

Supplemental Online Content

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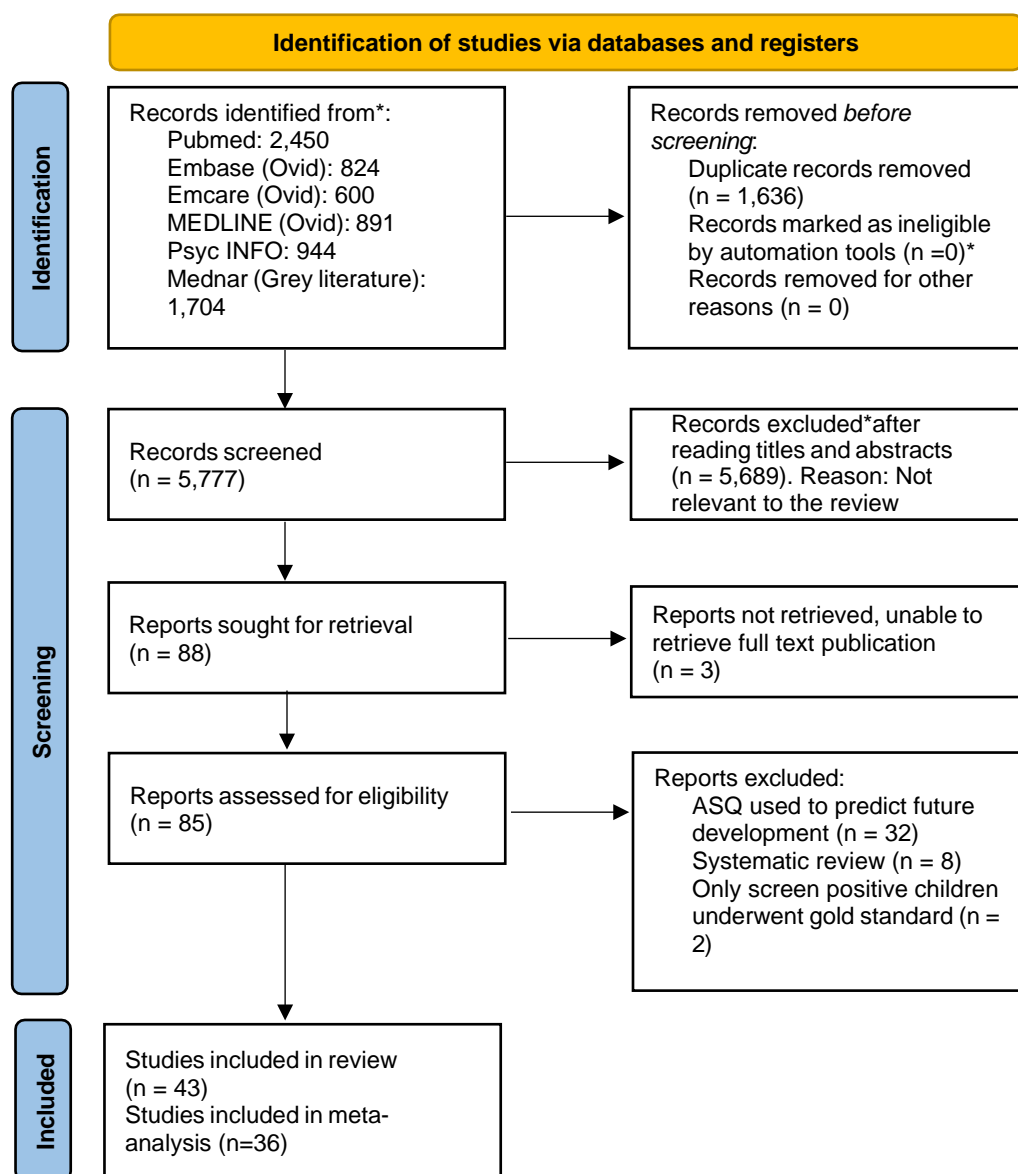
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This supplemental material has been provided by the authors to give readers additional information about their work.

eFigure1. PRISMA flow diagram of study selection



*No automation tools were used

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: <http://www.prisma-statement.org/>

eTable1. Characteristics of the included studies that used “>2SD below the mean” cut-off for ASQ

Study ID	Sample size	Study Design	Funding	Study Population	Age at Assessment (months)	Index Test	Reference Standard Test
Agarwal_2016³⁴ Singapore	141	Prospective	National Medical Research Council, Singapore	Preterm/VLBW survivors with birthweight ≤1250g without major congenital malformations	24 months	ASQ3 Delay: 2SD Domain: Any	Bayley-III Delay: 2SD; Bayley-III Subscale<70 Domain: Any
Bian_2012A³⁵ China	269	Prospective	Grant for Renewing the Public Health System in Shanghai	Children ages 3 to 5 years old, using a stratified sampling method based on the most recent Shanghai census reports	6 to 30 months	ASQ3, Chinese Delay: 2SD Domain: Any	BSID (2 nd Edition) Delay: 2SD; BSID Subscale<75 Domain: Any
Bian_2012B³⁵ China	253	Prospective	Grant for Renewing the Public Health System in Shanghai	Children ages 3 months to 5 years old, using a stratified sampling method based on the most recent Shanghai census reports	8 to 60 months	ASQ3, Chinese Delay: 2SD Domain: Any	DDST (2 nd Edition) Delay: 2SD; DDST Subscale<70 Domain: Any

Carmichael_2014A³⁶ USA	27	Retrospective	Information not available	Children aged 18 to 59 months (mean=41.52 months) with and without known disabilities	Mean of 42 months	ASQ3 Delay: 2SD Domain: Gross motor	PDMS (2nd Edition) Delay: 1SD Domain: Gross motor
Carmichael_2014B³⁶ USA	27	Retrospective	Information not available	Children aged 18 to 59 months (mean=42 months) with and without known disabilities	Mean of 42 months	ASQ3 Delay: 2SD Domain: Gross motor	PDMS (2nd Edition) Delay: 2SD Domain: Gross motor
Carmichael_2014C³⁶ USA	27	Retrospective	Information not available	Children aged 18 to 59 months (mean=42 months) with and without known disabilities	Mean of 42 months	ASQ3 Delay: 2SD Domain: Fine motor	PDMS (2nd Edition) Delay: 1SD Domain: Fine motor
Colbert_2021³⁷ # Gautemala	847	Prospective	National Institute of Allergy and Infectious Diseases (NIAID).	Children with postnatally acquired Zika virus 0 to 5 years of age	0-5 years	ASQ3, Spanish Delay: Standard Z-scores Domain: Any	Mullen Scales of Early Learning Delay: Standard T-scores Domain: any
Fauls_2020A³⁸ Australia	84	Prospective	Funding Information not available. Authors declared that there was no conflict of interest.	Children aged 0 to 5 years attending specialist clinic	27±18 months	ASQ3 Delay: 2SD Domain: Gross motor	NSMDA Delay: 1SD; Total score>12 Domain: Gross motor

Flamant_2011⁴ France	703	Prospective	Pays de Loire network of care from Assurance Maladie	Very preterm infants (<35 weeks gestational age)	24 months	ASQ2 Delay: 2SD Domain: Any	Revised Brunet-Lezine test Delay: 1SD Domain: Any
Fuengfoo_2020³⁹ # Thailand	100	Prospective	Funding Information not available. Authors declared that there was no conflict of interest.	Children who visited the Well Child Clinic and Child Development Center	12 to 36 months	ASQ3 Delay: 2SD Domain: Any	Bayley-III Delay: 2SD Domain: Any
Ga_2011A⁴⁰ Korea	111	Retrospective	Information not available	Children aged 4 to 60-months who visited the rehabilitation clinic	17.5±12.0 months	ASQ2, Korean Delay: 2SD Domain: Any	DDST (2 nd Edition) Delay: 2SD Domain: Any
Ga_2011B⁴⁰ # Korea	141	Retrospective	Information not available	Children aged 4 to 60-months who visited the rehabilitation clinic	17.5±12.0 months	ASQ2, Korean Delay: 2SD Domain: Any	Capute Scale Delay: 2SD; DQ below 75 Domain: Cognitive and language
Ga_2011C⁴⁰ # Korea	141	Retrospective	Information not available	4-months to 60-months-olds who visited the rehabilitation clinic	17.5±12.0 months	ASQ2, Korean Delay: 2SD Domain: Any	Capute Scale Delay: 1SD; DQ below 85 Domain: Cognitive and language

Ga_2011D⁴⁰ # Korea	69	Retrospective	Information not available	4-months to 60-months-olds who visited the rehabilitation clinic	17.5±12.0 months	ASQ2, Korean Delay: 2SD Domain: Any	AIMS Delay: 1SD; 10 th percentile Domain: Motor
Gollenberg_2009A⁴¹ USA	53	Prospective	Great Lakes Protection Fund, the Agency for Toxic substances and Disease registry, the Gerber Foundation, intramural funds from the Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health.	Infants born to mothers who participated in the New York State Angler Cohort Prospective Pregnancy Study	24 months	ASQ2 Delay: 2SD Domain: Any	BSID (2 nd Edition) Delay: 1SD; Subscale<85 Domain: Any
Gollenberg_2009B⁴¹ USA	53	Prospective	Great Lakes Protection Fund, the Agency for Toxic substances and Disease registry, the Gerber Foundation, intramural funds from the Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health.	Infants born to mothers who participated in the New York State Angler Cohort Prospective Pregnancy Study	24 months	ASQ2 Delay: 2SD Domain: Any	BSID (2 nd Edition) Delay: 2SD; BSID Subscale<70 Domain: Any

Gutierrez-Cruz_2019⁴² # Spain	88	Prospective	Information not available	Late preterm and Term	24 months	ASQ3 Delay: Unsure Domain: Individual domains	Brunet-Lezine Revised test Delay: DQ score Domain: Corresponding individual domains
Halbwachs_2013⁴³ # Germany	?452	Prospective	No support or Funding	Preterm infants (≤ 35 weeks of gestation) recruited.	60months	ASQ, (ASQ version unclear) Delay: Overall scores of 270 and 285 Domain: Any	WPPSI (3 rd Edition) Delay; 1SD; IQ<85 Domain: Any
Jang_2019⁴⁴ Korea	145	Retrospective	No funding	Infants recruited from outpatient developmental clinic.	4 to 71 months (Mean: 39.1 \pm 16.4 months)	ASQ2, Korean Delay: 2SD Domain: Any	BSID (Korean, 2 nd Edition) and WPPSI (Korean, 3 rd edition) Delay: 2SD Domain: Any
Juneja_2011A⁴⁵ India	50	Prospective	No funding	Recruited High Risk group (n=20) : Birthweight <2 kg, gestation age <37 weeks, CNS infection, genetic syndromes, CP, develop delay; and low risk group (n = 30) : no risk factors	18 months	ASQ2 Delay: 2SD Domain: Any	DASII Delay: 2SD; DQ<70 Domain: Any

Juneja_2011B⁴⁵ India	50	Prospective	No funding	Recruited High Risk group (n=20) : Birthweight <2 kg, gestation age <37 weeks, CNS infection, genetic syndromes, CP, develop delay; and low risk group (n = 30) : no risk factors	24 months	ASQ2 Delay: 2SD Domain: Any	DASII Delay: 2SD; DQ<70 Domain: Any
Kapci_2010⁴⁶ Turkey	833	Prospective	Scientific and Technical Research Council of Turkey	Children from preschool, special education school, hospitals, and community centres (both risk and normal population)	3 to 72 months	ASQ2, Turkish Delay: 2SD Domain: Any	DDST (2 nd Edition), GECDAS, or ADISI Delay: 1SD Domain: Any
Kerstjens_2015A⁴⁷ Netherlands	224	Prospective	The Netherlands Organization for Health Research and Development Cost-Effectiveness Program	Infants born <32 weeks without major congenital anomalies	24 months	ASQ3 Delay: 2SD Domain: Any	Bayley-III or any of blindness, deafness, CP Delay: 1SD; Bayley-III Subscale<85 Domain: Any
Kerstjens_2015B⁴⁷ Netherlands	224	Prospective	The Netherlands Organization for Health Research and Development Cost-Effectiveness Program	Infants born <32 weeks without major congenital anomalies	24 months	ASQ3 Delay: 2SD Domain: Any	Bayley-III or any of blindness, deafness, CP Delay: 2SD; Bayley-III Subscale<70 Domain: Any

