Author's response to reviews

Title: Paracetamol Use (and/or misuse) in Children in Enugu, South-East, Nigeria

Authors:

Herbert Obu (herbert.obu@unn.edu.ng)  
Josephat M chinawa (josephat.chinawa@unn.edu.ng)  
Agozie C Ubesie (zionagoz@yahoo.co.uk)  
Bismark C Eke (chriseke2006@yahoo.com)  
Ikenna K Ndu (ikennandu@gmail.com)

Version: 4 Date: 21 May 2012

Author's response to reviews: see over
Editor-in-Chief,
Biomed central journals
Dear Sir,

MANUSCRIPT CORRECTION: RESPONSES TO REVIEWER’S COMMENTS

The Authors are grateful to you, all the members of the Editorial Board and the Reviewers for giving us the opportunity to make corrections on our manuscript titled:

**Paracetamol Use (and/or misuse) in Children in Enugu, South-East, Nigeria.**

Please find below point-by-point corrections made, based on the Reviewer’s comments:

**Reviewer's report**

**Title:** The Use and Abuse of Paracetamol in Children by Caregivers in Enugu, South-east, Nigeria

**Version:** 3 **Date:** 18 April 2012

**Reviewer:** Urmila M Thatte

**Reviewer's report:**

Major Compulsory Revisions

Introduction
1. Reviewer's report: The drug is referred to as acetaminophen sometimes and paracetamol sometimes

AUTHORS’ response: The term acetaminophen has been dropped (safe for the opening statement to show that it is same as paracetamol: Abstract Page 2 line 1 ) and paracetamol adopted in all the text

2. Reviewer’s report: The Introduction can be more succinct.

AUTHORS’ response: The introduction is now brief and to the point. Some unimportant items have been deleted. See introduction, page 4

Methods:

1. Reviewer's report: If the service sees 840 patients per month why did the study include only 235 children over a 6 month period? The inclusion criteria mentioned do not indicate why so many children were not included?

AUTHORS’ response: Please the hospital has 480 beds and does not see 840 patients per month, this was a topographic error. We have carefully expunged this statement.

2. Reviewer’s report: The introduction clearly mentions, and I quote "This study assesses the administration of acetaminophen to under 6 children to identify patterns and factors associated with overdose.” However the methods section mentions the inclusion criteria as “Children aged between 6 weeks and 16 years and whose caregiver or parents gave consent”. There is some confusion about the age group actually studied.

AUTHORS’ response: The age of Children under study is actually 6 weeks to 16 years. These have been corrected throughout the manuscript. See
Results (under abstract) page 2 Line 1. See page 6 Study Population Line 1. See also page 9 line 6.

3. **Reviewer’s report:** From an ethics point of view, if older children were indeed recruited, was their “assent” obtained?

**AUTHORS’ response:** Yes older children were recruited and assent was sought for. Page 8 Ethical consideration Line 3.

4. **Reviewer’s report:** It is not clear how it was confirmed that the child had been given paracetamol and not any other medicine? How reliable was the verbal history of the care-giver in identifying the drug administered as paracetamol? What efforts were made to confirm this?

**AUTHORS’ response:** Paracetamol is a common drug that can be obtained everywhere in this country, so these caregivers and even older children recognize paracetamol and can even identify the packs. However efforts were made to confirm this by showing the care-givers the different formulations used in this environment which they easily identified. See study procedure Page 6 Line 4-5

Results

1. **Reviewer’s report:** The statistically significant difference reported in Table III is not completely clear as it is presented. Which groups differed (there are three age groups and three interventions) from which?

**AUTHORS’ response:** This statistically significant difference arose when Chi Square was used to compare all the three variables and they all differed from each other

2. **Reviewer’s report:** The manuscript says that “This study assesses the administration of acetaminophen to under 6 children to identify patterns and
factors associated with overdose” - however there is no attempt at assessing the actual dose given/taken by the child. How would overdose or abuse be measured?

**AUTHORS’ response:** There is a place in the questionnaire to determine the actual dose taken by the patient. We have added a table for this and discussed our findings and indeed detected that most of these children were given appropriate and therapeutic doses of paracetamol. See Page 7 Paragraph 1 (Methodology). See also table VI Page 22 and Discussion page 12 Paragraph 3.

Statistics:

1. **Reviewer’s report:** The methods section does not clarify what was being analysed. What tests were used? For what was the level of significance set? Sample size calculation is also not mentioned

**AUTHORS’ response:** This has been sorted out in data analysis. See data analysis page 8

Discussion:

1. **Reviewer’s report:** One of the statements that the authors raise in the discussion is “From this study majority of the paracetamol administered to our children are self prescribed with a possible tendency of abuse and overdose”. As paracetamol is an OTC drug this observation is expected. Also the results of the study in no way really convince me that there is potential for overdose as no attempts have been made to find out the knowledge, attitude or practices of the caregivers in
determining
the dose or administering paracetamol

AUTHORS' response: Attempts have now been made to determine the
doses of Paracetamol administered and we noted that though majority of the
paracetamol administered to our children are self prescribed, yet these
children were given appropriate and therapeutic doses of paracetamol by
their care givers. See Page 7 Paragraph 1 (Methodology). See also table VI
Page 22 and Discussion page 12 Paragraph 3.

