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3 **Screening for communication delay at the 18-month scheduled health**
4 **supervision visit in primary care**
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ABSTRACT

Background: Communication delays are often the first presenting problem in infants with a range of developmental disabilities. With early detection, intervention can be initiated. The 18-month Nipissing District Developmental Screen (NDDS) was created as a general developmental screening tool for use in primary care. Our objective was to examine how well the 18-month NDDS identifies communication delays.

Methods: Infants were recruited during scheduled health supervision visits. Parents completed both the 18-month NDDS and Infant Toddler Checklist (ITC). The ITC is a validated tool for detecting expressive speech and other communication delays. We assessed criterion validity (diagnostic test properties, overall agreement) for one or more “no responses” (1+NDDS flag) and two or more “no responses” (2+NDDS flag) using the ITC as a criterion measure.

Results: The study included 348 children (mean age 18.6 ± 0.7 months). The 1+NDDS flag had good to modest sensitivity (90% and 78%), poor specificity (64% and 64%), and a fair agreement (0.28) to identify expressive speech and other communication delays respectively. The 2+NDDS flag had poor sensitivity (43% and 67%), good specificity (86% and 89%) and moderate agreement (0.45) to identify expressive speech and other communication delays respectively.

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3 **Interpretation:** The low specificity of the 1+NDDS flag may lead to over-
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5 diagnosis and cause unnecessary concern for parents. The low sensitivity of the
6
7 2+NDDS flag may lead to under-diagnosis suggesting that infants who could
8
9 benefit from early intervention may not be identified. The NDDS does not have
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11 adequate characteristics to accurately identify children with a range of
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13 communication delays.
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20 **Key words:** infants, communication, speech concern
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Introduction

Communication delays are often the first presenting problem in young children with a range of developmental disabilities including isolated expressive speech delay, autism spectrum disorder (ASD) and intellectual disability.¹⁻³

Approximately 20% of toddlers have expressive speech delay, which resolves in about 50% by five years of age.⁴ Children with persistent communication delays have poorer outcomes in reading, spelling, math skills and increased emotional and behavioral difficulties.^{4,5} A recent systematic review commissioned by the US Preventive Services Task Force concluded that several screening tools can accurately identify speech and language delay in early childhood.⁶

Developmental screening has been identified as a priority topic by the Canadian Task Force on Preventive Health Care.⁷ The Nipissing District Developmental Screen (NDDS) is a parent-completed questionnaire that addresses different areas of development including communication.⁸ The Canadian Paediatric Society, supported by the College of Family Physicians of Canada, recommends the NDDS as one of the screening tools that could be used at the 18-month well-baby visit.⁹ The Government of Ontario has made the NDDS freely accessible. As a result, the NDDS is currently one of the most widely used developmental screening tools in Ontario.^{8,9} Despite this, the psychometric properties of the NDDS are not well known. The accuracy of the NDDS in identifying early communication delays has never been investigated.

The Infant Toddler Checklist (ITC) was originally developed for early identification of children who have or are at-risk for developing a communication

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3 impairment.^{1,10,11} More recently, the ITC was assessed for the accuracy of
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5 detecting a range of developmental delays, including language delay, global
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7 developmental delay, and ASD.¹²⁻¹⁴ The ITC has been shown to be valid, reliable
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9 and has good diagnostic test properties.^{1,11,13,14} The ITC is freely available online
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11 and is one of two measures recommended for the early detection of ASD in
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15 Canada.^{15,16}

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17 The identification of delays in speech and language acquisition is a core activity
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19 in child health supervision.¹⁷ Since the NDDS is one of the most widely used
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21 developmental screening tools in Canada, our primary objective was to assess
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23 the validity of the 18-month NDDS compared with the ITC. As parents and
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25 clinicians commonly monitor the number of words spoken in early childhood as a
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27 measure of language development, our secondary objective was to describe
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29 parent responses regarding their 18-month old child from both screening tools.
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41 **Methods**

42 **Participants and Setting**

43 This study used a cross-sectional design. Infants, aged 18-20 months, were
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45 recruited during scheduled health supervision visits from primary care practices
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47 participating in *TARGetKids!*, a practice-based research network in Toronto,
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49 Canada.¹⁸ The study protocol, including recruitment procedures, has recently
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51 been published.¹⁸

