Author’s response to reviews

Title: Indications and complications of intestinal stomas at a tertiary care hospital in a resource-limited setting: A Tanzanian experience

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Version: 3 Date: 19 Jan 2019

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Title: Indications and complications of intestinal stomas at a tertiary care hospital in a resource-limited setting: A Tanzanian experience" (BMGE-D-18-00027R1)

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Reviewer reports:

Reviewer 2:

1. Page 2 line 19 delete the word "it"

The word "it" has been deleted.

2. Page 2 line 24 Add the word "are" after "factors"

A word "are" has been added.
3. Page 2 line 41. You need to separate the population into children (< 18 yo) and adults >18yo throughout the entire paper. The mean age can then be calculated for each group. Reporting an overall mean age in this study is meaningless because the two groups have totally different etiologies requiring a stoma.

   Population has been separated as it was recommended by reviewer. Since reviewer wanted us to separate the population into children and adults throughout the entire paper, we went back to our original/raw data and we made analysis, the results we got, caused changes in almost the entire text. We had to edit many things in the text to fit the changes.

4. Add "in children and adults" to the title. This will tell the story better and more completely

   The words "in children and adults" have been added to the title.

5. There are multiple problems with verb tense etc that will require editing by professional editors. I will not provide any more suggestions from now on but these can be corrected by an editor.

   We have tried to make some corrections, if we have left some errors, we can be helped by an editor as it was suggested by a reviewer.

6. Page 6 line 27. Define SOPD

   SOPD has been defined as Surgical Out Patients Department

7. Page 6 lines 4 and 46 "stomy" needs to be changed to stoma and "stomal" respectably

   “Stomy” has been changed to stoma and stomal respectively.

8. Page 7 line 19 this sentence is absolutely critical BUT the way it is written means that there was direct supervision (what the readership will interpret as the consultant surgeon being in the operating room and overlooking or assisting the "surgeon" in the operating room. I am very sorry
but this reviewer does not believe that the consultant surgeon was actually in the OR all the time and especially if it was done "after hours" i.e. nights and weekends. You need to be able to define this accurately whether the operating surgeon was alone in the operating room or whether the consultant surgeon was actually in the OR at the time of creation of the stoma. This may be the *most important variable* to quantitate accurately.

I have deleted the word “direct” because most of the time, "after hours" junior doctors do emergency surgeries, life-saving procedures, like colostomy formation for anorectal malformations. Junior doctors are not allowed to take a patient to OR before consulting a specialist on call and being given go ahead. They usually consult senior doctors/specialists, but most of the time consultation is done over the phone. Specialists go to OR beyond working hours, at night and weekends when junior doctors fail to do a procedure. Junior doctors are normally asked if they are able to do an operation, when they say no, specialist goes to OR to do an operation, when they say yes, they can, they are given go ahead by the specialist to do an operation. When they face any difficult intraoperatively, they call for a help. To conclude, "after hours" few emergency operations were done under direct and some were done under indirect supervision of the specialists.

9. Page 8 line 4. Change " status of the operating surgeon" level of training of the operating surgeon"

Status of operating surgeon has been changed to level of training of the operating surgeon.

10. Page 8 line 37 add the phrase "12 month" after the word "the"

Sorry, it was traced but not seen.

11. Page 8 lines 42 here is also where you can separate the adults from the children. To report a median age of 8 with a range of one day to 86 years is meaningless.

The median age of 8 with a range of one day to 86 years has been deleted, instead, mean ages for the children and adults have been reported.

12. Page 8 lines 47 through 49 which group does this refer to? all patients or only the children. You also need to report these variables separately for the males and the females
The variables have been reported separately for the males and the females as it was recommended by a reviewer.