Kim_2016⁴⁸ Korea	206	Prospective	Funding Information not available. Authors declared that there was no conflict of interest.	Children with Language development delay as chief complaint	Mean: 30 months	ASQ2 Delay: 2SD Domain: Communication	SELSI and PRELS Delay: 2SD Domain: Speech and Language
King-Dowling_2015A⁵⁰ Canada	159	Prospective	Ontario's Ministry of Child and Youth Services	Children with no known physical impairments with IQ \geq 70	43 to 66 months	ASQ3 Delay: 2SD Domain: Fine motor, gross motor	MABC (2 nd Edition) Delay: 1SD Domain: Fine motor, gross motor
Klamer_2005⁵¹ # Denmark	30	Prospective	Dagmar Marshalls fund	Native Danish term and preterm infants.	39 months	ASQ 2 Delay: Combined overall score Domain: Any	WPPSI-R Delay: intelligence scores Domain: Cognitive, speech and language
Kwun_2015A⁵² # Korea	90	Retrospective	Funding Information not available. Authors declared that there was no conflict of interest.	Infants < 37 GA	18 to 24 months	ASQ1 Delay: 2SD Domain: Any	BSID (2 nd Edition) Delay: 1SD; MDI<85 Domain: Cognitive, speech and language
Kwun_2015B⁵² # Korea	90	Retrospective	Funding Information not available. Authors declared that there was no conflict of interest.	Infants < 37 GA	18 to 24 months	ASQ1 Delay: 2SD Domain: Any	BSID (2 nd Edition) Delay: 1SD; PDI<85 Domain: Fine motor, gross motor domain

Lepine_2021A⁵³ Canada	64	Prospective	Scholarship awarded to Mr Lépine by the Programme d'Excellence en Médecine pour l'Initiation En Recherche of the Faculty of medicine of the Université de Montréal and by the Heart and Stroke Foundation of Canada	Term infants who underwent surgical repair within first year of life.	12 months	ASQ3 Delay: 2SD Domain: Any	Bayley-III Delay: 1SD Domain: Any
Lepine_2021B⁵³ Canada	82	Prospective	Scholarship awarded to Mr Lépine by the Programme d'Excellence en Médecine pour l'Initiation En Recherche of the Faculty of medicine of the Université de Montréal and by the Heart and Stroke Foundation of Canada	Term infants who underwent surgical repair within first year of life.	24 months	ASQ3 Delay: 2SD Domain: Any	Bayley-III Delay: 1SD Domain: Any
Limbos_2011⁵⁴ Canada	331	Prospective	Funding Information not available. Authors declared that there was no conflict of interest.	Children presented to their primary care provider for routine care	32.3 ± 16.3 months	ASQ2 Delay: 2SD Domain: Any	Bayley-III and/ or WPPSI (3 rd Edition) and/ or VABS (2 nd Edition) and/or PLS (4 th Edition) Delay: 1SD; <10 th percentile Domain: Any

Lindsay_2008A⁵⁵ Australia	32	Prospective	National Health and Medical Research Council of Australia	Infants ≥ 34 weeks GA at birth with perinatal asphyxia	12 months	ASQ1 Delay: 2SD Domain: Any	BSID (2 nd Edition) Delay: 1SD (PDI/MDI) Domain: Any
Lindsay_2008B⁵⁵ Australia	32	Prospective	National Health and Medical Research Council of Australia	Infants ≥ 34 weeks GA at birth with perinatal asphyxia	12 months	ASQ1 Delay: 2SD Domain: Any	BSID (2 nd Edition) Delay: 2SD (PDI/MDI) Domain: Any
Mackin_2017⁵⁶ Canada	67	Retrospective	Undergraduate Research Opportunity Program Award (University of Ottawa), 2012 Summer Studentship Award (Children's Hospital of Eastern Ontario Research Institute)	Infants born <29 weeks	18 months	ASQ3 Delay: 2SD Domain: Any	Bayley-III Delay: 1SD Domain: Any
Mezawa_2019²⁰ Japan	308	Prospective	Ministry of the Environment, Japan.	Participants from Japan Environment and Children's Study pilot study preterm/ term at birth, low risk as well as high risk groups and patients who attended the National Center for Child Health and Development and the Nico Children Clinic in Tokyo, Japan	6 to 60months	ASQ3, Japanese Delay: 2SD Domain: Any	KSPD or DDST (2 nd Edition) Delay: 2SD Domain: Any

Noeder_2017A⁵⁷ USA	239	Prospective	Institutional Development Award (IDeA) from the National Institute of General Medical Sciences of the National Institutes of Health	Children with congenital heart disease underwent cardiac surgery during infancy	6 -36 months	ASQ3 Delay: 2SD Domain: Problem solving	Bayley-III Delay: 1SD Domain: Cognitive
Noeder_2017B⁵⁷ USA	228	Prospective	Institutional Development Award (IDeA) from the National Institute of General Medical Sciences of the National Institutes of Health	children with congenital heart disease underwent cardiac surgery during infancy	6 -36 months	ASQ3 Delay: 2SD Domain: Communication	Bayley-III Delay: 1SD Domain: Speech and language
Noeder_2017C⁵⁷ USA	242	Prospective	Institutional Development Award (IDeA) from the National Institute of General Medical Sciences of the National Institutes of Health	children with congenital heart disease underwent cardiac surgery during infancy	6 -36 months	ASQ3 Delay: 2SD Domain: Fine motor	Bayley-III Delay: 1SD Domain: Fine motor
Noeder_2017D⁵⁷ USA	244	Prospective	Institutional Development Award (IDeA) from the National Institute of General Medical Sciences of the National Institutes of Health	children with congenital heart disease underwent cardiac surgery during infancy	6 -36 months	ASQ3 Delay: 2SD Domain: Gross motor	Bayley-III Delay: 1SD Domain: Gross motor
O'Connor_2020A⁵⁸ Australia	65	Prospective	No Funding	Infants born to women reporting methamphetamine use during pregnancy Individual patient data provided by authors	12 months	ASQ3 Delay: 2SD Domain: Any	GMDS Delay: 1SD; GQ<85 Domain: Any

O'Connor_2020B⁵⁸ Australia	65	Prospective	No Funding	Infants born to women reporting methamphetamine use during pregnancy Individual patient data provided by authors	12 months	ASQ3 Delay: 2SD Domain: Any	GMDS Delay: 2SD; GQ<70 Domain: Any
Otalvaro_2018⁵⁹ Argentina	630	Prospective	No funding	Children who attended the routine health care check-up	1-66 months (median age appr 20 months)	ASQ3 Delay: 2SD Domain: Any	PRUNAPE Delay: 1SD; not documented Domain: Any
Schonhaut_2013⁶⁰ Chile	196	Prospective	Clinica Alemana research grants program and National Fund for Health Research	Preterm and Term infants from routine well child clinic	18months to 30 months	ASQ3 Delay: 2SD Domain: Any	Bayley-III Delay: 1SD Domain: Any
Sheldrick_2020⁶¹ USA	482	Prospective	National Institute of Child Health and Development (NICHD)	consecutive parents in waiting rooms at 10 pediatric primary care offices	9 to 42 months	ASQ3 Delay: 2SD Domain: Any	Bayley-III Delay: 1SD Domain: Any
Simard_2012A⁶² Canada	121	Prospective	Canadian Institutes of Health Research	29 to 36 ⁺⁶ weeks of gestation at birth, BW <2.5Kg	12 months	ASQ2 Delay: 2SD Domain: Problem solving, communication personal-social	BSID (2 nd Edition) Delay: 1SD; MDI<85 Domain: Cognitive, speech and language, personal-social

Simard_2012B⁶² Canada	119	Prospective	Canadian Institutes of Health Research	29 to 36 ⁺⁶ weeks of gestation at birth, BW <2.5Kg	12 months	ASQ2 Delay: 2SD Domain: Gross motor, fine motor	BSID (2 nd Edition) Delay: 1SD; PDI<85 Domain: Gross motor, fine motor
Simard_2012C⁶² Canada	109	Prospective	Canadian Institutes of Health Research	29 to 36 ⁺⁶ weeks of gestation at birth, BW <2.5Kg	24 months	ASQ2 Delay: 2SD Domain: Problem solving, communication, personal social	BSID (2 nd Edition) Delay: 1SD; MDI<85 Domain: Cognitive, speech and language, personal-social
Simard_2012D⁶² Canada	107	Prospective	Canadian Institutes of Health Research	29 to 36 ⁺⁶ weeks of gestation at birth, BW <2.5Kg	24 months	ASQ2 Delay: 2SD Domain: Gross motor, fine motor	BSID (2 nd Edition) Delay: 1SD; PDI<85 Domain: Gross motor, fine motor
Simpson_2021¹⁹ Australia	124	Prospective	Northern Territory Department of Education, NHMRC Project Grant (107833) and the Channel 7 Children's Research Foundation, Australian Government Research Training Program Scholarship, a Jack Keating Fund Scholarship, and a Science of Learning Research Centre PhD grant and ARC Science	Central Australian Aboriginal children between 2 to 48 months of age.	2 to 48 months	ASQ3-TRAK Delay: 2SD Domain: Any	Bayley-III or BDI (2 nd Edition) Delay: 2SD Domain: Any

			of Learning Research Centre				
Skellern_2001A⁶³ Australia	56	Prospective	Information not available	Premature < 31 weeks, CA ± 4 weeks of study age groups	12 months	ASQ1 Delay: 2SD Domain: Any	GMDS (Revised edition) Delay: 1SD Domain: Any
Skellern_2001B⁶³ Australia	24	Prospective	Information not available	Premature < 31 weeks, CA ± 4 weeks of study age groups	18 months	ASQ 1 Delay: 2SD Domain: Any	BSID (2 nd Edition) Delay: 1SD Domain: Cognitive, speech and language, personal-social
Skellern_2001C⁶³ Australia	43	Prospective	Information not available	Premature < 31 weeks, CA ± 4 weeks of study age groups	24 months	ASQ 1 Delay: 2SD Domain: Any	GMDS (Revised edition) Delay: 1SD Domain: Any
Skellern_2001D⁶³ Australia	13	Prospective	Information not available	Premature < 31 weeks, CA ± 4 weeks of study age groups	48 months	ASQ 1 Delay: 2SD Domain: Any	McCarthy Scale of Infant Abilities - GCI Delay: 1SD Domain: Any

Smith_2012⁶⁴ Australia	332	Prospective	March of Dimes Birth Defects Foundation	Infants who had undergone cardiac/non-cardiac surgery and healthy controls	12 months	ASQ2 Delay: 2SD Domain: Fine motor	Bayley-III Delay: 1SD Domain: Fine motor
Squires_1997³ USA	1,511	Prospective	National Institute on Disability and Rehabilitation Research and the March of Dimes Research Foundation	The sample was composed of children with medical risk factors, environmental risk factors, and a normative sample.	4-36 months	ASQ2 Delay: 2SD Domain: Any	GADNE (revised edition), BSID I, SBIT, MSCA Delay: 1.5SD Domain: Any
Srinithiwat_2014A⁷¹ Thailand	30	Prospective	Funding Information not available. Authors declared that there was no conflict of interest.	Children who attended the well-child clinic, developmental and behavioural clinic, general paediatric outpatient clinic and inpatient paediatric wards	18 months	ASQ3 Delay: 2SD Domain: Any	DDST (2 nd Edition) Delay: 1SD; 2 caution item or 1 delay Domain: Any
Srinithiwat_2014B⁷¹ Thailand	30	Prospective	Funding Information not available. Authors declared that there was no conflict of interest.	Children who attended the well child clinic, developmental and behavioural clinic, and general paediatric outpatient clinic and inpatient paediatric wards	24 months	ASQ3 Delay: 2SD Domain: Any	DDST (2 nd Edition) Delay: 1SD; 2 caution item or 1 delay Domain: Any
Srinithiwat_2014C⁷¹ Thailand	30	Prospective	Funding Information not available. Authors declared that there was no conflict of interest.	Children who attended the well child clinic, developmental and behavioural clinic, and general paediatric outpatient clinic and inpatient paediatric wards	30 months	ASQ3 Delay: 2SD Domain: Any	DDST (2 nd Edition) Delay: 1SD; 2 caution item or 1 delay Domain: Any

