Author’s response to reviews

Title: Why do participants drop-out: findings from a prospective pediatric cohort for fever surveillance established at Vellore, Southern India

Authors:

Sindhu Kulandaipalayam Natarajan (sindhukn@cmcvellore.ac.in)
Manikandan Srinivasan (manikandanmbbs06@gmail.com)
Sathyapriya Subramaniam (priyasathy96@gmail.com)
Anita Shirley David (anita.shirls@gmail.com)
Venkata Raghava Mohan (venkat@cmcvellore.ac.in)
Jacob John (jacob@cmcsph.org)
Gagandeep Kang (gkang@cmcvellore.ac.in)

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Author’s response to reviews:

BMC Medical Research Methodology

Cover letter with response to reviewers’ comments

Respected editor,

Thank you very much for your valuable comments and inputs for the manuscript titled “Why do participants drop-out: findings from a prospective pediatric cohort for fever surveillance established at Vellore, Southern India”.

We have addressed the comments and responded in detail as below. We have also highlighted the corrections (in yellow) in the main manuscript.

Thanking you,
Sincerely,

Sindhu Kulandaipalayam Natarajan, MD, DTM&amp;H
Assistant Professor,
The Wellcome Trust Research Laboratory,
Division of Gastrointestinal Sciences,
Christian Medical College,
Vellore,
Tamil Nadu - 632 004, India

For,

Prof Gagandeep Kang, MD, PhD, FRCPath, FAAM, FASc, FNASc, FNA, FFPH, FRS
The Wellcome Trust Research Laboratory,
Division of Gastrointestinal Sciences,
Christian Medical College,
Vellore,
Tamil Nadu - 632 004, India

Response to comments by Reviewer 1:

1. Abstract

The way the data are analyzed is lacking. Under Results it is not clear how many subjects were participating in the FGD study. The conclusion is too general (in my opinion) and do not refer to the specific outcome of the present study.

Response by authors: Thank you for the comment, we have now modified the abstract.
2. Keywords I wonder if these shouldn't be limited to: 'Cohort, longitudinal, drop-out, pediatrics' instead of the double and redundant keywords here.

Response by authors: We have modified the keywords as suggested.

3. Background

In the statement of the problem, drop-out ratios of other studies in a comparable field should be reported too. Comparison of attrition between Western and Eastern countries is interesting to make, as well as High Income Countries vs Low-Medium Income Countries. Factors of poor response and attrition are described, but the direction of the associations should be mentioned too. Sometimes references seem to be lacking (like in the sentence on internalization and understanding). The possible role of individual differences (personality, response tendencies) are not described too.

Response by authors:

• We have now added dropout rates specific to pediatric longitudinal studies
• Studies on drop-out rates from LMIC countries are limited in literature, and hence we cited relevant drop-out rates from HIC countries
• We have added direction of association for factors associated with poor responses and attrition in a cohort study
• We have added the reference for internalization and understanding involved in the informed consent process
• We have included the sentence on the personality influence in the participation of subjects in the longitudinal studies

4. The aim of the study is broader than what is investigated. The aim 'Eliciting knowledge and attitude' is hardly studied or realized. (This might be a matter of rephrasing and making a distinction between direct and future aim). At the other hand, establishing the percentage of drop-outs is not an aim here. Notwithstanding this, it is presented in the Result section, suggesting that it is also a focus of this study. If it is, it should be mentioned as a separate research question too. Otherwise, it should be presented as a part of the background. In both cases the percentage drop-outs have to be compared with those of their studies, to see if this is relatively high, moderate or small. This can be in the Discussion (when it is an aim of the study) or in the background part (when it concerns information which is already available)
Response by authors: Thank you for pointing this out, we have re-worded the aim of our study, that includes the estimation of percentage of drop-outs in the VTS study. We have included the comparison of VTS drop-out rate with rates of the same from other studies in the discussion.

5. Methods

From the analysis, it becomes clear that there is a quantitative part and a qualitative part in the study.

Problems I met are:

Inclusion and exclusion criteria for VTS are not described.

Figure 1, describing the flow of the VTS study, is not present in my version of the manuscript.

The description of the methods of surveillance (telephone interview, questionnaire, home visit) is not presented. Though not being an expert in this field, I wonder how reliable parental report of fever is. It is also important to know if the diagnostics and treatment of the positive cases are for free or should be paid by the parents.

Details of the number of FGDs, the specific questions, the number of participants in each and the way these qualitative data are analysed should be added. F.i. how were the transcripts analysed to obtain themes, by how many raters, how were discrepancies resolved etc. (There is quite a lot of literature devoted to the analysis of qualitative data by now).

In the statistical comparison of groups with large sample sizes like here, the use of Cohen’s d is to be recommended as neglectable differences can easily lead to a significant outcome too.

I was a bit confused reading that both children and parents could drop-out (see p10). If so, what is the difference between these drop-out rates?

Group dynamics were noted by the facilitator. What has been done with these data?

No mentioning of ethical clearance (or its unnecessity) was made.

Response by authors:

• Thank you for pointing out these points
• We have added two sentences indicating the inclusion and exclusion criteria
• Sorry, for the technical problem. We hope that you are now able to access Figure 1 that describes the flow of VTS study
• The surveillance method is actually depicted in Figure 1 in detail and we did not want to duplicate the same in the methods.