13. Page 8 line 56 - page 9 line 17 and. Page 9 lines 43-47. the indications need to be reported separately for the children and the adults- again these represent two totally different age groups with different indications for stomal creation. Also there may end up being a difference in complication rate as well as complication rate according to the experience and level of training of the operating surgeons as well as the actual presence of a consultant surgeon in the Operating room? Stomas are much more difficult to make in children

As recommended by the reviewer, the indications has been rephrased and reported separately for the children and the adults

14. Page 9 line 12 delete the attempt to describe a mean and SD for the congenital anomalies just give the range and may be also those requiring a stoma in the first 2 weeks of life- a much more risky procedure with greater morbidity

The attempt to describe a mean and SD for congenital anomalies have been deleted

15. Page 9 line 14 change the mean to 5.8 years and round off the SD to 2.6

Mean has been changes to 5.8 years and SD has been rounded off to 2.6

16. Page 9 line 16 the difference in age is unimportant and the statistical difference is fully expected. Delete this sentence - it is meaningless and you appear naive in even reporting it.

The difference in age and the statistical difference have been removed

17. Page 9 lines 33 and 34. Again the need for an emergency operation will vary because of age. These data should be reported separately for the two age groups.

As it was recommended by the reviewer, the data were reported in two separate groups for the children and the adults.

18. Page 10 line 4 again the complication rate should be reported separately for children and for adults in each anatomic location
As recommended by the reviewer, the data were reported in two separate groups for the adults and for the children.

19. Page 10 line 31 round off the numbers; you cannot measure a one hundredths of a day!
Numbers have been rounded off as it was recommended by a reviewer.

20. Page 10 Definitive (curative) surgery and Line 57 - page 11 line 33 again the 2 groups of adults and children need to be reported separately
As recommended by a reviewer, the data were reported in two separate groups for the adults and for the children.

21. Page 11 line 34. Do you mean "intraperitoneally " rather than intraoperatively"? 
We meant intraperitoneally. The word intraoperativelly has been changed to intraperitoneally

22. Page 12 line 14 -19. Is this section really necessary? The populations are totally different? Aren't there other published papers from Africa on this same topic that you could compare your practice to that of others? This would be more meaningful than comparing your experience with that of the experience of surgeons in the developed world or elsewhere who primarily deal with adults?
We agree that published papers from Africa would be better as recommended by reviewer, unfortunately, if they have been published, they are not accessed that is why a published paper from developed country which dealt with adults has been used/quoted. There is a paucity of published and accessible information from Africa regarding stomas.

23. Page 12 line 32 did Ahmed and colleagues treat only adults? Or only children? Or both. In each case you need to compare apples with apples (adults with adults) and oranges with oranges (children with children) -see why separating the population into adults and children is crucial. This will convert your study into a very well written and analyzed one that then will be quoted- Grouping all ages into one category confuses the issues of etiology as well as complications
Ahmed and colleagues treated children and adults. Patients less than 12 years were excluded in their study. This means that, patients who were less than 18 and >12 years were included in the study plus adults.

24. Page 12 line 57 did Husain et al treat only adults?

Yes, Husain et al treated only adults.

25. Page 13 lines 4-7. Here is where you need to be fully transparent and exact. When you say "despite adequate supervision by senior doctors" what does this mean? "adequate supervision" to most readers means "direct advice and oversight IN THE OPERATING ROOM - not prior training and not over the phone. I will admit, my guess is that there was minimal or no direct supervision at night or on weekends - and here is your problem- you can determine this by looking at the day of the week and the hour of the day when these emergency procedures were performed- I really doubt (though maybe you can determine this) that you will be able to document if a consultant surgeon was actually on the OR or not by looking at the operative report- too many potential problems of poor or inaccurate documentation.

My guess is that there was rarely a consultant surgeon in the OR for the emergency cases and this is why the complication rates were so much greater when performed by a junior doctor (and you have never described what you mean by a junior doctor) vs a consultant doctor. I really do not believe the sentence on page 13 line 7. If the consultant surgeon was there, then under his/her direct supervision, the should be NO difference when they were directly there as you imply on page 13 line 22 and then describe on page 14 lines 57 - 60 this does not agree with your statement that the operating surgeons had direct supervision.

Clarification and changes have been made.

Junior doctors are surgical registrars and residents while consultant surgeons are surgeons professionally/specialists. To avoid confusion a word specialist has been used in the text for consultant surgeon.

