Question 4(a)

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
Author: Allen CW Year: 2006 ID: [66] Country: Australia AIM: 1. Estimate the sensitivity, specificity and positive and negative likelihood ratios of the SCQ in identifying ASD from other developmental disorders. 2. Compare the sensitivity and specificity of the SCQ with the predictions of the referrer to see if it added value. Study design: Uncontrolled observational Consecutive	Patient groups: All referrals to CDU aged 2-6 years over a 9 month period. 100 children identified. CDU is a state wide specialist tertiary referral clinic at The Children's Hospital at Westmead. Exclusion criteria: Parents who didn't respond. Demographics: Number: 81 Age: 26-84 months. Ethnicity: Not reported. Subgroups: Language: Not reported. Gender: -Male 66 (81.48%) Intellectual disability: Not reported Visual impairment: Not reported. Hearing impairment: Not reported. Gestational age: Not reported. Source of referral: Predominantly by paediatricians, psychiatrists and preschool special education services.	Surveillance tool under investigation: ●SCQ: a screening tool for children at high risk of developmental problems Threshold & Data set SCQ has 40 questions. Cut off: 11, >15 Adequately described? Yes. Operator no/experience Parents without experience. Comparison/Diagnostic Criteria tool: ●DSM-IV: CARS, Bayley's scales of infant development II, history/examination, observation, reviews of reports from other professionals who interact with the child and physical examination. Threshold and Data set Combination of about assessments against DSM-IV criteria. Adequately described? Yes. Operator no/experience Not reported – presumed MDT	Differential diagnosis - ASD Language disorder only Mild/moderate developmental delay only Language disorder and developmental delay other	 20/81 (24.7%) 21/81 (25.9%) 7/81 (8.6%) 5/81 (6.2%)	Funding: Not reported. Limitations: 1. The total sample size is large enough; however, for each age group the sample size is small. Blinding: Yes. Parents were asked to complete the SCQ prior to their child's appointment. The investigator scoring the SCQ was blinded to the outcome of the multidisciplinary assessment. Timing of tests: Not reported. Verification (ref/index test x100) 100% Also reported: 1. Comparison of referrer and SCQ in prediction of ASD. 2. *Mean SCQ* score and developmental level in children with ASD Mild DD (n=6) *14* (SD 3.7) Mild/Mod DD (n=7) *19*

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
recruitment? Yes. Study dates: Not reported					(SD 5.6) Mod DD (n=10) *19* (SD 7.4) Unknown (n=4) *16* (SD 5.4) 3.Non-ASD diagnoses -language disorder n=20 -mild/mod DD n=21 -language disorder and DD n=7 -other n=5 Of the 81 responses only 56 were for children referred for ASD so only these are use din the results . We are unable to calculate sensitivity and Specificity for age groups and children with ID
Author: Arvidsson T **Year:** 1997 **ID:** 144 **Country:** Sweden **Study design:** Uncontrolled observational **Consecutive recruitment**	**Patient groups:** 12 children with suspicion of autism (have three or more of the ICD-10 symptoms of childhood autism) have been picked out in a regular examination at well-baby clinic. These 12 children came from an original sample, which consist of all 1941 children born in the years 1988-1991 and living in the community of Molnlycke on the Swedish west coast on 31 Dec, 1994. **Exclusion criteria** Not reported.	**Diagnosis criteria:** ICD-10. **Diagnosis assessment:** ICD-10, twice parent interviews using both structured and semi-structured techniques, Swedish ADI-R. The final diagnosis was made in case conference. -Operator experience: Experienced, a medical practitioner with considerable experience of autism and its spectrum disorders.	Differential diagnosis - autism ADHD Conduct disorder Mental retardation	 1/12 (8.3%) 1/12 (8.3%) 1/12 (8.3%)	**Funding:** Not reported. **Limitations:** 1) Small sample size 2) Potential false negative have not been examined. 3) The diagnostic tool and members of diagnosis group were not well reported. **Also reported:** Of the whole sample (12), 9 children are ASD (75%).

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
Yes. **Study dates** Not reported. **Evidence level:** Low.	**Demographics:** **Number**:12 (Note: The following data are all of those 9 ASD children since no data for the 3 non-ASD children were reported.) **Age: (Unit: Years)** **Mean:** 5.5 **Range:** 3-6 **Ethnicity:** Not reported. **Subgroups:** **Intellectual Disability:** Not reported **Language:** Not reported **Gender:** - **Male:** 7(58.3%) **Visual impairment:** Not reported **Hearing impairment:** Not reported **Communication impairment** Not reported **Gestational age:** Not reported **Source of referral:** Not reported	**Diagnosis group:** Case conference. The members are Not reported. **Inter-rater reliability:** Not reported. **Adequately reported:** No, the diagnostic tool and members of diagnosis group were not well reported.			
Author: Baron-Cohen S **Year:** 2000 **ID:** 149 **Country:** U.K **Study design:** Uncontrolled	**Patient groups:** 32 children who have been identified as high/medium risk of autism in the population screening using CHAT. The whole screened population of 17,173 children came from 9 districts in the South East Thames Health Region, U.K. The social class distribution of this population was broadly representative of the U.K.	(**Note:** All the following diagnostic information were found in another paper titled 'Autism Spectrum Disorders at 20 and 42 months of age: stability of clinical and ADI-R diagnosis') **Diagnosis criteria:** Clinical consensus according to ICD-10. (at 42 months) **Diagnosis assessment:** Parental interview using the	Differential diagnosis - ASD: Language disorder Developmental delay/ learning difficulties Typicvally developing	 7/32 (21.88%) 2/32 (6.25%) 3/32 (9.38%)	**Funding:** SBC, AC and GB from Medical Research Council. **Limitations:** 1. Due to limited resources, only half of the medium risk group could be re-screened. And for the 22 children who met the criteria on the second CHAT, 2 of