• A prior background work before the implementation of the VTS study revealed that parental report of fever was the most feasible and reliable way to capture fever in their children in this community. Also, this is a community with which we have been working with closely for over the last 18 years, and the robust rapport established between this community and us was the biggest strength of this study.

• Yes, the blood culture performed in the VTS study and the treatment of positive cases were free of cost (borne by the study). We have included this information now.

• We have incorporated the number of FGDs conducted with the average number of parents/primary caregivers who participated in these discussions. Questions asked in the FGDs are included in Table 5.

• A paragraph on analysis of the transcripts obtained has been added.

• To avoid the biased p-value estimates using the Z-test which is an issue in studies with large sample sizes, we have now used Chi-square test to obtain p-values in Table 1 and Table 2. The use of Chi-square test for this was also suggested by Reviewer 2, and hence we have now corrected Tables 1 and 2 using the same.

• The VTS study is a pediatric longitudinal cohort with children aged between 1 and 15 years. Consent was obtained from parents/primary caregivers of these children. It was the parents’/primary caregiver’s decision to withdraw consent and thereby their child’s/children’s participation from the study. So, we interviewed the parents/primary caregivers of these children who dropped from the study. We have now included this in explicit in the methods.

• We have now included information on the group dynamics, and also added what we observed in the results section.

• We have now mentioned about ethical clearance in the methods section.

6. Results

The description of the population in Table 1 and in the text, should be more balanced; highlights in the text, details in the table. Definitions of SES subgroups is important to know for comparison with other studies. The p-values are not very informative with such high sample sizes.
It is not clear how many children were already dropping-out in the first measurement (so without any participation at all and in which way/s they (and/or their parents) differed from the other children.

Response by authors:

• We have added a footnote to Table 1 and 2 indicating the SES classification used, and referenced the same
• We have added the p-values to highlight the heterogeneity in the population of the 4 areas with reference to religion, age distribution, type of family, SES, highest education in the household and mother’s education as these are important determinants of drop-out rates in cohort studies in this setting
• The drop-outs in the study were captured real-time with the progress of the study. There were no specific intervals or time-points when drop-out rates were assessed. The term “weighted’ drop-out rate seems to have caused this confusion, and hence we have now modified the same. Thank you for very kindly pointing this out.

7. Table 4 shows the reasons for drop-out, but it is not clear how these were obtained: are these found in the FGD's? Is there the possibility for the subjects to give more than one reason?

Response by authors: We have now modified the heading for Table 4 as follows: “Reasons for dropouts as recorded at the time of censorship in the Vellore Typhoid Surveillance (VTS) study (n= 404)” Whenever a study participant migrated from the study area or dropped out from the VTS study, as per the study protocol, it was mandatory for the study team to complete a censorship form. The censorship form had 5 categories of reasons for drop-outs as mentioned in Table 4, and the supervisor was expected to confirm and them mark the reason accordingly. No, it was not possible to have more than one reason in the censorship form.

8. The concept of weighted drop-out was unknown to me. I found an article by Schmidt and Woll in BMC Medical Research and Methodology (2017) 17:164 on this topic. If relevant, it is good to refer to that, unless it is a well-known concept in epidemiological research.

The description of how the FGDs were carried out should be transferred to the Method section (where I missed it). It is confusing to see that sometimes in the qualitative part numbers are reported and sometimes not. Also, the distinction between the two groups (participant with and without withdrawal) is not clear. In one case, it is mentioned in a table, in the other case in the next, which renders its reading difficult.
Response by authors:

- Thank you very much for this important point. We have created a confusion here by using the term ‘weighted’ drop-out rates. We referred to the above-mentioned paper which talks about drop-out rate with reference to the time contributed by each participant in the study, and this was not the case in our study. Hence, we have modified the term “weighted” drop-out rate to “Drop-out rate adjusted to area-wise contribution to the cohort enrolled”
- We have modified the methods to include the description of the FGDs.
- We have also modified the results for clarity.

9. Discussion

The building-up can be improved considerably. I prefer to have summary of the main outcome first, after which a comparison is made with the previous literature (in this case on reasons for drop-out/withdrawal). This comparison is lacking here. Other parts that deserve to be discussed here are: 'limitations of the study', 'suggestions for future research'.

Response by authors:

- We have now worked on the discussion including comparisons using previous literature
- A sentence on limitation of the study has been added
- Suggestions for future research has been included in the last paragraph of discussion

10. References

Overall the references seem relevant

Response by authors: Thank you.

Response to comments by Reviewer 2:

1. In table 2 the authors used the Z test to compare between 2 proportions, it would be better to use the chi-square test to compare between groups putting in consideration the independent variables as Religion, socio-economic status, mother education, type of family, etc.

Response by authors: Thank you for the input. We have now added p-values using Chi-square test for Table 2.
2. In the ethics consideration section; the author mentioned that ethical clearance was obtained from Institutional Review Board and Ethics Committee of Christian Medical College, but nothing was mentioned about the consent process and how privacy and confidentiality of study participants was protected specially in focus group discussion.

Response by authors: We have added a paragraph on the consent process and privacy/confidentiality of the study participants in the focus group discussion.

3. The authors are requested to revise the statistical analysis of table 2 to consider using the chi-square test and hence to be reflected on the result and discussion section. the ethical consideration section to be revised to add a paragraph on consent process and protecting privacy and confidentiality of study participants.

Response by authors: We have revised the statistical analysis of Table 2 and reflected the same in the text. We have also added a paragraph on the consent process and privacy/confidentiality of the study participants in the focus group discussion.