PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	High birth weight in a sub-urban hospital of Cameroon: an analysis of the clinical cut-off, prevalence, predictors and adverse outcomes
AUTHORS	Choukem, Simeon-Pierre; Njim, Tsi; Atashili, Julius; Shield, Julian; Mbu, Robinson

VERSION 1 - REVIEW

REVIEWER	Forough Mortazavi Sabzevar University of Medical Sciences, Iran
REVIEW RETURNED	26-Feb-2016

GENERAL COMMENTS	How the sample size for the prospective study was calculated? it seems that 200 pregnant mother was not enough for doing a multivariate regression analysis. you must explain it in the method section and if it is the case, in the limitation section. Due to the low sample size, it is better to report numbers rather than percents in the result section. page 14 line 22

REVIEWER	Alphonsus N. Onyiriuka University of Benin Teaching Hospital; Nigeria
REVIEW RETURNED	02-Mar-2016

GENERAL COMMENTS	ABSTRACT Line 6: HBW per se does not “carry a grave prognosis” Authors should rephrase the sentence. Does the journal style allow subheadings in the abstract i.e., design, setting, participants, results, conclusion, article summary, strength and limitations of study, key words. This style of writing abstract is alien to me. I my opinion structured abstract should consist of: Background/Aim(s), Methods, Results, Conclusion, Key words. The authors should re-write the abstract to conform with standards for structured abstract, unless this in line with BMJ OPEN journal style/format. INTRODUCTION Lines 6/7: The authors should cross check the definition because there appears to be some grammatical error. Lines 48/49: Delete the sentence; In this respect, …… sub-urban Cameroon.12 The sentence is irrelevant. METHODS Line 10: Change “analysis” to “audit” Line 13: Change “prevalence” to “prevalent” Line 29: The selection of participants was described in a previous study by the same authors.12 Lines 34 and 42: change “woman-newborn” to “mother-infant”

	Line 45: delete < 40 RESULTS/ TABLES & FIGURES Line 52: Where is figure 2? Line 14: Where is figure 3? DISCUSSION Lines 29-31: Their prevalence …… countries like Nigeria.2 This reference is a review article and unlikely to be derived from Nigeria. The authors should cross check and correct it. Line 55: Wrong reference i.e., ref 22 Cameroon study and 23 Tanzanian study. Where is the reference for Botsowana study? REFERENCES There a lot of inconsistency in method of referencing. For example, some journal title are written in full while some are abbreviated. Lines 45/46: Ref 1.Wrongly written. What is the name of the town and page numbers. Is this a Chapter in a book or what? Ref 5.Wrongly written. It should be: Nig J Med 2010

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name
Forough Mortazavi

Institution and Country
Sabzevar University of Medical Sciences, Iran

Please state any competing interests or state 'None declared':
there is no competing interest

Please leave your comments for the authors below
How the sample size for the prospective study was calculated? it seems that 200 pregnant mother was not enough for doing a multivariate regression analysis. you must explain it in the method section and if it is the case, in the limitation section.
The formula: N=(Zcrit)2p(1−p)/D2 was used where N is the sample size of the study group, σ is the assumed SD (standard deviation) for the group, which is taken to be 0.42kg [Negi KS, Kandpal SD, M. K. Epidemiological Factors Affecting Low Birth Weight. JK Sci. 2006;8(1):31-4.]. The CI (confidence interval) is 95% and we took the limits of the 95% CI to be no more than 0.05kg above or below the mean birth weight for the study group, and p which is the estimated prevalence of high birth weight is 10.4% [Lawoyin TO. A prospective study on some factors which influence the delivery of large babies. J Trop Med Hyg. 1993;96(6):352-6.]. From the above equation, the number of babies required was (1.960)20.104(1−0.104)/0.12 =35.8. Therefore, the minimum number of HBW babies required to calculate the prevalence of high birth weight was 36.
However, we obtained only 28 babies with HBW in this prospective phase and we have discussed this overall small sample size as a potential limitation in the limitations section of the manuscript.
Thank you.

Due to the low sample size, it is better to report numbers rather than percents in the result section.
page 14 line 22
We have reported results as numbers. Thank you.