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53 Children were included if their parents completed both the 18-month
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55 NDDS and the ITC. Participant characteristics were collected using a
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3 standardized instrument based on the Canadian Health Measures Survey.¹⁹
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5 Exclusion criteria were: children with health conditions affecting growth, acute or
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7 chronic conditions (other than asthma), known severe developmental delay, and
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9 families unable to communicate in English. All data were entered into a web-
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11 based data management system (Medidata Rave ®). Research Ethics Boards
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13 approval was obtained from the Hospital for Sick Children and St. Michael's
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15 Hospital, Toronto, Canada.
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21 22 **Measures**

23 24 *18-month Nipissing District Developmental Screen (NDDS)*

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26 The 18-month NDDS is a one page, 17-item parent-completed tool. Each
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28 question addresses one or more areas of development: fine motor, gross motor,
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30 emotional, social, self-help, learning, thinking, communication.⁸ Ten questions
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32 address communication.
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37 In 2011, the wording of question six: "Does your child say 5 or more
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39 words?" was changed to "Does your child say 20 or more words?". The NDDS
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41 authors provide a rationale for this change, highlighting the importance of early
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43 referral to a speech pathologist in children with a suspected delay and refer to
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45 the MacArthur-Bates Communicative Developmental Inventories (MB-CDI).^{20, 21}
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47 In our study we used the 2011 version of the NDDS.
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51 The NDDS takes five minutes to complete. Response options are "yes" or
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53 "no". One or more "no" responses (i.e., the child does not demonstrate the
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55 behaviour) indicates the need for further assessment and/or referral. This is
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3 known as the “one flag” rule (1+NDDS flag). The “two flag” rule requires a
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5 minimum of two “no” responses for referral and/or follow-up (2+NDDS flag).
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8 Currently, the instructions of the 18-month NDDS recommend a “one flag” rule to
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10 follow-up with the healthcare and/or childcare professional regarding the child’s
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12 development.⁸ Since there is little known about the validity of the NDDS to
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14 identify communication problems, we assessed both the “one flag” and “two flag”
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16 rule for the NDDS with the ITC.
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22 *Infant Toddler Checklist (ITC)*

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24 The ITC is a one page, 24-item parent-completed tool.^{10, 15} The ITC was
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26 developed to measure language predictors in order to determine if a
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28 communication evaluation is needed.^{1,10,11} It is a standardized tool with normative
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30 scores for monthly intervals for children 6-24 months of age. Most questions are
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32 answered with a 3-point scale; “not yet” “sometimes” “often”. The ITC takes five
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34 minutes to complete and two minutes to score.^{1,14} Scoring produces three
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36 composite scores (social composite, expressive speech composite, symbolic
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38 composite) and a total score. The total score and each of the three composite
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40 scores are dichotomized as “concern/no concern” using the 10th percentile cut-
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42 point. It is recommended that a child should be carefully monitored if the
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44 expressive speech composite is below the 10th percentile (concern for
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46 expressive speech delay) and the ITC should be re-administered again in three
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48 months.^{10,15} Additionally, it is recommended that a child should be referred for an
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3 evaluation if the social composite, symbolic composite or the total score is below
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5 the 10th percentile (concern for other communication delay).^{10,15}
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10 **Statistical analysis**

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12 Means, standard deviations and percentages were calculated to
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14 characterize the study participants. We assessed criterion validity of the 18-
15
16 month NDDS by calculating diagnostic test properties and overall agreement. For
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18 the purpose of our analysis, the ITC was considered a criterion measure.
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20 Diagnostic test properties (sensitivity, specificity, positive predictive value,
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22 negative predictive value) of the 18-month NDDS compared with the
23
24 dichotomized scores of the ITC were calculated (with 95% confidence intervals).
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26 For a screening tool, a sensitivity of 80% and a specificity of 90% are generally
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28 recommended.²² For developmental screening tools, a sensitivity between 70%-
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30 80% and a specificity of 80% has been suggested.²³
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36 Cohen's kappa coefficients were calculated as measure of overall
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38 agreement between the NDDS and ITC. Cohen's kappa gives a quantitative
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40 assessment of how well the two tools agree. Levels of agreement below 0.20,
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42 between 0.21-0.40, between 0.41-0.60, and above 0.61 are considered poor, fair,
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44 moderate, and good, respectively.²⁴
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48 Finally, we described the number of words spoken by 18-month old
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50 children according to parent responses on a comparable single question on both
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52 the NDDS and ITC calculating proportions. All analyses were performed with IBM
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54 SPSS 20.
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Results