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
observational **Consecutive recruitment** No. **Study dates** Not reported. **Evidence level:** Low.	**Exclusion criteria** Children with profound developmental delay, gross physical disability, or those already recognised as having a mental handicap were excluded from the screening sample. **Demographics:** **Number**:32 **Age: (Unit: Months)** **Mean:** 18.7 ± 1.1 **Ethnicity:** Not reported **Subgroups:** Intellectual Disability: Not reported Language: Not reported Gender: - Male: 9016 (52.5%) Visual impairment: Not reported Hearing impairment: Not reported Communication impairment Not reported Gestational age: Not reported Source of referral: Not reported	ADI-R, clinical assessment using a structured schedule of elicited child-investigator interaction, psychometric assessment using the Griffiths scale of infant development or Leiter international performance scale, and language assessment using the Reynell developmental language scales. The same assessment procedure was repeated at 42 months. And at 42 months all children were assigned ICD-10 diagnoses. -Operator experience: Experienced. **Diagnosis group:** Three experienced clinicians. **Inter-rater reliability:** Not reported. **Adequately reported:** Yes.			them did not continue to participate in the project. **Also reported:** Of the whole sample (32), 20 children are ASD (62.5%), which including 10 (31.25%) childhood autism and 10 (31.25%) PDD-NOS.
Author: Barrett S **Year:** 2004 **ID:** 137 **Country:**	**Patient groups:** 37 children who all showed some autistic features and be referred to the Royal Children's hospital autism assessment program. **Exclusion criteria** (For STAT database) - Children with severe sensory	**Diagnosis criteria:** DSM-IV **Diagnosis assessment:** No specific assessment used in the diagnostic procedure was reported. Diagnoses of language disorder are made on the basis of evidence of	Differential diagnosis - ASD Language disorder	15/37 (40.5%)	**Funding:** Not reported. **Limitations:** 1) Small sample size 2) The diagnostic procedure of referred children is not adequately described, and the author also states 'Diagnosis is

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
Australia **Study design:** Uncontrolled observational **Consecutive recruitment** Not reported. **Study dates** Not reported. **Evidence level:** Low.	or motor impairments - Children have been identified genetic or metabolic disorders - No parental permission to use data. **Demographics:** **Number**:37 **Age: (Unit: Years)** **Mean:** 5.5 **Range:** 4-7.9 **Ethnicity: N (%)** Not reported. **Subgroups:** **Intellectual Disability:** **Mean:** 84 **SD:**14.2 **Language:** Not reported **Gender:)** - **Male:** 32(86.49%) - **Female:** 5(13.51%) **Visual impairment:** Not reported **Hearing impairment:** Not reported **Communication impairment** All participants spoke in short phrases or sentences, except for one boy. **Verbal IQ:** **Mean:** 79 **SD:**14.9 **Gestational age:** Not reported **Source of referral:** Not reported.	communication impairments, the exclusion of other diagnoses, and speech pathologists' formal and informal assessment of the child's receptive language abilities, language structure, and use of language in conversations. -Operator experience: Not reported. **Diagnosis group:** Expert multidisciplinary autism assessment teams (Paediatrician, psychologist and speech pathologist) **Inter-rater reliability:** Not reported. **Adequately reported:** No, because the specific assessments of ASD and LD used in the diagnostic procedure were Not reported.			never infallible. The difficulty is particularly acute with children who may be on the boundary of overlapping conditions.' **Also reported:** Of the whole sample (37), 22 children are ASD (59.5%), which include 20(54.1%) autistic disorder patients and 2 (5.4%) PDD-NOS patients.
Author:	Patient groups:	Surveillance tool under	Differential diagnosis - ASD		Funding:

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
Corsello A Year: 2007 ID: 73 Country: U.S.A AIM: Investigate how well the SCQ function as a clinical screening instrument in a larger, younger American sample of children with ASD or non-spectrum disorders. Study design: Uncontrolled observational Consecutive recruitment? Yes Study dates: Not reported Evidence level Very low	590 children between 2 and 16 years who were consecutive referrals to two university-based clinics specializing in children with possible ASDs and/or were participants in research within the autism centres. Eventual diagnosis- ASD: n=438. Non-ASD: n=151 Exclusion criteria: Children with missing items that would have changed their SCQ classification. Demographics: **Total sample** Number=590 Age: 2-16 years Ethnicity: 495 Caucasian, 43 African-Americans, 48 other ethnicities and 4 with missing data. **Autism (AD):** Number=282 Age: µ=84.34 **PDD-NOS (PD):** Number=157 Age: µ=96.09 **Non-spectrum (NS):** Number=151 Age:µ=93.09 Ethnicity: -Caucasian: 495(83.90%) -African Americans: 43(7.29%) -Other: 48(8.14%) -Missing: 4(0.68%)	investigation 1: ●SCQ[1] Threshold & Data set 40 item questionnaire. Cut-off >=15 or 12 Adequately described? Yes Operator no/experience Parents with no experience. Comparison/Diagnostic Criteria tool: ●DSM-IV : IQ, ADI-R and ADOS score, and unstructured telephone teacher interviews Threshold and Data set Consensus diagnosis by two examiners over 1-3 hour sessions and had access to all assessment results. Adequately described? Yes Operator no/experience Experienced (e.g., a child psychiatrist, clinical psychologist)	Communication disorder ADHD Mental retardation Down syndrome Foetal alcohol syndrome Mood / anxiety disorder Other Psychiatric / development disorders	36/590 (6.1%) 30/590 (5.1%) 26/590 (4.4%) 18/590 (3.1%) 18/590 (3.1%) 12/590 (2.0%) 11/590 (1.9%)	National institute of Mental health. Grants: R01 MH 066496 and R01 MH46865 to Dr Lord. Limitations: 1) Unsure is all sample were referrals. (“some participants had been part of a control group in a research project”) Blinding: Yes – parents completed the SCQ prior to diagnostic assessment and clinicians were unaware of the SCQ scores when performing diagnostic assessment. Timing of tests: SCQ completed prior to the diagnosis. Verification (ref/index test x100) 100%. Also reported: 1) The accuracy of SCQ, ADOS, ADI-R in identifying autism, not only ASD. 2) Non-spectrum disorders: - communication disorder n=36 - ADHD n=30

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
	Subgroups: Language: Not reported Gender: -Male: 462(78.31%) Intellectual disability: **Nonverbal IQ:** AD: Mean=68.92 PD**:** Mean=91.26 NS: Mean=78.44 **Verbal IQ:** AD**:** Mean=52.02 PD: Mean=90.01 NS: Mean=78.51 Visual impairment: Not reported Hearing impairment: Not reported Gestational age: Not reported Source of referral: Not reported				- mental retardation n=26 - Down syndrome n=18 - Fetal alcohol syndrome n=18 - mood/anxiety disorder n=12 - other dev/psych disorder n=11 3) Differences in IQ, age, gender and maternal education between groups.
Author: Dietz C **Year:** 2006 **ID:** 145 **Country:** Netherlands **Study design:** Uncontrolled observational **Consecutive recruitment** No. **Study dates**	**Patient groups:** 73 children who had positive result in both 4-item and 14-tiem ESAT (Early Screening of Autistic Traits Questionnaire) screening test and are willing to receive further assessment, from the original 31,724 children who visited well-baby clinics and received screening test from Oct, 1999 to Apr, 2002 in the province of Utrecht, the Netherlands. Also reported: Although attendance of well-baby clinics is not compulsory, most children up to 4 years of age are taken to these clinics. In the first year, attendance is as high as 98%, with an average of 6 visits in the	**Diagnosis criteria:** DSM-IV; Diagnostic classification of mental health and developmental disorders of infancy and early childhood (1994) **Diagnosis assessment:** ***Screening tool:*** **4 item ESAT.** Which including 2 items measure play behaviour, one item measures the readability of emotions, and one item about the reaction to sensory stimuli, all of which extracted from the original 14-item ESAT tool. **-Operator experience:** Not	Differential diagnosis - ASD General mental retardation Language disorder Other DSM-IV (ADHD, reactive attachment disorder, et ac.) Other	13/73 (18%) 18/73 (25%) 11/73 (15%) 13/73 (18%)	**Funding:** Supported by grants 940-38-045 and 940-38-014 (Chronic Disease Program), by grand 28.3000-2 of the Praeventiefonds-ZONMW, by the Netherlands Organisation for Scientific Research, by a grand from the Dutch Ministry of Health, Welfare and Culture, and by grants from Cure Autism Now, and the Korczak Foundation. **Limitations:** No data on the false-negative cases of screening tool was

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
Oct, 1999 to April, 2002 **Evidence level:** Very low.	first year. **Exclusion criteria** 115 children who tested positive in 4-item ESAT test and 27 children tested positive in both 4-tiem and 14-item ESAT test that have dropped-out of this study. **Demographics:** **Number**:73 **Age: (Unit: Months)** **Range:** 14-15 **Ethnicity:** Not reported **Subgroups:** Intellectual Disability: Not reported Language: Not reported Gender: Not reported Visual impairment: Not reported Hearing impairment: Not reported Communication impairment Not reported Gestational age: Not reported Source of referral: 100% from Well-baby Clinics. -	reported. **14-item ESAT.** Be conducted at 14-month follow-up for children who tested positive in 4-item ESAT. **-Operator experience:** Experienced. A trained child psychologist ***Extensive diagnostic* investigations (42 months)** (for children who tested positive in 14-item ESAT test) Standardized parental interview Developmental history Vineland social-emotional early childhood scales. Autism diagnostic observation schedule or ADOS-G. Paediatric examination and medical workup **Operator experience** of all 5: Not reported. ***Additional investigations:*** Parent questionnaire			reported. High drop-out rate. **Also reported:** Of the whole sample (73), 18 children are ASD (25%).

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
		ASQ(Autism Screening Questionnaire) at 42-month follow-up. CHAT Infant/Toddler checklist for communication and language development Some items of ADI-R Mullen Scales of Early Learning (conducted for 225children (90%), for the remaining 25 children who did not cooperate with MSEL, 19 were given Dutch translation of the Bayley scales; and 6 were given Psycho-educational Profile Revised. Videotaped materials. Re-examinations of cognitive development were made at age 24 months **Diagnosis group:** Three experienced child psychiatrists. **Inter-rater reliability:** For the diagnosis of ASD and non-ASD: 92% of 38 cases. For all diagnosis categories:			

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
		79% of 38 cases. **Adequately reported:** Yes.			
Author: Ehlers S Year: 1999 ID: 70 Country: Sweden AIM: To evaluate the ASSQ as a screening instrument and aid for the identification of those behaviourally disturbed children at risk of having ASD. Study design: Uncontrolled observational Consecutive recruitment? Yes Study dates: 8 months	Patient groups: Consecutive referrals to neuropsychiatric clinic over 8 months. 110 children with various kinds of behavioural disorders Exclusion criteria: - moderately and severely retarded children were excluded (as ASSQ not designed to capture characteristics of these children) - mild retardation included. Demographics: Number: 110 Age: 6-17 year olds Ethnicity: Not reported Subgroups: Language: Not reported Gender: 87 (79%) boys Intellectual disability: 13 (12%) had mild mental retardation (IQ 50-70) in addition to Dx Visual impairment: Not reported Hearing impairment: Not reported Gestational age: Not reported Source of referral: Not reported	Surveillance tool under investigation: ● ASSQ Threshold & Data set Completed twice, once at time 1 during visit to clinic, and once 2 weeks later (via mail) Adequately described? Yes Operator no/experience Parent (n=110) questionnaire, thus no experience. If agreed the students teacher (n=107) was also completed ASSQ Comparison/Diagnostic Criteria tool: ● DSM-IV: 2 hours with psychiatrist, 2 hours with psychologist, extensive history. Threshold and Data set Consensus diagnosis Adequately described? Yes Operator no/experience Psychiatrist / Case conference	Differential diagnosis of ASD Attention-deficit and disruptive behavioural disorders Learning disorders	 58/110 (52.7%) 31/110 (28.2%)	Funding: Grants from Wilheim and Martina Lundren Foundation, and the RBU Foundation, the Sven Jerring Foundation and the Clas Groschinsky memorial Foundation and the Swedish medical Research council. Limitations: 1. Population only includes patients with behavioural problems and does not specify what problems. 2. Does not define moderate / severe mental retardation. 3. Decreased response rate for time 2 questionnaire (via mail) Blinding: Not reported Timing of tests: ASSQ completed during time 1, prior to diagnostic evaluation Verification (ref/index test

