Author's response to reviews

Title: An Assessment of Orofacial Clefts in Tanzania

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Author's response to reviews: see over
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Dear Dr. Shipley

Thank you for the review of our manuscript, “The Pattern of Orofacial Clefts at Bugando Medical Center in Mwanza, Tanzania”, and for the constructive comments from the editorial board member. Please find attached a revised manuscript that addresses the comments of the editorial board member, as follows:

1. The board member felt that – owing to the retrospective nature of our study - our analysis should be restricted to a presentation of the data and results (Editorial Board Member, point 1), i.e. without going into a detailed analysis of their significance for the epidemiology of orofacial clefts in East African. As per their suggestion, we have removed the following sections:

   i) "Owing to the study design, [...] to obtain representative results for African nations." From the abstract conclusion (Editorial Board Member, point B)

   ii) "We made no attempt to establish the prevalence of orofacial clefts in Tanzania,[...] retrospective studies do not lend themselves to reliable estimates of the prevalence of such congenital anomalies.," From the discussion (Editorial Board Member, point C)

   iii) "A more important limitation is the potential bias in the severity of cases [...] analyze the data that we do have and interpret them in light of these important limitations." from discussion. From the discussion (Editorial Board Member, point D)

2. The board member also suggested that we not analyse and compare the data for patterns of distribution of orofacial clefts, as this requires knowledge of the underlying causes for differences in these patterns. However, we feel that these patterns are an integral and valid part of the data that can be gleaned from retrospective studies. Merely highlighting differences in the patterns of clefts in Africa and other low and middle income countries (LMICs) does not in and of itself require a causative explanation, but rather points to a potentially interesting difference among populations. As we discuss in the text, this difference may warrant further research to determine whether it has a biological or methodological basis. Therefore, we have chosen to leave the table (formerly Table 4, now Table 3) as
a "significant finding", and to discuss its implications briefly in the text.

3. The board member suggested we merge all our tables into a single table showing all demographic data, and present the significant data in the text results. As per their suggestion, we have reduced the number of tables from 5 to 3. We have kept Table 1, which provides some background information on the distribution of orofacial clefts in different regions of the world. Table 2 now contains all the demographic data from our study, including the distribution of clefts by type, laterality, sex and region of origin (formerly Tables 2, 3 and 5). Finally, Table 3, as mentioned above, shows a comparison of our data with that of similar retrospective studies in LMICs in Africa and elsewhere. Although the editorial board member suggested we compare our results to other authors in the discussion text, we feel that, given the large number of studies to compare, Table 3 provides a more useful and clear summary of these comparative data. The data from Table 2 and the most significant differences observed in Table 3 are presented in the text results as well.

4. The board member also suggested: Present statistically significant data (and delete insignificant data) (Editorial Board Member, point G). We have done the following on the result section of abstract:
   a. We have presented significant data on laterality of clefts
   b. We have omitted “Sex distribution of particular orofacial clefts showed a small but non-significant female predominance in CL group and male predominance in CP and CL”

5. We have concluded (both in the abstract and main article) by stating the significant findings of our study and omitted sections that were trying to describe the pattern of orofacial clefts. (Editorial Board Member, point 2)

6. We have changed the title to “An Assessment of Orofacial Clefts in Tanzania” (Editorial Board Member, point 3)

7. Our study didn’t investigate about the outcome of orofacial clefts at Bugando Medical Centre as this was not the goal of the study. We have explained this as a limitation (in the discussion section). This is to respond to Editorial Board Member, point H.

8. We have made minor changes/additions to the text to keep our message consistent, given the significant sections that were removed (see above). New sentences are highlighted (in yellow) in the text.
9. All requested formatting changes have been made. Specifically, we have formatted the tables and reference section according to *BMC Oral Health*'s recommended format.

I hope that you will be satisfied with these substantial changes. On behalf of my co-authors, I would like to thank the reviewers and the editorial board member once again for their time and valuable input. We look forward to your decision regarding our manuscript.

Sincerely,

Mange Manyama, MD