Concerning supervision of junior doctors by seniors, at night or during weekends, when patients come to the hospital, the first doctor to attend patients is a junior doctor. Then junior doctor consults specialist for advice, corrections and inputs. The patients are investigated and diagnosed by junior doctor after being given an advice, then junior doctor consults specialist over the phone after having all investigation results. The diagnosis is confirmed. If patients need emergency operation, junior doctor is asked by a senior doctor if she or he is able to do an operation, if he or she says he is able to do it, he or she is given go ahead (when they face difficulties intraoperatively, they call for a help from seniors), but if she or he says she is not able to do it, a
specialist goes to the OR to do an operation. Most of the time they say that they can do it, that is why there was minimal or no direct supervision at night and on weekends, there was rarely a specialist in the OR for the emergency cases.

In the paragraphy where there was a word direct supervision, I have deleted the word “direct”, because junior doctors are advised over the phone, specialists go to OR when junior doctors say they can not do an operation or when they face difficulties intraoperatively. Junior doctors are not allowed to take a patient to theatre before consulting a specialist on call over the phone and being given go ahead, that is why we say there is supervision of the junior doctors by senior doctors either directly or indirectly.

To conclude, concerning emergency operations, few emergency operations were done under direct and many of them were done under indirect supervision of the junior doctors by specialists.

26. Page 13 lines 51-56. You need to report the incidence according to transverse loop vs sigmoid end colostomies here as well as in the table.

The incidence has been added as it was recommended by a reviewer.

27. Page 14 line 34. Other cause of bowel retraction is obesity, bowel wall edema, ischemia in a devascularized segment that was exteriorized

Other causes of bowel retraction have been added.

28. Page 15 line 22, again were the stomas closed by junior doctors without any direct supervision? My guess is that many were! You need to look into this or at the least describe your impression of whether the consultant surgeons were really there IN THE OR or not.

All elective surgeries are done by senior doctors, sometimes junior doctors do them but this is true that, when elective surgery is done by junior doctor, it is always done under direct supervision, means physical presence of a senior doctor.

Though "after hours" it is very rare for the specialists to go to OR, but for elective cases, specialists are always in OR, they do all elective surgeries, even if junior doctor does elective surgery, s/he does it under direct supervision of the specialists.
Corrections have been made, the findings concerning post colostomy closure complications, on page 11, they do not tally with the real situation. The truth is that, colostomy closure procedures are done electively by specialists. In the previous submitted manuscript, it was written that majority of the colostomy closure procedures were done by junior doctors, something which was not understood to us because that is not a realistic. Raw/original data were reviewed, it was found that when data analysis was done, data have been changed, the number for the seniors was for the juniors and vice versa, changes have been done. So reported results for seniors in the previous submitted manuscript was for juniors and vice versa. The majority of the colostomy closure procedures were done by senior doctors. Though few were done by junior doctors under direct supervision of specialists, still complication rate was higher in stoma closed by junior doctors. We do not know the reasons for this finding. May be senior doctors did not pay attention to what has been done by the juniors in their presence. Reasons for this finding should be investigated. We need to find the cause for this finding and solution.

29. Page 15 lines 43-58. When you say extraperitoneal closure, what do you mean? Was the anastomosis left exteriorized for several days and then interiorized? If so when was it placed back into the peritoneum?

Extraperitoneal closure means, after the detachment of the stoma from the abdominal wall, two ends are taken out of the abdominal wall for anastomosis. Loop and divided stomas can be closed extraperitoneally, means no need to open the abdomen through extended incision and when anastomosis is done, the two ends stay outside abdominal cavity, that is extraperitoneal closure, if there is stool spillage from the proximal part when anastomosis is done, stool will not come into contact with the peritoneal organs or cavity, when anastomosis is completed, bowel is returned into the peritoneal cavity through a site where stoma was created and the abdomen is closed in the same setting. When a Hartman's procedure is done, during colostomy closure, abdomen should be opened through extended incision to have a good expose for the purpose of finding the distal part, when anastomosis is done, it is done within the abdominal cavity because of the extended incision, if there is stool spillage, stool will come into contact with the peritoneal cavity and organs.

30. Page 16 lines 11-14. Here is where the truth comes out. You say "improper technique" are you really saying "lack of supervision"? Because if the junior doctors had direct supervision the technique would not be "improper".