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
					x100) 100% Also reported: Teachers tended to score 2 points higher than parents.
Author: Gray KM Year: 2008 ID: 67 Country: Australia AIM: To evaluate the screening properties of the DBC-ES in a community sample of very young children with suspected developmental delay Study design: Uncontrolled observational Consecutive recruitment? yes	Patient groups: Referrals of children aged 18-48 months with or suspected of developmental delay for evaluation for autism. N = 207 Exclusion criteria: Nil reported Demographics: Total sample Number: 207 Age: 20.5 – 51.3 months (mean 38.3mo SD 7.00) Ethnicity: Not reported Gender: 83.1% male PDD Diagnosis Number: 142 - 110 autistic disorder - 23 PDD-NOS Age: 22.2 – 50.6 months (mean 37.8mo SD 6.8) Ethnicity: not stated Gender: 86.6% male No PDD Diagnosis Number: 65 - 43 developmentally delayed - 61 had a language delay of	Surveillance tool under investigation: ● DBC-ES: aims to differentiate children with DD+autism from DD-autism. Threshold & Data set DBC-ES is 17 items from DBC-P. Each item rated on 0-2 scale. Cut-off: ≥11 Adequately described? Yes Operator no/experience DBC-ES completed by parent (no experience) Comparison/Diagnostic Criteria tool: ●DSM-IV: information derived from ADI, ADOS, PEP-R/WPPSI-III, RDLS, VABS, DBC-P. Threshold and Data set Consensus diagnoses between 2 physicians. Adequately described? Yes Operator no/experience Physicians - experienced	Differential diagnosis - ASD Developmental delay Mixed receptive-expressive language disorder Expressive language disorder Other	 43/207 (20.8%) 20/207 (9.7%) 1/207 (0.5%) 1/207 (0.5%)	

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
Study dates: Not reported. Evidence level:	more than 6 months Age: 20.5-51.3 months (mean 39.4 mo SD 7.4) Ethnicity: Not reported Gender: 75.9% Subgroups: Language: Not reported Intellectual disability: 99 (69%) of the PDD children were below age equivalent 21 months, 15 (32%) of the non-PDD group were at this level Visual impairment: Not reported Hearing impairment: Not reported Gestational age: Not reported Source of referral: Early childhood agencies and paediatricians, small number of self referrals.				
Author: Honda H **Year:** 2009 **ID:** 142 **Country:** Japan **Study design:** Uncontrolled observational **Consecutive recruitment**	**Patient groups:** 19 children who born in 1988, underwent YACHT-18 (Young autism and other developmental disorders check-up tool) at 18 months of age and got positive screen result in the refinement stage. Also reported: These 19 children comes from a cohort study of 3,036 children who were born in 1988 and received the YACHT-18 screening during routine health checkups at the age of 18 months at the Yokohama Aoba PHWC. Of these, 222 children who had	**Diagnosis criteria:** DSM-IV **Diagnosis assessment:** **1. Early screening.** Extraction and refinement (E&R) strategy was used, which consist of two stages: first comes extraction stage, which means using YACHT-18 to flag all children with even the slightest problem in order to reduce false negatives to a minimum; and then is second stage: refinement stage, which aims to reduce false positives as much as possible. This stage	Differential diagnosis - ASD ADHD Mental retardation Learning disorders	 5/19 (26.3%) 2/19 (10.5%) 1/19 (5.3%)	**Funding:** Supported by grants 940-38-045 and 940-38-014 (Chronic Disease Program), by grand 28.3000-2 of the Praeventiefonds-ZONMW, by the Netherlands Organisation for Scientific Research, by a grand from the Dutch Ministry of Health, Welfare and Culture, and by grants from Cure Autism Now, and the Korczak Foundation. **Limitations:**

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
No. **Study dates** Oct, 1999 to April, 2002 **Evidence level:** Very low.	already been diagnosed with some kind of disease or disorder before screening have been excluded. **Exclusion criteria** Children who had already been diagnosed with some kind of disease or disorder before screening. **Demographics:** **Number**:19 **Age: (Unit: Months)** **Mean:** 18 **Ethnicity:** Not reported **Subgroups:** **Intellectual Disability:** Not reported **Language:** Not reported **Gender:** Not reported **Visual impairment:** Not reported **Hearing impairment:** Not reported **Communication impairment** Not reported **Gestational age:** Not reported **Source of referral:** - GP: 100% from Yokohama Aoba PHWC.	includes follow-up via telephone call, home visit, psychological consultation, weekly group meeting; also includes specialized assessment in 'joint clinic', which consisting of a developmental psychiatrist, a clinical psychologist and a social worker who team up with the public health nurses. **-Operator experience**: Experienced for those work in joint clinic, for the others Not reported. **2. Diagnosis stage.** Be conducted in Yokohama rehabilitation centre. However, no further information is provided. **-Operator experience**: Not reported. **Diagnosis group:** The final diagnosis group is Not reported. But members of joint clinic (which refer children to YRC) are reported as one developmental psychiatrist, a clinical psychologist, and a social worker who team up with the public health nurses. **Inter-rater reliability:** Not reported.			1. No data on the false-negative cases of screening tool was reported. 2. High drop-out rate. **Also reported:** Of the whole sample (19), 11 children are ASD (57.9%), which include 3(15.8%) Autistic disorder patients and 8 (42.1%) PDD-NOS patients.

