Author's response to reviews

Title: Burden of Leprosy in Malawi: Population-based Cross-sectional Study

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Version: 4 Date: 27 June 2012

Author's response to reviews: see over
Reviewer's report

Title: Burden of Leprosy in Malawi: Population-based Cross-sectional Study

Version: 3  Date: 9 June 2012

Reviewer: ANIL KUMAR

Reviewer's report:

1. Comment
Paper has been improved but still not ready for publication.

Response
Thank you.

2. Comment
While computing sample size, national prevalence of 0.5 is taken but it per 10000 population and sample size has not been adjusted for this. It should have come to be a large size??. One can assume based on personal experience that reported prevalence is low and actual may be 10 times (0.5*10-5/10000, P=0.005) and then compute sample size.

Response
This is a very interesting comment. Perhaps we are thinking too much. If we go to the basics, sample size determination of Epidemiological surveys (the formula of which was used in this survey), assumes that variables are normally distributed i.e. the fall in a bell-shaped curve hence the use of log or square- root in the formula to enhance the normality. In the bell-shaped curve of bi-nominal distribution of dichotomous variables, the biggest sample size is obtained at p= 0.5. Therefore whenever prevalence is unknown, it is advisable to set p= 0.5 because it where one can get the highest sample size. This is epidemiological fact and it is not our intention to argue for or against it in this paper. We simply used it by assuming that the prevalence of leprosy in the study was 0.5

However, your suggestion provides a room to prove or disapprove this point of 0.5 as the point where one can get highest sample size.

Using the formula:
N= \( Z^2 \times P(1-P) / e^2 \)

Where N= sample size, Z= level of confidence, P= baseline level of the selected indicator and e= margin of error, set at \( P= 0.005 \) (as suggested), Z= 1.96 (at 95% confidence interval), e= 0.05.

N= 1.96X1.96X0.005(1-0.005)/0.05X0.05 = 0.01911196/0.0025 = 7.6
Thus at \( P = 0.005 \), the minimum sample size (unadjusted) is 8 compared to 384 when \( P \) is set at 0.5. At \( p=0.9 \), the sample size is 138.

**Conclusion:** We would like to maintain the bell-shaped curve approach/thinking under which the above formula for sample size determination of Epidemiological surveys was developed. Using this formula, \( P \) can never be 0 or 1 and the highest sample size is reached at \( P=0.5 \).

3. **Comment**
Population characteristics are not representative of population like sample skewed for female (60.2%), younger children (<5) not included –must correlate if national data also do so. This must be required for comparison with national PR.

**Response**
Thank you for this comment. It is indeed true that females were over-represented (60% of the participants were females). We have stated this as one of the limitations of our study on page 9, last sentence under Limitations of the study.

For easy referencing, this is what has been added: “Over-representation of females (60% of participants were females) was another limitation of this study. Relatively fewer males participated in the study because there were away working in the fields as the study population was predominantly subsistence farmers. It was not known whether this group had different study characteristics”.

As regards to correlating/comparing/weighting the study findings to the national data, we would like to emphasize that the study was not designed to get a national representative sample. It was conducted only in 4 out of 28 districts in Malawi. The purpose was to randomly sample some communities and check whether leprosy cases are still occurring. If Yes to what level based on the population screened, are there child cases etc as part of evaluating Leprosy Programme. Secondly, national data is facility-based while this study was population based hence could not be directly compared. However, national facility data (figure 1 and figure 2) have been made available since it was part of the evaluation of the National Leprosy Programme.

In the detailed methods, results and discussion we have attempted to make it clear about where the population-based study was conducted (4 districts) and their findings overall and by district and the trends from National facility data.

In future, if we have resources, we will conduct a nationwide population-based study designed to get a national representative sample to estimate leprosy prevalence and disabilities. That data will be weighed to national population figures by gender, sex, urban/rural.

In summary, it is our considered view that data from the study which was not designed to get a national representative sample, only conducted in 4 out of 28 districts could not be weighted to national population distribution by gender, age and urban/rural and that population- based data can not be compared to facility-based data.
4. Comment
If we look at 66 active leprosy cases detected in the sample examined, it suggests 37 new cases and 29 either on treatment or defaulters of earlier treatment. If we adjust to this ratio (37/29) for under reporting, national PR equals to 0.9. Why your nationals and readers through out could believe that PR of 104 is close to actual.

Response
Thank you. The overall leprosy prevalence 104 per 10,000 population in 4 study areas (not national) was arrived at the detection of 66 leprosy cases out of 6338 people screened (66/6338X10,000) as stated in the abstract and on page 6 under Results sub-title “Population-based prevalence of leprosy”. The national leprosy prevalence in Malawi has continuously been stated under Introduction, Results on page 7 sub-title “Trends of leprosy indicators at national level and in selected districts: 2006-2011” and in the discussion. The difference between population-based prevalence in 4 districts and national prevalence are also clearly stated in tables and figures even in their titles. Why nationals and readers will be confused and take prevalence from only 4 out of 28 districts as the actual national leprosy prevalence is beyond our control. We have no other better way of showing that the two are different.

As regards to adjusting the national prevalence using the suggested ratio, this could be one of the uses of our data after publication.

5. Comment
For valid reasons, one has to go back to those who did not reported in camps/clinics. This group is certainly the one with low level of disease in question but may not be disease free.

Response
Thank you for this comment. The involvement of chiefs and community health workers was aimed at sustaining promotion of community awareness on leprosy and encouraging people to go the nearest health facility as stated in the methods and also under limitation of the study on page 9. The district health officials who took part in this study will be following up the promotion of community awareness; not as part of the study but as a routine programme implementation on community participation.

6. Comment
Single leprosy is one area of concern, young children is another area of concern and working males who did not participate is third are of concern.

Response
Thank you for this comment. These are some of the messages that we would like to share with the world that leprosy is still a challenge. We found a total 66 cases out of 6338 people that were screened. Up to 37 people had leprosy but were not treatment and 8 of them were disabled from leprosy. Worse still, 9 children had leprosy and were not on treatment. However, health facility data from the same area were showing that there were no child cases and very few people had
leprosy. This is our message we would like to put across. Therefore we share your public health concerns.

Less participation from males is limitation of this study as stated above and under study limitations. The promotion of community awareness that was set up could address this concern.

7. **Comment**
I would like to see these revisions before paper is acceptable.

**Response**
Revisions and/or explanations have been made accordingly to the best of our ability.

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

**Response**
Thank you.

**Comment**
**Quality of written English:** Acceptable

**Response**
Thank you.

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

**Response**
Thank you.

**Comment**
**Declaration of competing interests:**
I have no competing interests but would appreciate the publication if suggested revisions are included

**Response**
Thank you