Reviewer: 2

Reviewer Name
Alphonsus N. Onyiriuka

Institution and Country
University of Benin Teaching Hospital; Nigeria

Please state any competing interests or state 'None declared':
I have no competing interest

Please leave your comments for the authors below
ABSTRACT
Line 6: HBW per se does not "carry a grave prognosis" Authors should rephrase the sentence.
The sentence has been rephrased to read: "High birth weight (HBW) increases the risk of maternal and foetal morbidity and mortality". Thank you.

Does the journal style allow subheadings in the abstract i.e., design, setting, participants, results, conclusion, article summary, strength and limitations of study, key words. This style of writing abstract is alien to me. I my opinion structured abstract should consist of: Background/Aim(s), Methods, Results, Conclusion, Key words. The authors should re-write the abstract to conform with standards for structured abstract, unless this in line with BMJ OPEN journal style/format.
The structuring we used in the abstract is what is recommended by the BMJ open instructions to authors. Thank you.

INTRODUCTION
Lines 6/7: The authors should cross check the definition because there appears to be some grammatical error.
We have corrected the error. Thank you.

Lines 48/49: Delete the sentence; In this respect, …… sub-urban Cameroon.12
The sentence is irrelevant.
The sentence has been deleted. Thank you.

METHODS
Line 10: Change "analysis" to "audit"
We have changed accordingly. Thank you.

Line 13: Change "prevalence" to "prevalent"
Thank you. In keeping with the original meaning, we have reworded the statement by adding commas and articles. It now reads: "…to determine the prevalence, the predictors, and the adverse outcomes of HBW."

Line 29: The selection of participants was described in a previous study by the same authors.12
We have changed accordingly. Thank you.

Lines 34 and 42: change "woman-newborn" to "mother-infant"
We have changed. Thank you.

Line 45: delete < 40
We have deleted. Thank you.

RESULTS/ TABLES & FIGURES
Line 52: Where is figure 2?
Line 14: Where is figure 3?
The figures were not meant to be included since it was stated that the selection of participants was described in a previous study by the same authors. The 2 figures have therefore been duly removed. Thank you

DISCUSSION
Lines 29-31: Their prevalence …… countries like Nigeria.2 This reference is a review article and unlikely to be derived from Nigeria. The authors should cross check and correct it.
The reference has been corrected to: "26. Adesina OA, Olayemi O. Fetalmacrosomia at the University College Hospital, Ibadan: a 3-year review. J ObstetGynaecol 2003;23(1):30-3."

Line 55: Wrong reference i.e., ref 22 Cameroon study and 23 Tanzanian study. Where is the reference for Botsowana study?
This was actually an error. The references were supposed to be for Nigeria, Cameroon and Tanzania (not Botswana). This error has been corrected. Thank you.

REFERENCES
There a lot of inconsistency in method of referencing. For example, some journal title are written in full while some are abbreviated.
These inconsistencies have been corrected. Thank you.

Lines 45/46: Ref 1.Wrongly written. What is the name of the town and page numbers. Is this a Chapter in a book or what?
The reference has been corrected. It is a book chapter. But it is an electronic copy without page numbers. Thank you.

Ref 5.Wrongly written. It should be: Nig J Med 2010
We have corrected. Thank you.

VERSION 2 – REVIEW

REVIEWER	Forough Mortazavi Sabzevar University of Medical Sciences, Iran
REVIEW RETURNED	07-Apr-2016

GENERAL COMMENTS	In my opinion, such a study is not enough for recommending to change the cutoff for HBW unless the you bring a reference indicating that a new cutoff can be recommended by only conducting a descriptive study with a large sample size without comparing two cutoffs. I think more information is needed, for example; you should compare two cutoffs (3850 vs. 4000) in terms of maternal and neonatal complications. since the sample size is low, you should at least show that using the new cuttoff increased the number mothers or neonates with complications. you claimed more than you found in this study.