Steenis_2015A⁶⁵ Netherlands	565	Prospective	ZonMW	Healthy and at-risk children 18 to 42 months	18-42 months	ASQ3 Delay: 2SD Domain: Any	Bayley-III Delay: 1SD Domain: Any
Steenis_2015B⁶⁵ Netherlands	565	Prospective	ZonMW	Healthy and at-risk children 18 to 42 months	18-42 months	ASQ3 Delay: 2SD Domain: Any	Bayley-III Delay: 2SD Domain: Any
Vanvuchelen_2017A⁶⁶ Belgium	43	Prospective	Marguerite-Marie Delacroix grant (Tienen, Belgium)	High-functioning children with autism spectrum disorder	22-54 months (mean 40 months)	ASQ2 Delay: 2SD Domain: Gross motor	PDMS (2 nd Edition) Delay: 1SD; Score<7 Domain: Gross motor
Vanvuchelen_2017B⁶⁶ Belgium	43	Prospective	Marguerite-Marie Delacroix grant (Tienen, Belgium)	High-functioning children with autism spectrum disorder	22-54 months (mean 40 months)	ASQ2 Delay: 2SD Domain: Gross motor	PDMS (2 nd Edition) Delay: 2SD; SS<4 Domain: Gross motor
Vanvuchelen_2017C⁶⁶ Belgium	43	Prospective	Marguerite-Marie Delacroix grant (Tienen, Belgium)	High-functioning children with autism spectrum disorder	22-54 months (mean 40 months)	ASQ2 Delay: 2SD Domain: Fine motor	PDMS (2 nd Edition) Delay: 1SD; Score<7 Domain: Fine motor
Vanvuchelen_2017D⁶⁶ Belgium	43	Prospective	Marguerite-Marie Delacroix grant (Tienen, Belgium)	High-functioning children with autism spectrum disorder	22-54 months (mean 40 months)	ASQ2 Delay: 2SD Domain: Fine motor	PDMS (2 nd Edition) Delay: 2SD; SS<5 Domain: Fine motor

Veldhuizen_2015A⁶⁷ Canada	587	Prospective	Ministry of Children and Youth Services of Ontario	Children younger than 2 years and born 4 weeks or more premature	1-36 months	ASQ3 Delay: 2SD Domain: Any	Bayley-III Delay: 2SD Domain: Any
Veldhuizen_2015B⁶⁷ Canada	587	Prospective	Ministry of Children and Youth Services of Ontario	Younger than 2 years and born 4 weeks or more premature	1-36 months	ASQ 3 Delay: 2SD Domain: Problem solving	Bayley-III Delay: 2SD Domain: Cognitive
Veldhuizen_2015C⁶⁷ Canada	587	Prospective	Ministry of Children and Youth Services of Ontario	Younger than 2 years and born 4 weeks or more premature	1-36 months	ASQ 3 Delay: 2SD Domain: Fine motor	Bayley-III Delay: 2SD Domain: Fine motor
Veldhuizen_2015D⁶⁷ Canada	587	Prospective	Ministry of Children and Youth Services of Ontario	Younger than 2 years and born 4 weeks or more premature	1-36 months	ASQ 3 Delay: 2SD Domain: Gross motor	Bayley-III Delay: 2SD Domain: Gross motor
Veldhuizen_2015E⁶⁷ Canada	587	Prospective	Ministry of Children and Youth Services of Ontario	Younger than 2 years and born 4 weeks or more premature	1-36 months	ASQ 3 Delay: 2SD Domain: Communication	Bayley-III Delay: 2SD Domain: Speech and language
Woodward_2011A⁶⁸ USA	219	Prospective	National Institute of Child Health and Human Development and grants from the General Clinical Research Centers Programs at the University of New Mexico, Tufts-New	BW between 500-999 grams and the need for mechanical ventilation at 12-48 hours of age	18 to 22 months	ASQ2 Delay: 2SD Domain: Any	BSID (2 nd Edition) Delay: 1SD Domain: Any

			England Medical Center, and the University of Colorado				
Woodward_2011B⁶⁸ USA	219	Prospective	National Institute of Child Health and Human Development and grants from the General Clinical Research Centers Programs at the University of New Mexico, Tufts-New England Medical Center, and the University of Colorado	BW between 500-999 grams and the need for mechanical ventilation at 12-48 hours of age	18 to 22 months	ASQ2 Delay: 2SD Domain: Any	BSID (2 nd Edition) Delay: 2SD Domain: Any
Yu_2007⁶⁹ United Kingdom	828	Prospective	Information not available	Children who born to mothers treated with MgSO4 for the treatment of preeclampsia	12 – 60 months	ASQ2 Delay: 2SD Domain: Any	BSID (2 nd Edition) or DDST (2 nd Edition) or GMDS or Neurosensory disability Delay: 2SD; or severe neurosensory disability Domain: Any
Yue_2019A⁷⁰ China	630	Prospective	111 project Yaojiang Shi, the National Natural Science Foundation of China, the International Initiative for Impact Evaluation, UBS Optimus Foundation and the Fundamental	Children from Qinba (rural) region of China	13-18 months	ASQ3 Delay: 2SD Domain: Problem-solving	Bayley-III Delay: 2SD Domain: Cognitive

			Research Funds for the Central Universities				
Yue_2019B⁷⁰ China	630	Prospective	111 project Yaojiang Shi, the National Natural Science Foundation of China, the International Initiative for Impact Evaluation, UBS Optimus Foundation and the Fundamental Research Funds for the Central Universities	Children from Qinba (rural) region of China	13-18 months	ASQ3 Delay: 2SD Domain: Communication	Bayley-III Delay: 2SD Domain: Speech and language
Yue_2019C⁷⁰ China	630	Prospective	111 project Yaojiang Shi), the National Natural Science Foundation of China, the International Initiative for Impact Evaluation, UBS Optimus Foundation and the Fundamental Research Funds for the Central Universities	Children from Qinba (rural) region of China	13-18 months	ASQ3 Delay: 2SD Domain: Fine motor, gross motor	Bayley-III Delay: 2SD Domain: Fine motor, gross motor
Yue_2019D⁷⁰ China	493	Prospective	111 project Yaojiang Shi, the National Natural Science Foundation of China, the International Initiative for Impact Evaluation, UBS Optimus Foundation and the Fundamental Research Funds for the Central Universities	Children from Qinba (rural) region of China	19-24 months	ASQ3 Delay: 2SD Domain: Problem solving	Bayley-III Delay: 2SD Domain: Cognitive

Yue_2019E⁷⁰ China	493	Prospective	111 project Yaojiang Shi, the National Natural Science Foundation of China, the International Initiative for Impact Evaluation, UBS Optimus Foundation and the Fundamental Research Funds for the Central Universities	Children from Qinba (rural) region of China	19-24 months	ASQ3 Delay: 2SD Domain: Communication	Bayley-III Delay: 2SD Domain: Speech and language
Yue_2019F⁷⁰ China	493	Prospective	111 project Yaojiang Shi, the National Natural Science Foundation of China, the International Initiative for Impact Evaluation, UBS Optimus Foundation and the Fundamental Research Funds for the Central Universities	Children from Qinba (rural) region of China	19-24 months	ASQ3 Delay: 2SD Domain: Fine motor, gross motor	Bayley-III Delay: 2SD Domain: Fine motor, gross motor

Included in the systematic review, but not meta-analysis

ADSI – Ankara Development Screening Inventory; AIMS – Alberta Infant Motor Scale; ASQ – Ages and Stages Questionnaire; ASQ-TRAK – ASQ version that is culturally and linguistically adapted ASQ-3 for Australian Aboriginal children; BDI – Batelle Development Index; BSID – Bayley Scale of Infant Development; DASII – Developmental Assessment Scale for Indian Infants; DDST – Denver Developmental Screening Test; GADNE – Gesell and Armatruda Developmental and Neurologic Examination; GCI – General Cognitive Intelligence; GECDAS – Gazi Early Childhood Development Assessment Scale; GMDS – Griffiths Mental Development Scales; GQ – General Quotient (Griffiths Mental Development Scales); KSPD – Kyoto Scale of Psychological Development; MABC – Movement Assessment Battery for Children; MDI – Mental Development Index (Bayley Scale of Infant Development); MSCA – McCarthy Scales of Children’s Ability; NSMDA - Neurological, sensory, motor, developmental assessment; PDI – Psychomotor Development Index (Bayley Scale of Infant Development); PDMS - Peabody Developmental Motor Scales; PLS – Preschool Language Scales; PRELS – Preschool Receptive-Expressive Language Scale); PRUNAPE – Prueba Nacional de Pesquisa (National Screening Test of Latin America); SBIT – Stanford-Binet Intelligence Test ; SELSI – Sequenced Language Scale for Infants; VABS – Vineland Adaptive Behavior Scales; VLBW – Very low birth weight; WPPSI – Wechsler Preschool and Primary Scale of Intelligence; WPPSI-R – Wechsler Preschool and Primary Scale of Intelligence (revised edition).

eTable2. Characteristics of the included studies that used “>1SD below the mean” cut-off for ASQ

Study ID	Sample size	Study Design	Funding	Study Population	Age at Assessment (months)	Index Test	Reference Standard Test
Fauls_2020B³⁸ Australia	74	Prospective	Funding Information not available. Authors declared that there was no conflict of interest.	Children aged 0 to 5 years attending a specialist clinic	27.3 (18.4) months	ASQ3 Delay:1SD Domain: Gross motor	NSMDA>9 (minimal) Delay: 1SD; Total score>9 Domain: Gross motor
Hwarng_2021A²¹ Singapore	127	Prospective	AM-ETHOS Duke Medical Student Fellowship Award	<32 weeks and/or <1250 grams followed up at the Neonatal Neurodevelopmental Clinic	12 months	ASQ 3 Delay:1SD Domain: Gross motor	PDMS (2 nd Edition) Delay: 1SD Domain: Gross motor
Hwarng_2021B²¹ Singapore	127	Prospective	AM-ETHOS Duke Medical Student Fellowship Award	<32 weeks and/or <1250 grams followed up at the Neonatal Neurodevelopmental Clinic	12 months	ASQ 3 Delay:1SD Domain: Fine motor	PDMS (2 nd Edition) Delay: 1SD Domain: Fine motor
Hwarng_2021C²¹ Singapore	113	Prospective	AM-ETHOS Duke Medical Student Fellowship Award	<32 weeks and/or <1250 grams followed up at the Neonatal Neurodevelopmental Clinic	18 months	ASQ 3 Delay:1SD Domain: Communication	PLS (4 th edition) Delay: 1SD Domain: Speech and language

Kim_2010A⁴⁹ Korea	138	Retrospective	Information not available	Preterm infants < 32 weeks or less than 1,500 grams. Infants with HIE were excluded.	18 months	ASQ2 Delay:1SD Domain: Any	Bayley-III Delay: 1SD Domain: Any
Kim_2010B⁴⁹ Korea	138	Retrospective	Information not available	Preterm infants < 32 weeks or less than 1,500 grams. Infants with HIE were excluded.	18 months	ASQ2 Delay:1SD Domain: Any	Bayley-III Delay: 2SD Domain: Any
King-Dowling_2015B⁵⁰ Canada	159	Prospective	Ontario's Ministry of Child and Youth Services	Children with no known physical impairments with IQ ≥ 70	43 to 66 months	ASQ3 Delay:1SD Domain: Fine motor, gross motor	MABC (2 nd Edition) Delay: 1SD Domain: Fine motor, gross motor
Lepine_2021C⁵³ Canada	63	Prospective	Scholarship awarded to Mr Lépine by the Programme d'Excellence en Médecine pour l'Initiation En Recherche of the Faculty of medicine of the Université de Montréal and by the Heart and Stroke Foundation of Canada	Term infants who underwent surgical repair within first year of life.	12 months	ASQ3 Delay:1SD Domain: Any	Bayley-III Delay: 1SD Domain: Any
Lepine_2021D⁵³ Canada	81	Prospective	Scholarship awarded to Mr Lépine by the Programme d'Excellence en Médecine pour	Term infants who underwent surgical repair within first year of life.	24 months	ASQ3 Delay:1SD Domain: Any	Bayley-III Delay: 1SD Domain: Any

			l'Initiation En Recherche of the Faculty of medicine of the Université de Montréal and by the Heart and Stroke Foundation of Canada				
Lindsay_2008C⁵⁵ Australia	32	Prospective	National Health and Medical Research Council of Australia	Infants ≥34 weeks GA at birth with perinatal asphyxia	12 months	ASQ Delay:1SD Domain: Any	BSID (2 nd Edition) Delay: 1SD Domain: Any (either MDI/PDI)
Noeder_2017E⁵⁷ USA	239	Prospective	Institutional Development Award (IDeA) from the National Institute of General Medical Sciences of the National Institutes of Health	Children with congenital heart disease underwent cardiac surgery during infancy	6 -36 months	ASQ3 Delay:1SD Domain: Problem solving	Bayley-III Delay: 1SD Domain: Cognitive
Noeder_2017F⁵⁷ USA	228	Prospective	Institutional Development Award (IDeA) from the National Institute of General Medical Sciences of the National Institutes of Health	Children with congenital heart disease underwent cardiac surgery during infancy	6 -36 months	ASQ3 Delay:1SD Domain: Communication	Bayley-III Delay: 1SD Domain: speech and language
Noeder_2017G⁵⁷ USA	242	Prospective	Institutional Development Award (IDeA) from the National Institute of General Medical Sciences of the	Children with congenital heart disease underwent cardiac surgery during infancy	6 -36 months	ASQ3 Delay:1SD Domain: Fine motor	Bayley-III Delay: 1SD Domain: Fine motor

