Jan

Comment 1:
I wonder whether the authors could be a bit more systematic in identifying these issues that limit the generalisability of results since this is a crucial point - generalisability is essentially what readers are looking for drawing on the findings of systematic reviews. The factors that could be considered are variations in context (including comparator, cost structures), methodology, perspective and intervention design.

- This has been addressed on p. 14 (“There were fundamental differences in these three studies in terms of…”), with greater discussion on page 17 and 18: “Vaccine delivery by LHWs can be characterized as a complex intervention, whose components usually include behaviours, parameters of behaviours (e.g. frequency, timing) and methods of organising and delivering those behaviours (e.g. type(s) of practitioner, setting and location); the number of groups or organisational levels targeted by the intervention; and the number and variability of outcomes [35]…. Like effectiveness outcomes, the costs of (complex) interventions are strongly determined: by contextual factors; or the exact combination and ‘dose’ of intervention components; or the behavioural pre-dispositions of participants or providers. A population’s attitude toward health care and interventions, compliance and adherence, utility valuations of health status, and incentives, such as level of co-payment, are also important components that can have a significant impact on cost-effectiveness [36]. The difficulty in generalising or transferring economic evaluation results to other places arises because we do not know what caused the particular relationship between opportunity costs and outcomes in each instance (i.e. programme implementation). With more complex interventions, it becomes even harder to explain how a specific bundle of intervention components (and their associated resource use), provided in a given context, have generated the levels and types of outcomes measured [37].”

Comment 2:
On page 17 the paper discusses some of the ‘technical’ characteristics of the studies. I think this would be better labelled ‘methodological characteristics’ and could be broadened to discuss more specifically the type of costs included e.g. were cost offsets such as reduced hospitalisations from reduced number of cases factored in? To what extent were other health system costs included? (In other words how incremental was the analysis?) How was effectiveness valued?

- It is difficult to address the issue of how incremental was the analysis based on the way the results were presented in the three studies, however the other issues raised are addressed on pages 14-15: “There were fundamental differences in these three studies in terms of: variations in context, including differences in setting and location (Philadelphia [17] versus Amazonian Ecuador [18] versus Seattle [19]); comparator used (doing nothing [17, 19] versus a second strategy [18]);…”
- And: “Regarding the items that were costed, while there was some standardization, there were also significant differences in what items were included, as well as how
the same items were costed differently, among the three studies, mainly based on their intervention and context-specificity: Direct costs: etc. … Both the comparability of the findings of these studies and their wider generalizability is hindered by these factors, and we address this point in greater detail in the discussion.”

Comment 3:
One of the CEAs estimated life years saved and another estimated QALYs but no detail was given as to how they were estimated. Were the studies done alongside clinical trials or were they modelled costs-effectiveness analyses?
- This has been addressed on page 14: “…intervention design (costs assessed alongside an education and outreach project for Hepatitis B vaccination [17], cost-effectiveness comparison of two routine childhood vaccination programmes [18], and a cost-effectiveness analysis conducted alongside a randomized, controlled trial of a community-based outreach initiative and differences in populations targeted [19]).”

Comment 4:
Conversely summaries of the studies and their findings on pages 10-14 could probably be shifted into an appendix.
- The summaries of costing studies have been moved to Appendix 2 and synthesized on page 11 to read “For the studies which did not fulfill the definition of a full economic evaluation yet did contain some data on the vaccination- and human resource-related costs of vaccination programmes, four studies looked at LHWs delivering vaccinations only [20-23], five studies looked at promoting vaccinations, such as canvassing, publicizing and persuading people to get vaccinated [24-28], and two studies reported using LHWs for both promotion and vaccination [29, 30]. Comparing costs in any meaningful way was difficult due to the differences in outcome reporting. More in-depth descriptions of these studies can be found in Appendix 2.”
Reviewer: Sara Bennett

Major Essential Revisions:
1) I found the sections of the paper which addressed “new institutional economics” and sustainability the least convincing parts of the paper. While there are important policy issues within these spheres with respect to the cost-effectiveness of lay health workers. I would suggest that prior to publication the authors re-write these aspects of the paper so that the focus is very clearly on the cost-effectiveness of lay health workers (rather than a more general discussion of the need to incorporate institutional economics into cost-effectiveness analysis). Specific suggestions regarding this are given in the specific comments below.

- Thank you for this and the other more specific suggestions. These aspects have been edited and altered in line with the suggestions.

1.1) Pg 5 – I did not find the discussion of affordability or financial sustainability very illuminating. Often affordability is used to focus in particular on the household side, although it obviously could be used as referenced here [ref 10], but I found the concept not very clear. When there are multiple funders of a health programme, some may become less or more important over time, but the programme can still be sustainable.

- This has been clarified with the deletion of the sentence “This, in turn, has implications for the longer-term financial sustainability of the programme”, and incorporation of the national government perspective, under the assumption that they are the main decision-makers for the part of the health care system governing LHWs.