Participant characteristics

We included 348 children with a mean age of 18.6 months (\pm 0.7 months) (Table 1). On the NDDS, 138 (39.7%) children had 1+flag and 54 (15.8%) had 2+flags (Figure 1). On the ITC, 21 (6.0%) children were identified with an expressive speech delay (concern on the expressive speech composite); 27 (7.8%) children were identified with a communication delay needing referral (concern on the social composite, symbolic composite, or total score).

Diagnostic test properties of the 18-month NDDS compared with the ITC

To identify children with an expressive speech delay, the 1+NDDS flag was sensitive (90%, 95% CI 68%-98%) but not specific (64%, 95% CI 58%-69%).

The 2+NDDS flag reduced the sensitivity (43%, 95% CI 23%-66%) but increased the specificity (86%, 95% CI 82%-90%). To identify children with other communication delays (concerns on the communication composite, symbolic composite or total score), the 1+NDDS flag was modestly sensitive (78%, 95% CI 57%-90%) but not specific (64%, 95% CI 58%-69%). The 2+NDDS flag reduced the sensitivity (67%, 95% CI 46%-83%) but increased the specificity (89%, 95% CI 85%-92%). (Tables 2 and 3).

Overall agreement of the 18-month NDDS with the ITC

The 1+NDDS flag had a fair agreement (Cohen's kappa 0.28) with the need for monitoring or referral for communication delays on the ITC (concerns on any

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3 composite or total score). The 2+NDDS flag had a moderate agreement (Cohen's
4 kappa 0.45) with the need for monitoring or referral for communication delays on
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6 the ITC (concerns on any composite or total score).
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10 11 12 *Description of parent responses regarding the number of words spoken*

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15 Question 6 of the 18-month NDDS "Does your child speak more than 20 words?"
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17 was the question with the greatest number (n=85, 24.4%) of parents responding
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19 "no" (Figure 2). Question 17 on the ITC "About how many different words does
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21 your child use meaningfully that you recognize?" identified five (1.3%) children
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23 who spoke no words at all, 21 (6.0%) who spoke 1-3 words, 81 (23.3%) who
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25 spoke 4-10 words, 133 (38.2%) who spoke 11-30 words and 107 (30.7%) who
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27 spoke more than 30 words.
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32 33 **Interpretation**