			National Institutes of Health				
Noeder_2017H⁵⁷ USA	244	Prospective	Institutional Development Award (IDeA) from the National Institute of General Medical Sciences of the National Institutes of Health	Children with congenital heart disease underwent cardiac surgery during infancy	6 -36 months	ASQ3 Delay:1SD Domain: Gross motor	Bayley-III Delay: 1SD Domain: Gross motor
Simard_2012E⁶² Canada	121	Prospective	Canadian Institutes of Health Research	Infants born between 29 and 36 6/7 weeks of gestation at birth, BW <2.5Kg	12 months	ASQ2 Delay:1SD Domain: Problem solving, communication, personal-social	BSID (2 nd Edition) Delay: 1SD; MDI<85 Domain: Cognitive, speech and language, personal-social
Simard_2012F⁶² Canada	119	Prospective	Canadian Institutes of Health Research	Infants born between 29 and 36 6/7 weeks of gestation at birth, BW <2.5Kg	12 months	ASQ2 Delay:1SD Domain: Fine motor, gross motors	BSID (2 nd Edition) Delay: 1SD; PDI<85 Domain: Fine motor, gross motors
Simard_2012G⁶² Canada	109	Prospective	Canadian Institutes of Health Research	Infants born between 29 and 36 6/7 weeks of gestation at birth, BW <2.5Kg	24 months	ASQ2 Delay:1SD Domain: Problem solving, communication, personal social	BSID (2 nd Edition) Delay: 1SD; MDI<85 Domain: Cognitive, speech and language, personal-social

Simard_2012H⁶² Canada	107	Prospective	Canadian Institutes of Health Research	Infants born between 29 and 36 6/7 weeks of gestation at birth, BW <2.5Kg	24 months	ASQ2 Delay:1SD Domain: Fine motor, gross motor	BSID (2 nd Edition) Delay: 1SD; PDI<85 Domain: Fine motor, gross motor
Steenis_2015C⁶⁵ Netherlands	565	Prospective	ZonMW	Healthy and at-risk children 18 to 42 months	18-42 months	ASQ3 Delay:1SD Domain: Any	Bayley-III Delay: 1SD Domain: Any
Steenis_2015D⁶⁵ Netherlands	565	Prospective	ZonMW	Healthy and at-risk children 18 to 42 months	18-42 months	ASQ3 Delay:1SD Domain: Any	Bayley-III Delay: 2SD Domain: Any
Woodward_2011C⁶⁸	169	Prospective	National Institute of Child Health and Human Development and grants from the General Clinical Research Centers Programs at the University of New Mexico, Tufts-New England Medical Center, and the University of Colorado	Birthweight between 500-999 grams and the need for mechanical ventilation at 12-48 hours of age	18-22 months	ASQ2 Delay:1SD Domain: Any	BSID (2 nd Edition) Delay: 2SD Domain: Any
Yue_2019G⁷⁰ China	630	Prospective	111 project Yaojiang Shi, the National Natural Science Foundation of China, the International Initiative for Impact Evaluation, UBS Optimus Foundation	Children from Qinba (rural) region of China	13-18 months	ASQ3 Delay:1SD Domain: Problem solving	Bayley-III Delay: 1SD Domain: Cognitive

			and the Fundamental Research Funds for the Central Universities				
Yue_2019H⁷⁰ China	630	Prospective	111 project Yaojiang Shi, the National Natural Science Foundation of China, the International Initiative for Impact Evaluation, UBS Optimus Foundation and the Fundamental Research Funds for the Central Universities	Children from Qinba (rural) region of China	13-18 months	ASQ3 Delay:1SD Domain: Communication	Bayley-III Delay: 1SD Domain: speech and language
Yue_2019I⁷⁰ China	630	Prospective	111 project Yaojiang Shi, the National Natural Science Foundation of China, the International Initiative for Impact Evaluation, UBS Optimus Foundation and the Fundamental Research Funds for the Central Universities	Children from Qinba (rural) region of China	13-18 months	ASQ3 Delay:1SD Domain: Fine motor, gross motor	Bayley-III Delay: 1SD Domain: Fine motor, gross motor
Yue_2019J⁷⁰ China	493	Prospective	111 project Yaojiang Shi, the National Natural Science Foundation of China, the International Initiative for Impact Evaluation, UBS Optimus Foundation	Children from Qinba (rural) region of China	19-24 months	ASQ3 Delay:1SD Domain: Problem solving	Bayley-III Delay: 1SD Domain: Cognitive

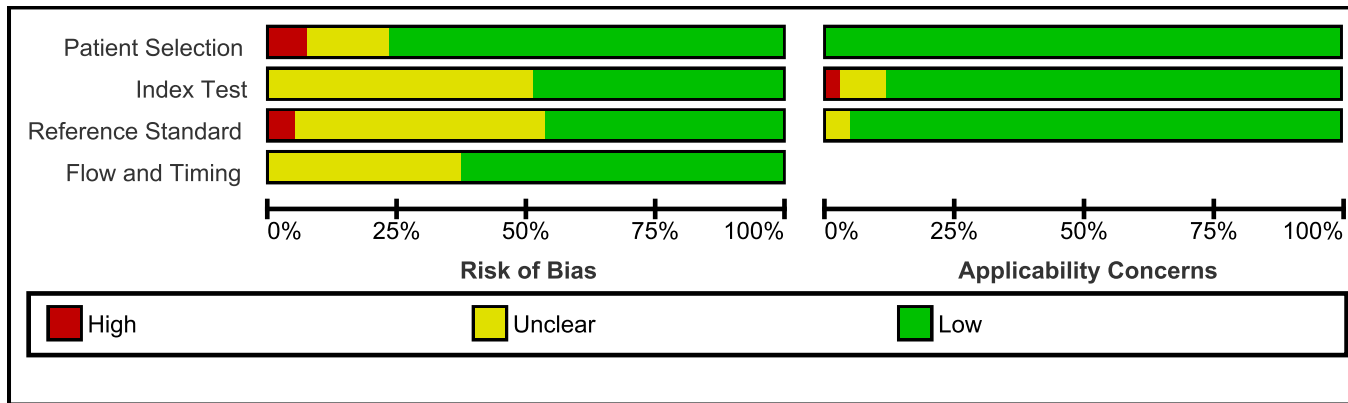
			and the Fundamental Research Funds for the Central Universities				
Yue_2019K⁷⁰ China	493	Prospective	111 project Yaojiang Sh), the National Natural Science Foundation of China, the International Initiative for Impact Evaluation, UBS Optimus Foundation and the Fundamental Research Funds for the Central Universities	Children from Qinba (rural) region of China	19-24 months	ASQ3 Delay:1SD Domain: Communication	Bayley-III Delay: 1SD Domain: Speech and language domain
Yue_2019L⁷⁰ China	493	Prospective	111 project Yaojiang Shi, the National Natural Science Foundation of China, the International Initiative for Impact Evaluation, UBS Optimus Foundation and the Fundamental Research Funds for the Central Universities	Children from Qinba (rural) region of China	19-24 months	ASQ3 Delay:1SD Domain: Fine motor, gross motor	Bayley-III Delay: 1SD Domain: Fine motor, gross motor

Included in the systematic review, but not meta-analysis

ADSI – Ankara Development Screening Inventory; AIMS – Alberta Infant Motor Scale; ASQ – Ages and Stages Questionnaire; ASQ-TRAK – ASQ version that is culturally and linguistically adapted ASQ-3 for Australian Aboriginal children; BDI – Batelle Development Index; BSID – Bayley Scale of Infant Development; DASII – Developmental Assessment Scale for Indian Infants; DDST – Denver Developmental Screening Test; GADNE – Gesell and Armatruda Developmental and Neurologic Examination; GCI – General Cognitive Intelligence; GECDAS – Gazi Early Childhood Development Assessment Scale; GMDS – Griffiths Mental Development Scales; GQ – General Quotient (Griffiths Mental Development Scales); KSPD – Kyoto Scale of Psychological Development;

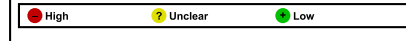
MABC – Movement Assessment Battery for Children; MDI – Mental Development Index (Bayley Scale of Infant Development); MSCA – McCarthy Scales of Children’s Ability; NSMDA - Neurological, sensory, motor, developmental assessment; PDI – Psychomotor Development Index (Bayley Scale of Infant Development); PDMS - Peabody Developmental Motor Scales; PLS – Preschool Language Scales; PRELS – Preschool Receptive-Expressive Language Scale); PRUNAPE – Prueba Nacional de Pesquisa (National Screening Test of Latin America); SBIT – Stanford-Binet Intelligence Test ; SELSI – Sequenced Language Scale for Infants; VABS – Vineland Adaptive Behavior Scales; VLBW – Very low birth weight; WPPSI – Wechsler Preschool and Primary Scale of Intelligence; WPPSI-R – Wechsler Preschool and Primary Scale of Intelligence (revised edition).

