Reviewer's report

Title: Barriers to immunization and the design of research-based communication strategies in Colombia

Version: 2 Date: 12 March 2014

Reviewer: Barbara Rath

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Major compulsory revisions:

1. More work needs to be done to structure the article and to emphasize key/take-home messages. Thorough statistical analysis and testing for confounders as well as plausibility/quality checks of questionnaires are needed. Results and interpretation of results should be separated more clearly.

2. One major methodological concern is the restriction of the study to parents who decided not to vaccinate their children. By focusing on this group only, a control group is lacking. How can we be certain that the same factors described as reasons for non-compliance did not also apply to parents who had their children vaccinated regularly and on time? This limitation should be addressed in the discussion section.

3. Overall, the discussions section includes many useful suggestions how communication could be improved, these suggestions however are not evaluated in the survey. Most conclusions are not (currently) supported by the data.

Minor essential revisions:

4. Consider summarizing the local territories for international readership or provide more information on regional differences with respect to socio-demographics, economics, exposures/policies etc. Consider supporting these with government statistics, or census data, if available.

Abstract:

5. Results are not entirely clear. What were the reasons for non-immunization, where exactly are the barriers? What were the differences between groups? Which communication strategies are recommended, how could the situation be improved? Which kind of studies would be needed to develop/validate/establish “research-based communication strategies”?

Introduction:

6. Vaccination program includes “13 antigens” (this is unclear, many vaccines contain multiple antigens, please provide number and type of vaccines administered)

7. It would also make sense to present the national immunization schedule in a
brief overview table. According to official health data in Columbia/by WHO, Which vaccines are known to be well-accepted, which ones were least popular and why? What exactly is the hypothesis for this study?

Methodology:
8. Describe qualitative research in more detail. Two separate sections in Methods and Results sections should clearly delineate the qualitative from the quantitative research phase. Which preliminary results in the qualitative (focus group?) research lead to which hypothesis to be tested by which questions in the survey?

9. Page 7: It seems unusual that IRB approval was not sought. Initial qualitative analysis was conducted in 2010. How was “verbal consent” recorded? Was the study registered and if yes, where?

10. Page 9: IRB informed later (2013)/retroactively to issue a waiver. An IRB waiver should be sought before the study is initiated. Need to verify with respect to research publication ethics!

11. What kind of problem would have triggered home visits “to correct the issue”? 
12. What is meant by “service-related factors that might inhibit immunization”?

13. The statement „Discussions lasted approximately two hours and participants were compensated for their time“ contradicts the previous statement: „Participants could discontinue interviews at any time and received no compensation for their time."

14. How were participants compensated and by whom? Did this only apply to the qualitative research phase or to the survey or both? Please specify.

15. Page 9: considerable overlap between response options (for example: “parental fear”, “father does not think vaccine is safe”) how were these potential confounders addressed in the analysis?

16. Section ”Data Analysis”: Parts of the section describe the design of the questionnaire rather than the analytical method used. Later it is stated that statistical analysis was not conducted? Which hypotheses were then tested, why the restriction to descriptive analyses?

Results:
17. Why did only 10% meet inclusion criteria, which were the inclusion criteria, the criteria should be clearly stated in the methods section, possibly in a text box. Also the overall timeline of the study should be presented in a graph or table.

18. „Twenty-nine percent self-identified as Afro- Colombian and 8.6% as indigenous. Participants had a total of 5709 children aged <5 years.“

How does this compare to the overall population in the region/country?

19. „Of 4802 participants, 4738 (98.7%) possessed vaccination cards for their children"

20. One would expect that possession of a vaccination card could be one of the inclusion criteria? How else did the investigators confirm that vaccinations were
incomplete?

21. 50% unaware that children were undervaccinated: Of the 1725 participants claiming to lack this knowledge, 1056 (61.2%) said that health workers failed to provide them with clear information.

22. These findings are important, as they may indeed constitute key findings in this investigation. Apparently, parents are insufficiently informed by physicians and public health officials (including EPI!) and need more information on what constitutes an complete vaccination record. Other factors may be minor in comparison.

23. Additional statistical analysis would be helpful in demonstrating interdependencies between variables.

24. “According to participants, healthcare workers generally provide caregivers with necessary information on vaccination.”, again, seems to contradict the above statement.

25. “Only 150 (3.1%) participants indicated that they had to once pay for vaccines.“ Consider having the manuscript reviewed by a native English speaker.

26. Page 12: „refusal of healthcare personnel to open a vaccine vial for one child (n=390).“ This is another key finding with potential implications for policy makers, this should be emphasized!

27. Communication strategies: how do the parents’ perceptions match with the actual /intended use of communication strategies used by local governments? The survey among parents provides information about the perceived communication strategies. These perceptions need to be investigated with respect to actual interventions. (check for bias due to levels of knowledge/awareness!)

28. There is increasing evidence that the internet is the most important communication strategy for some parents, TV, print media and others are not mentioned, why?

29. The establishment of subgroups makes sense, but the level of overlap between groups is unclear and the connection to self-assigned reasons for non-vaccination is unclear.

30. Example for potential overlap between groups/ confounders:

31. “lack of immunization card” and „refusal to immunize a child who lacked a vaccination card“

32. “Health centers” and “healthcare system” may represent an artificial distinction, if healthcare centers run out of vaccines, this, too, may be due to a problem in the healthcare system (supply chain/management issue).

33. Reversely, children will not get immunized without an appointment. Lack of appointments could also point to a problem with the vaccinator or the healthcare center, rather than the overall system.

34. Whereas “unfriendliness” could very well be attributed to the vaccinator, not the center?
35. Page 16, finally, an “Initial hypothesis” is formulated, this needs to be stated in the beginning of the paper! The hypothesis “new communication strategies are needed” is however, is not specifically addressed in this survey.

36. “For this reason, multivariate analytical techniques were used to categorize participants according to groups of related reasons. A participant may belong to one group, while being influenced by factors in other groups.”

- Multivariate analyses were used? This is not stated in the methods or results sections.
- Concern: “people” do not vaccinate versus “why do I not vaccinate” – why were the questions phrased anonymously in a (subjective) opinion survey?

COI/funding statements:
37. EPI system evaluating itself – consider reporting this as a potential COI.
38. What was the reimbursement for the polling company and who paid for it? The analysis was conducted by whom? Please revise the COI statement accordingly.

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests.