

PEER REVIEW HISTORY

BMJ Paediatrics Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Assessment of developmental outcome in very low birth weight infants in southern Africa using the Bayley Scales of Infant Development (III)
AUTHORS	Ballot, Daynia; Ramdin, Tanusha; Rakotsoane, David; Agaba, Faustine; Chirwa, Tobias; Davies, Victor; Cooper, Peter

VERSION 1 - REVIEW

REVIEWER	Potterton, Joanne University of the Witwatersrand, Johannesburg, South Africa Competing interests: None
REVIEW RETURNED	09-Jun-2017

GENERAL COMMENTS	<p>This is a well written paper which covers an important and relevant topic. The background information is concise and sets the context of the study well. The methodology is clear and well described. The results and ensuing discussion are in line with the aims of this study and provide important new insights into the field. The authors are candid in identifying the limitations of their study and draw appropriate conclusions.</p> <p>There are a few minor changes/ additions that I would like to suggest:</p> <p>Be consistent in the use of BSID III not BSID 111 or BSID 3</p> <p>Line 49 insert of...." survival of these infants</p> <p>Line 56 delete that.... "reported that ELBW survivors to be at"</p> <p>Page 5 paragraph 2: The term "surrounding areas" is somewhat misleading. It is easy to interpret it as areas closely surrounding the hospital rather than areas surrounding the province in which the hospital is situated (which is how I think it was intended). To readers who are not familiar with the context the distances that this implies may not be appreciated.</p> <p>Page 6: It is stated that the SA government child support grant was used as a measure of poor socio-economic status. This suggests that only South African children who are eligible for this grant were included. However in the limitations of the study it states that one third of subjects were foreign nationals. What was used as a measure of poor socio-economic status for non-SA families?</p> <p>One of my main concerns with this paper is the limited information given on the control group. A table providing some background demographic information on this group would be helpful.</p> <p>Maternal HIV status is provided for the VLBW group but not for the</p>
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	<p>control group. No HIV status is provided for any of the infants This is an important confounding factor for development in this population. Given the concerns around development of HIV exposed uninfected infants and the well documented risk of developmental delay in HIV infected infants I think that, if available, this information would be extremely interesting, especially given that almost 25% of the VLBWI mothers were HIV infected. If the data is not available it should be identified as a possible confounding factor.</p> <p>Add n values to tables 2,3 and 4.</p> <p>In the discussion it may be helpful for readers not familiar with the setting to know that this study was conducted at a large academic hospital and that the same care, and therefor the same outcomes may not be seen in infants who do not have access to similar levels of facility. The statement at the end of the 1st paragraph of the discussion may be somewhat optimistic given that many infants in rural areas in South Africa will not have access to tertiary healthcare.</p>
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REVIEWER	<p>Goulart, Ana Lucia MD, PhD, Professor of Pediatrics Federal University of São Paulo, São Paulo, Brasil Competing interests: No competing interests to declare</p>
REVIEW RETURNED	16-Jun-2017

GENERAL COMMENTS	<p>Dear Authors</p> <p>The subject of this manuscript is interesting and would bring contributions for neonatologists, neurologists, general pediatricians and others health professionals, in regard to neurodevelopment of preterm infants in a developing country.</p> <p>However, this study presents some methodological problems, as follow:</p> <ul style="list-style-type: none"> - The authors intended to compare the developmental outcome of preterm very low birth weight infants and "normal infants". The developmental outcome of the "normal infants" was reported in another study that has been submitted for publication, and the authors selected a group of 50 infants who were assessed at the same mean chronological age as the VLBWI. There was no sample size calculation to compare the groups. - The authors don't mention that the study was approved by an Ethical Committee, as well as the written informed consent from parents - The authors informed that BSID-III assessments were done by an appropriately trained physiotherapist or pediatrician. The coefficients of agreement between examiners were calculated? The same physiotherapist and pediatrician evaluated both groups - preterm and term infants? - The demographic and clinical information of the "normal infants" were not showed - In Table 5, showing the "Comparison of developmental delay
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	<p>between VLBWI and Control groups", it would be interesting to show the 95% confidence intervals.</p> <p>- The absence of sample size calculation should be included in "Study limitations"</p> <p>Sincerely Ana Lucia Goulart Professor of Pediatrics, Neonatal Division. Federal University of São Paulo, SP, Brazil.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1

1. Noted – all changed to BSID (III)
2. Line 49 – of inserted
3. Line 56 – that deleted
4. Page 5 paragraph 2 – the surrounding areas has been changed to “neighbouring provinces and countries”
5. The issue regarding assessment of sociodemographic status in foreign nationals has been added to the study limitations
6. Information on the control group has been added to the results
7. Only one VLBWI was HIV infected – this has been added to the discussion – page 14 second last paragraph
8. n has been added to the tables
9. The issue of lack of access to tertiary services for all VLBWI has been added as the second paragraph in the discussion on page 13.

Reviewer 2

1. A sample size calculation has been added to the methods – Page 6 last paragraph
2. The results for the whole control group (n=74) who were tested at a slightly older age and for a sub – group (n=50) are reported in Table 2 (this replaces Figure 2)
3. The ethics section has been added to methods (this was mentioned under declarations)
4. The coefficient of agreement is added to the Methods – paragraph 3 – page 6. A statement has also been added to clarify that both VLBWI and control infants were evaluated by the same physiotherapist and paediatricians (Page 6 – second paragraph)
5. Information about the normal infants has been added and referenced (it is another publication)
6. Confidence intervals have been added to the table

Editor’s comments

1. The subjective discussion in the first version is noted – our VLBWI survivors are at risk of handicap. The discussion, conclusion, abstract and “what this study adds” have been changed to focus on the 6.6% of VLBWI with developmental delay. The fact that the study was conducted in an academic setting and that infants born in regional or district hospitals will probably have worse outcomes has been added as paragraph 2 in the discussion.

2. Sample size calculation has been added to the methods.

3. The ethics section has been relocated to “Methods”

4. The % column in Table 1 has been deleted.

In addition, the comparison between the study group and controls has been reported as Table 2 – which replaces figure 2.