eFigure2: Risk of Bias of included studies-summary graph

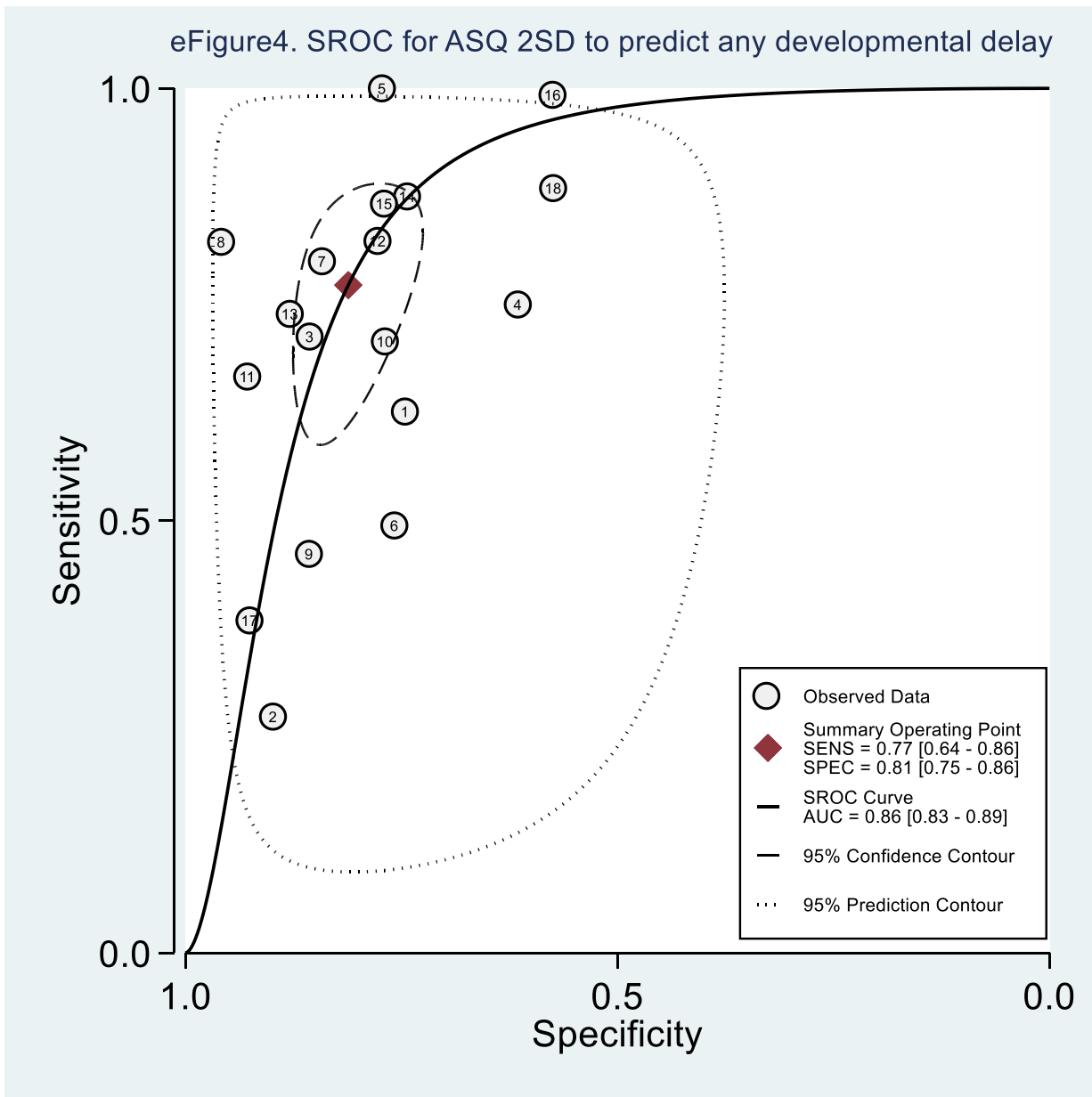


eFigure3: Methodological Quality of included studies

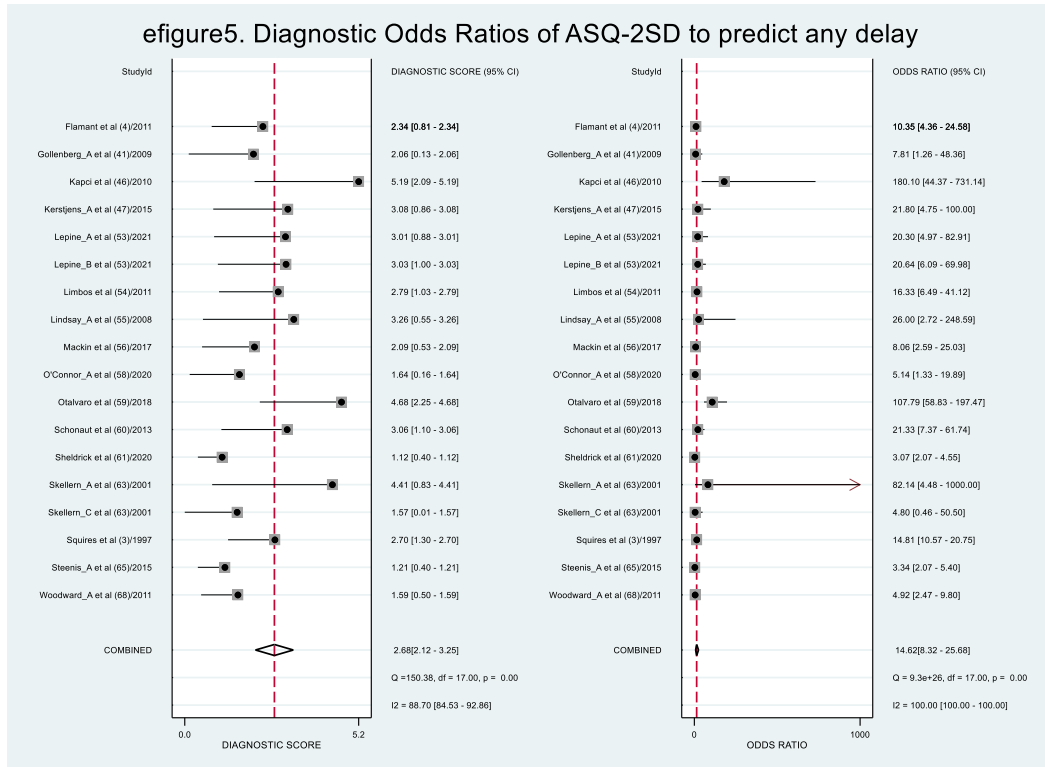
	Risk of Bias				Applicability Concerns		
	Patient Selection	Index Test	Reference Standard	Flow and Timing	Patient Selection	Index Test	Reference Standard
Agarwal_2016 (34)	●	?	●	?	●	●	●
Bian_2012 (35)	●	?	●	?	●	●	●
Carmichael_2014 (36)	●	?	?	●	●	●	●
Colbert_2021(37)	●	?	?	●	●	●	●
Fauls_2020 (38)	?	?	●	●	●	●	●
Flamant_2011 (4)	●	●	?	●	●	●	●
Fuengfoo_2020 (39)	●	?	?	●	●	●	●
Ga_2011 (40)	●	?	?	●	●	●	●
Gollenberg_2009 (41)	●	?	?	?	●	●	●
Gutierrez-Cruz_2019 (42)	●	?	?	●	●	?	?
Halbwachs_2013 (43)	●	?	●	●	?	?	●
Hwang_2021 (21)	●	?	?	?	●	●	●
Jang_2019 (44)	?	?	?	?	●	●	●
Juneja_2011 (45)	●	●	●	●	●	●	●
Kapci_2010 (46)	●	●	?	●	●	●	●
Kerstjens_2015 (47)	?	●	●	●	●	●	●
Kim_2010 (49)	●	?	?	?	●	●	?
Kim_2016 (48)	●	?	?	?	●	●	●
King-Dowling_2015 (50)	●	●	●	●	●	●	●
Klamer_2005 (51)	?	?	?	?	●	●	●
Kwun_2015 (52)	●	?	?	?	●	●	●
Lepine_2021 (53)	●	●	●	?	●	●	●
Limbos_2011 (54)	●	●	●	●	●	●	●
Lindsay_2008 (55)	●	●	●	?	●	●	●
Mackin_2017 (56)	?	●	●	?	●	●	●
Mezawa_2019 (20)	●	●	●	●	●	●	●
Noeder_2017 (57)	●	●	●	?	●	●	●
O' Connor_2020 (58)	●	?	●	●	●	●	●
Otalvaro_2018 (59)	?	?	●	?	●	●	●
Schonaut_2013 (60)	●	●	●	●	●	●	●
Sheldrick_2020 (61)	●	●	●	?	●	●	●
Simard_2012 (62)	●	●	●	●	●	●	●
Simpson_2021 (19)	●	●	●	●	●	●	●
Skellern_2001 (63)	●	●	●	?	●	●	●
Smith_2012 (64)	●	●	?	?	●	●	●
Squires_1997 (3)	●	?	?	●	●	?	●
Srinithiwat_2014 (71)	?	?	?	●	●	●	●
Steenis_2015 (65)	●	●	●	●	●	●	●
Vanvuchelen_2017 (66)	●	?	?	?	●	●	●
Veldhuizen_2015 (67)	●	●	●	●	●	●	●
Woodward_2011 (68)	●	●	?	●	●	●	●
Yu_2007 (69)	●	?	?	?	●	?	●
Yue_2019 (70)	●	?	?	●	●	●	●



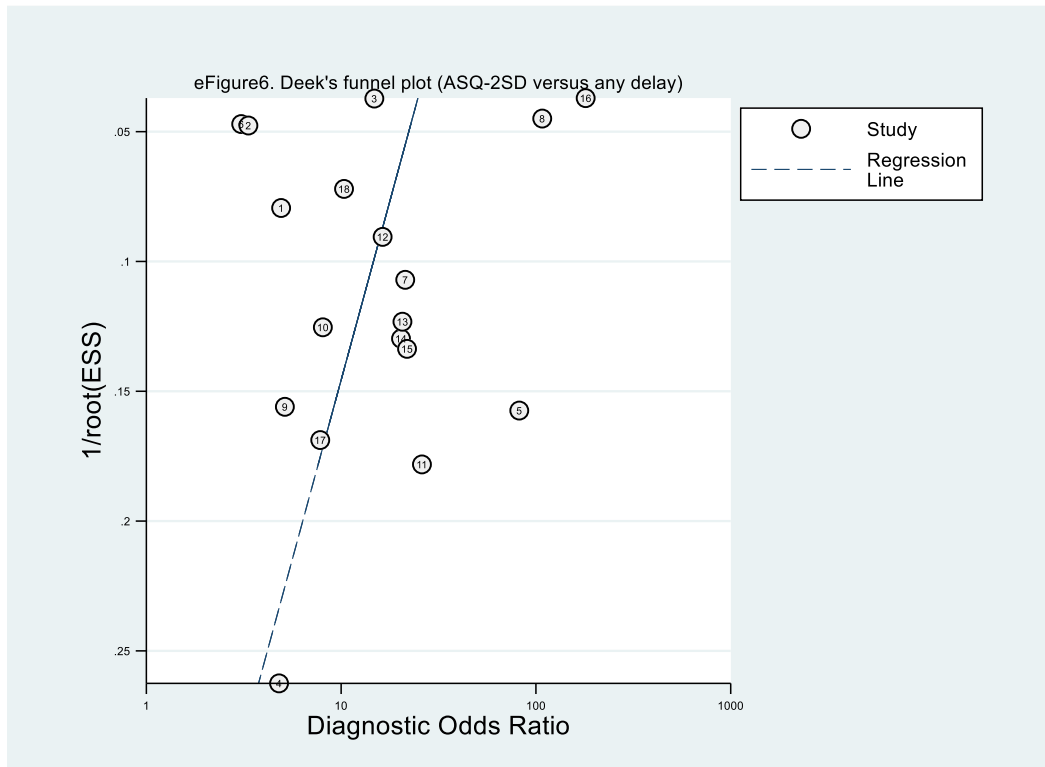
eFigure 4: SROC for ASQ-2SD to predict “any delay”



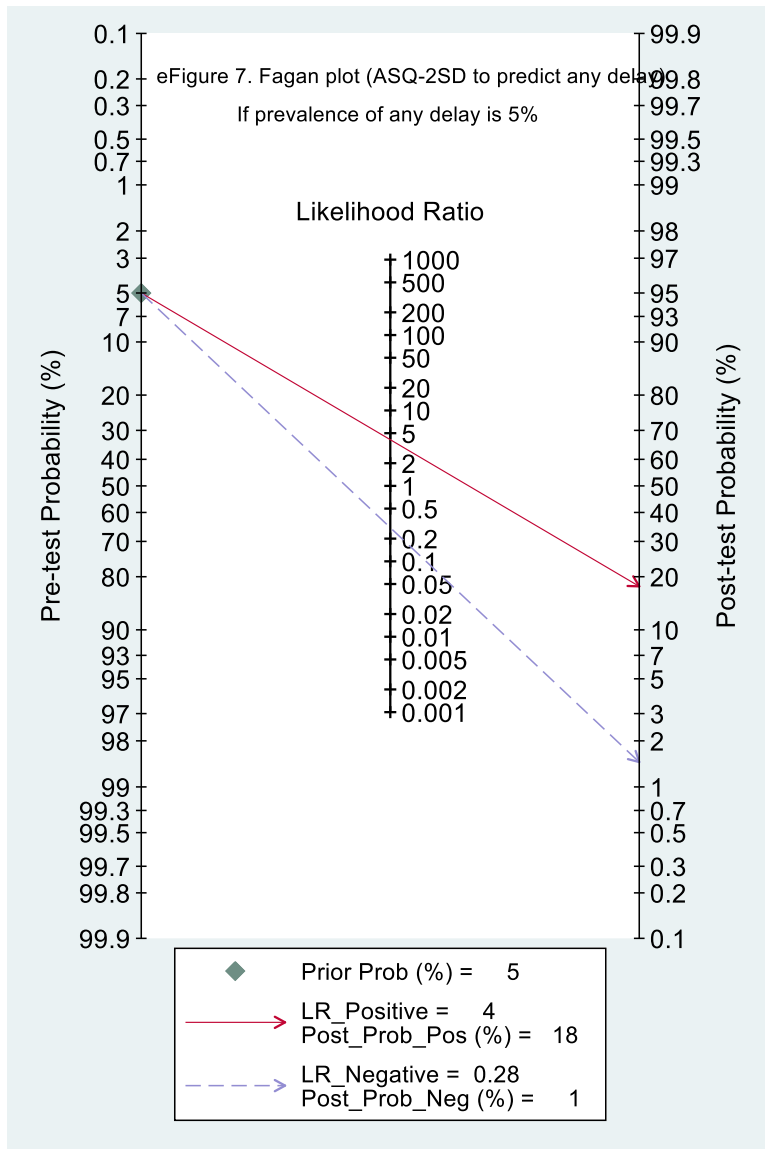
eFigure5: Diagnostic Odds Ratio of ASQ-2SD to predict “any delay”



eFigure6: Funnel plot for publication bias (ASQ-2SD to predict “any delay”)



