Author’s response to reviews

**Title:** The Pattern of Orofacial Clefts at Bugando Medical Centre in Mwanza, Tanzania

**Authors:**

Mange Manyama (manyama73@yahoo.com)  
Campbell Rolian (cprolian@ucalgary.ca)  
Japhet Gilyoma (jgilyoma@bugando.ac.tz)  
Cassian C Magori (cmagori@bugando.ac.tz)  
Kilalo Mjema (kaymjema@gmail.com)  
Erick Mazyala (emazyala@yahoo.com)  
Emmanuel Kimwaga (emmanuelkimwaga@hotmail.com)  
Benedikt Hallgrimsson (bhallgri@ucalgary.ca)

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**Author’s response to reviews:** see over
Dear Dr. Shipley –

Please find attached a manuscript entitled “The Pattern of Orofacial Clefts at Bugando Medical Center in Mwanza, Tanzania” for your consideration as a research article in *BMC Oral Health*. In this article, we present an overview of the pattern of orofacial clefts observed in a large referral hospital in northwest Tanzania. We find that the distribution of orofacial clefts is in many respects similar to other parts of the world (e.g. by sex and laterality). However, we also find significant differences with observed relative frequencies of different types of clefts in Asia and South America. We conclude that these differences, which have been observed in other African studies, may reflect a combination of underlying biological and sampling factors.

Please note that this is a second revision of a manuscript previously submitted to *BMC Oral Health* (MS. # 4556563234378899). On behalf of my co-authors, I would like to thank the reviewers for their thoughtful comments. Whenever possible, we took the reviewers’ suggestions into account, and as a result we feel the manuscript has been greatly improved. Below is a detailed description of the changes to the manuscript.

**Reviewer 1**

i) **Ascertainment biases (e.g. for laterality) still exist because this was a clinic-based study. Showing similarities and differences in phenotype distribution with data from the literature does not prove soundness of data in this case.**

We agree with the reviewer but we do not agree that this limitation means that our results are of no value, if properly interpreted with caveats. We’ve added text into the discussion which addresses this issue specifically. The only real solution to the issue that the author raises is to obtain prospective data or birth defects registry type data. This is simply not a realistic option in the East African context. Prospective data would be extraordinarily difficult to collect in any kind of unbiased way for the same reasons that the reviewer has identified. A birth defects registry exists only in South Africa and the infrastructure elsewhere in Africa simply does not support this and will not for quite some time in all likelihood. This means that the data that we present and analyze are the best means that we have at our disposal to gain an insight into the epidemiology of CLP in the population that we are studying. Genetic analyses of CLP in this population are underway, through the FaceBase consortium. We need this kind of information as background for these studies. Our worry is that the concerns of the reviewer, legitimate as they are, are letting the perfect get in the way of the good. We think that a reasonable solution is to have these limitations up front in the paper and discuss how they relate to interpretation of our data. The reader can then make a well
informed interpretation of our results. The alternative, which I suspect is the view of the reviewer, is to say that no insight into the epidemiology of CLP in sub-Saharan Africa (outside of South Africa) is possible. We think that this is an unnecessarily rigid position because hospital records, like those on which we base our analysis, do contain useful if imperfect information that can inform ongoing research on the genetics of CLP.

ii) Authors mix the concepts of associated and syndromic cases of oral clefts.

We agree with the reviewer that the low proportion of associated cases probably reflect differential mortality rates among cleft cases associated with anomalies in vital internal organs rather than lack of access to a geneticist in the medical team. We have amended the text to reflect this.

I hope that you will be satisfied with these changes. I would like to thank the reviewer once again for their time and valuable input. I look forward to your decision on our manuscript, and thank you for considering it for publication in *BMC Oral Health*.

Sincerely,

Mange Manyama, MD