RESEARCH PAPER

# INCLEN Diagnostic Tool for Autism Spectrum Disorder (INDT-ASD): Development and Validation

MONICA JUNEJA, DEVENDRA MISHRA, PAUL SS RUSSELL, SHEFFALI GULATI, VAISHALI DESHMUKH, POMA TUDU, RAJESH SAGAR, DONALD SILBERBERG, VINOD K BHUTANI, JENNIFER M PINTO, MAUREEN DURKIN, RAVINDRA M PANDEY, MKC NAIR, NARENDRA K ARORA AND INCLEN STUDY GROUP*

*From the INCLEN Trust International, New Delhi, India.*

*Correspondence to: Dr Narendra K Arora, Executive Director, The INCLEN TRUST International, F1/5, Okhla Industrial Area, Phase-1, New Delhi, India. nkarora@inclentrust.org*

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**Objective**: To develop and validate INCLEN Diagnostic Tool for Autism Spectrum Disorder (INDT-ASD).

**Design**: Diagnostic test evaluation by cross sectional design

**Setting**: Four tertiary pediatric neurology centers in Delhi and Thiruvanthapuram, India.

**Methods**: Children aged 2-9 years were enrolled in the study. INDT-ASD and Childhood Autism Rating Scale (CARS) were administered in a randomly decided sequence by trained psychologist, followed by an expert evaluation by DSM-IV TR diagnostic criteria (gold standard).

**Main outcome measures**: Psychometric parameters of diagnostic accuracy, validity (construct, criterion and convergent) and internal consistency.

**Results**: 154 children (110 boys, mean age 64.2 mo) were enrolled. The overall diagnostic accuracy (AUC=0.97, 95% CI 0.93, 0.99; *P*<0.001) and validity (sensitivity 98%, specificity 95%, positive predictive value 91%, negative predictive value 99%) of INDT-ASD for Autism spectrum disorder were high, taking expert diagnosis using DSM-IV-TR as gold standard. The concordance rate between the INDT-ASD and expert diagnosis for 'ASD group' was 82.52% [Cohen's κ=0.89; 95% CI (0.82, 0.97); *P*=0.001]. The internal consistency of INDT-ASD was 0.96. The convergent validity with CARS (r = 0.73, P= 0.001) and divergent validity with Binet-Kamat Test of intelligence (r = -0.37; P=0.004) were significantly high. INDT-ASD has a 4-factor structure explaining 85.3% of the variance.

**Conclusion**: INDT-ASD has high diagnostic accuracy, adequate content validity, good internal consistency high criterion validity and high to moderate convergent validity and 4-factor construct validity for diagnosis of Autistm spectrum disorder.

**Keywords**: *Childhood; Neuro developmental disorders; Resource limited settings; Childhood austism rating scale; Pervasive developmental disorders.*

Autism Spectrum Disorder (ASD) is widely recognized for many decades, yet there are no definitive or universally accepted diagnostic criteria. [1]. Most diagnostic systems and measures consider ASD to be a 3-symptom cluster disorder with varying severity and etiology. This is reflected in the diagnostic systems of Diagnostic and Statistical Manual of Mental Disorders- IV Text Revision (DSM-IV TR) and International Classification of Diseases-10 (ICD-10), as well as the various measures that evolved from them [2,3]. However, the field trials of the draft version of Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5) have supported a 2-symptom cluster model [4,5] of varying severity.

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The construct, core and behavioral symptoms as well as the reliability of the diagnosis of ASD in diverse socio-cultural settings using the available tools have been problematic. In addition to the evolving construct of ASD globally, the timing of the presentation of this group of disorders [6] and racial differences have been documented to bring about variations in the core symptoms and

*INCLEN STUDY GROUP: **Core Group:** *Alok Thakkar, Arun Singh, Gautam Bir Singh, Manju Mehta, Manoja K Das, Nandita Babu, Praveen Suman, Ramesh Konanki, Rohit Saxena, Satinder Aneja, Savita Sapra, Sharmila Mukherjee, Sunanda K. Reddy, Tanuj Dada.* **Extended Group:** *A.K Niswade, Archisman Mohapatra, Arti Maria, Atul Prasad, B.C Das, Bhadresh Vyas, G.V.S Murthy, Gourie M. Devi, Harikumaran Nair, J.C Gupta, K.K Handa, Leena Sumaraj, Madhuri Kulkarni, Muneer Masoodi, Poonam Natrajan, Rashmi Kumar, Rashna Dass, Rema Devi, Sandeep Bavdekar, Santosh Mohanty, Saradha Suresh, Shobha Sharma, Sujatha S. Thyagu, Sunil Karande, T.D Sharma, Vinod Aggarwal, Zia Chaudhuri.*

associated behavioral features [7]. In multi-centric studies, the diagnostic distinctions among sub-categories of ASD has been unreliable across centers even while using standard diagnostic instruments, supporting a shift from a categorical to dimensional approach in the diagnosis of ASD [8]. The use of detailed and explicit appropriateness criteria has significantly enhanced the diagnostic yield in other medical disciplines [9]. Furthermore, currently available diagnostic instruments for ASD are patented [10,11], not available in different Indian languages, and fee is to be paid each time the instrument is used. To overcome several of these limitations, INCLEN Diagnostic Tool for Autism Spectrum Disorder (INDT-ASD) was developed for identification and diagnosis of ASD using appropriateness criteria developed for Indian context.

## METHODS

### *Development of Appropriateness Criteria and Instrument*

A team of 49 national experts from different parts of India and six international experts (pediatricians, child psychiatrists, pediatric neurologists, epidemiologist, pediatric otorhinolanringologists, clinical psychologists, special educators, specialist nurses, speech therapist, occupational therapists and social scientists) developed the appropriateness criteria and tool over three rounds of 2-day workshop in 2006-2007. During this process, the clinical criteria for ASD as presented in the ICD-10, DSM-IV TR Autism Diagnostic Observation Schedule (ADOS), Childhood Autism Rating Scale (CARS), Gilliam Autism Rating Scale (GARS), Modified Checklist for Autism in Toddlers (M-CHAT) and clinicians' views on the construct of ASD were reviewed. Pools of items were selected by the panel using the modified Delphi technique [12]. From the pool of items, the symptoms were rank-ordered by the panel members, and further reduced using endorsement rate approach [13].

The construct and its sub-construct were adapted for its appropriateness in the Indian cultural context and converted into symptoms clusters for the clinicians and psychologists to rate during the diagnostic workup. The tool was named as INCLEN Diagnostic Tool for ASD (INDT-ASD). The tool has two sections: Section A has 29 symptoms/items and Section B contains 12 questions corresponding to B and C domains of DSM-IV-TR, time of onset, duration of symptoms, score and diagnostic algorithm. It takes approximately 45-60 minutes to administer the instrument and score. A trichotomous endorsement choice ('yes', 'no', 'unsure/not applicable') is given to the assessor/ interviewer. In addition, the clinician/psychologist has to make behavioral observations on the child and score the item as well. For any discrepancy in parental response and interviewer's assessment, it is indicated for each question whether parental response or assessor's observation should take precedence. Each symptom/item is given a score of '1' for 'Yes' and '0' for 'No' or 'unsure/not applicable'. Presence of ≥ 6 symptoms/item (or score of ≥ 6), with at least two symptom/item each from impaired communication and restricted repetitive pattern of behavior, is used to diagnose ASD [***Web Appendix* I**].

The instrument was first developed in English, and forward and backward translated to Hindi and Malayalam by two teams with two independent, bilingual translators in each, to achieve the proximity of the source and target versions. This instrument was piloted (first pilot psychometric evaluation round, described below). Based on the feedback, the instrument was modified in Hindi version and then forward translated to English, Malayalam and six additional Indian languages (*Odia, Konkani, Urdu, Khasi, Gujarati and Telugu*) and backward translated in a similar manner.