REVIEWER	Alphonsus N. Onyiriuka University of Benin, Benin City; Nigeria
REVIEW RETURNED	14-Apr-2016

GENERAL COMMENTS	ABSTRACT Page 3 line 25: Women who delivered in the hospital over a 6-year period (retrospective) Page 3, Line 36 For consistency, authors should use percentile and not centile. Page 4 , line 8-30: Sub heading Article summary – Is this in keeping with the journal's style otherwise delete it. Methods: Line 50: Who are minors in this study? The study involved mothers and newborns. Newborns cannot sign assent and this should be deleted. I do not think that any mother is a minor. Is it a hospital policy for mothers to stay for 3 days after normal delivery? The authors should clarify this. Who conducted the physical examination including weighing of the babies and how was consistency ensured? What steps were taken to minimize weighing errors? Page 7 If fetal heart rate < 120 beats/min represent fetal distress What about fetal heart rate persistently above 160 beats/min? Line 32: How was the pre-pregnancy BMI determined? Line 45: Given that the blood glucose levels of these babies were not determined, were the babies managed as dictated by their clinical condition? This is unethical because such babies may suffer from the adverse effects of hypoglycaemia – a well recognized problem in HBW babies. CONCLUSION Page 16 line 16 Based on the suggested new cut-off value, one out of every seven babies born in the hospital has HBW. There are some grammatical errors and the authors need to correct them.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name
ForoughMortazavi

Institution and Country
Sabzevar University of Medical Sciences, Iran

Please state any competing interests or state 'None declared':
I have no competing interest

Please leave your comments for the authors below
In my opinion, such a study is not enough for recommending to change the cut-off for HBW unless the you bring a reference indicating that a new cutoff can be recommended by only conducting a descriptive study with a large sample size without comparing two cutoffs. I think more information is needed, for example; you should compare two cutoffs (3850 vs. 4000) in terms of maternal and neonatal complications. since the sample size is low, you should at least show that using the new cuttoff increased the number mothers or neonates with complications. you claimed more than you found in this study.

Thank you for your comments.
We agree that the number of events (28) in the prospective phase was rather small. However,

reaching statistical significance (p=0.04) suggests that the 4000 cut off may be inappropriate.The WHO recommended the need to develop region-specific cut-off values.
We used the same data to suggest that the cut-off for low birth way may be increased from 2500 to 2600g (Njim T, Atashili J, Mbu R, Choukem SP. Low birth weight in a sub-urban area of Cameroon: an analysis of the clinical cut-off, incidence, predictors and complications. BMC Pregnancy and Childbirth. 2015; 15:288). Similarly, in the present study, we compared the prevalence of complications amongst mother-neonate pairs who fell in the category (3850g – 4000g) with mother-neonate pairs who fell in the category <3850g; we showed that mothers who fell in the newly created category (3850g – 4000g) were more likely to have complications related to HBW (post-partum hemorrhage, p = 0.04) than women with babies <3850g (Last paragraph of the results; page 13). This suggests that using the cut-off value of 4000g ignores women with babies weighing 3850g – 4000g who are equally at higher risk of post-partum hemorrhage.
Owing to the small sample size, we have tempered our claims by emphasizing in the conclusion the need for more studies in order to confirm our preliminary findings.

Reviewer: 2

Reviewer Name
Alphonsus N. Onyiriuka

Institution and Country
University of Benin, Benin City; Nigeria

Please state any competing interests or state 'None declared':
I have no competing interest

Please leave your comments for the authors below
ABSTRACT
Page 3 line 25: Women who delivered in the hospital over a 6-year period (retrospective)
Thank you for your correction.

Page 3, Line 36 For consistency, authors should use percentile and not centile.
Thank you. We have corrected.

Page 4 , line 8-30: Sub heading Article summary – Is this in keeping with the journal's style otherwise delete it.
Thank you for your comment. We confirm that the sub-heading "article summary" strictly followthe journal' style.

Methods:
Line 50: Who are minors in this study? The study involved mothers and newborns. Newborns cannot sign assent and this should be deleted. I do not think that any mother is a minor.
Thank you for your comment.
In this study we recruited all women who came to the Buea Regional Hospital to deliver. In Cameroon, the legal age for consent is 21 years. All pregnant women who were below this age had to sign an assent form while their guardians signed a guardian consent form. This was also a prerequisite for us to obtain ethical approval from the institutional review board.
We have therefore revised the statement to read "Informed consent was then obtained after delivery. Legal minors (mothers aged < 21 years) and their guardians had to sign assent and guardian consent forms respectively."

Is it a hospital policy for mothers to stay for 3 days after normal delivery? The authors should clarify

this.
Thank you for your comment.
The policy in the maternity unit of the Buea Regional Hospital as in other hospitals in the country is to keep mothers for a minimum safety period of three days after delivery. However, mothers may be discharged as soon as they are fit to go home especially if they face financial constraints, provided that there is no complication. We have corrected this statement to read “The newborns and their mothers were observed until the day of discharge, which could be up to 10 days for complicated deliveries which included caesarean sections and instrumental deliveries.”

