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Use of the Screening Tool for Autism in Two-Year-Olds (STAT) for children under 24 months

An exploratory study

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ABSTRACT The study examined the properties of the Screening Tool for Autism in Two-Year-Olds (STAT) for children under 24 months. The STAT provides a standard context for observing social-communicative behavior in play, imitation, and communication. Seventy-one children received the STAT between 12 and 23 months of age and a follow-up diagnostic evaluation after 24 months. All had an older sibling with an autism spectrum diagnosis (n = 59) or had been referred for evaluation for concerns about autism (n = 12). Signal detection analysis resulted in a cut score of 2.75 for this sample, which yielded a sensitivity of 0.95, specificity of 0.73, positive predictive value of 0.56, and negative predictive value of 0.97. False positives were highest for the 12- to 13-month-old age group; STAT screening properties were improved when the sample was limited to children 14 months and older. Implications for using the STAT with children under 24 months are discussed.

KEYWORDS *autism; early identification; infant; sensitivity; specificity*

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Prevalence studies within the past 5 years have suggested that autism spectrum disorders (ASDs) may be present in as many as three to six out of every 1000 children (Centers for Disease Control and Prevention (CDC), 2006; Chakrabarti and Fombonne, 2005; Williams et al., 2006; Yeargin-Allsopp et al., 2003). As a consequence, pediatricians and other healthcare providers are likely to see a significant number of these children in their practice settings. Increasing evidence for the benefits of early intervention

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(Cohen et al., 2006; Harris and Delmolino, 2002; Sallows and Graupner, 2005; Smith et al., 2000) has led to a keen interest in identifying children with autism at the earliest age possible. Several professional practice parameters and guidelines, including those of the American Academy of Neurology (Filipek et al., 2000) and the American Academy of Pediatrics (AAP) (Committee on Children with Disabilities, 2001; Johnson et al., 2007), have recognized the importance of early identification of autism and have advocated for early screening and developmental surveillance. In fact, the most recent clinical report from the AAP recommends that all infants receive routine screening for autism at their 18- and 24-month well-baby visits (Johnson et al., 2007). Because of their early and continued contact with children and their families, pediatricians play a critical role in recognizing early red flags and referring at-risk children for further evaluation or intervention at the youngest age possible (Dosreis et al., 2006), and the new AAP guidelines provide resources and strategies to assist them in early identification (Johnson et al., 2007).

Although there is replicated evidence that the diagnosis of autism in children can be made accurately as young as 24 months (Lord et al., 1994; Stone et al., 1999), the reliability and stability of diagnosis below 24 months have not yet been investigated as systematically. Moreover, the two gold standard diagnostic measures for autism – the Autism Diagnostic Observation Schedule (ADOS: Lord et al., 2000) and the Autism Diagnostic Interview (ADI–R: Lord et al., 1997) – were not developed for children under 24 months, and their utility for these young ages is not yet known. Nevertheless, there is mounting evidence from several lines of research that behavioral differences exist between children with and without autism prior to the age when the formal diagnosis of autism can be made with confidence.

In particular, early social-communicative deficits in children under 24 months have been found at the group level in studies using a variety of methodologies, including retrospective parental reports (Watson et al., 2007; Wimpory et al., 2000) and analysis of early home videotapes (Baranek, 1999; Clifford et al., 2007; Osterling et al., 2002; Werner et al., 2000), and prospective studies of infants at risk by virtue of failing early screening measures (Charman et al., 1997; Swettenham et al., 1998; Wetherby et al., 2004) or having an older sibling with autism (Bryson et al., 2007; Cassel et al., 2007; Goldberg et al., 2005; Mitchell et al., 2006; Presmanes et al., 2007; Stone et al., 2007; Sullivan et al., 2007; Yirmiya et al., 2006; Zwaigenbaum et al., 2005). Social-communicative differences in the first or second year of life between groups of high-risk children who do and do not receive a subsequent diagnosis of autism have been found for behaviors including: responding to one's name or to joint attention bids (Baranek, 1999; Osterling and Dawson, 1994; Sullivan et al., 2007; Werner et al.,

2000; Wetherby et al., 2004; Zwaigenbaum et al., 2005), looking at others (Adrien et al., 1993; Maestro et al., 2002; Osterling and Dawson, 1994; Osterling et al., 2002; Swettenham et al., 1998; Wetherby et al., 2004; Zwaigenbaum et al., 2005), sharing enjoyment (Bryson et al., 2007; Maestro et al., 2002; Swettenham et al., 1998; Wetherby et al., 2004; Zwaigenbaum et al., 2005), and directing attention to share one's interest in objects or events (Osterling and Dawson, 1994; Wetherby et al., 2004). In addition, this research has revealed that not all social-communicative markers are present at all ages (Bryson et al., 2007; Cassel et al., 2007; Maestro et al., 2005), as the first 2 years of life are characterized by rapid advancements in these behavioral domains (e.g. Adamson, 1995; Carpenter et al., 1998; Mundy et al., 2007; Tomasello, 1995; Venezia et al., 2004).