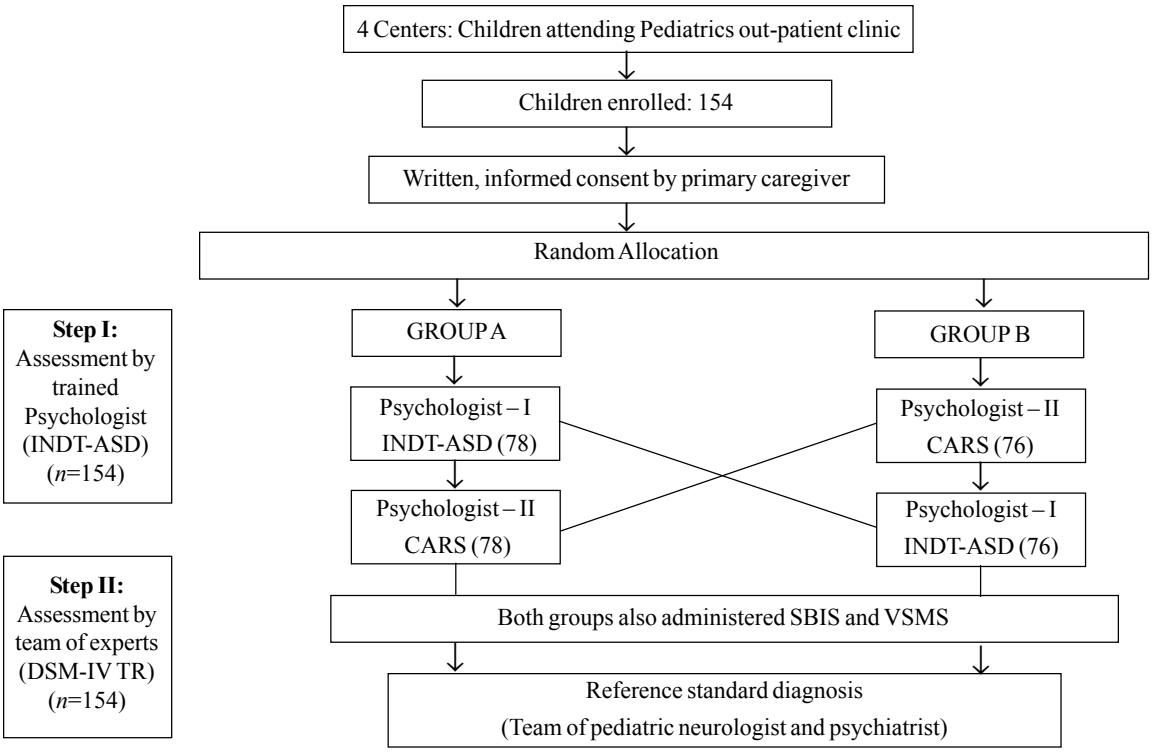
### *Psychometric evaluation*

The first round of psychometric (pilot) testing for INDT-ASD was done with 266 children at two sites (New Delhi-178 and Thiruvananthapuram-88). These included 81 children of ASD, 120 with other neuro-developmental disorders (NDDs) and 65 with typical development. However, as the ability of INDT-ASD to differentiate autism from other NDDs (specificity 69%) and the agreement with CARS [14] was moderate (kappa=0.69), further training and modifications in translation (12 items), item changes (3 items) and reframing (7 items with new examples) was done.

In the second round, psychometric (field) testing of the INDT-ASD was conducted in four public sector tertiary-care pediatric referral centers: All India Institute of Medical Sciences (AIIMS), Maulana Azad Medical College (MAMC), and Lady Hardinge Medical College (LHMC), New Delhi; and Child Development Centre (CDC) in Thiruvananthapuram.

Consecutive children (2-9 yr) with written informed consent from their primary caregivers were enrolled into the study from the Child development and Child neurology outpatient clinics. The children were recruited until the *a priori* sample size was reached. The validation exercise was conducted from June 2008 to April 2010.

