Reviewer's report

Title: Lessons and implications from a mass immunization campaign in squatter settlements of Karachi, Pakistan: an experience from a cluster-randomized double-blinded controlled trial [NCT00125047]

Version: 1 Date: 12 March 2006

Reviewer: Jonathan A Sterne

Reviewer's report:

General

This paper reports methods and baseline data from a cluster-randomised trial in Pakistan. It is potentially suitable for publication in Trials. However, the inclusion of further relevant information about the design and conduct of the trial, the characteristics of participants at baseline, and the adverse effects observed could make the paper considerably informative.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

The CONSORT statement now provides the standard for reporting randomized controlled trials, and has been modified to deal with cluster randomized trials (BMJ 2004; 328: 702-8). However it is often difficult, given the severe space constraints on articles in medical journals, to report all the relevant information. Therefore, articles such as this are an opportunity to report in more detail on the conduct of relevant aspects of the trial. The authors could improve greatly, for example, on the reporting of methods of randomization. How was the randomization sequence generated? How, precisely, were the randomization strata defined (these could be displayed in a table or depicted in a figure)? What steps were taken to ensure that the allocation sequence was concealed? (In the context of this trial, this would mean that it was impossible for anyone to interfere with the chosen allocation, for example by re-randomizing because they did not like the chosen allocation). How many clusters and individuals were randomized to the two groups? (This could be reported without revealing which group contained the Vi PS vaccine and which the hepatitis A vaccine). Who conducted the procedure of labelling the vaccines as C or M, and what procedures were used to ensure that the identifying information was not passed to any of the investigators or study personnel? Similarly, I suggest that in the revised version of the paper the authors consider how they could report in more detail on other information about the conduct of the trial that is required by the CONSORT statement.

There is evidence that the primary outcomes reported in final trial reports are often not those specified in the protocols. Therefore I suggest that the authors include information on what outcome measures will be used to assess vaccine efficacy, and how it is planned that these will be measured.

The authors give some information on the numbers of adverse events. I suggest that they also explain precisely how adverse events were defined, how their occurrence was ascertained and recorded, and how many of each type of event occurred. It would be acceptable to report this information for both vaccine groups combined.

Minor comments
Abstract: much of the information contained in the “conclusions” section should in fact be in the “results” section.

Page 5 paragraph 1: I completely agree that vaccine research and development agendas are tailored to the needs of wealthier countries, but I do not think that it is “especially true” that persons living in slums in South Asia are at a disadvantage compared to other impoverished people in low income countries.

Page 5 paragraph 2: this needs rephrasing because it sounds as if all persons approached gave consent. Results presented later make it clear that this was not the case.

Page 11 paragraph 2: was there any particular reason that the letters C and M were chosen?

Page 12 paragraph 2: define the abbreviation AE before you use it for the first time.

Page 13 paragraph 3, and Table 1. Consider presenting this information in the form of (the upper part of) a CONSORT flow chart.

Page 16 paragraph 3: it would be helpful if, as well as outlining positive lessons learned and successful aspects of the trial, the authors also identified problems that occurred, how these were addressed and how, with hindsight, they such problems might have been avoided.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article whose findings are important to those with closely related research interests

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

Statistical review: No, the manuscript does not need to be seen by a statistician.