PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (see an example) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Determinants of Vulnerability in Early Childhood Development in Ireland – a Population Level Study
AUTHORS	Curtin, Margaret; Madden, Jamie; Staines, Anthony; Perry, Ivan

VERSION 1 - REVIEW

REVIEWER	Sally Brinkman Co-Director, Fraser Mustard Centre Telethon Institute for Child Health Research Centre for Child Health Research, University of Western Australia Australia. I declare to have no competing interests in this paper.
REVIEW RETURNED	29-Dec-2012

THE STUDY	Methods: 1) Second paragraph - "All eligible children" - What was the consent procedure? Passive or active parent consent or no consent? How did the data collection manage to obtain all eligible children? 2) The validation work of the EDI in Canada and Australia has been cited but there is no detail of any validation work conducted in Ireland for the EDI. Was any content validity conducted? How do we know the questions are relevant for the Irish setting? Was there any concurrent or construct validity testing conducted? 3) There is mention that the parental questionnaire was adapted to Ireland - can you provide an example to the reader. Also there is no citation for the parent questionnaire developed at McMaster. 4) Was there any attempt to Rasch model the EDI to determine if 10% made sense for the cutpoints for developmental vulnerability considering the distribution of results from the Irish sample? How did the Irish cutpoints compare to the Canadian cutpoints for vulnerable, at risk and on track? 5) There should be a participant flow diagram included for the study.
RESULTS & CONCLUSIONS	Results: Results intro section. 1) Should include details of how the sample from city Cork differs/similar to the demographics of the whole of Ireland. For non Irish readers this would be helpful. Vulnerability section. 1) "The majority of children scored well on each domain". Of course they did because the domains were scored in a way to make sure that this was the case. The cutpoints have been made arbitrarily at 10% to define "vulnerability" and 25% to define "at risk". This is not really a result. The results are how these proportion of children change across the different demographic sub-populations. 2) "In total 12% of children were vulnerable in one domain". This can't be correct. The percentage should be higher than that considering that 10% of children are vulnerable in each single

	domain. 3) Table 3 - make the headings of the columns clear. Presumably "%vulnerable" actually means percent vulnerable on one or more of the 5 domains. 4) Table 4 - I am not sure that I understand what is being presented here. If model 1 is only adjusting for age gender and ESL why aren't these the only three variables shown with results in comparison to model 2 where all variables are reported which are presumably the same variables as what is referred to as "all other variables" in the footnotes. Discussion: 1) Suggest including a small discussion of figure 1 - i.e. how the patterns of demographics have a different impact on the different domains. 2) The cut points for vulnerability have been created arbitrarily and thus caution needs to be given to statements like "However, a significant minority of over one quarter (28.6%) were not developmentally ready to engage in and thereby benefit fully from school". Without predictive validity analyses these statements need to be made with caution. How do we know that making the cut points at 10% are right for Ireland and that indeed these children classified as developmentally vulnerable aren't ready for school? A statement needs to be included noting that Rasch and predictive validity analyses need to be conducted to test the veracity of such claims. 3) Discussion should include reference to findings previously published between the parental questionnaire and the EDI in Canada - i.e. do we see the same strength/magnitude of association for the determinants? (for example: Janus, M. (2011). Transition to school: Child, family, and community-level determinants. In: Laverick, D.M., & Jalongo, M.R. (eds.), Transitions to early care and education. Educating the young child, 4(3), pp. 177-187). 4) The last paragraph could be enhanced by a broader review of the literature (for example Hertzman, C. and R. Williams (2009). "Making Early Childhood Count." Canadian Medical Association Journal 180: 68-71. and the early childhood chapter discussing proportionate universality in Marmot, M. (2010). Fair Society, Healthy Lives: The Marmot Review, The Marmot Review. and also taking this a little further with reference to the EDI: Lynch, J. W., C. Law, et al. (2010). "Inequalities in child healthy development: Some challenges for effective implementation." Social Science and Medicine 71(7): 1219-1374. 5) The last paragraph also needs to discuss the implications for Ireland to continue to differentiate this paper from others already publishing such results
REPORTING & ETHICS	CONSORT/STROBE Participant flow diagram should be presented. Ethics: Unclear if passive or active parental consent for the child level data collection was used. Were all eligible children recruited participants? If so, was there no parental consent? and how was this passed by ethics? Redundant publication: The main weakness of the manuscript is that there isn't anything very new reported. The claim that this is the first such study in Europe is incorrect. To differentiate this paper from others there should be am emphasis on the fact that the EDI hasn't been used in Ireland before and that the determinants of child development for