***Fig.* 1** depicts the method for patient selection, assessment and interview. At every center, the study coordinator, who was not part of any assessment, evaluated the children attending the clinic for eligibility




*INDT-ASD: INCLEN Diagnostic Tool for Autism Spectrum Disorder (INDT-ASD); CARS: Childhood Autism Rating Scale; SBIS: Standford-Binet Intelligence Scale; VSMS: Vineland Social Maturity Scale; DSM-IV TR: Diagnostic and Statistical Manual of Mental Disorders Text Revision.*

**FIG. 1** *Process of subject grouping, randomization and assessment for psychometric validation of INDT-ASD.*

and enrolled them in the study. The subjects were randomly allocated into Group A (*N*=78) and Group B (*N*=76). In Group A, INDT-ASD was administered followed by CARS and the sequence was reversed in Group B. This was done by independent psychologists to minimize rating bias. Thereafter, each child was assessed by a two-member expert team (pediatric neurologist and child psychiatrist) who based their diagnosis on DSM-IV TR criteria. The diagnostic protocol required approximately four hours over two days, and consisted of (*i*) a face-to-face interview with parent/primary caregiver, as well as (*ii*) direct observations of children in play activities. Each evaluator was blinded to original diagnosis and assessment results of other evaluator; their evaluations were separately sealed in opaque envelops immediately after the assessment.

*Sample size and sampling technique:* Sample size for diagnostic accuracy was calculated assuming the sensitivity and specificity of INDT-ASD to diagnose ASD to be 85%, with a precision of ±10% at 95% confidence level. The sample size was calculated to be 50 children in each of the three categories: ASD, other NDD, and normal development. This sample was also adequate for exploratory factor analysis during validation [15]. CARS was used to study the convergent validity of INDT-ASD as well as divide the participants in to mild and severe autism groups [16]. The Stanford-Binet Intelligence Scale (SK Kulshreshtha, Hindi version) (SBIS) [17] and Vineland Social Maturity Scale (VSMS) [18] were used in all subjects to measure divergent validity of INDT-ASD.

The CARS is a 15-item behavior-rating scale designed to detect and quantify symptoms of autism. Each item on the CARS is scored on a Likert scale, from 1 (no symptoms of autism) to 4 (severe symptoms). The maximum CARS score is 60, and a score of 30.5 is suggestive of autism. Children with scores of 30.5 to 37 are rated as mildly-moderately autistic, and 37.5 to 60 as severely autistic by CARS.

A comprehensive and structured three day training workshop was conducted for psychologists using standardized manual developed for INDT-ASD, CARS, SBIS, and VSMS. Separate training groups (A and B; ***Fig.* 1**) of psychologists for INDT-ASD and CARS were

created. Both groups were trained to administer SBIS and VSMS. Two pediatric neurologists and two child psychiatrists with over ten years of professional experience were the trainers.

*Data processing and statistical analysis:* Participants' assessment details were entered into a pre-designed instrument with unique identification numbers. Statistical analysis was done using SPSS (version 19) and MedCalc (version 12.2.1.0) after data was entered into Intelligent Character Recognition (ICR) sheets. These were processed using ABBYY Form Reader 4.0 software. Psychometric parameters of diagnostic accuracy, construct validity, criterion validity and internal consistency of INDT-ASD were estimated. The performance of INDT-ASD was compared with CARS for convergent validity.

IndiaCLEN Review Board and the local Institutional Review Boards/Ethical Committees of all the participating centers provided approval for the study. Written informed consent was obtained from parent/primary caregiver and verbal assent from children, whenever possible. At the end of the assessment, parents were informed regarding the child's needs and appropriate referrals were facilitated, when warranted.

## RESULTS

The mean (SD) age of enrolled children was 64.2 (25.3) months ($n$=154; 110 boys). Ninety children had average and 64 had subnormal intelligence.

According to the expert diagnosis based on DSM-IV TR (considered as the gold standard), 51 children were diagnosed as ASD: autism (44), Pervasive developmental disorder not otherwise specified (PDD-NOS) (5), Rett syndrome (1), and CDD (1). Severe ASD was present in 41 and mild-to-moderate in 10 children. Forty-nine "Other NDDs" included intellectual disability (29), neuro-motor impairments including cerebral palsy (6), epilepsy (4), attention-deficit/hyperactivity disorder (2), vision/hearing impairment (2), and speech and language disorder (1); multiple NDDs were noted among 5 children.

