Author's response to reviews

Title: Prevalence of suspected developmental delays in early infancy: Results from a regional population-based longitudinal study

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Author's response to reviews: see over
Dear Editor.

Thank you for the valuable comments from you and the reviewer and for your encouragement to submit a revised version of our manuscript “Prevalence of suspected developmental delays in early infancy: results from a regional population-based longitudinal study”.

The comments were very helpful, and we have done our best to attend to the concerns both in the enclosed cover letter as well in the revised manuscript.

Our response to the reviewer’s comments are attached below.

We hope that the changes and clarifications provided in this revision have improved the manuscript and that it is acceptable for publication in BMC Pediatrics.

Looking forward to hearing your decision.

Sincerely,

Lisbeth Valla
Response to the reviewers comments

Reviewer # 1
Comment 1:
The authors provide a helpful overview of the context of early child healthcare in Norway. They also suggest an important reason to estimate developmental delay prevalence rates is to engage in program planning and policy development for early intervention. To this end, it would be helpful for the authors to provide some context for early intervention service delivery in Norway – who is eligible? How are services provided and financed?

Response:
Thank you for pointing on the importance to provide some context for early intervention service delivery in Norway. We have included some information about this issue at page 4 from line 106-117.
For your information the Ministry of Health and Care Services (HOD) has the overall responsibility for government policy on health and care services in Norway and for providing good and equal health and care services for the population. HOD directs these services by means of comprehensive legislation, annual budgetary allocations, and through various governmental institutions. The Norwegian Directorate of Health sets national guidelines with recommendations and advice based on current scientific knowledge that are intended to assist service providers with the judgement they have to make to achieve soundness and quality of service. These guidelines are not directly legally binding, but they should play a substantial role in shaping the decisions that have to be made. The local Community Health Care Act (1982) requires all municipalities to organize maternity care, well baby clinics for 0-5 years old, school health services in primary, secondary school (1-10-grade), and high school (3years). In additional, youth health centers. The publicly organized services are offered to pregnant women and to all parents with children and adolescents from 0 to 20 years old. The service is free and shall among other tasks, keep a record of physical, mental and social health status and other matters that are of concern for children’s health and welfare (Norwegian Directorate of Health 2004). The public health nurses (PHNs) meet the family frequently and have a central role in this service. The amount and content of EI services at the primary care level varies to some extent between municipalities depending on how high priority EI has among the local authorities. If more specialized evaluation and treatment is needed a referral from the local GP is necessary and parental consent is required for referral to specialist services.
Comment 2:
It would be helpful for the authors to address the attrition of participants and how this might have influenced the results. For example, it appears that a relatively large proportion of the babies <2500 grams did not complete ASQ’s at each time point.

Response:
Attrition is always a problem in longitudinal studies. We have now included additional information (i.e. mean and range) about the participants’ birth weight and gestational age in a note under Table 1. We discuss how this might have influenced the results under Limitations, page 15.

Comment 3:
Tables 2 and 3 are difficult to read. It would be helpful to streamline the results and perhaps only present the prevalence rates and an asterisk to correspond to p-values (Table 3). For table 2, perhaps the actual cut-off values aren’t needed. Perhaps this can be presented in an Appendix to make Table 2 easier to read.

Response: Table 2 has been simplified as recommended. In table 3 we have simplified by deleting the chi square statistics, the information in these numbers is mostly present in the p-values. We would prefer to keep the p-values since they contain valuable information that is not covered by their categorization into asterisks. For instance, there are important differences between p-values .049 and .016, and between .052 and .952.

Comment 4:
Also, I’m wondering if the authors considered examining rates of infants who had delays in more than one area. To this end, the rate of children who scored at or below the cut-off in one area differs from the distribution of individual delays suggesting a need to investigate this further. Moreover, how many children who had delays at 4 months also had them at 6 and 12-months? This would be important for EI program planning.

Response: We agree that information about the rates of infants with delays in more than one area is valuable. Information about the proportion of children with delays in more than one area at 4, 6 and 12 months are now included in the result section (page 9) and the discussion section (page 12).
We also agree that information regarding the number of children with delays at several assessment points is highly relevant for EI program planning. However, this information is complicated to present since there to some extent are different participants with this information available at each assessment point. Specifically, at 4 months 87 children of 1244 had delays. Of these 87, 15 (17.2% of 87) also had delays at 6 months while this information was lacking for 6 children of the 87 screen positive children at 4 months. Of these 15 with screen positive ASQ at 4 and 6 months two children (13.3%) also had difficulties at 12 months, information was lacking for 6 children. Looking at 6 months only, 68 of 1192 children had delays. Of these 68, 9 children (13.2% of 68) also had delays at 12 months while this information was lacking for 26 children. We do not think this rather complicated information is suitable for inclusion in the article. However, if it is your opinion that this information should be included in the article we accept this.

Comment 5:
Later in the manuscript, the authors discuss that their sample is predominately higher income and well-educated. This seems to have very important implications for interpretation of the results (especially comparisons to US norms) that should be addressed more explicitly in the paper

Response: We discuss how this might have influenced the results under Limitations, page 15.

Comment 6:
On page 11, lines 287-291 and page 12, lines 292-298 the authors compare their findings to similar studies, I found this section confusing because it wasn’t clear at times which study the authors were referring to (theirs or a different one). And, as written, seems to undermine the robustness of their findings. I would suggest revising this section.