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
		Adequately reported: Yes for the early screening stage; but not for the final diagnostic stage.			
Author: Harel S **Year:** 1996 **ID:** 140 **Country:** U.S.A **Study design:** Uncontrolled observational **Consecutive recruitment** Yes **Study dates** Not reported. **Evidence level:** Very low.	**Patient groups:** 323 children with speech, language and communication disorders that had been referred to a child development centre from 1984-1988. **Exclusion criteria** Children did not contain sufficient documented information. Children referred for psychomotor delay or mental retardation or non-language-related deficits. **Demographics:** **Number**:323 **Age: (Unit: Months)** **Mean:**39 **Range:** 20-52 **Ethnicity: N (%)** *Parents Asian or African: 213 (66%) East European: 107(33%) Other: 3(1%) **Subgroups:** **Intellectual Disability: N (%)** - Yes: 12(3.72%)	**Diagnosis criteria:** **ASD:** DSM-IV **DLD:** Classification of DLD proposed by Rapin and Allen. **Diagnosis assessment:** **ASD:** DSM-IV. **DLD:** NOT REPORTED -Operator experience: Experienced. **Diagnosis group:** **DLD:** A senior speech and hearing pathologist, who integrated the details of each case file and arrived at the specific conclusions. **ASD:** NOT REPORTED **Inter-rater reliability:** Not reported. **Adequately reported:** No, the assessment tool is not fully reported.	Differential diagnosis - ASD Developmental language disorder	294/323 (91%)	**Funding:** The institute of child development and paediatric neurology, Albert Einstein college of medicine, New York **Limitations:** The diagnostic tool is not adequately reported. **Also reported:** Of the whole sample (323), 29 children are ASD (9.0%), which include 12 (3.7%) autism patients, 17 (5.3%) other ASD patients.

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
	- No: 311(96.28%) Assessment tool: PIQ (Performance IQ of Wechsler preschool and primary scale of intelligence) **Language:** Not reported **Gender: Male:** 246(72%) **Visual impairment:** Not reported **Hearing impairment:** Not reported **Communication impairment** Not reported **Gestational age:** Not reported **Source of referral:** - GP:100%				
Author: Kamp-Becker I **Year:** 2009 **ID:** 139 **Country:** Germany **Study design:** Uncontrolled observational **Consecutive recruitment** Not reported. **Study dates** Not reported. **Evidence level:**	**Patient groups:** 140 children who have been referred for possible autism to Department of child and adolescent psychiatry, Philipps-University Marburg, Germany. **Exclusion criteria** Not reported. **Demographics:** **Number**:140 **Age: (Unit: Years)** **Whole group:** **Range:** 6-24 Table 6.1 Age of different patient group **Patient group** / **No** / **Age (mean)** / **Age (SD)** Asperger / 52 / 11.85 / 4.40 HFA / 44 / 12.83 / 5.08 Atypical autism / 8 / 15.10 / 3.67 Non- / 35 / 12.05 / 4.29	**Diagnosis criteria:** DSM-IV and ICD-10. **Diagnosis assessment:** ADOS-G, semi-structured autism specific parent interview using ADI-R, the Vineland adaptive behaviour scales, German version of the Wechsler intelligence scales, WISC-III. -Operator experience: Experience, trained examiners. **Diagnosis group:** Experienced clinicians. For each patient, DSM-IV/ICD-10 psychiatric diagnosis had been established by at least two expert clinicians. **Inter-rater reliability:**	Differential diagnosis - ASD ADHD Emotional disorder Receptive speech disorder Schizoid personality disorder Other personality disorder Delay of development Learning disability	 18/140 (12.9%) 6/140 (4.3%) 3/140 (2.1%) 3/140 (2.1%) 2/140 (1.4%) 2/140 (1.4%) 2/140 (1.4%)	**Funding:** German Max Planck association received by H. Remschmidt in 1999. **Limitations:** 1) The information of whether the patients have been recruited consecutively and what is the exclusion criteria are Not reported. **Also reported:** Of the whole sample (140), 104 children are ASD (74.3%), which include 52 (37.1%) AS patients, 44 (31.4%) high-functioning autism patients and 8 (5.7%) PDD-NOS patients.

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
Very low.	autism	For 17 videotaped ADOS-G assessments, the kappa values ranged from 0.42 to 1.0, with mean equals to 0.75. For the autism/non-autism distinction the agreement is 100%. **Adequately reported:** Yes.			
Author: Lord Year: 1995 ID: 108 Country: USA	**Patient groups:** 34 children referred to MDT developmental disorders clinic. All had delayed speech and language. Recruitment of children under age 3 sought through letters and presentations at meetings from usual sources of referral inc paediatricians, pediatric neurologists, family doctors,	**Diagnostic tool /method** ADI-R Threshold & Data set Le Couteur, 1994 Child had to receive scores that exceeded cut-offs in each of 3 areas: social interaction, communication and restricted, repetitive behaviours	Differential diagnosis - autism Rett syndrome Spastic diplegia + severe mental retardation	 3/30 (10.0%) 1/30 (3.3%)	**Funding:** Alberta Heritage fund for Medical Research and PHS. Limitations: Small study size, no exploration of possible confounders such as other features of the children or parent

Ethnicity: N (%)
Not reported.