The INDT-ASD had high diagnostic accuracy against expert evaluation using DSM-IV-TR for diagnosing ASD (***Table* I**). The area under-curve (AUC) for INDT-ASD against the expert diagnosis, was 0.97 (95% CI 0.93, 0.99; $P$=0.0001). None of the symptoms/items in the criteria were assigned a score of '0' by more than half of the children with autism in this study. The high concordance rate of 82.5% and a significant kappa value (Cohen's $\kappa$=0.89; 95%CI 0.82, 0.97; $P$=0.001) between the INDT-ASD and expert diagnosis indicated a high criterion validity for INDT-ASD. The INDT-ASD had a false positive rate of 5.8%. All the five false positive cases had "other NDDs": cerebral palsy (N=3), intellectual disability (N=1), and speech and language disorder (N=1). One child with ASD was missed (false negative). No normal child was misclassified as having autism.

The convergent validity between the INDT-ASD and CARS was high (r = 0.73, $P$= 0.001). Divergent validity calculated by correlating INDT-ASD scores to the SBIS showed a moderate negative correlation (r = -0.37; $P$=0.004).

To investigate the construct validity, we explored the factor structure of the items in the INDT-ASD. We extracted the factors with an Eigen value of >1 and thus, a 4-factor structure was derived. There was no INDT-ASD item that did not achieve the required factor loading (0.4) on to at least one factor (***Web Table* I**). In INDT-ASD, 14 symptoms/items loaded onto the socialization-communication factor, three symptoms/items loaded onto the repetitiveness-socialization factor, two symptoms/items loaded on to the restricted repertoire of interest factor, and finally all the 10 sensory symptom factor also cross-loaded on to other factors. This four-factor structure explained 85.3% of the variance.

The Cronbach's $\alpha$ coefficient for the whole construct of ASD was high ($\alpha$ = 0.96) suggesting that the INDT-ASD in this population has high internal consistency and Cronbach's $\alpha$ coefficients for the sub-constructs ranged between 0.82 and 0.96.

The performance of INDT-ASD was equally good among pre-school (<6 yrs) and primary-school children (≥6 yrs), among both genders, children with normal and subnormal intellectual ability, and in children with mild to moderate and severe ASD (AUC between 0.78 and 0.99).

## DISCUSSION

Diagnosis of ASD involves eliciting extensive history, and detailed observation by experienced clinicians and psychologists. The sensitivity and specificity of ASD of INDT-ASD was 98% and 95.1%, respectively in our study. This is better than the performance documented in the DSM-III field trial [19] and the ICD-10 field trial [20]. The DSM-IV TR [21] sensitivity of 93% is closer to our findings, although the specificity was only 78%. The specificity of INDT-ASD is similar to that of DSM-5 (95%) but the sensitivity is much higher (76%) [22].

High Cronbach's alpha coefficient for internal consistency demonstrated that the symptom clusters of INDT-ASD as used in the Indian context were homogeneous. Some previous studies for homogeneity of the symptom groups support our findings [21], whereas others differ with the present findings [23,24].

**TABLE I** DIAGNOSTIC ACCURACY OF INDT-ASD AGAINST EXPERT DIAGNOSIS USING DSM-IV TR CRITERIA

| *Comparison Group* | *Sensitivity % (95% CI)* | *Specificity % (95% CI)* | *Positive predictive value % (95% CI)* | *Negative predictive value % (95% CI)* | *Positive likelihood ratio % (95% CI)* | *Negative likelihood ratio % (95% CI)* |
|---|---|---|---|---|---|---|
| ASD *vs.* normal | 98.0 (89.5-99.9) | 95.1 (89.0-97.9) | 90.9 (80.4-96.1) | 99.0 (94.5-99.8) | 20.1 (8.5-47.5) | 0.02 (0.003-0.1) |
| Autism *vs.* normal | 95.5 (84.9-98.7) | 90.9 (84.1-95.0) | 80.8 (68.1-89.2) | 98.0 (93.1-99.7) | 10.49 (5.7-19.0) | 0.05 (0.01-0.1) |
| ASD *vs.* other NDD | 98.0 (89.5-99.5) | 87.8 (75.8-94.3) | 89.3 (78.5-95.0) | 97.0 (88.2-99.6) | 8.00 (3.7-16.9) | 0.02 (0.003-0.1) |
| Autism *vs.* other NDD | 95.5 (84.9-98.7) | 82.1 (70.2-90.0) | 80.8 (68.1-89.2) | 95.8 (86.0-98.8) | 5.34 (3.0-9.4) | 0.05 (0.01-0.2) |
| INDT-ASD total score > 5 and possibility of ASD | 98.1 (93.0-100) | 90.8 (83.3-95.7) | 85.7 (74.5-93.3) | 98.9 (94.0-100) | 10.6 (9.9-11.5) | 0.02 (0.03- 0.2) |