2. Reviewer's report: The conclusions and recommendations made by the
authors (while may be true based on a lot of other generated literature)
cannot be said to have stemmed from this study

AUTHORS' response: The conclusion and recommendations have now
been tailored and are deducible from the study. See Recommendation and
conclusion; Page 13

3. Reviewer's report: The discussion does not mention the limitations of the
study

AUTHORS' response: Limitation of the study has now been added. See
Limitation Page 13

Reviewer's report:

References:

1. The references are old and may not be relevant today (e.g. the 15th edition
dated 1996 of Nelson’s Book of Pediatrics is quoted while the current edition
is

the 19th edition dated 2011. Several more recent references on the topic are
also available

2. The references are not written in order. I cannot seem to find reference 9.

Two references - Utpal et al and Grandins et al are numbered 4 while Abbott et al and Thomas et al are numbered 14

3. Some references are incomplete (e.g. reference no. 7, 12)

AUTHORS’ response: The references have been rewritten in its entirety.
See References; Page 14

General Comments

1. Reviewer’s report: The style of the paper is more in the form of a protocol than a research paper

AUTHORS’ response: The manuscript have been modified to some extent to improve its quality

2. Reviewer’s report: The objective/research question is not very clearly defined or described in the introduction although it is mentioned in a later section of aims and objectives.

AUTHORS’ response: The objective/research question has been clearly defined in introduction. See introduction page 5

3. Reviewer’s report: The title is “The Use and Abuse of Paracetamol in Children by Caregivers in Enugu, South-east, Nigeria” however the study does not really assess abuse and is therefore misleading

AUTHORS’ response: The study now assesses abuse and we found out that these children were given appropriate and therapeutic doses of paracetamol
by their care givers. See Page 7 Paragraph 1 (Methodology). See also table VI Page 22 and Discussion page 12 Paragraph 3.

**Level of interest:** An article of limited interest

**Reviewer’s report:** Quality of written English: Needs some language corrections before being published

**AUTHORS’ response:** We have improved on the language used in this study as much as possible

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests

2nd Reviewer

**Reviewer’s report**

**Title:** The Use and Abuse of Paracetamol in Children by Caregivers in Enugu,

South-east, Nigeria

**Version:** 3 Date: 28 April 2012

**Reviewer:** Rajamohanan pillai

**Reviewer’s report:**

1) **Reviewer’s report:** The question is not well posed but objectives are clear. So this can be considered as identical to questions.

**AUTHORS’ response:** Thanks for the commendation; however the questions and aim have been made clearer in introduction. see introduction Page 4 Last Paragraph
2) **Reviewer’s report:** The methods are appropriate for these objectives. But in the description of the population mentioned the study as cross-sectional prospective study. This is not an appropriate terminology for design.

**AUTHORS’ response:** Thanks for commending our methodology. We have rectified the terminology to an observational prospective study. See Page 6, Study population and Page 2, Methods

3) **Reviewer’s report:** The data is not complete. For example, the total number of subjects studied is differently reported in different places. (in results section it is mentioned that 234 children were enrolled. But all the tables show less than this number as totals(Table II-203). Most of the tables don't show row totals and column totals. In the text, results section, when the authors mention about the caregiver details they give percentages without actual numbers. This is confusing.

**AUTHORS’ response:** Participants were asked to respond to only the questions that they were sure of the answer and/or want to answer. In that sense, there were different numbers of responses per question. This explains why the tables show less than this number as totals.

The actual numbers of the caregivers as well as the percentages have now been included. See result Page 9 and 10. We have added row totals and column totals where necessary in the table.

4) partly only

5) **Reviewer’s report:** The discussion is weak because all observations given in the tables are not completely discussed and not seen compared with
results from other studies in this area.

AUTHORS’ response: The discussion has been re written as much as possible, all observations given in the table are discussed and results compared to other studies in other areas. See Discussion Page 11

6) No

7) No

8) Reviewer’s report: Yes the title conveys the message about the study findings

AUTHORS’ response: Thanks for the commendation

9) Reviewer’s report: yes acceptable after modifications

AUTHORS’ response: Modifications have been done by the authors based on reviewer’s comments. We hope that this manuscript will be accepted.

Level of interest: An article of importance in its field

Quality of written English: Reviewer’s report: Needs some language corrections before being published

AUTHORS’ response: We have done our best possible to improve the English used in this study.

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

'I declare that I have no competing interests'

Once again, the Authors thank you, the Editorial Team and the Reviewers most sincerely for your critical review and suggestions which have improved the write up of this manuscript.

We hope this revised version of the manuscript will now be suitable for
publication in your Journal.

Thank you Sir.

Dr. Chinawa JM MB; BS (PH), FMCPaed.

Corresponding Author