Who conducted the physical examination including weighing of the babies and how was consistency ensured? What steps were taken to minimize weighing errors?
Thank you for your comment.
The physical examination and the weighing of the 200 babies in the prospective phase was carried out by a single observer, one of the authors (TsiNjim). Consistency was ensured by making sure that all the weights of the babies were measured by this author.
In order to minimize errors, the following standard operating procedure was used.
All babies were weighed within sixty minutes after delivery as significant postnatal weight loss occurs after this time frame. All the babies were weighed using the same Holtex®+ digital baby scale making sure that the reading before weighing was at 0000.0kg. The babies were all weighed without clothes or any accessories.

Page 7 If fetal heart rate < 120 beats/min represent fetal distress What about fetal heart rate persistently above 160 beats/min?
Thank you for your comment.
The statement has been corrected to read: “Throughout the labour, the foetus was monitored for the presence of acute foetal distress (foetal heart rate < 120 beats per minute or persistently above 160 beats per minute and/or green meconium-stained amniotic fluid at delivery)” which was actually what was considered.

Line 32: How was the pre-pregnancy BMI determined?
Thank you for your comment.
For the women who had their pre-pregnancy BMI measured (n = 131), their pre-pregnancy weight was obtained from their hospital records ensuring that the weight obtained from the records was within 1 month before their last normal menstrual period.

Line 45: Given that the blood glucose levels of these babies were not determined, were the babies managed as dictated by their clinical condition? This is unethical because such babies may suffer from the adverse effects of hypoglycaemia – a well recognized problem in HBW babies.
Thank you for your comment.
Because the policy in the maternity was to systematically breastfeed or give sugar to all babies immediately after birth, the Institutional Review Board did not grant us the approval to do capillary glucose measurement which was not standard clinical practice. They considered that the risk (pain due to finger prick) outweighed the potential benefit since babies would have received sugar or breast milk anyway.

CONCLUSION
Page 16 line 16 Based on the suggested new cut-off value, one out of every seven babies born in the hospital has HBW.
Thank you. We have corrected.
There are some grammatical errors and the authors need to correct them.
Thank you. The manuscript has been read and grammatical errors corrected.

VERSION 3 - REVIEW

REVIEWER	Alphonsus N. Onyiriuka University of Benin Teaching Hospital, Nigeria
REVIEW RETURNED	10-May-2016

GENERAL COMMENTS	Please leave your comments for the authors below Abstract: Page 3; Replace subheading “Objective” with Background/Aim Methods: Page 7, line 51 Legal minors in Cameroon (mothers aged < 21 years). Women < 21 years old may not be regarded as minors in other countries. Number 5. Comment on research ethics not possible because method of recruitment was not described in the present study but in a previous study. Discussion: Page 13 line 25: The reference is 8,16 and not 816. Page 13 line 54, Check spelling : Is it emphasises or emphasizes? Page 14, line 8: The reference is 9,24 and not 924

VERSION 3 – AUTHOR RESPONSE

Reviewer: 2

Reviewer Name
Alphonsus N. Onyiriuka

Institution and Country
University of Benin Teaching Hospital, Nigeria

Please state any competing interests or state ‘None declared’:
No competing interest

Please leave your comments for the authors below
Please leave your comments for the authors below

Abstract: Page 3; Replace subheading “Objective” with Background/Aim
The subheading has been replaced with “Background and Aims”.

Methods: Page 7, line 51 Legal minors in Cameroon (mothers aged < 21 years). Women < 21 years old may not be regarded as minors in other countries.
The statement has been deleted.
Number 5. Comment on research ethics not possible because method of recruitment was not described in the present study but in a previous study.
The statement on ethical approval is in the last paragraph of the methods section (page 8).

Discussion: Page 13 line 25: The reference is 8,16 and not 816.
The citation as been corrected.
Page 13 line 54, Check spelling: Is it emphasises or emphasizes?
We have kept the spelling “emphasizes”, which is correct in English (emphasizes is American ‘English”).
Page 14, line 8: The reference is 9,24 and not 924
The citation has been corrected.