*n=51 for ASD, 54 for normal, 44 for autism, 49 for other NDD; INDT-ASD: INCLEN Diagnostic Tool for Autism Spectrum Disorder; DSM-IV TR: Diagnostic and Statistical Manual of Mental Disorders Text Revision; ASD: Autism Spectrum Disorder; NDD: Neuro-developmental Disorder.*

The agreement rate between INDT-ASD and DSM-IV-TR (used by expert team) is better than that reported for the DSM-III, DSM-III-R and ICD-10 [19]. Our false positive rate of 5.8% is comparable with that of the values reported for DSM-III but lower than that of DSM-III-R [19]. In our study, children with cerebral palsy and intellectual disability had impairment in proto-declarative and proto-imperative pointing and were poorly communicative. This possibly resulted in false positivity of INDT-ASD. The false negative diagnosis was also far lower than that reported for DSM-III and DSM-III-R [19]. The only false negative case in the current study had low-average Intelligence quotient (IQ) with mild autism symptoms.

The convergence between the INDT-ASD and CARS was high suggesting that the construct of autism as measured by INDT-ASD and CARS are theoretically related to each other. The negative correlation between INDT-ASD and IQ as measured by SBIS shows that INDT-ASD has the ability to diverge from theoretical constructs that are different from its own, like construct of autism from other childhood disabilities. However, data for comparison of the concurrent validity for DSM and ICD are not readily available in the literature.

The factor analysis of the symptom clusters of autism, as a measure of external validity of the construct has yielded diverse structure models across different studies [23-28]. For instance, the study by Tadevosyan-Leyfer, *et al.* [26] demonstrated a 6-factor structure, while other studies have documented a classical 3-factor [26] like represented in DSM-IV-TR and ICD-10 or alternative 3-factor structure [29,30] and even a 1-factor structure explaining the construct of autism. Our item loading, the 4-factor structure and 85.3% of variance being explained, makes it closer to the existing model offered by Tanguay, *et al*. [25]. The main methodological differences, such as population characteristics, factor-extraction and factor-retention procedures, language versions, and statistical approaches, are aspects that might explain the variability of findings across these factor analyses of the autism criteria.

As the study was conducted in tertiary-care hospitals, the participants may not be representative of the children with autism in the general population and those presenting in primary and secondary care. Further community-based studies to establish the sensitivity and specificity of INDT-ASD are suggested. Another limitation is that the tool was validated in children 2-9 years of age, and may not capture the diagnosis in children less than two years of age. Moreover, a larger sample size could have generated more stable factor structure models thereby improving the confidence in the validity of identified constructs,

**WHAT IS ALREADY KNOWN?**

- Autism spectrum disorder (ASD) is a clinical diagnosis by experienced and trained developmental pediatricians, child psychiatrists and psychologists. Currently available diagnostic tools are developed for Western populations and are subject to payment of fee.

**WHAT THIS STUDY ADDS?**

- The INDT-ASD is a simple, validated diagnostic algorithm for Autism Spectrum Disorders in children, designed on DSM-IV TR criteria through expert consensus.

providing more accurate estimates of sensitivity, specificity, and predictive values.

Establishing the appropriateness of the international criteria in the Indian context enhances the possibility of accurate clinical diagnosis and paves way to developing as well as validating new measures for autism in India. With similar approach and appropriate modification, tools may be developed for use in other resource limited settings.

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