1.2) Further I wondered why there was not a clearer discussion of cost-effectiveness (given the title of the article). For government the question of cost-effectiveness, and whether the intervention is more or less cost-effective than alternative ones, is perhaps key. Also at least some of the interest in LHW programmes is that they are sometimes perceived to be cheaper than working through regular health staff. I think it would be helpful to state this plainly.

- Thank you for this comment. This has been addressed on p. 5 with the following statement: “For governments and funding agencies, the question of whether an intervention is more or less cost-effective compared to alternative interventions, as well as whether there are sufficient funds to pay for the intervention, are factors that influence decision-making. Part of the growing interest in LHW programmes is related to the perception that they are cheaper than those that use professional health staff.”

1.3) Pg5 – institutional economics – similarly, further down the same page there is a rather vague discussion about institutional economics and its relevance to this question. It was not clear what you were trying to say, and the example provided at the end of the para (top pg 6) seems like an example of economies of scope – not of the elusive institutional dimensions. I think you would be better off focusing in on a few elements of LHW programmes where institutional issues are important – for example, as you point out later, LHW programmes may help build communities and intensify social capital; to what extent has this been examined by evaluations? At one point later on you mention transaction costs – they may be important to LHW programmes, but I could
see them cutting in a number of different directions, is there anything specific that you would like to analyse here?

- This paragraph has been re-written to: “These considerations have practical implications for economic evaluations of health worker programmes, and specifically LHW programmes. Generally, conventional economic evaluations, particularly cost-effectiveness analysis, focus narrowly on health outcomes, and do not take into account the role of human-made institutions in shaping economic behaviour. Nor do current economic evaluation methods capture social non-health benefits, such as community empowerment and higher social capital, which may have positive or negative values, and are related to programme-induced changes in the wider community [2]. Through their overly reductionist perspective, conventional economic evaluations of LHW programmes are ill-equipped to deal with institutional changes [11], such as changes in local governance or differences in social values, which are especially important at the community-level. Institutional economics, alternatively, considers the social norms and networks which govern individual and group behaviour and are an important dimension to consider when looking at the cost-effectiveness of LHW programmes. For example, the training of programme staff and other activities that are seen as institution-building, with benefit flows beyond the duration of the programme, are treated as a resource input when valuating outcomes. However, within an institutional economics framework, they may also be considered an intermediate output, with its entire cost subject to amortization as per capital costs [11].” and deletion of the last sentence which appeared to be a confusing example.

1.4) Pg 7, objective 3 is not clear – it implies that affordability and sustainability may contribute to the costs and cost-effectiveness of LHWs???? I would try to simplify and state more clearly what you are trying to do here. Maybe you are simply trying to assess the affordability and sustainability of LHW vaccination programmes based on the evidence available to you.

- This has been re-worded to: ‘Identify factors that contribute to the costs and cost-effectiveness of LHWs and vaccine interventions, and examine how theories of institutional economics can contribute to understanding the costs and cost-effectiveness of LHW programmes.’

2) I would encourage them to think further about how best to structure the rather long results section (pg 9-14) which goes through each study individually and describes the nature of the intervention and the cost-effectiveness findings. For example, it might be feasible to cluster studies according to the role that LHWs played (were they directly administering immunizations, or was their role to canvass and persuade people to get vaccinated). Some way of structuring this information in a slightly more synthetic manner might both make it easier to read, and perhaps offer slightly greater meaning than currently.

- The study descriptions were moved to Appendix 2, and summarized within the manuscript as follows: ‘For the studies which did not fulfil the definition of a full economic evaluation yet did contain some data on the vaccination- and human resource-related costs of vaccination programmes, four studies looked at LHWs delivering vaccinations only [20-23], five studies looked at promoting vaccinations, such as canvassing, publicizing and persuading people to get vaccinated [24-28], and
two studies reported using LHWs for both promotion and vaccination [29, 30]. Comparing costs in any meaningful way was difficult due to the differences in outcome reporting. More in-depth descriptions of these studies can be found in Appendix 2."

3) Somewhat relatedly, I found the paper quite long and believe that its length could be cut a little – partly by getting rid of some of the more theoretical discussions of new institutional economics, and partly by further synthesizing (or moving to tables this descriptive part of the results section)

- The summaries of costing studies have been moved to Appendix 2 and synthesized on page 11 to read “For the studies which did not fulfill the definition of a full economic evaluation yet did contain some data on the vaccination- and human resource-related costs of vaccination programmes, four studies looked at LHWs delivering vaccinations only [20-23], five studies looked at promoting vaccinations, such as canvassing, publicizing and persuading people to get vaccinated [24-28], and two studies reported using LHWs for both promotion and vaccination [29, 30]. Comparing costs in any meaningful way was difficult due to the differences in outcome reporting. More in-depth descriptions of these studies can be found in Appendix 2.”

Minor Essential Revisions:

4. I would suggest placing the QUORUM chart further down next to the results section that describes the process – the chart is not entirely clear on its own.