One important challenge facing autism researchers is finding ways to translate this empirical knowledge about very early behavioral differences into clinical applications, such as identifying risk factors for individual children and determining ages at which specific behavioral markers are most salient. To date, several autism-specific screening measures have been developed for primary care settings, including the Checklist for Autism in Toddlers (CHAT: Baird et al., 2000; Baron-Cohen et al., 1992), the Modified Checklist for Autism in Toddlers (M–CHAT: Robins et al., 2001), the Pervasive Developmental Disorders Screening Test–II (PDDST–II: Siegel, 2004), and the Early Screening of Autistic Traits Questionnaire (ESAT: Swinkels et al., 2006). However, in many communities, practical issues such as long delays between referral and diagnostic evaluation and lack of autism-specialized early intervention providers may serve as disincentives for early referral for evaluation or intervention (Dosreis et al., 2006; Wiggins et al., 2006; Zwaigenbaum and Stone, 2006).

One viable strategy for increasing the access of very young children to appropriate intervention services may be the use of interactive screening measures for autism. Whereas parent-report screening tools have practical advantages in their cost-effectiveness and convenience, they can be limited by parents' understanding of the questions and constructs and the need for follow-up interviews to improve screening accuracy (Eaves et al., 2006; Robins and Dumont-Mathieu, 2006). Interactive screening tools have the advantage of providing clinicians with the opportunity to directly observe the subtle social and communicative impairments that comprise the earliest features of autism (Rutter, 2006). These deficits may not be recognized as readily by parents, who are often unaware of the extent to which they have to work to elicit social behaviors from their children with autism (Baranek, 1999). In addition to determining risk status, interactive screening measures can provide a platform for discussing behavioral concerns with parents, and can yield information that is translatable into specific intervention goals.

The major drawback of interactive screening measures is that they usually require more time and training to use, and may therefore be less practical for primary healthcare settings. However, the combined use of parent-report screening tools in primary care settings and interactive tools in referral settings may help bridge the gap between referral and service provision for children identified as at risk for autism.

The Screening Tool for Autism in Two-Year-Olds (STAT: Stone et al., 2000; 2004) is an interactive, play-based level 2 screening measure that consists of 12 activities assessing key social-communicative behaviors including play, communication, and imitation. Although the STAT was initially developed and validated for children between 24 and 36 months of age, pilot work has suggested that the social-communicative context and activities provided in the STAT are also well suited for children under age 2. The purpose of the present study was to investigate the screening properties of the STAT for children under 24 months.

Method

Participants

Children eligible for participation were those who: (1) were at increased risk for autism (i.e. younger siblings of children with autism spectrum disorders or children referred for concerns about autism); (2) received the STAT between 12 and 23 months (inclusive); and (3) received a follow-up assessment after 24 months. Participants were identified by searching the STAT database for children within the appropriate age range who had received a subsequent evaluation that included a diagnostic evaluation after 24 months. This database contains data for children meeting the following criteria: (1) no severe sensory or motor impairments; (2) no identified genetic or metabolic disorders; and (3) parental permission to use data for research purposes. All parents provided informed consent, and appropriate IRB approvals were obtained prior to conducting this study.

The resulting sample consisted of 71 children (44 male, 27 female) whose initial screening took place between 2000 and 2006. The majority ($n = 59$) were recruited from a longitudinal research project enrolling younger siblings of children with ASD (Sibs-ASD). An additional sample (DEV, $n = 12$) consisted of children receiving evaluations for developmental concerns related to autism. The average length of time between the initial and follow-up visits was 15 months (SD = 5.3). The mean cognitive score (MSEL early learning composite) at the initial evaluation was 95.8 (SD = 15.4) and at the follow-up evaluation was 93.5 (SD = 23.3). Sample characteristics are displayed in Table 1.