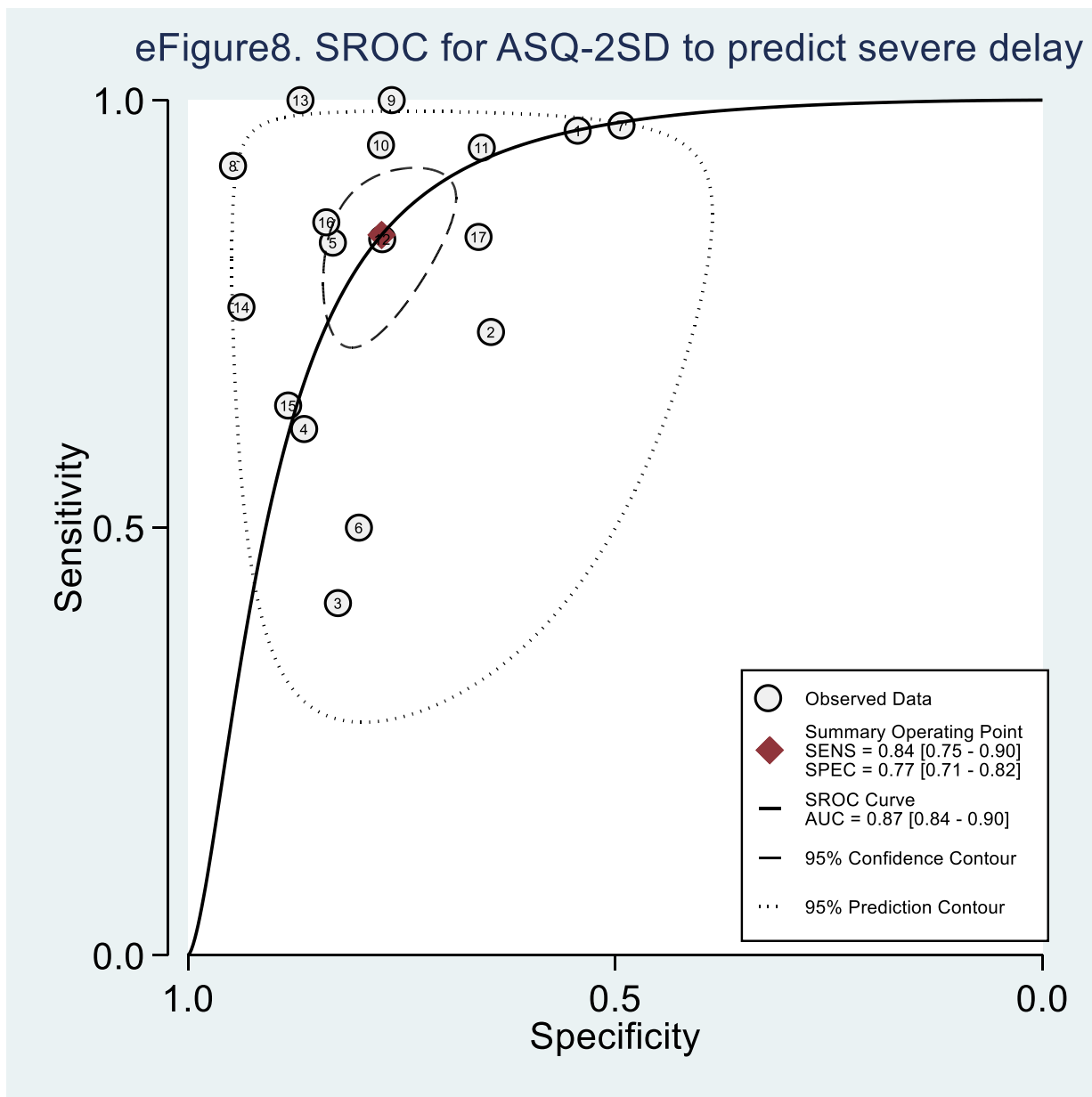
eFigure 7: Fagan nomogram if baseline prevalence is of “any delay” is 5% (ASQ-2SD to predict “any delay”)



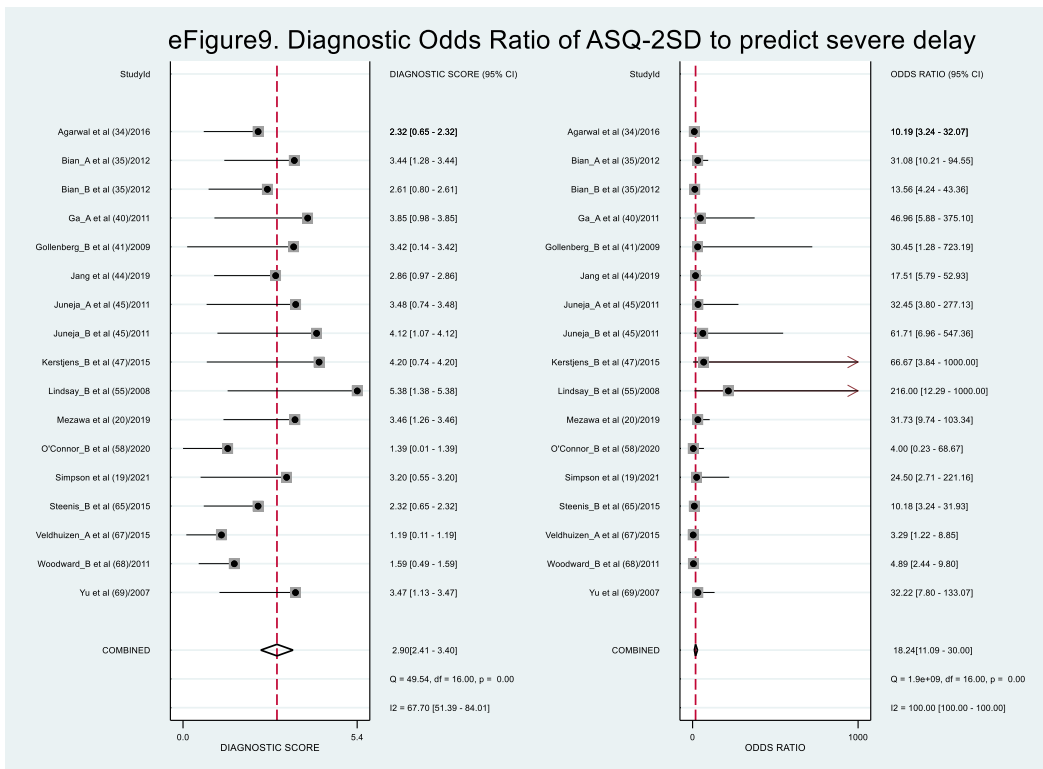
eTable3: Post-test probabilities for various pre-test prevalence of “any delay” based on the results of ASQ-2SD

Pre-test probability of “any delay”	Post-test probability of “any delay” if the child fails on ASQ-2SD	Post-test probability of “any delay” if the child passes on ASQ-2SD
5%	18%	1%
10%	31%	3%
15%	42%	5%
20%	51%	7%

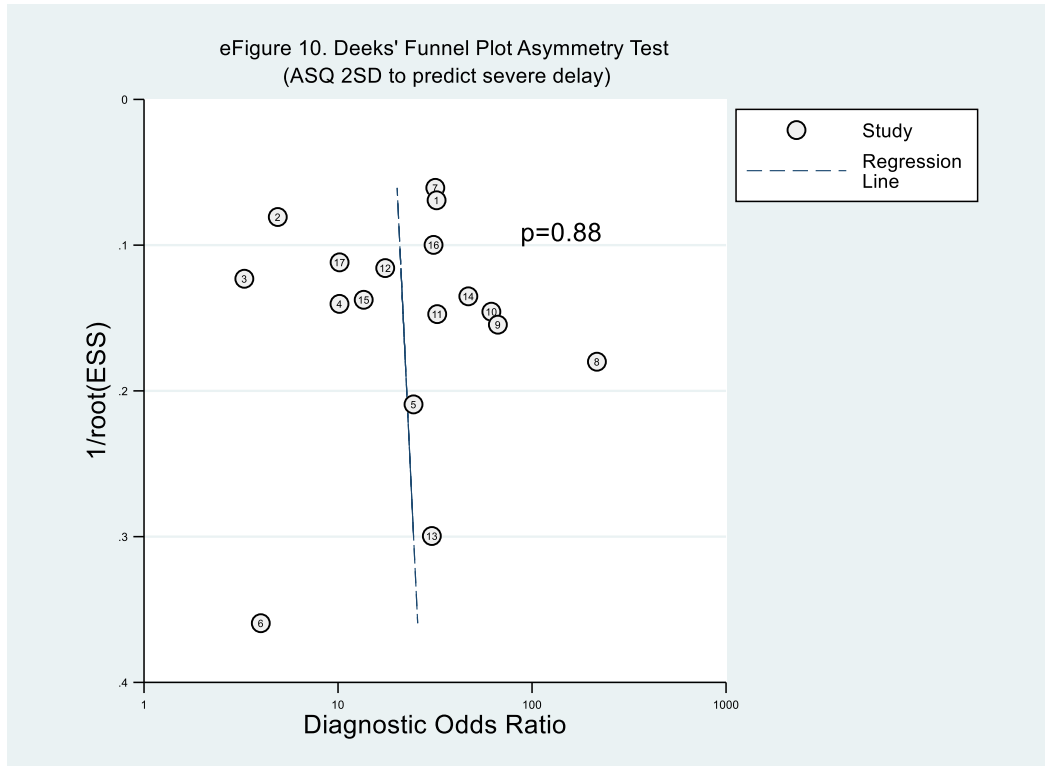
eFigure8: SROC of ASQ-2SD to predict “severe delay”



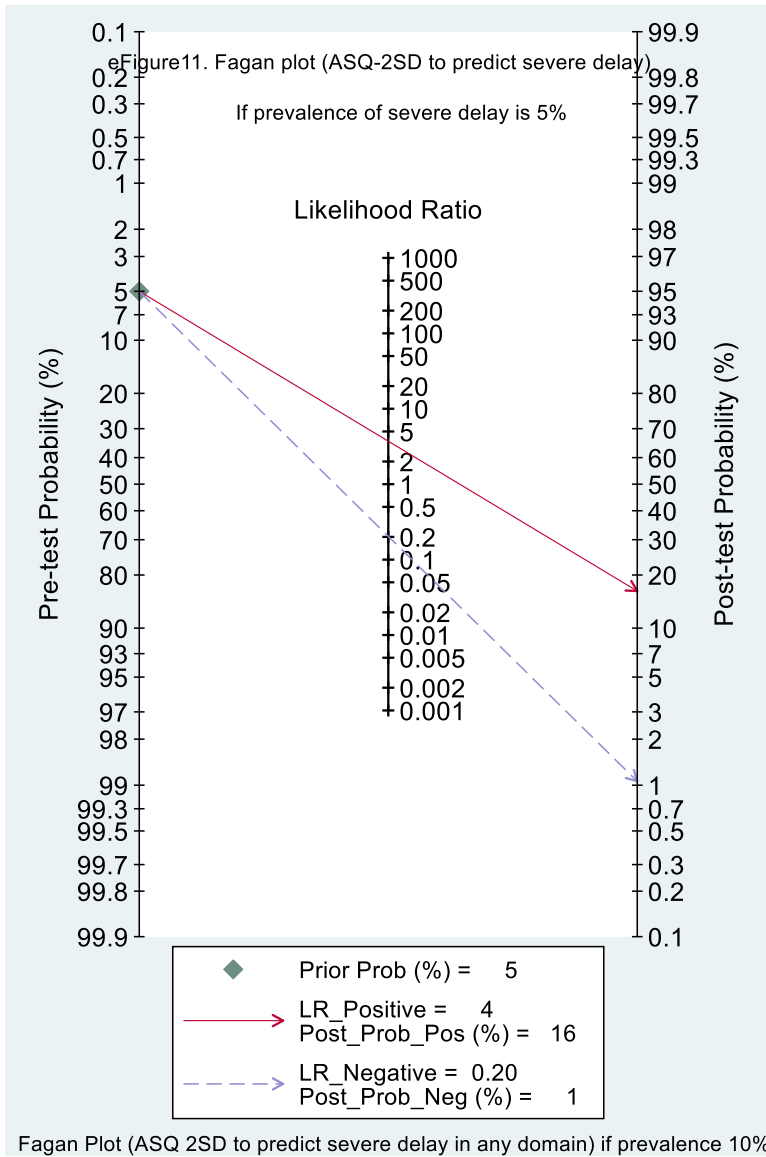
eFigure9: Diagnostic Odds Ratio of ASQ-2SD to predict “severe delay”



eFigure10: Funnel plot for publication bias (ASQ-2SD to predict “severe delay”)



eFigure11: Fagan nomogram if baseline prevalence of “severe delay” is 5% (ASQ-2SD to predict “severe delay”)



eTable4: Post-test probabilities for various pre-test prevalence of “severe delay” based on the results of ASQ-2SD

Pre-test probability of “severe delay”	Post-test probability of “severe delay” if the child fails on ASQ-2SD	Post-test probability of “severe delay” if the child passes on ASQ-2SD
5%	16%	1%
10%	29%	2%
15%	40%	3%
20%	48%	5%

eTable5: Results of studies included in the systematic review, but could not be pooled in the meta-analysis