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35 This is the first study to investigate whether the 18-month NDDS can identify
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37 communication delays in early childhood in a primary care setting. Compared
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39 with the ITC, the 1+NDDS flag had modest to good sensitivity, poor specificity,
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41 and fair agreement, to identify expressive speech delay and other communication
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43 delays. Thus, the 1+NDDS flag cut-point may result in a large number of false
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45 positives leading to over-diagnosis. The 2+NDDS flag had poor sensitivity, good
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47 specificity and moderate agreement, to identify expressive speech delay and
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49 other communication delays. Thus, the 2+NDDS flag cut-point may result in a
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51 large number of false negatives leading to under-diagnosis. Taken together,
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53 these findings suggest that the NDDS, at either cut-point, may not have adequate
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3 characteristics to accurately identify children with a range of communication
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8 There are no studies of the NDDS in the published literature. However, the
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10 report by Dahinten and Ford compared the previous (pre-2011) version of the
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12 NDDS with the Bayley Scales of Infant Development II (BSID-II) at three ages (4,
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14 18, 24 months; total n=118).²⁵ The authors identified a higher sensitivity and
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16 specificity of the NDDS when using the 2+NDDS flag rule and -2SD cut-off
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18 compared to the 1.5SD cut-off for the BSID-II. The authors concluded that the
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20 NDDS was able to identify severe developmental delays but less effective at
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22 identifying milder delays.²⁶ Preliminary results from the Psychometric
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24 Assessment of the NDDS Study by Cairney et al. concluded that the 2011
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26 version of the NDDS was very good at identifying children without developmental
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28 delay, but when used alone it potentially misses children who would benefit from
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30 further assessment.²⁷ Our findings are consistent with this previous research.
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36 In contrast to the NDDS, the ITC has undergone substantial validation
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38 over the past two decades. The ITC was originally developed and normed in a
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40 sample of US infants.^{1,28} Concurrent and predictive validity in another sample of
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42 more than 300 infants identified moderate to large correlation coefficients with
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44 receptive and expressive language outcomes at 2 years (measured with the
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46 Mullen Scales of Early Learning or the Preschool Language Scale).¹ In two
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48 further studies of infants 12-24 months of age (n=232 and n=915), the ITC was
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50 found to have a sensitivity of 87% and 86%, and a specificity of 75% and
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52 83%.^{11,13} However, these results should be interpreted with caution, as the
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3 participants were not randomly sampled from the general population and
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5 therefore had a higher prevalence of communication delays. In two samples of
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7 children with a diagnosis of autism spectrum disorder (ASD) (n=18 and n=60),
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9 the sensitivity of the ITC at 12-24 months of age was 95%.^{12,13} The ITC was
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11 recently assessed in primary care (137 pediatricians from 30 offices) at the 12
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13 month visit.¹⁴ Of 10,479 ITCs completed, 1,318 were positive (12.5%).¹⁴ In a
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15 subsample of 184 children who screened positive and agreed to an assessment
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17 with a psychologist, the positive predictive value of the ITC was 75% for a range
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19 of developmental disorders (ASD, language delay and global development
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21 delay).¹⁴ A survey of 92 participating pediatricians believed that the ITC was a
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23 valuable screening tool.¹⁴ The 13.8% prevalence of a positive ITC found in our
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25 study is similar to that of the study in primary care practices.¹⁴
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32 In our study, almost a quarter of the 18-month old infants did not speak 20
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34 words or more according to parent report on the NDDS. Almost a third of the 18-
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36 month old infants spoke 10 words or less according to parent report on the ITC.
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38 Data from “Wordbank”, an open database about children’s vocabulary growth
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40 that archives data from the MB-CDI of more than 5000 children, demonstrates a
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42 very wide vocabulary range at 18 months; from 13.9 words (10th percentile) to
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44 269 words (90th percentile).²⁹ The BSID (3rd edition) indicates that fewer than
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46 eight words spoken for a 24-month-old is 1.33 standard deviations below the
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48 normative mean.²⁵
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53 Our data demonstrates that many more parents responded “no” to
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55 question 6 than any other question on the 18-month NDDS. This single question
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3 accounted for more than 60% of infants with a 1+NDDS flag. As parents
4 commonly monitor their child's vocabulary, explanation about the broad
5 vocabulary range at 18-months should be provided to parents who may worry
6 unnecessarily over concerns identified with the 18-month NDDS. Additionally, it
7 is important for child healthcare practitioners to be aware of the wide range of
8 word attainment at 18-months, and the fair agreement and low specificity of the
9 1+NDDS flag for identifying children with expressive speech delay as compared
10 with the ITC.
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22 Strengths of this study include the use of a large infant population, and
23 implementation in a primary care setting in Ontario, where the NDDS is routinely
24 administered. This study also has some limitations. Children's communication
25 was not assessed with an independent, standardized measure for comparison
26 with the ITC and NDDS, such as the MB-CDI or the BSID. Because this study
27 was conducted with a large group of infants in primary care, this was not feasible.
28 Additionally, the NDDS is a general development screening tool whereas the ITC
29 was initially developed to target communication delays, so it would be expected
30 that some items (e.g., gross motor) on the NDDS would not correlate with the
31 ITC. However a majority of questions of the 18-month NDDS address
32 communication and the ITC has a high positive predictive value for detecting
33 global developmental delay, making the comparison of both questionnaires
34 justifiable. Additionally, the authors of the NDDS did not provide independent
35 domains (e.g. "communication domain") therefore a specific validation was not
36 feasible.
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Conclusion

Our results demonstrate that infants with communication delays will not be adequately identified with the 18-month NDDS. The low specificity of the 1+NDDS flag may lead to over-diagnosis and cause unnecessary concern for parents. The low sensitivity of the 2+NDDS flag may lead to under-diagnosis suggesting that infants who could benefit from early intervention may not be identified. The NDDS does not have adequate characteristics to accurately identify children with a range of communication delays. With communication delays often being the first presenting problem in young children with a range of developmental disabilities, the ITC may be a more promising screening tool for assessing developmental delay in early childhood.