Table 1 **Sample characteristics**

	Sibs-ASD (n = 59)	*DEV (n = 12)*	*Total (n = 71)*
Mean (SD) initial age	15.9 (3.7)	18.9 (4.0)	16.4 (3.6)
Range	12–23	16–22	12–23
Mean (SD) follow-up age	32.5 (4.6)	25.6 (2.6)	31.3 (5.0)
Range	24–42	24–31	24–42
Diagnostic outcome (no.):			
Autism	3	9	12
PDD-NOS	6	1	7
Developmental delay	4	2	6
Language impairment	1	0	1
Broad autism phenotype	8	0	8
No concerns	37	0	37
Male no. (%)	34 (58%)	10 (83%)	44 (62%)
Caucasian no. (%)	48 (81%)	10 (83%)	58 (82%)
Mothers with partial college no. (%)	53 (90%)	7 (58%)	60 (85%)

At the initial evaluation, all children received the STAT, and results from the Mullen Scales of Early Learning (MSEL: Mullen, 1995) were available for 86 percent. At the follow-up evaluation, children received the STAT, the MSEL, and a diagnostic assessment, and were classified into six mutually exclusive outcome categories, defined *a priori*: autism, pervasive developmental disorder not otherwise specified (PDD-NOS), developmental delay (DD), language impairment (LI), broader autism phenotype (BAP), and no concerns. Diagnostic decisions were made by licensed psychologists who were experienced in the diagnosis of young children with autism. Assignment to autism spectrum categories was based on the ADOS (Lord et al., 2000) and clinical diagnostic criteria provided in the *Diagnostic and Statistical Manual of Mental Disorders–Text Revision* (DSM-IV-TR: American Psychiatric Association, 2004). Assignment to the DD and LI categories was based on performance on the MSEL. Criteria for a DD diagnosis were: (1) MSEL early learning composite at least 1.5 SD below the mean; and (2) visual reception and/or fine motor *T*-score at least 1.5 SD below the mean. Criteria for an LI diagnosis were: (1) no DD diagnosis; and (2) receptive language and/or expressive language *T*-score at least 1.5 SD below the mean. The BAP category was used for children who did not qualify for any of the diagnoses above, but for whom there were clinical concerns related to social-communicative functioning; both clinical concerns and a score exceeding the cutoff on the ADOS social domain were required. Children not meeting

criteria for any of the other categories were classified into the no concerns category.

Measures

Screening Tool for Autism in Two-Year-Olds (STAT: Stone et al., 2000; 2004) The STAT is an interactive measure that takes 20 minutes to administer and consists of 12 activity-based items that assess a range of social-communicative behaviors. It was developed as a level 2 screen to identify risk for autism in children between 24 and 36 months old in referral settings. The STAT assesses four behavioral domains: play (two items), requesting (four items), directing attention (four items), and motor imitation (four items). Within each domain, items are scored pass or fail according to specific criteria provided in the manual. The number of failures in each domain is averaged to obtain a domain score ranging from 0 to 1. For example, if a child fails one of the two play items, he would receive a score of 0.5 for that domain; if a child fails one of the four imitation items, he would receive a score of 0.25 for that domain. The four domain scores are then summed, yielding a total STAT score that ranges from 0 to 4, with higher scores representing more impaired performance, and a cut score of 2 indicating autism risk. The STAT has demonstrated strong psychometric properties for 24- to 36-month-olds, including sensitivity and specificity, interobserver agreement, test–retest reliability, and concurrent validity with the ADOS and clinical diagnosis (Stone et al., 2004).

Mullen Scales of Early Learning (MSEL: Mullen, 1995) The MSEL is a measure of cognitive function that was developed for use with children from birth through 68 months, and has demonstrated strong test–retest reliability, interscorer reliability, and concurrent validity with other cognitive and language measures. It includes four cognitive scales – visual reception (non-verbal problem-solving), fine motor, receptive language, and expressive language – that yield *T*-scores with a mean of 50 and an SD of 10. Scores on the four cognitive scales are used to derive the early learning composite (ELC), which has a mean of 100 and an SD of 15.

Autism Diagnostic Observation Scale (ADOS: Lord et al., 2000) The ADOS is a semi-structured observational assessment of play, social interaction, and communicative skills that was designed as a diagnostic tool for identifying autism spectrum disorders. Four different modules are available for individuals of different ages and language levels. Each module provides a set of behavioral ratings and an algorithm with cutoffs corresponding to a classification of autism, autism spectrum (i.e. PDD-NOS), or non-spectrum.