Corrections and clarifications have already been done.
31. Page lines 21- 24 shouldn't you say that transverse loop colostomies should rarely be done? Be more definitive. In our 1200 bed hospital, I have not seen a transverse loop colostomy performance in over 20 years.

   Changes have been done as it was recommended by reviewer but we did not include the word "loop", we have said transverse colostomies should rarely be done because in table 5, stoma-related complications according to univariate and multivariate logistic regression analysis which shows that transverse colostomy was found to be significantly associated with high complication rates and not transverse loop colostomies.

32. Concerning the tables- See table 1 you have essentially already separated the total into two groups because congenital diseases rarely have the stoma created after age 18, and acquired diseases that you report rarely occur in children.

   Tables 2, 3, 4, 6, children and adults were separated. However, the changes in the tables have causes a lot of changes in the entire text especially numbers. In the previous submitted manuscript, we had 6 tables and 2 figures but now we had 2 figures but now we 7 tables and only one figure.

33. You have the chance to turn this into a very good comprehensive paper AND one that challenges the government and your hospital to provide better care for the patients -meaning much more training and supervision of emergency operations performed by inadequately trained and inadequately supervised junior doctors.

   This really is the message of your paper and no matter how you try to camouflage it, the message is obvious whether your hospital or consultant surgical staff wants to hear it.

   Thank you for the comments, corrections and inputs. We have tried to make corrections, it is our hope that we have made it better.

   Thank you again,
Other corrections

1. Major correction.

Stoma formation related complications

We noted that our observation was not the same as the findings we got from the study, so we decided to review our original/raw data. According to our observation, we see a lot of prolapsed colostomies and surgical site infection as common stoma formation related complications. We rarely see denuded peristomal skin complication. What was in the submitted manuscript was not correct. We noted some mistakes during the data entry process. We have already done corrections in the whole document, in the results section, table and discussion. The reference which supported the previous finding has already been removed in the list, adjustment of the list of references has also already been done. Initially we had 32 references, now, after removing one reference, we have 31 references. So denuded peristomal skin complication is not the most common as it was reported earlier, but it is one of the rare stoma formation related complications.

2. Minor corrections

Page 1

Italic word "department" has been replaced by a world "unit"

In the first conclusion section, page 3, a word "is" has been replaced by a word "are"

Background

Page 3, the words "experienced surgeons" have been replaced by a word "Specialists" Page 4, word "older persons" have been replaced by a word "adult"

Page 5, the word "who", after a word population has been changed to "which"

Methods

Study design and settings

a number "900" has been replaced by a number "950".
Page 6, methods and Study population sections

A word "who" has replaced a word "which"

A word "medicine" has been added after a word "emergency"

Words "were included in the study" have been added

A letter "S" has been added in the word "hospital"

A letter "S" has been added in the word "procedure"

A word "surgical" has been added before the word "registrar",

A word "senior" has been removed before the word "resident"

Page 7

Words "silk or" have been removed before a word "vicryl"

Words "under the supervision of a senior doctor" have been added without including a word "direct" before a word "supervision".

Page 8, study population section

The last line, the word "colostomy" has been replaced by "stoma formation" and a word "its" has been deleted.

Page 11, stoma closure section

A word "direct" has been added before a word "supervision"

Page 12, discussion section

A word "children" has been added after a word "were"

A number "5" has been changed to "18" twice before a word "year".
Page 13, discussion section

Words "basic surgical trainees" have been replaced by "junior doctors"

A word "formation" has been added after a word "stoma"

A word "unprepared health care personnel" has been replaced by the words "inadequately preparations of patients"

Page 15

Word "adequate" and "surgical trainees" have been changed to "direct" and "junior doctors"

“respectively.

Results

Demographic characteristics

Page 8, a word "requiring" has been changed to "required"

Conclusion section

Words "improper operative technique" have been removed

We think lack of often close and direct supervision of the junior doctors by specialists and may be inadequate surgical technique of the junior doctors can contribute to the complication findings, that is why direct supervision of junior doctors by specialists has been recommended.