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Table 1: Participant characteristics

Characteristic	n = 348	
	n (%)	
Age (months) mean (\pm SD)	18.6	(0.7)
Sex, male	192	(55.2)
Maternal education		
- College / University	328	(94.4)
Nipissing District Developmental Screen		
1+ flag	138	(39.7)
2+ flags	54	(15.8)
Infant Toddler Checklist		
Expressive speech delay ¹	21	(6.0)
Other communication delays ²	27	(7.8)

¹ **Need to monitor:** expressive speech composite below the 10th percentile

² **Need for referral:** social composite, symbolic composite or the total score below the 10th percentile

Table 2: Diagnostic test properties of the +1 NDDS flag compared with the ITC.

1+ NDDS flag	ITC		ITC	
	Expressive Speech delay¹		Other communication delays²	
	Yes	No	Yes	No
Positive	19	119	21	117
Negative	2	208	6	204
Sensitivity (%) (95% CI)	90 (68-98)		78 (57-90)	
Specificity (%) (95% CI)	64 (58-69)		64 (58-69)	
PPV (%) (95% CI)	14 (9-21)		15 (10-23)	
NPV (%) (95% CI)	99 (96-100)		97 (94-99)	

¹ **Need to monitor:** expressive speech composite below the 10th percentile

² **Need for referral:** social composite, symbolic composite or the total score below the 10th percentile

Table 3: Diagnostic test properties of the +2 NDDS flag compared with the ITC.

2+ NDDS flag	ITC		ITC	
	Expressive Speech delay ¹		Other communication delays ²	
	Yes	No	Yes	No
Positive	9	45	18	36
Negative	12	282	9	285
Sensitivity (%) (95% CI)	43 (23-66)		67 (46-83)	
Specificity (%) (95% CI)	86 (82-90)		89 (85-92)	
PPV (%) (95% CI)	17 (8-30)		33 (21-48)	
NPV (%) (95% CI)	96 (93-98)		97 (94-99)	

¹ **Need to monitor:** expressive speech composite below the 10th percentile

² **Need for referral:** social composite, symbolic composite or the total score below the 10th percentile

Figure 1: Percentage of children and the total number of questions failed on the 18-month NDDS

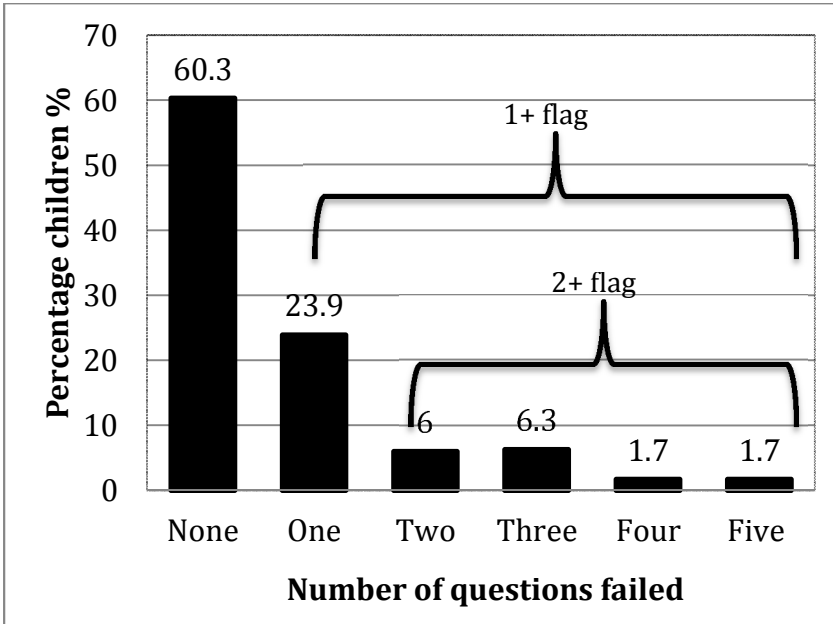


Figure 2: Percentage of parents responding with "no" and "yes" to the 18-month NDDS individual questions