Subgroups:
Intellectual Disability:
Table 6.2
IQ, VIQ and VIQ of the whole sample

	No.	Mean	SD
VIQ	140	107	20.54
PIQ	140	93	18.03
Full IQ	140	101	18.31

Language: Not reported
Gender: Male: 134(95.7%)

Visual impairment: Not reported
Hearing impairment: Not reported
Communication impairment
Not reported
Gestational age: Not reported
Source of referral: Not reported

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
Study design: Uncontrolled observational Consecutive recruitment? Yes Study dates: Not reported Evidence level: Very low	speech pathologists and audiologists, encouraged to refer if suspected autism or PDD, including those where referral may have been delayed due to young age. Exclusion criteria: 3 diagnosed with Rett Syndrome 1 spastic diplegia and profound mental retardation Demographics: Number: 30 Age at first assessment:25-35 months Age at second assessment: 38-52months Ethnicity: West Indian 2 Asian 2 Native Canadian 2 Caucasian 28 (4 excluded unclear which) Subgroups: Intellectual Disability: Not reported Language: Not reported Gender: Male 25 Visual impairment: 2 had visual impairment Hearing impairment: All had hearing assessments 1 had moderate hearing loss Gestational age: - Preterm (<38 weeks) 2 - Term (38 + weeks) 32 Source of referral: Not reported	Adequately described? Yes Operator no/experience One of 2 examiners who had previously established reliability (item by kappa >0.75, %agreement >90) with each other and several authors of the ADI At time 2 ADI administered by 1 of 2 research assistants, both not familiar with child			reporting ability Blinding: examination by psychiatrist blind to initial assessment diagnosis compared to time 2diagnosis by author who conducted time 1 and time 2 assessments Author making clinical judgment at T1 and T2 blind to ADI-R score Timing of tests: Time 1 25-35 months time 2 12-15 months later Verification (percentage undergoing assessment at both time points) 100% Also reported: Child psychiatrist and author agreed about T2 diagnosis in 29 of 30 cases. Child psych judgements are used as T2 outcomes

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
Author: Perry A Year: 2005 ID: [138] Country: Canada AIM: 'what is the degree and pattern of concordance between … DSM-IV and CARS' Study design: Uncontrolled observational Consecutive recruitment? No Study dates: Not reported Evidence level: Very low	Patient groups: Preschool children referred for initial developmental-diagnostic assessment or second opinion. Exclusion criteria: None reported Demographics: Number: 274 Age: Mean = 51.1 ± 11.0 months Range = 24 – 72 months Ethnicity: Not reported Subgroups: Language: 18% from French speaking families Gender: 75% male Intellectual disability: Not reported Visual impairment: Not reported Hearing impairment: Not reported Gestational age: Not reported Source of referral: Not reported	Diagnostic tool under investigation: 1 **CARS** Standardized observation instrument which can incorporate parent report. 15 items in 4 domains, socialization, communication, emotional response, sensory sensitivities. Threshold & Data set Scores >30 is taken as indicative of Autism Adequately described? Yes Operator no/experience Trained raters	Differential diagnosis - ASD Mental retardation Language delays only or 'slow learners' Other	 45/274 (16.4%) 42/274 (15.3%) 23/274 (8.4%)	Funding: Ontario Ministry of Children and Youth Services Limitations: Serious Blinding: No, same clinician used CARS and made DSM-IV diagnosis Timing of tests: CARS carried out before DSM-IV Verification (ref/index test x100) CARS: 100% Indirectness: Some – no data on patient relevant outcomes Test carried out on an appropriate Population: Yes Test carried out by an appropriate professional: Yes
Author: Rellini E Year: 2004 ID: [141] Country: Italy AIM: ''to verify agreement	Patient groups: Children referred for disturbances related to autistic spectrum disorders Exclusion criteria: None reported Demographics: Number: 65 Age:	Diagnostic tool under investigation: 1 **CARS** Standardized observation instrument which can incorporate parent report. 15 items in 4 domains, socialization, communication, emotional response, sensory sensitivities.	Differential diagnosis - ASD ADHD R/E language disorder	 1/65 (1.5%) 1/65 (1.5%)	Test carried out by an appropriate professional: Yes

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
between DSM-IV diagnostic criteria and total scores for CARS and ABC in the diagnosis of autism and to study the correlation between the two diagnostic scales' Study design: Uncontrolled observational Consecutive recruitment? Not reported Study dates: 1998 - 2000 Evidence level: Very low	Mean = 4.9 + 2.2 years Range = 1.5 – 11 years Ethnicity: Not reported Subgroups: Language: Not reported Gender: 89% male Intellectual disability: Not reported Visual impairment: Not reported Hearing impairment: Not reported Gestational age: Not reported Source of referral: Not reported	Threshold & Data set Scores >30 is taken as indicative of Autism Adequately described? Yes Operator no/experience Not reported			
Author: Snow A Year: 2008 ID: [74] Country: USA AIM: 1) To assess and	Patient groups: Consecutive referrals for possible PDDs at a specialty clinic in a large Midwestern hospital. N=82 Exclusion criteria: Nil stated. Demographics: Whole group Number: 82 Age: mean age 42.7 months (SD 14.1, range 18-70)	Surveillance tool under investigation: ●MCHAT For children between 18 and 48 months (n=56). Threshold & Data set - any 3 of all 23 items - ≥2 of 6 critical items Adequately described? Yes Operator no/experience Parent/carer questionnaire	Differential diagnosis - ASD Receptive/expressive language disorder Global developmental delay Developmental language delay apraxia Oppositional defiant disorder Communication disorder NOS Selective mutism Disruptive behaviour disorder NOS Reactive attachment disorder Cerebral palsy/metabolic disorder	 13/82 (15.85%) 3/82 (3.66%) 3/82 (3.66%) 2/82 (2.44%) 2/82 (2.44%) 1/82 (1.22%) 1/82 (1.22%) 1/82 (1.22%) 1/82 (1.22%) 1/82 (1.22%)	Funding: Not stated. Limitations: Groups were not matched for cognitive or adaptive functioning. Only assessing younger children who are referred for assessment may create sampling bias, these children may have more severe symptoms as