	children residing in Ireland haven't been published before. To add interest to the paper for an international audience, it would be interesting to compare the mean results gained in Ireland to results publicly reported in Canada, Australia and the US for example.
GENERAL COMMENTS	- The title of the paper should include "in Ireland" - Article Summary, Article Focus, first dot point - should include "in Ireland" - Article Summary, Strengths and limitations of the study - first dot point is incorrect. The EDI has been used in Moldova, Kosovo, the Netherlands, Sweden, London, Estonia and Scotland, with three of these implementations being regional population data collections. - Background, page 4, second paragraph, last sentence - insert "childhood" between early and vulnerability. - Background, page 4, fourth paragraph. Third sentence is incorrect. The EDI has been used in Europe and some of these implementations have been regional population studies. - Methods, fourth paragraph - referencing style changes and the cites are not included in the reference list. - Page 6, Explanatory variables section, third paragraph, second sentence - should be "has been proven" - Page 7, vulnerability section, second sentence - domain should be plural. - Discussion, second paragraph, fourth paragraph and sixth paragraph - referencing format changes and all the cites aren't included in the reference list.

REVIEWER	Nazeem Muhajarine, PhD Professor and Chair, Community Health and Epidemiology, College of Medicine University of Saskatchewan Saskatoon, Saskatchewan, Canada
REVIEW RETURNED	24-Jan-2013

GENERAL COMMENTS	The continuing contribution that papers such as these make is the amassing of the evidence base supporting a population health approach to measuring, monitoring and evaluating the ECD status in population groups, different from an approach often taken to diagnose and identify individual children at highest risk for poor developmental and school outcomes. The rationale for this study is well captured in the authors' own words in page 4 (Background) of the manuscript. They state: "[ ] The relatively large numbers of children with less pronounced development delay are a potentially greater burden than a small number of children at high risk leading to a need for a population health approach. Yet, measurement of child development is usually in the form of a diagnostic which aims to identify children at greatest risk and provide appropriate individual care, leaving a dearth of research evidence on which to build population level strategies. In this context a direct population level evidence base on normal child development is needed." This rationale casts the paper in a positive light at the outset. However, the paper raises several questions—mostly methodological—and below I will visit each of these in order. Article Summary

	1. The summary provided is reasonable except for use of the term, community level (line 13), under Article focus. This paper doesn't include a focus on community level variables, and therefore this term needs to be removed. Had the paper had a focus on community level variables, it would require a different analysis altogether than the logistic regression analysis presented. Abstract 2. Line 7: When referring to the domain names of the Early Development Instrument, it would be useful to give the full name of the domains and use the same names as found in the literature. This consistency will be appreciated by the readers. For example, rather than "Physical" please say "Physical health and wellbeing," etc. Methods 3. Page 4, Line 36: "stated" should be "states" 4. Page 4, Line 48: "Junior infants" sounds odd. Did the authors mean to say "junior kindergarteners" 5. Page 4, Line 55: Amongst the eligibility criteria is "being in class more than one month". Typically in other jurisdictions where EDI is implemented the "time in class" threshold is more stringent, e.g., 4-5 months in the classroom (e.g., typically EDI implemented in Feb-Mar of the school year, which begins in the previous Sept. (See lines 32-33, page 5 in this paper.) Was there a particular rationale that this particular threshold was picked in this study? 6. Also, did the eligibility criteria include a requirement of one student participant per one household/parent respondent? 7. First paragraph (page 4, lines 46-51): It would be important to know whether the declining schools (to participate in the study overall as well as those not agreeing to administer the parental questionnaire) in any way are introducing a bias. Are the children in the schools declining to participate different from those children in schools who agree to participate? 8. Related to point 3 above, it is critical to demonstrate in this study to what extent is the sample included is an accurate representation of the population of kindergarten-aged children (5-6 yrs) in the jurisdiction where this study was done. There is some results presented in table 2 comparing total EDI sample and subsample with information from the parental questionnaire. However, age is not included as a variable in this table, which is a very important variable to include. Further the real comparison that needs to be presented is the similarity between the sample included in the study and the actual population of 5-6 year olds in Cork, Ireland. This has important implications later when the authors go on to present population attributable fractions based on their sample data. 9. Page 5, Line 4: "McMasters" should be McMaster 10. Page 5, Line 18: For evidence of validity and relevance of EDI to students with different cross-cultural backgrounds (Canadian Aboriginal students versus non-Aboriginal students for example) see: Muhajarine N, Puchala C, Janus M. Does the EDI equivalently measure facets of school readiness for Aboriginal and Non-Aboriginal children? Social Indicators Research 2011;103:299-314. 11. Page 5, line starting at 56: The definition of and the