Due to the young ages of our sample, only modules 1 and 2 were administered in the present study. The ADOS has demonstrated strong psychometric properties, including test–retest reliability and interobserver agreement.

Analysis

The screening properties of the STAT were examined using signal detection procedures, also referred to as receiver operating characteristics (ROCs). This analysis is used to identify levels of sensitivity (i.e. proportion of children with ASD who are correctly identified as at risk) and specificity (i.e. proportion of children without ASD who are correctly identified as *not* at risk) that are associated with different cut scores. Because the STAT focuses on social and communicative behaviors, which develop rapidly during the second year of life, it was expected that children under 24 months would pass fewer items, creating a need for a higher cut score to maintain acceptable levels of sensitivity and specificity. In choosing a cut score, greater importance was placed on sensitivity than specificity, because the consequences of failing to identify children at risk for autism were considered to be more problematic than those of over-identifying children as at risk (i.e. because the latter group may have other developmental disorders).

Results

Results of the follow-up evaluation revealed the following number (%) of children in each diagnostic category: autism 12 (17%), PDD-NOS seven (10%), DD six (9%), LI one (1%), BAP eight (11%), and no concerns 37 (52%). Table 1 displays the outcome classifications obtained for each referral sample. For the signal detection analyses, children in the autism and PDD-NOS categories were combined to form an ASD outcome group, and children in all other categories (including BAP) were combined to form a non-ASD outcome group.

Results of the signal detection are presented in Figure 1 and Table 2. As illustrated in Table 2, the original STAT cut score of 2 (which corresponds to the value of 1.875) demonstrates high sensitivity (1.0) but low specificity (0.40). The optimal cut score for this younger sample was 2.75 (corresponding to the value of 2.625), which demonstrates a sensitivity of 0.95 and a specificity of 0.73. Positive predictive value (PPV) and negative predictive value (NPV) were also calculated for each cut score. PPV measures the proportion of children who screen positive (i.e. at risk) who actually have ASD, and NPV measures the proportion of children who screen negative (i.e. not at risk) who do *not* have ASD. Using the cut score of 2.75, PPV was 0.56 (i.e. 18/32 true positives) and NPV was 0.97 (i.e. 38/39 true negatives). Thus 14 children were over-identified as having ASD (false positives),

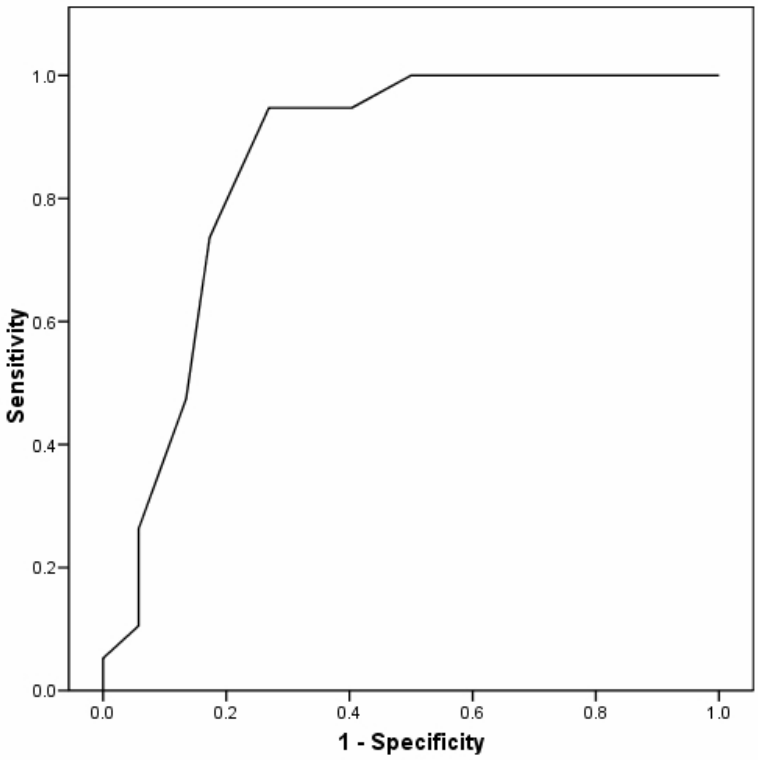

Figure 1 **ROC curve for entire sample (*n* = 71). Diagonal segments are produced by ties. Optimal cut score is 2.75**

and one child with ASD was missed (false negative). The child with ASD who was not identified with this cutoff was a 21-month-old girl who obtained a STAT score of 2.25. She failed all the items on the directing attention domain, but passed at least one item on the play, requesting, and motor imitation domains.