- The chart placement has been moved to the bottom of the first paragraph of the Results section.

5. Pg 10, insert a sentence signalling that the first three studies described are cost-effectiveness studies. It would be helpful in the text if you could consistently identify the country where the study was done.

- This has been made more specific and now reads: “Given the small number of studies identified, the following section provides a short description of each paper (all costs in US dollars, unless otherwise specified), with the first three studies described consisting of the cost-effectiveness studies.”

6. Calderon-Ortiz – appears to be reported in N$ whereas all other studies are in US$.

- This has been addressed in the tables, as well as on p. 36: “Results showed that in the intervention area, vaccinators required 42 days to vaccinate approximately 100 children at a total cost of US$ 533.43, while it took 60 days to vaccinate approximately 100 children in the control area for a cost of US$ 762.05. For the purpose of this review, Mexican pesos (N$) were converted to US$ based on the exchange rate at the mid-point of the study period, August 1, 1994 (N$1 = US$ 0.294).”
7. I found the section beginning on pg 19 on LHWs and institutional economics unconvincing – partly because you have not done a very good job at defining institutional economics (which after all is a large field with lots of different sub-fields), so the key points in the analysis were obscure. I think it would be very legitimate for the paper (indeed important) for it to discuss the broader (largely unquantified) benefits of LHW programmes in terms of building community solidarity, community development etc. But the examples actually provided in this section were not clear. The reference to transaction costs was rather mystifying and I am not convinced that the broader discussion about conventional versus less conventional economic evaluations strengthens the paper.

- On p. 16, we included the following definition of institutional economics as it relates to the health sector: “Institutional economics addresses the role of human-made institutions in shaping economic behaviour, with the understanding that economic analyses and understanding should also consider the political and social system within which economics is embedded.”

- The transaction cost statement has been re-worded to: ‘Furthermore, economic evaluations did not take into account the potential reduction in transaction costs resulting from the LHW being a recognized member of the community, which in itself provides social capital and reduces the amount of time and need for developing new social networks, trust and access to community’s resources.’

8. The section on Sustainability was slightly better than the preceding section, but also rather muddled. There is one very clear question about at what point in the life of the programme was the evaluation and costing conducted. This seems an important issue that is worth some discussion in terms of limitations of the study – but is not really about sustainability. Sustainability is a broad concept that encompasses financial sustainability but also a variety of other factors – political commitment, community demand, institutional capacity to deliver. I would suggest that while all of these are important, with the exception of financial sustainability they are a bit of distraction from your core focus on cost-effectiveness of programmes. I believe that if you wanted to do an analysis of the sustainability of LHW vaccination programmes, then your approach, data extraction etc, would look different from what you have reported in this paper. Accordingly, I would suggest that you more narrowly focus this section of the paper, reporting simply on studies that have explored questions of financial sustainability (while acknowledging that other aspects of sustainability are also important).

- Thank you for your comment. This was addressed by distinguishing different aspects of ‘sustainability’ on p. 20 and narrowing the focus to the studies that have explored questions of financial sustainability. Furthermore, we have included definitions of sustainability and clarifying its importance given the complexity of LHW programmes. “Tied to these institutional factors are issues surrounding the sustainability of LHW programmes. Sustainability refers to the continuing ability of a project to meet the needs of its community [45], beyond the period of an intervention [46]. When assessing sustainability, it is useful to differentiate between the sustainability of measured effects, which is difficult to assess when programmes are evaluated for only a few months; the sustainability of the programme’s interventions, regardless of its effects (our focus here); and continued financial viability, which is linked to the programme sustainability. Gruen et al. [47] propose that sustainable health programmes be regarded as complex systems that
encompass the programmes themselves, the health problems targeted by these programmes and the programmes’ drivers or key stakeholders, all of which interact dynamically within any given context. In their systematic review of studies associated with health-programme sustainability, they identified a wide range of factors, including context and resource availability, amongst others [47]. Shediac-Rizkallah and Bone [48] and Bossert [49] note that factors that affect sustainability include programme design, organizational aspects, and contextual attributes including local health policy and social, cultural, and environmental characteristics. As programme sustainability is strengthened by input and support from all facets of the community, this may be linked to the costs that the community and country can afford to maintain, the stage of their economic development, and the importance of community self-reliance and self-determination [50].”

9. Box 2 – recommendations for future research. Does your third bullet imply multi-country studies?? Final bullet, I am not sure what you mean by “assessing the impact on cost-effectiveness of using an institutional economics framework”? Are you suggesting that issues of implicit contracts and informational asymmetries are addressed, that governance issues are analysed, that a transaction cost analysis is conducted, that assessments of institutional evolution be undertaken? For this recommendation to have any meaning it needs to be much more sharply specified.

- Clarified to indicate the possibility of within or between countries; not necessarily multi-country, given diversity within many countries
- Regarding the final bullet: this has been clarified to include the stated suggestions.