	operationalization of developmentally 'vulnerable' measure is acceptable, but I would suggest that the authors consider normalizing the threshold/cut-off scores (i.e., 10th percentile) to an external population. Given the claim that this is a first study using EDI in the Europe region, there may not be a large population base standard to refer to when defining the developmental vulnerability, but if this is the case, it would be reasonable to adapt a reference standard from elsewhere, such as Canada or Australia. Developing vulnerability status using normalized threshold values will allow the authors of this study to compare results from this population to those of others, and potentially over time as well. It would be helpful to cite ref #13 in this paragraph. 12. Page 6, Line 19-21: Why was the identification of whether the student was a "Member of the Travelling Community" determined by informants from schools? Wouldn't a better source for this information be the parents themselves? 13. What was the rationale for including the set of explanatory variables that were included in this report. The study collected a wider range of data (for example, as reported, child health and development; child care; pre-school; school; family; neighbourhood; and background information) but only a handful of explanatory variables were included and reported. 14. Page 6, Line 39: Consistent terminology (rather than "developmental scores" here and elsewhere "EDI scores" (e.g., Line 51) a consistent terminology applied for the final EDI scores would be appreciated). 15. Page 6, Line 43: Who was the source for the "pre-school attendance" variable? Please indicate. 16. Page 6, line 54: It would be useful to indicate a little more detail on the calculation of the Population Attributable Fraction (e.g., give the formula used in the "punaf" method in STATA). Results 17. Table 4 (page 12) need reference groups for variables included in the table. 18. It would be better to identify any statistically significant selection forces between the full sample and the sample who returned completed and valid parental questionnaires. In other words, how is the subsample of students for whom parents provided additional information significantly different from the full sample of students and what implications does this present on the internal and external validity of the results (for example, how would the finding that reading stories to children in the past week was strongly related to developmental vulnerability in the multivariable models could be different if a higher percentage of the sample were included in this phase of the analysis?). Discussion 19. Page 8, Lines 46-47: References cited here are not included in the list of references, such as Carpiano, 2009, Kohen, 2009. It seems that any references that are cited in the APA format (author, date), as opposed to the Vancouver format, are not listed in the references. This should be fixed. 20. Page 8, Line 49-50: The reference to biologically determined developmental delay is mentioned as 5-8% (a paper by Hertzman--#18—is cited to support this claim). It is not clear, however, the empirical basis for this biologically determined

	developmental delay threshold. I have encountered references to this biologically determined vulnerability at a slightly higher level—namely 10%; in any event, a stronger empirical support to a biological threshold would be necessary. 21. The discussion, in particular passages that expands on the implications of some of the main findings, such as male children, ESL children, younger children having higher risks of developmental vulnerability, is not as well developed as one would hope. Statements calling for universal early childhood programmes that are cognizant of "these variations" are too general. The authors should be encouraged to develop more specific (to local context, etc) and practical implications emanating from the findings of their study. Supplement material (i.e., Checklist) 22. Item # 19 (Limitations) are not discussed in pages 5-6. 23. Items #20 (Interpretation) and 21 (Generalizability) could be expanded. (I don't see much on these two items on "page 6.") The generalizability of results would be enhanced if the vulnerability measure was developed based on normed data.

VERSION 1 – AUTHOR RESPONSE

Reply to Reviewer: Sally Brinkman
Co-Director, Fraser Mustard Centre
Telethon Institute for Child Health Research
Centre for Child Health Research, University of Western Australia
Australia
Methods
1 Changed to 'invited to participate'. Full details of the consent process have been added to the 'Data collection' section of the revised manuscript
2 Content validity: Prior to implementation, the EDI was assessed by an experienced educational researcher. After implementation, in a detailed qualitative study, some teachers in designated disadvantaged schools expressed concern with one question related to the child's ability to count to 20. All other questions were deemed appropriate.
Internal validity: Cronbach alpha's included in the revised manuscript
No construct or concurrent validity implemented
Issues related to validity are noted in the discussion
3 Citation for McMaster included. The parental questionnaire has been included as an appendix.
4 We had not previously considered Rasch modelling but are now discussing the possibility with colleagues who have experienced in this area. However, it will not be feasible to do Rasch modelling in the timeframe of this paper.