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
compare the sensitivity and specificity of M-CHAT and SCQ 2) assess the agreement of both tools and their reliability 3) determine which M-CHAT and SCQ items best differentiate PDDs from DDs 4) explore the impact of subject characteristics on scores of both instruments <u>Study design:</u> Uncontrolled observational Consecutive recruitment? Yes Study dates: Not reported <u>Evidence level:</u> Very low	Ethnicity: 87% Caucasian, 6% African American, 7% other (eg; Hispanic, Asian-American) <u>PDD[2] group</u> Number: 54 Age: mean age 39.2 months (SD 12.3) Ethnicity: 42 (82%) Caucasian <u>Non-PDD group</u> Number: 28 Age: mean age 49.5 months (SD 15.1) Ethnicity: 20 (87%) Caucasian Diagnoses: Receptive/expressive language disorder (n-13), global developmental delay (n=3), developmental language delay (n=3), apraxia (n=2)m oppositional defiant disorder (m=2), communication disorder NOS (n=1), selective mutism (n=1), disruptive behaviour disorder NOS (n=1), reactive attachment disorder (n=1), cerebral palsy/metabolic disorder (n=1) <u>Subgroups:</u> Language: Not reported Gender: Whole group – 63 males (77%). PDD group – 44 males (70%). Non PDD group – 19 males (68%). Intellectual disability: Not	●SCQ For children between 30 and 70 months (n=65) Threshold & Data set 40 items, verbal children score 0-39, non verbal children scored 0-33. Cut off >15 for PDDs. Adequately described? Yes Operator no/experience Parent/carer questionnaire Informants: PDD group – 41 mothers, 12 fathers and one guardian. μ age 33.3 years (SD 5.4). 34 (63%) graduated from college. Non-PDD group – 26 mothers, 1 father and 1 adoptive parent. μ age 31.5 years. 19 (68%) graduated from college. <u>Comparison/Diagnostic Criteria tool:</u> ●DSM-IV: VABS, GARS, WPPSI, LIPS-r, ADOS, PDD-BI. Threshold and Data set Consensus diagnosis by multidisciplinary team. Adequately described? Yes Operator no/experience Multidisciplinary team; developmental paediatrician,			presenting earlier. <u>Blinding:</u> Parents and clinicians were blind to the child's scores on the M-CHAT and SCQ. <u>Timing of tests:</u> Index test done prior to reference test. <u>Verification (ref/index test x100)</u> 100% <u>Also reported:</u> Comparison of groups (PDD vs non-PDD): non PDD group older than PDD. No difference between groups in regard to cognitive function, adaptive behaviour score and ethnicity. Demographic form collected information about child and informant. Childs age gender, ethnicity, previous medical, genetic or psychiatric diagnosis and psychotropic medicine use. Informant age, relationship to the child, educational level and age of first concern about the

[2] PDD = includes autism and PDD-NOS

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
	reported Visual impairment: Not reported Hearing impairment: Not reported Gestational age: Not reported Source of referral: Not reported	speech and language pathologist, psychologist. Results of diagnostic assessment were retrieved from patient charts following completion of assessment process.			child development. Overlapping Sample Children in 30-48 month age range correctly classified MCHAT critical items - 21/29 (72%) PDD - 5/10 (50%) non PDD - efficiency 0.67 (CI 0.51-0.81) MCHAT any 3 items - 24/29 (83%) PDD - 5/10 (50% non PDD - efficiency 0.74 (CI 0.59-0.86) SCQ - 21/29 (72%) PDD - 3/10 (30%) non PDD - efficiency 0.62 (CI 0.45-0.77) Internal consistency of MCHAT and SCQ. Relationship between total scores and subject characteristics.
Author: Sponheim E **Year:** 1995 **ID:** 143	**Patient groups:** All patients (25) at the national centre for child and adolescent psychiatry in Oslo who are suspected of having a developmental disorder and autism.	**Diagnosis criteria:** ICD-10 and DSM-III-R. **Diagnosis assessment:** ICD-10, DSM-III-R, ABC and CARS. -Operator experience:	Differential diagnosis - ASD Disintegrative disorder Specific developmental disorder of speech Emotional disorder Mental retardation	 1/25 (4%) 7/25 (28%) 4/25 (16%) 5/25 (20%)	**Funding:** National centre for child and adolescent psychiatry, Oslo, Norway **Limitations:** 1. Small sample size.

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
Country: Norway **Study design:** Uncontrolled observational **Consecutive recruitment** Yes **Study dates** Not reported **Evidence level:** Very low.	**Exclusion criteria** None. **Demographics:** **Number**:25 **Age: (Unit: Years)** **Range:** 1.6-17.3 **Ethnicity:** Not reported **Subgroups:** **Intellectual Disability:** - Yes: 15(60%) **Language:** Not reported **Gender: Male:** 21(84%) **Visual impairment:** Not reported **Hearing impairment:** Not reported **Communication impairment** Not reported **Gestational age:** Not reported **Source of referral:** Not reported	Experienced, trained before test was conducted. **Diagnosis group:** Two child psychiatrists. **Inter-rater reliability:** Not reported. Only said 'consensus between the team members' **Adequately reported:** Yes.			**Also reported:** Of the whole sample (25), 8 children are ASD (32%), which include 7 (28%) autism patients and 1(4%) AS patients.
Author: Scheirs J **Year:** 2009 **ID:** 146 **Country:** Netherlands **Study design:** Uncontrolled observational **Consecutive**	**Patient groups:** Children referred to the child and adolescent department of a large outpatient institution for mental health in the south of the Nether lands during 2003-2007, for behavioural problems or psycho-social maladjustment displayed in school or at home. **Exclusion criteria** Not reported. **Demographics:** **Number**:115 **Age: (Unit: Years)**	**Diagnosis criteria:** Expert consensus based on DSM-IV-TR diagnostic criteria. **Diagnosis assessment:** Developmental histories of the children as revealed from clinical interviews with the parents; observation as well as extended neuropsychological testing of the children themselves. -Operator experience: Experienced.	Differential diagnosis - ASD ADHD	40/115 (34.8%)	**Funding:** Institution for Mental Health in Eindhoven (GGzE). **Limitations:** 1. Retrospective study 2. The diagnosis assessment used in the study was not adequately reported. **Also reported:** 1. Of the whole sample (115), 55 children are PDD-NOS (47.8%),