Table 2 **Results of signal detection**

Cutoff value[a]	*Sensitivity*	*Specificity*	*PPV*	*NPV*
1.875	1.0	0.40	0.38	1.0
2.125	1.0	0.50	0.42	1.0
2.375	0.95	0.60	0.46	0.97
2.625	0.95	0.73	0.56	0.97
2.875	0.74	0.83	0.61	0.90
3.125	0.47	0.87	0.56	0.82

[a] Scores greater than or equal to those indicated correspond to sensitivity and specificity figures.

To further understand the utility of the STAT for children under 24 months, we examined the pattern of false positives in terms of children's age and outcome category (see Table 3). It was expected that the proportion of false positives would be highest at the youngest ages. To examine this prediction, the sample was divided into three age subgroups: 12–13 months, 14–17 months, and 18–23 months. These age divisions were chosen to represent roughly equivalent sizes ($n = 21$, 23, and 27, respectively). The percentage of false positives in each age subgroup was 38 percent for the 12- to 13-month-olds, 13 percent for the 14- to 17-month-olds, and 11 percent for the 18- to 23-month-olds. Chi-square analyses confirmed that the 12- to 13-month subgroup differed significantly from the older groups in the number of children who were over-identified, $\chi^2(1, 71) = 6.36$, $p = 0.012$. Signal detection was subsequently rerun, removing the 12- to 13-month-olds from the analysis. Results revealed that 2.75 continued to be the optimal cut score, with a sensitivity of 0.93, specificity of 0.83, PPV of 0.68, and NPV of 0.97.

It was also predicted that the proportion of false positives would be lowest in the no concerns group. Due to small numbers, the DD and LI diagnostic groups were combined. The percentage of false positives for each resulting outcome category was 43 percent for DD/LI, 50 percent for BAP, and 19 percent for no concerns. Because our specific prediction was that children for whom there were no concerns at outcome would differ from those whose behavior elicited concerns, a chi-square analysis was run comparing children in the no concerns category to the combined group of children in either the DD/LI or BAP outcome category. Results confirmed that children in the no concerns category were significantly less likely to be false positive than were children with DD/LI or BAP, $\chi^2(1, 52) = 4.18$, $p = 0.04$.

Table 3 **Number of false positives by age and outcome category**

Age (months)	*n*	*No. who screen positive*	*No. false positives*	*Outcome category*		
				DD/LI	*BAP*	*No concerns*
12–13	21	13	8	1 (1)	2 (4)	5 (11)
14–17	23	8	3	0 (0)	1 (1)	2 (17)
18–23	27	11	3	2 (6)	1 (3)	0 (9)
Total	71	32	14	3 (7)	4 (8)	7 (37)

Parentheses indicate total number of children in each outcome category for that age group.

Discussion

The STAT is an interactive level 2 screening tool that provides a set of 12 activities for eliciting social and communicative behaviors that represent core deficit areas of autism. It was originally developed for children between 24 and 36 months and takes about 20 minutes to administer. The purpose of the present study was to determine whether the STAT can be used as an autism screen for children under 24 months. Results provide preliminary evidence that the original STAT items, administration, and scoring procedures – though developed for 2-year-olds – can also be used effectively for children under 24 months old. Our findings also highlight some important developmental considerations related to autism screening at young ages.

Although the STAT items and scoring procedures were appropriate for this younger age group, the original cut score of 2 that is used for 2-year-olds resulted in an unacceptable degree of over-identification of children without ASD. This finding reflected the higher rate of item failures (i.e. less sophisticated social-communicative skills) among children in this younger age group. As a result, a higher cut score (i.e. allowing for more item failures) of 2.75 was required to obtain adequate sensitivity and specificity for children 12–23 months old. Moreover, this new cut score demonstrated stronger screening properties for children who were 14 months and older, compared with those under 14 months. The highest rates of false positives and over-identification of children without ASD were found in the 12- to 13-month-old group. Removing the 12- to 13-month-olds from the sample resulted in improved specificity and PPV and the following screening properties: sensitivity 0.93, specificity 0.83, PPV 0.68, and NPV 0.97.