Response: We appreciate these comments and have tried to revise this section in a way that hopefully is less confusing and more clear to the reader.
Comment 7:
On page 12, lines 299-310, the authors address the issue of a high prevalence of gross motor delay. I’m wondering what some plausible explanations for this finding are. Assuming the rate is actually far less than the US, are their culture differences (e.g., more tummy time or floor time) that could explain this? A discussion explaining these findings would be helpful and probably more relevant that the presentation of motor delays in older children in the US. Finally, given that the authors wanted to learn more about rates of developmental delay to assist with EI,

Response:
We have revised this section and discuss some plausible explanations for the relatively low rates of motor delays compared to prevalences from other countries.

Comment 8:
I’m wondering what the implications of the findings are for EI in Norway? Are the results valid? Should they be used to determine EI eligibility?

Response:
This prevalence estimate is more relevant for determining the need for assessment services than for planning interventions. ASQ is validated in the US version, we have noted as a limitation that the Norwegian version should have been validated. Prevalence data on suspected developmental delays (SDD) in young infants are scarce and a necessary first step in order to plan for early intervention. This information is now included at page 1 in the discussion section, line 364

Reviewer # 2:

Comment 1.
The authors state that the current study is important in order to determine the prevalence of developmental delay in Norway, in part for service planning. It would be more accurate to state that the study is examining the prevalence of suspected developmental delay, as a formal evaluation will be needed to determine if the screen positive children truly have a delay. Thus, this prevalence estimate could
be helpful in determining the need for assessment services; treatment services would depend on the estimate of children who truly have a delay rather than the number of children who screen positive.

**Response:** We agree that it would be more accurate to state that the study is examining the prevalence of suspected developmental delay and that this estimate could be helpful in determining the need for assessment services. We have replaced development delay (DD) throughout the text with suspected developmental delay (SDD). The heading is also changed accordingly.

Comment 2:
The article contains several spelling and grammatical mistakes. As an example, the authors use the terms “suspect” and “suspected” developmental delay; the latter would seem to be the most appropriate choice. Other examples include the use of plurals (p. 4 line 102: “American Academy of Pediatrics recommends…” and p. 7 line 181 “...children who score 2 SD or more below average are considered…”).

**Response:** The article has now been checked for grammar and spelling mistakes and we hope that this has contributed substantially to improve the entire English text.

Comment 3:
If possible, it would be helpful for the authors to include additional information about the variation in gestational age and birth weight, as this could significantly affect the results. For example, results would likely be very different if the sample contained a relatively small number of extremely preterm/low birth weight infants as compared to a higher number.

**Response:** Information about gestational age and birth weight range and mean values are included in table 1.

Comment 4:
On page 3, references should be considered for the sentence on lines 88-89.

**Response:** Reference is considered for this sentence.

Comment 5:
On page 6, the authors state that “all parents with ASQ screen positive infants were offered further evaluation…”. It is not clear if that was the study protocol, or if quality checks/chart reviews were conducted to ensure that 100% of screen positive children were offered referrals. Lack of appropriate intervention for screen-positive children has been a concern in the United States.
Response:
Originally, it was part of the study protocol that all screen positive infants were offered further assessment. However, not all parents that were offered further assessment regarded this as necessary, partly because of the frequent monitoring of the child’s development by use of ASQ.

Comment 6:
The authors state that the study population is “low risk.” However, preterm and low birth weight infants were included in the study population. Perhaps it would be more accurate to describe the sample as a community-based sample, as these characteristics have previously been demonstrated to be risk factors for developmental delay.

Response:
We agree that it is misleading to use the term low-risk and have replaced it with terms such as regional-based or population-based sample.

Comment 7:
It would be helpful to understand why non-Norwegian speaking parents were not excluded from the study. It appears that they self-selected out of the study by not participating.

Response:
It is a stated aim of the Norwegian health authorities that all citizens should have equal access to health services, and the aim of this study was to include the entire population as far as possible. However, a larger proportion of the parents with non-Scandinavian origin did not consent to participation.

Comment 8:
The authors may wish to specify in the abstract and earlier in the manuscript that corrected gestational age was used to determine the time of administration for preterm infants, as this is an important methodological point.

Response:
We have now included the information about corrected gestational age in the abstract.
Editor's comment:

"Please include the full name of the Research Ethics Committee that approved the study in the methods section. On the title page, please remove the author suffixes (if you wish, details on the qualifications/background of the authors can be added to an Authors' Information section next to the Acknowledgements section at the end of the paper). Please check through the revised manuscript to ensure accuracy and clarity of grammar and language. Where authors of studies are cited in the text, please ensure all have an associated reference number in square brackets, as some appear to be missing."

Response: We have supplied the full name of the Research Ethics Committee that approved the study and removed the author suffixes on the title page. We have also fixed grammar, language and references mistakes.

Please note that there are some minor changes in Table 1. The number of participants have been reduced by 3 and 4 persons as some single ASQ items were lacking for these persons. Prevalence estimates are now based on participants with no single item missing and the corrected number at each time point is 1244 at 4 months, 1192 at 6 months and 832 at 12 months. There are also some phrases and references added to the discussion in section 345 - 368.