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
recruitment Not reported. **Study dates** Not reported. **Evidence level:** Very low	**Range:** 6-16 **Mean:** 9.7 ± 2.8 **Ethnicity:** Not reported **Subgroups:** Intellectual Disability: *PDD-NOS group:* Range of FIQ: 66-136 *ADHD group:* Range of FIQ: 76-123 *Combined diagnosis of PDD-NOS and ADHD:* Range of FIQ: 76-116 Language: Not reported Gender: Male: 91 (79.1%) Visual impairment: Not reported Hearing impairment: Not reported Communication impairment Not reported Gestational age: Not reported Source of referral: practitioners or youth care organizations.	**Diagnosis group:** Clinical psychologists or youth psychiatrists. **Inter-rater reliability:** Not reported. **Adequately reported:** No.			20 children had PDD-NOS plus ADHD (17.4%). 2. Children with mental retardation (FIQ<70) were generally not referred to this institution. However, intelligence was not used in any way as a criterion for including cases in this study.
Author: Stone W **Year:** 2008 **ID:** 147 **Country:** U.S.A **Study design:** Uncontrolled observational	**Patient groups:** Children identified through STAT database who: -were at increased risk for autism - received the STAT between 12 and 23 months (inclusive) of age - received a follow-up assessment after 24 months. **Exclusion criteria** (For STAT database) - Children with severe sensory or motor impairments - Children have been identified	**Diagnosis criteria:** Not reported. **Diagnosis assessment:** Not reported. -Operator experience: Not reported. **Diagnosis group:** Experienced, licensed psychologist who were experienced in the diagnosis of young children with autism. **Inter-rater reliability:**	Differential diagnosis - ASD Developmental delay Language impairment Broad autism phenotype [1] No concerns Note: [1] Broad autism phenotype: Children who did not qualify for any of the diagnoses of ASD, DD or LI, but for whom there were clinical concerns related to social-communicative functioning.	 6/71 (9%) 1/71 (1%) 8/71 (11%) 37/71 (52%)	**Funding:** Grant number R01 HD043292 and a NAAR Mentor –Based postdoctoral fellowship. Partial support was also provided by grant numbers P30 HD15052, T32 HD07226, I32 MH18921, and the Vanderbilt Kennedy Centre Marino Autism Research Institute. **Limitations:** 1) Small sample size, with only 19 ASD patients.

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
Consecutive recruitment Yes. **Study dates** Not reported. **Evidence level:** Very low.	genetic or metabolic disorders - No parental permission to use data. **Demographics:** **Number**:71 **Age: (Unit: Months)** **Mean:** 16.4 ± 3.6 **Range:** 12-23 **Ethnicity:** Caucasian: 58(82%) -Others: 13 (18%) **Diagnosis criteria of ASD:** DSM-IV-TR **Subgroups:** Intellectual Disability: Mean cognitive score (MSEL) at initial evaluation was 95.8 (SD 15.4) Language: Not reported Gender: Male: 44(62%) Visual impairment: Not reported Hearing impairment: Not reported Communication impairment Not reported Gestational age: Not reported Source of referral: -A longitudinal research project enrolling younger siblings of children with ASD: 59 (83.1%) -Children receiving evaluations for developmental concerns related to autism: 12 (16.9%)	Not reported. **Adequately reported:** Yes.			2) The sample was recruited via university-based medical centre, rather than community-based settings. **Also reported:** Of the whole sample (71), 19 children are ASD (27%), which include 12 (17%) autism patients and 7 (10%) PDD-NOS patients.
Author: Webb E **Year:**	**Patient groups:** Children who have been identified as positive in the two-stage screening test. The initial	**Diagnosis criteria:** ICD-10 diagnostic criteria. **Diagnosis assessment:**	Differential diagnosis - ASD Abuse/neglect ADHD Learning difficulties	 13/50 (26%) 7/50 (14%) 3/50 (6%)	**Funding:** Department of epidemiology, statistics and public health, UWCM;

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
2003 **ID:** 148 **Country:** U.K **Study design:** Uncontrolled observational **Consecutive recruitment** No. **Study dates** Not reported. **Evidence level:** Very low.	screening test was using a questionnaire based on ICD-10; and the second round screening test was using ASSQ. Children who have failed >=2 domains of ASSQ will be recruited for full assessment. The whole screened population of 11,692 children were born between 1 Sep 1986 and 31 Aug, 1990, recruited from 69 primary schools in Cardiff. **Exclusion criteria** Children attending private or special schools. Children who are either unable or unwilling to participate in the project. **Demographics:** **Number**:50 **Age: (Unit: Years)** **Range:** 7-11 **Ethnicity:** Not reported **Subgroups:** Intellectual Disability: Not reported Language: Not reported Gender: Male: 44 (88%) Visual impairment: Not reported Hearing impairment: Not reported Communication impairment Not reported	For those children whose ASSQ score was greater than 21, their health notes from hospital and community, and their special educational needs status were reviewed. For some children whose information was insufficient, a joint assessment was undertaken by a developmental paediatrician and a psychiatrist from the learning disability team. This assessment included a full developmental and family history and an unstructured diagnostic interview, a process informed by the paper by Filipek et al. (1999) on the screening and diagnosis of autistic spectrum disorders. If the above assessment was still inconclusive, then a further in-depth assessment will be taken, which included an evaluation of understanding social situations and tests of facial expression. -Operator experience: Experienced. **Diagnosis group:** Child psychiatrists. **Inter-rater reliability:** Not reported.	Tourette syndrome Other	2/50 (4%) 12/50 (24%)	Cardiff and Vale NHS Trust. **Limitations:** High drop-out rate (10 children, 16.67%) of children who have been identified as ASD positive using the two-stage screening test. **Also reported:** Of the whole sample (50), 13 children are ASD (26.0%), which including 8 (16%) AS/HFA patients, 4 (8%) PDD-NOS patients and 1(2%) ASD phenol-copy.

Study Details	Patients	Diagnostic information	Differential diagnosis	Result: N(%)	Comments
	Gestational age: Not reported Source of referral: Not reported	**Adequately reported:** Yes.			