These findings serve as a reminder that the rapid changes in social-communicative development that occur within the second year of life must be considered in developing effective methods of early identification of autism. Because social and communication behaviors appear to be the most universal of the early symptoms of autism, it will be critical to determine which social and communication behaviors, *at which developmental periods*, are associated with a diagnosis of autism. Only then will we be able to generate screening methods and measures that are sufficiently sensitive to move the age of detection earlier.

To date, the ESAT is the only other screening measure for autism with published data for children as young as 14 months (Dietz et al., 2006). The ESAT is a level 1 parent-report screener designed for children 14–15 months old. When evaluated in a large random population of 31,724 children, 18 children were identified with ASD, and the PPV was 0.25 (Dietz et al., 2006). The low sensitivity and high false-positive rate for the ESAT relative to the STAT are likely results of the many differences between the

two measures. For example, PPV is inherently lower for level 1 screeners than for level 2 screeners, due to the lower base rates of the disorder in population samples. In addition, information about subtle differences in children's social-communicative behavior may be more readily obtained through child–examiner interactions than through parental reports (Stone et al., 1994). In fact, Dietz et al. (2006) noted that parents of children with ASD evaluated their children's behavior more positively than did experts.

One strength of the present study relative to previous STAT studies was the inclusion of children with autism *or* PDD-NOS in the ASD sample. Children with PDD-NOS have been excluded from earlier studies describing STAT development (Stone et al., 2000; 2004). The inclusion of children with milder autism symptomatology (i.e. PDD-NOS diagnoses) might be expected to make discrimination between the ASD and non-ASD groups more difficult, especially because children with characteristics of the broader autism phenotype (i.e. social-communicative concerns) were included in the non-ASD sample. The results obtained in this study point to the robustness of the screening properties of the STAT.

Perhaps the greatest limitation of this study is the small sample size, particularly for children receiving an outcome diagnosis of ASD ($n = 19$). Although small samples such as these are not unprecedented in autism research (Le Couteur et al., 1989), these results should be considered preliminary until they can be replicated. In particular, the current sample was too small to enable us to conduct independent validation of the cut scores; thus our results are more likely to be sample specific. Another important limitation is that this study was conducted within a university-based medical center, rather than in more naturalistic home or community-based settings. Consequently, these findings cannot yet be generalized to the numerous other settings in which the STAT may be used. Extension of this work to home and community settings is needed.

The identification of autism – or autism risk – at young ages requires consideration of several clinical and ethical issues. False-positive screening or assessment results may cause excessive (and undue) strain on parents. Specialized early intervention services may not be available or sufficient to accommodate the needs (or numbers) of young children who are identified as at risk. The relative efficacy of different treatments has not yet been assessed for very young children, and potential caveats associated with certain treatments may not be fully recognized at this time (see Zwaigenbaum et al., 2007, for a review of these issues). Moreover, the accuracy and long-term stability of a very early diagnosis of autism is not yet known. On the other hand, the implications of failing to identify children with autism at young ages, and withholding the opportunity for them to participate in the interventions that are currently available, may be much more costly in

the long run, both to families and to society. It also appears to be the case that many children who score false positive on early screenings for autism have other forms of developmental delays or disorders that warrant further evaluation or intervention (Dietz et al., 2006; Eaves et al., 2006; Zwaigenbaum and Stone, 2006). In the present study as well, false positives were twice as common in the groups of children for whom there were later clinical concerns (i.e. DD, LI, BAP) relative to those in the no concerns group.

These results have several implications for clinical practice. Of prime importance is the recognition that level 2 autism screening may be possible for children as young as 14 months. The STAT is currently used in a range of referral settings, such as developmental pediatrics practices, child find programs, diagnostic evaluation centers, and early intervention programs. The development of a cut score for children under 24 months will increase its flexibility and utility with children for whom there are early concerns about social-communicative development. Second, interactive screening tools can enable pediatricians and other clinicians to help concerned parents obtain information about their child's development and receive necessary services in a timely manner. Interactive screening measures can occupy a unique position in the referral–evaluation–intervention process, by serving the dual purposes of identifying autism risk status and providing observations of core social-communicative behaviors that can be used to develop intervention goals. By providing targeted interventions at young ages, we may be more likely to capitalize on the developing architecture of the brain and have a greater positive impact on children's developmental trajectories (Knudsen, 2004; Ramey and Ramey, 1999).

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