Study ID	Results	Author's conclusions
Colbert_2021³⁷	Internal consistency reliability for the ASQ was adequate. Test-retest reliability ranged from low to moderate ($r = 0.08-0.43$; $p < 0.05-0.01$). There was significant variability in mean scores over time across ASQ domain scores. In terms of validity, the ASQ did not discriminate adequately between children who performed within or below age-expectations on performance-based developmental testing (Mullen Scales of Early Learning).	The ASQ did not demonstrate adequate psychometric properties in rural Guatemala. These results indicate that existing caregiver report screening measures of early childhood development should be utilized with caution in low resource settings, and alternative methods for assessment or in the development and utilization of caregiver report measures should be considered.
Fuengfoo_2020³⁹	Concurrent ASQ-3, Thai version compared with BSID-III had a sensitivity of 78.6%, 96.7%, and 83.3% among children at 12, 30 and 36 months old, respectively. The specificity was at 90.3%, 95.7%, and 98.7% among 12, 30 and 36-month-old children, respectively. The validity for 30-month-old children was very high and had almost perfect kappa agreement of 0.81 to 1, while the validity among children at 12 and 36-month-old was substantial (kappa agreement of 0.67 to 0.86).	ASQ-3, Thai version is a suitable developmental screening tool for children at 12, 30 and 36 months old in time-limited circumstances and with insufficient health personnel. The validity of the ASQ-3, Thai version is acceptable when compared to the standardized Bayley-III. The questionnaire is faster to complete than the child development progress assessment using the Bayley-III.
Ga_2011B⁴⁰	Concurrent K-ASQ2 $>2SD$ from the mean in any domain to predict cognitive or language delay using Capute scale (DQ <75) found sensitivity, specificity, PPV, NPV, PLR and NLR of 0.90, 0.63, 0.65, 0.89, 2.41, 0.16	K-ASQ showed relatively high concurrent validity with DQ 75 on the Capute scale.
Ga_2011C⁴⁰	Concurrent K-ASQ2 $>2SD$ from the mean in any domain to predict cognitive or language delay using Capute scale (DQ <85) found sensitivity, specificity, PPV, NPV, PLR and NLR of 0.76, 0.75, 0.87, 0.59, 3.05, 0.32	K-ASQ showed moderate concurrent validity with DQ 85 in the Capute scale
Ga_2011D⁴⁰	Concurrent K-ASQ2 $>2SD$ from the mean in any domain to predict motor delay using AIMS (below 10 th percentile) found sensitivity, specificity, PPV, NPV, PLR and NLR of 0.80, .077, 0.78, 0.78, 3.4, 0.26.	K-ASQ showed relatively high concurrent validity with DQ 75 in the Capute scale

Gutierrez-Cruz_2019 ⁴²	The correlation between the language assessment with the revised Brunet-Lézine scale and the ASQ-3 questionnaire was good, with a Pearson correlation coefficient of 0.7 ($p < 0.001$)	Late preterm infants have less language development at two years of age. Prematurity and male gender are risk factors for alterations. The assessment of language with the ASQ-3 questionnaire can be useful to detect alterations.
Halbwachs_2013 ⁴³	An ASQ cut-off value of 285 had optimal discriminatory power for identifying children with IQ scores <85. ASQ values <285 were significantly associated with a higher risk of sub-optimal neurologic outcomes (sensitivity of 0.80, specificity of 0.54 for IQ <85).	ASQ at five years is a simple and cost-effective tool that can detect a severe developmental delay in preterm children regardless of maternal education level, while its capacity to identify children with mild delay appears to be limited.
Klamer_2005 ⁵¹	The overall ASQ score correlated significantly with IQ ($p=0.007$). The children born extremely preterm had an ASQ score of 71.06 SD below the score of the term children ($p=0.048$).	The ASQ may serve as a useful tool to measure developmental deficit in groups of children born preterm and serve as a low-cost research tool.
Kwun_2015A ⁵²	If \geq one ASQ (Korean) domain failed is compared to MDI <85, the sensitivity, specificity, PPV, and NPV are 0.58, 0.80, 0.52, and 0.84, respectively.	The ASQ (Korean) showed low validity in comparison to MDI and PDI of BSID-II in preterm infants at a corrected age of 18-24 months. However, the communication domain showed moderate correlations with MDI. The failure in more than one domain of the ASQ (Korean) was significantly correlated with the failure in MDI.
Kwun_2015B ⁵²	If \geq one ASQ (Korean) domain failed is compared to PDI <85, the sensitivity, specificity, PPV, and NPV are 0.5, 0.73, 0.19, and 0.92, respectively.	
Kim_2010B ⁴⁹	The sensitivity of K-ASQ (1SD) compared with Bayley-III (2 SD) at 18 months was 0.72, the specificity was 0.93	ASQ was created for the purpose of screening the entire population during the development process. It has high specificity. Because of low sensitivity, ASQ as a screening test may have some limitations in preterm infants. K-ASQ showed a higher sensitivity at 18 months than at 8 months.
Srinithiwat_2014A ⁷¹	A fair to moderate agreement (Kappa agreement = 0.338-0.606) was found between the ASQ-3 Thai and the DDSTII. Sensitivity of the ASQ-3 Thai (2SD) with DDST-II (1SD) at the age of 18 months was 66.7%. Specificity was 78.6%.	Due to a fair to moderate agreement but low sensitivity between the ASQ-3 Thai and DDST-II, other validated tools should accompany the clinical usage of the tool. Further investigations are needed to support its usage, particularly the validation of the tool with other standardized developmental diagnostic tools.
Srinithiwat_2014B ⁷¹	Sensitivity of the ASQ-3 Thai (2SD) with DDST-II (1SD) at the age of 24 months was 88.2%. Specificity was 71.4%.	
Srinithiwat_2014C ⁷¹	Sensitivity of the ASQ-3 Thai (2SD) with DDST-II (1SD) at the age of 30 months was 54.5%. Specificity was 90.9%.	

eTable6: Summary of Findings and Certainty of Evidence: Should ASQ at 2SD be used to diagnose Any developmental delay in children aged 12-60 months?

Sensitivity		0.77 (95% CI: 0.64 to 0.86)		Prevalences 10% 15% 20%							
Specificity		0.81 (95% CI: 0.75 to 0.86)									
Outcome	No of studies (No of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 100 patients tested			Test accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Other considerations	pre-test probability of 10%	pre-test probability of 15%	pre-test probability of 20%	
True positives	16 studies 6089 patients	cohort & case-control type studies	serious ^a	not serious	very serious ^b	not serious	Strong association; Publication bias undetected	8 (6 to 9)	12 (10 to 13)	15 (13 to 17)	⊕⊕○ ○ Low
False negatives								2 (1 to 4)	3 (2 to 5)	5 (3 to 7)	
True negatives	16 studies 6089 patients	cohort & case-control type studies	serious ^a	not serious	very serious ^b	not serious	Strong association Publication bias undetected	73 (68 to 79)	69 (64 to 75)	65 (60 to 70)	⊕⊕○ ○ Low
False positives								17 (11 to 22)	16 (10 to 21)	15 (10 to 20)	

Explanations

- a. Nearly 50% of included studies had high or unclear risk of bias in one or more domains
- b. Very high statistical heterogeneity

eTable7: Summary of Findings and Certainty of Evidence: Should ASQ at 2SD be used to diagnose “Severe delay” in children aged 12-60 months?

Sensitivity		0.84 (95% CI: 0.75 to 0.90)		Prevalences			10%	15%	20%		
Specificity		0.77 (95% CI: 0.71 to 0.82)									
Outcome	№ of studies (№ of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 100 patients tested			Test accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Other considerations	pre-test probability of 10%	pre-test probability of 15%	pre-test probability of 20%	
True positives	15 studies 3942 patients	cohort & case-control type studies	serious ^a	not serious	very serious ^b	not serious	Strong association; Publication bias unlikely	8 (8 to 9)	13 (11 to 14)	17 (15 to 18)	⊕⊕○ ○ Low
False negatives								2 (1 to 2)	2 (1 to 4)	3 (2 to 5)	
True negatives	15 studies 3942 patients	cohort & case-control type studies	serious ^a	not serious	very serious ^b	not serious	Strong association; Publication bias unlikely	69 (64 to 74)	65 (60 to 70)	62 (57 to 66)	⊕⊕○ ○ Low
False positives								21 (16 to 26)	20 (15 to 25)	18 (14 to 23)	

Explanations

c. Nearly 50% of studies had high or unclear risk of bias in many domains

d. Substantial statistical heterogeneity (I²>90%)

eTable 8: Summary of Findings and Certainty of Evidence: Should ASQ Motor domain at 2SD be used to diagnose “Any motor delay” in children aged 12-60 months?

Sensitivity		0.41 (95% CI: 0.26 to 0.57)					Prevalences 10% 15% 20%				
Specificity		0.94 (95% CI: 0.87 to 0.97)									
Outcome	No of studies (No of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 100 patients tested			Test accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Other considerations	pre-test probability of 10%	pre-test probability of 15%	pre-test probability of 20%	
True positives	7 studies 1417 patients	cohort & case-control type studies	serious ^a	not serious	very serious ^b	not serious	publication bias strongly suspected ^c	4 (3 to 6)	6 (4 to 9)	8 (5 to 11)	⊕○○○ ○ Very low
False negatives								6 (4 to 7)	9 (6 to 11)	12 (9 to 15)	
True negatives	7 studies 1417 patients	cohort & case-control type studies	serious ^a	not serious	very serious ^b	not serious	publication bias strongly suspected strong association ^c	85 (78 to 87)	80 (74 to 82)	75 (70 to 78)	⊕○○○ ○ Very low
False positives								5 (3 to 12)	5 (3 to 11)	5 (2 to 10)	

Explanations

e. many of the included studies had unclear or high risk of bias in some of the domains

f. Significant statistical heterogeneity

g. Only 7 studies included, publication bias could not be assessed.

eTable10: Summary of Findings and Certainty of Evidence: Should ASQ-cognitive/language domain at 2SD be used to diagnose “any cognitive/language delay” in Children aged 12-60 months?

Sensitivity		0.44 (95% CI: 0.24 to 0.65)		Prevalences 10% 15% 20%							
Specificity		0.93 (95% CI: 0.81 to 0.95)									
Outcome	No of studies (No of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 100 patients tested			Test accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Other considerations	pre-test probability of 10%	pre-test probability of 15%	pre-test probability of 20%	
True positives	2 studies 697 patients	cohort & case-control type studies	not serious ^a	not serious	very serious ^b	serious ^c	publication bias strongly suspected ^d	4 (2 to 7)	7 (4 to 10)	9 (5 to 13)	⊕○○○ ○ Very low ^b
False negatives								6 (3 to 8)	8 (5 to 11)	11 (7 to 15)	
True negatives	2 studies 697 patients	cohort & case-control type studies	not serious ^a	not serious	very serious ^b	not serious	publication bias strongly suspected strong association ^d	84 (73 to 86)	79 (69 to 81)	74 (65 to 76)	⊕⊕○○○ Low
False positives								6 (4 to 17)	6 (4 to 16)	6 (4 to 15)	

Explanations

- i. both studies didn't have any risk of bias in almost all the domains
- j. Very high statistical heterogeneity ($I^2 > 80\%$)
- k. wide confidence intervals
- l. Publication bias could not be assessed in view of less than 10 studies

eTable12: Summary of Findings and Certainty of Evidence:: Should ASQ at 1SD be used to diagnose “any delay” in children aged 12-60 months?

Sensitivity		0.79 (95% CI: 0.63 to 0.90)		Prevalences			10%	15%	20%		
Specificity		0.67 (95% CI: 0.42 to 0.85)									
Outcome	No of studies (No of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 100 patients tested			Test accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Other considerations	pre-test probability of 10%	pre-test probability of 15%	pre-test probability of 20%	
True positives	4 studies 798 patients	cohort & case-control type studies	serious ^a	not serious	serious ^b	not serious	publication bias strongly suspected ^c	8 (6 to 9)	12 (9 to 14)	16 (13 to 18)	⊕○○○ ○ Very low
False negatives								2 (1 to 4)	3 (1 to 6)	4 (2 to 7)	
True negatives	4 studies 798 patients	cohort & case-control type studies	serious ^a	not serious	very serious ^d	not serious	publication bias strongly suspected ^c	60 (38 to 77)	57 (36 to 72)	54 (34 to 68)	⊕○○○ ○ Very low
False positives								30 (13 to 52)	28 (13 to 49)	26 (12 to 46)	

Explanations

p. 3 of the included studies had unclear risk of bias in many domains

b. I² = 75%

c. Publication bias could not be assessed in view of less than 10 studies

d. I² = 92%

eTable 13: Summary of Findings and Certainty of Evidence: Should ASQ-1SD be used to diagnose “severe delay” in children?

