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Title	Diagnostic accuracy of developmental screening in primary care at the 18-month health supervision visit: a cross-sectional study
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Reviewer 1	Dr. Irene Drmic
Institution	McMaster University, Offord Centre for Child Studies, Hamilton, Ont.
General comments (author response in bold)	<p>The purpose of the current paper is to determine how well the 18-month Nipissing District Developmental Screen (NDDS) identifies communication delays. Infants aged 18-20 months (mean age <math>18.6 \pm 0.7</math> months) were recruited during scheduled health supervision visits from primary care practices. Children (<math>n=348</math>) whose parents completed the 18-month NDDS and Infant Toddler Checklist (ITC) were included in the study. Results indicated that the 1+NDDS flag had good to modest sensitivity and poor specificity, and fair agreement to identify expressive speech and other communication delays. Thus, the low specificity may lead to over-diagnosis and cause unnecessary concern for parents. The 2+NDDS flag had poor sensitivity and good specificity, and moderate agreement to identify expressive speech and other communication delays. Thus, the low sensitivity may lead to under-diagnosis and potentially miss infants who could benefit from early intervention services. Taken together, the NDDS is not a good tool to accurately identify children with a range of communication delays.</p> <p>Overall, this is a well-written paper that provides important information about the utility of the NDDS as a screening measure during the 18-month health supervision visit. It is important to examine the utility of the NDDS as a screening tool, given the importance of identifying developmental concerns early in order to initiate early intervention services. The results of this paper are consistent with previous reports (Cairney et al., 2011).</p> <p>Below are just a few thoughts to consider for further elaboration and recommendations:</p> <p>The NDDS provides a snapshot of the child's development to discuss with parents.</p> <p>1. Would the authors still consider this a useful tool to facilitate communication between parents and caregivers about communication and other developmental concerns?</p> <p><b>In this study, we did not measure if the use of the NDDS resulted in a more detailed discussion about developmental concerns with caregivers. Unfortunately this was not within the scope of our study. We did not assess clinical outcomes and we have addressed this limitation in our discussion (page 16, line 349).</b></p> <p>2. Also, another limitation of this data is that it did not measure level of clinician concern after discussing the red flag(s) that were checked by parents.</p> <p><b>See our response to comment 1.</b></p> <p>3. The intent of the measure is to facilitate discussion of concerns, leading to more detailed information about concerns and better insight into whether further follow-up is needed. Thus, there is no way of knowing whether this tool is useful at identifying more subtle communication or other developmental concerns after a more detailed discussion with parents. It is important to note this limitation in this (and previous research).</p> <p><b>Please see our feedback to comment 1.</b></p> <p>The purpose of the NDDS is to identify delays in various areas of development as early as possible, not only for communication. The authors focused on communication and concluded that "the NDDS does not have adequate characteristics to accurately identify children with a range of communication delays". Given that there is not a communication domain on the NDDS, the authors noted not being able to specifically validate communication.</p> <p>4. However, since question 6 (Say more than 20 words?) accounted for more than 60% of infants with a 1+NDDS flag, I am left wondering that if parents endorse this specific communication-related concern, how accurately this is question identifies communication delays in children?</p> <p><b>The reviewer proposes a very interesting question. The accuracy of the NDDS compared with the ITC (a well validated communication screening tool) was the objective of our study. Since question 6 was the most commonly endorsed question on the NDDS, we believe that this question is likely</b></p>

	<b>not very accurate in identifying communication delays. Parents should be informed about the broad vocabulary range at 18-months to reduce unnecessary concerns identified with the NDDS (page 15, line 328).</b>
<b>Reviewer 2</b>	Dr. Jessica Brian
Institution	Bloorview Research Institute, University of Toronto, Toronto, Ont.
General comments (author response in bold)	<p>Thank you for the opportunity to review this manuscript. I only have a few suggested edits, outlined below:</p> <p>1. Page 6, Ln 26: "The ITC is a validated tool for detecting expressive speech and other communication delays" -Perhaps change to "expressive language" - also please mention age range for validation sample.</p> <p><b>We changed this according to the reviewer's suggestion. The age range in which the tool is validated is described in the method section of the main manuscript (page 10, line 214).</b></p> <p>2. Ln 32: "for one or more "no responses" (1+NDDS flag) and two or more "no responses"" -I assume the authors are referring to "No" responses (i.e., the parent responded "No" to a given item), rather than "No Responses" (this suggests that no response was given). Please rephrase this throughout.</p> <p><b>We have changed this according to the reviewer's suggestion.</b></p> <p>3. P11. Ln 30: "For a screening tool, a sensitivity of 80% and a specificity of 90% are generally recommended for developmental screening tools," --Please clarify the distinction being made here (between a screening tool and a developmental screening tool).</p> <p><b>For most screening tools, a sensitivity of 80% and a specificity of 90% are generally recommended. However for developmental screening tools, because of behavioral noncompliance a sensitivity between 70-80% and a specificity of 80% has been suggested. We have made this more clear in the text. (p11, line 237).</b></p> <p>4. Discussion: Can the authors consider further the relative merits of the NDDS vs. ITC? That is, I'm trying to understand why the NDDS is used so widely given the lack of strong psychometrics. --In recommending the ITC over the NDDS, do you anticipate any systemic barriers to making this practice change? For example, I understand that the NDDS is also used widely in daycares in Ontario -could these practitioners also use ITC? If not, what would you recommend in order to make this practice change?</p> <p><b>We thank the reviewer for these thoughtful questions. In our study we compared the NDDS with the ITC. We have not investigated the (long term) developmental outcomes of children that were screened with the ITC in our population. Therefore we feel it is too early to make a strong recommendation for the ITC at this point. The NDDS was recommended by an Expert Panel reporting to the Ministry of Children and Youth Services. Any changes in the recommended developmental screening tool would require thorough discussion between practitioners, decision makers and policy makers. Randomized controlled trial evidence is needed to investigate if screening with the ITC will improve child development outcomes. Future research will also need to address possible systemic barriers in using the ITC.</b></p>