Paragraph 2 of The 'Developmental Scoring' section of the revised manuscript has been amended to include comparison with the Canadian cut-off points and justification of the use of 10% cut-off.
5 A participant flow chart has now been included as Figure 1
Results Intro section:
1 A section on children in Ireland has been added to the Background providing demographic details for Ireland and a note on the homogeneity of the Irish population and education system.
Vulnerability section.

1 We accept this point and have amended the manuscript accordingly.
2 This refers to the % of children vulnerably in one domain only. A further 17% were vulnerable in 2 or more domains. This has been amended to read more clearly in the revised manuscript.
3 A footnote has been added to the table to clarify this point.
4 In the first column, age, gender and ESL were entered. Then each of the subsequent variables were tested individually with these three core potential confounders. In the second column, one model was used for all the variables. The footnotes have been adjusted to clarify this.
Discussion
1 Paragraph added to the discussion in the amended manuscript
2 Point accepted. We have clarified this in the discussion.
3 The discussion has been amended to include these points. However, the focus of the paper is primarily on the utility of the EDI and, therefore we have not dealt with this in great detail. A future paper will focus more on the Parental outcomes.
4 The discussion has been extensively amended to incorporate the focus on approaches and research on early childhood development as outlined in these papers.
5 The discussion has been amended to include a stronger focus on the implications for Ireland
6 CONSORT/STROBE
Participant flow diagram included as Figure 1
7 Ethics:
The consent procedure and ethical approval have been clarified in the manuscript
8 We have not been able to find reports of population-level studies using the EDI in Europe. Extensive searches of the published and grey literature have been carried out. We would be grateful for details of these studies.
There are also only two published studies (from Canada and Mexico) using population-level EDI data combined with parental data providing high quality, proximal information on the children's lives.
9 Included
10 Included
11 See point 8 above
12 Inserted
13 See point 8 above
14 This has been corrected in the manuscript
15 Amended in the manuscript
16 This has been corrected in the manuscript
17 Amended in the manuscript

Reply to Reviewer: Nazeem Muhajarine, PhD
Professor and Chair, Community Health and Epidemiology, College of Medicine
University of Saskatchewan
Saskatoon, Saskatchewan, Canada

1. Article Summary
The term 'community level' has been removed from the revised manuscript
2. Abstract
This has been amended in the revised manuscript
Methods
3 Corrected in the manuscript
4 'Junior Infants' is the official term used in Ireland for the first year of formal education. This is the equivalent of Senior Kindergarten in Canada. The term 'Pre-school' is used in Ireland for the equivalent of Junior Kindergarten.
5 This has been clarified in the manuscript. Yes, the same threshold of being in 'Junior Infants' for at

least 4-5 months was applied. The one month refers to an additional requirement of being in that particular teacher's class for at least 1 month – this threshold was applied because it is also standard in other jurisdictions.
6 No
7 The composition of the declining schools was such that it would not affect the demographic profile of the study. This has been clarified in the manuscript
8 A paragraph has been added to the introduction to explain the homogenous nature of the Irish population.
Table 2 has been replaced with a more detailed table which outlines the differences between those for whom we have parental data and those for whom we do not. While the overall sample is representative of children in Cork and thereby can be generalised to other urban populations in Ireland. The subset for whom parental data is available excludes some of the more vulnerable children and therefore, results are not wholly representative. However, the return rate of 63% on the parental questionnaire is very high in comparison to similar studies in Ontario where the return rate has been around 40%.
9 Corrected in the manuscript
10 This has been included in the revised manuscript
11 Cut-off points from the Canadian normative sample were used as a cross-reference with the Irish cut-off points. This has been outlined in the manuscript
12 This has been done because parental data was not available for all the children from the Traveller community. The children would have already been identified by the parents to the teachers as members of the Traveller community.
13 This is the first paper published with this data set. We picked the variables on which we had good a-piori reason to expect developmental delay. The main focus of this paper is on the EDI data – future work with focus on the parental data. Had we tried to do both, this paper would be very long and lacking in focus.
14 This has been corrected in the revised manuscript
15 In the initial analysis, as discussed in this paragraph, teacher reports were used because children for whom parental questionnaires had not been returned, were included. In subsequent analysis parental reports were preferred. However, for the majority of children parental and teacher reports concurred. The sentence indicates that these are 'risk items from the teacher-filled EDI questionnaire'.
16 Further detail and reference are included. The formula has not been included as this is too long.
17 Table 4 has been amended to include reference groups
18 Table 2 has been replaced with a much more detailed table which outlines the significant differences between the children for whom parental questionnaires have and have not been returned. This is outlined in the results section and discussed under the 'limitations' section in the discussion. Children with greater risk of vulnerability have been excluded. However, the 63% return rate this is much higher than the average 40% return rate where a similar questionnaire has been used in Ontario.
Discussion
19 This has been corrected in the revised manuscript
20 There is considerable debate as to the level of biologically determined disability/ developmental delay with in-country estimates varying widely. Reference to this is now included in the manuscript
21 The discussion has been expanded and amended to reflect more on the local context.
Supplement material
22 This has been expanded in the discussion
23 This has been addressed in the discussion