Sensitivity		0.88 (95% CI: 0.73 to 0.95)									
Specificity		0.53 (95% CI: 0.35 to 0.71)									
		Prevalences									
		5%	10%	15%							
Outcome	No of studies (No of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 100 patients tested			Test accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Other considerations	pre-test probability of 5%	pre-test probability of 10%	pre-test probability of 15%	
True positives (patients with severe developmental delay)	3 studies 773 patients	cohort & case-control type studies	serious ^a	not serious	serious ^b	not serious	publication bias strongly suspected strong association ^c	4 (4 to 5)	9 (7 to 10)	13 (11 to 14)	⊕⊕○○ Low
False negatives (patients incorrectly classified as not having severe developmental delay)								1 (0 to 1)	1 (0 to 3)	2 (1 to 4)	
True negatives (patients without severe developmental delay)	3 studies 773 patients	cohort & case-control type studies	serious ^a	not serious	serious ^b	serious ^d	publication bias strongly suspected ^c	50 (33 to 67)	48 (32 to 64)	45 (30 to 60)	⊕○○○ Very low
False positives (patients incorrectly classified as having severe developmental delay)								45 (28 to 62)	42 (26 to 58)	40 (25 to 55)	

Explanations

- a. high or unclear ROB in at least one or more domains
 b. I2 90%
 c. Publication bias could not be assessed due to only 3 included studies
 d. Wide CI

eTable14: Summary of Findings and Certainty of Evidence: Question: Should ASQ motor domain at 1SD be used to diagnose "any motor delay" in children aged 12-60 months?

Sensitivity		0.64 (95% CI: 0.53 to 0.73)									
Specificity		0.79 (95% CI: 0.70 to 0.85)									
Outcome	No of studies (No of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 100 patients tested			Test accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Other considerations	pre-test probability of 10%	pre-test probability of 15%	pre-test probability of 20%	
True positives	6 studies 2322 patients	cohort & case-control type studies	serious ^a	not serious	very serious ^b	not serious	publication bias strongly suspected ^c	6 (5 to 7)	10 (8 to 11)	13 (11 to 15)	⊕○○○ ○ Very low
False negatives								4 (3 to 5)	5 (4 to 7)	7 (5 to 9)	
True negatives	6 studies 2322 patients	cohort & case-control type studies	serious ^a	not serious	very serious ^b	not serious	publication bias strongly suspected ^c	71 (63 to 77)	67 (60 to 72)	63 (56 to 68)	⊕○○○ ○ Very low
False positives								19 (13 to 27)	18 (13 to 25)	17 (12 to 24)	

Explanations

- q. 4 of the included studies had high/unclear risk of bias in some domains
- r. Very high statistical heterogeneity ($I^2 > 80$)
- s. Publication bias could not be assessed in view of less than 10 studies

eTable15: Summary of Findings and Certainty of Evidence: Question: Should ASQ motor domain at 1SD be used to diagnose severe motor delay in children aged 12-60 months?

No data

eTable16: Summary of Findings and Certainty of Evidence: Should ASQ- cognitive/language at 1SD be used to diagnose “any cognitive/language delay” in children aged 12-60 months?

Sensitivity	0.58 (95% CI: 0.39 to 0.75)				
Specificity	0.79 (95% CI: 0.71 to 0.85)				
		Prevalences	10%	15%	20%

Outcome	No of studies (No of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 100 patients tested			Test accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Other considerations	pre-test probability of 10%	pre-test probability of 15%	pre-test probability of 20%	
True positives	4 studies 2954 patients	cohort & case-control type studies	serious ^a	not serious	very serious ^b	not serious	publication bias strongly suspected ^c	6 (4 to 8)	9 (6 to 11)	12 (8 to 15)	⊕○○○ ○ Very low
False negatives								4 (2 to 6)	6 (4 to 9)	8 (5 to 12)	
True negatives	4 studies 2954 patients	cohort & case-control type studies	serious ^a	not serious	very serious ^b	not serious	publication bias strongly suspected ^c	71 (64 to 77)	67 (60 to 72)	63 (57 to 68)	⊕○○○ ○ Very low
False positives								19 (13 to 26)	18 (13 to 25)	17 (12 to 23)	

Explanations

- a. 3 of the included studies had unclear risk of bias in some domains
- b. Very high statistical heterogeneity ($I^2 > 90\%$)
- c. Publication bias could not be assessed in view of less than 10 studies

eTable17: Summary of Findings and Certainty of Evidence: Question: Should ASQ- cognitive/language at 1SD be used to diagnose “severe cognitive/language delay” in children aged 12-60 months?

No data.

eTable18: Results of sensitivity analyses

ASQ details	N. of studies/ N. of comparisons/ Sample size	Sensitivity (95% CI)	Specificity (95% CI)	PLR (95% CI)	NLR (95% CI)	DOR (95% CI)	AUC (95% CI)
ASQ 2SD to predict any delay (using only ASQ version 3)	8/9/2370 47A,53A, 53B, 56, 58A, 59,60, 61,65A	0.69 (0.53, 0.81) I²=93.8%	0.85 (0.79, 0.90) I²=92%	4.6 (3.0, 7.1)	0.37 (0.23, 0.58)	13 (6, 28)	0.86 (0.83, 0.89)
ASQ 2SD to predict severe delay (using only ASQ version 3)	8/9/2517 19,20, 34,35A, 35B,47B, 58B, 65B, 67A	0.80 (0.64, 0.90) I²=89.8%	0.79 (0.71, 0.85) I²=95%	3.8 (3.0, 4.8)	0.25 (0.14, 0.46)	15 (8, 28)	0.86 (0.82, 0.88)

ASQ 2SD to predict any delay (using only ASQ version 2)	6/6/3588 3,4, 41A, 46, 54, 68A	0.83 (0.56, 0.95) I ² =95.7%	0.76 (0.64, 0.85) I ² =98%	3.5 (2.5, 4.7)	0.23 (0.09, 0.60)	15 (6, 38)	0.84 (0.80, 0.87)
ASQ 2SD to predict severe delay (using only ASQ version 2)	6/7/1393 40A,41B, 44,45A, 45B,68B, 69	0.87 (0.76, 0.93) I ² =73.7%	0.73 (0.62, 0.83) I ² =92.2%	3.3 (2.2, 4.8)	0.18 (0.10, 0.33)	18 (8, 39)	0.87 (0.84, 0.90)
ASQ 2SD to predict any delay (using only studies with low risk of bias)	2/2/761 60, 65A	0.36 (0.12 0.69) I ² =89.7	0.89 (0.56, 0.98) I ² =89.7	3.9 (0.51 21.2)	0.72 (0.27 1.9)	4.6 (0.55, 37.7)	0.68 (0.43, 0.86)
ASQ 2SD to predict severe delay (using only studies with low risk of bias)	5/6/1684 19, 20, 45A, 45B, 65B, 67A	0.84 (0.61, 0.95) I ² =94.5%	0.75 (0.63, 0.84) I ² =96.2%	3.3 (2.5, 4.5)	0.21 (0.08, 0.54)	16 (6, 39)	0.84 (0.81, 0.87)

ASQ 2SD to predict any delay (using studies having sample size > 145)	10/10/5645 3, 4, 46, 47A, 54, 59, 60, 61, 65A, 68A	0.79 (0.61, 0.91) I ² =97.1%	0.80 (0.71,0.87) I ² =98.1%	4 (2.8, 5.7)	0.26 (0.13, 0.51)	16 (7, 35)	0.86 (0.83, 0.89)
ASQ 2SD to predict severe delay (using studies having sample size > 145)	7/8/3203 20, 35A,35B, 47B, 65B, 67A, 68B, 69	0.83 (0.64, 0.93) I ² =93.2%	0.75 (0.65, 0.84) I ² =98%	3.4 (2.5, 4.5)	0.23 (0.11, 0.47)	15 (7, 31)	0.85 (0.81, 0.87)
ASQ 2SD to predict any delay (using only prospective studies)	15/17/6022 3, 4, 41A, 46, 47A, 53A, 53B, 54, 55A, 58A, 59, 60, 61, 63A, 63C, 65A, 68A	0.78 (0.64, 0.87) I ² =95.2%	0.82 (0.75, 0.86) I ² =96.8%	4.2 (3.2, 5.4)	0.27 (0.17, 0.45)	15 (8, 28)	0.86 (0.83, 0.89)
ASQ 2SD to predict any delay (using only retrospective studies)	Only one study (56)						

ASQ 2SD to predict severe delay (using only prospective studies)	13/15/3686 19,20,34, 35A, 35B, 41B, 45A, 45B, 47B, 55B, 58B, 65B, 67A, 68B, 69	0.85 (0.74, 0.92) I ² =88.2%	0.77 (0.70, 0.82) I ² =96.5%	3.6 (2.9, 4.6)	0.19 (0.11, 0.34)	19 (10, 34)	0.86 (0.83, 0.89)
ASQ 2SD to predict severe delay (using only retrospective studies)	2/2/256 40A, 44	0.82 (0 .68, 0.91) I ² =0%	0.82 (0.69,0.91) I ² =0%	4.7 (2.3, 9.4)	0.22 (0.11, 0.43)	21.8 (8.2,57.8)	0.82 (0.74,0.88)
ASQ 2SD to predict any delay on BISD II	3/3/242 41A, 55A, 68A	0.52 (0.42 0.63) I ² =1%	0.84 (0.76 0.90) I ² =1%	3.3 (2.0 5.6)	0.56 (0.39 0.81)	5.9 (3.1, 11.0)	(0.71, (0 .64, 0.77)
ASQ 2SD to predict severe delay on BISD II	7/8/1583 35A, 41B, 44, 45A, 45B, 55B, 68B, 69	0.89 (0.80, 0.94) I ² =75.1%	0.76 (0.65, 0.84) I ² =96.2	3.7 (2.5, 5.4)	0.15 (0.8, 0.27)	25 (11, 59)	0.90 (87, 0.92)

ASQ 2SD to predict any delay on Bayley-III	7/8/2009 47A,53A, 53B, 54, 56, 60, 61, 65A	0.70 (0.54, 0.83) I ² =92.2%	0.81 (0.76, 0.85) I ² =82.9%	3.7 (3.0. 4.7)	0.36 (0.22, 0.59)	10 (5, 19)	0.84 (0.80, 0.87)
ASQ 2SD to predict severe delay on Bayley-III	5/5/1625 19, 34, 47B, 65B, 67A	0.75 (0.50, 0.90) I ² =73.8%	0.80 (0.74 0.85) I ² =86.5%	3.7 (2.8 4.9)	0.32 (0.15 0.68)	12 (5, 30)	0.84 (0.80 0.87)
ASQ 2SD to predict any delay in children 12-24 months	4/4/332 53A, 55A, 56, 68A	0.70 (0.58, 0.79) I ² =48%	0.77 (0.69, 0.83) I ² =0%	3.0 (2.1 4.2)	0.40 (0.28 0.56)	8 (4, 14)	0.78 (0.75, 0.82)
ASQ 2SD to predict severe delay in children 12-24 months	4/4/314 45A, 55B, 58B, 68B	0.85 (0.68, 0.94) I ² =69%	0.76 (0.63 0.85) I ² =79%	3.6 (2.1 6.1)	0.20 (0.08 0.49)	18 (5, 71)	0.88 (0.84 0.90)
ASQ 2SD to predict any delay in children ≥24 months	6/6/1153 4, 41A, 47A, 53B, 58A, 63C	0.73 (0.55, 0.86) I ² =79%	0.79 (0.66 0.88) I ² =95%	3.5 (2.4 5.3)	0.34 (0.21 0.56)	10 (6,18)	0.83 (0.80, 0.86)

ASQ 2SD to predict severe delay in children \geq24 months	4/4/439 34, 41B, 45B, 47B	0.94 (0.75, 0.99) I²=15%	0.76 (0.68, 0.82) I²=61.3%	3.8 (2.7, 5.4)	0.08 (0.01, 0.39)	51 (8, 328)	0.88 (0.85, 0.91)
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ASQ result **Developmental delay present** **Developmental delay absent** **Total**
Failed TP **FP**

Passed FN **TN**

Total P **S-P** **S (No. of all children)**

TP = Sensitivity*P; TN = Specificity*(S - P); FP = (S-P)-TN; FN = P-TP.