VERSION 2 – REVIEW

REVIEWER	Sally Brinkman Co-Director, Fraser Mustard Centre, Telethon Institute for Child Health Research, Australia.
REVIEW RETURNED	14-Mar-2013

THE STUDY	The amendments from the previous review have been addressed appropriately. However, it is clear from the following newsletter http://www.offordcentre.com/readiness/pubs/EDI_Newsletter_Spring_2012.pdf that there have been other implementations of the EDI in Europe. Perhaps these have not been published in the academic literature, however I think there still needs to be caution/conservativeness given to the claim that this is the first study using the EDI in Europe.

REVIEWER	Nazeem Muhajarine, PhD Professor and Chair, Community Health and Epidemiology, College of Medicine University of Saskatchewan Saskatoon, Saskatchewan, Canada I declare no competing interest with this manuscript.
REVIEW RETURNED	08-Mar-2013

GENERAL COMMENTS	Having read the revised manuscript (the version with the tracked changes, starting on page 18) there are yet a few clarifications and changes that I recommend below before the paper is accepted for publication. Page 21 of 49 -line 12: insert the word “representativeness” in front of demographic so it reads: “… would not have affected the representativeness of the demographic composition…” -line 40: suggest changing the sentence to read: “…the EDI had good internal consistency by domains …” Table 3 I still think that including reference groups for variables presented in this table would make the results clearer. Page 24 In line 10 it is stated that the percentage of children identified as having special needs as 6.6% but later in line 21 the percentage for the overall sample is stated as 6.15%. Why is there a discrepancy? Line 30: Figure 1 should be Figure 2.

	Table 5 How does one interpret the PAFs that have 95% confidence interval that includes 0? Clearly these estimates, which include a 0 in the confidence interval, are consistent with the null hypothesis. In the total PAF (90.7%), were these PAFs that include a 0 in the CIs included in the calculation? Page 25 Line 48: Please remove the citations to work reported in APA format. Page 26 Line 28: The sentence that ends with "…biologically determined disability." Conflates developmental vulnerability with disability. The term "disability" should be removed and instead replaced by developmental vulnerability.

VERSION 2 – AUTHOR RESPONSE

Reply to reviewers comments
March 2013

We would again like to thank the reviewers for their very helpful feedback on this manuscript and for recommending it for publication.

1. Thank you for the newsletter outlining areas where the EDI has been implemented worldwide. We have adjusted the text to account for the fact that population-level implementation has taken place in Kosovo, Scotland and Sweden. If results from these studies become available we would be grateful for further details.

2. Page 21
Line 12: the word 'representativeness' has been included.
Line 40: the sentence has been amended to read 'the EDI has good internal consistency by domains

3. Table 3: I apologise. I had included the reference groups in Table 4 but not in this one. This has now been amended.

4. Page 24
Line 10: this was a typographical error which has now been amended
Line 30: this has also been amended

5. Table 5 The 95% confidence interval crossed 0 because the 95% confidence interval of the OR crossed 1. We have included these in the table because in some instances this is due to small numbers (vulnerable families less well represented in the study) and in other instances the variable has become insignificant when entered into a model with other variables. The reason for estimating PAF in the first instance was to identify the factors which have greatest impact in the population - gender and language status. We agree that inclusion of total PAF can be misleading and needs to be interpreted cautiously. We have decided to exclude this row in the table as there is no room left in the

text (we have reached the word limit) to give adequate attention to it’s interpretation.

6. Page 25, line 48: This has been amended.

7. Page 26, line 28: This sentence has been changed to ‘developmental vulnerability’.