Developmental Screening using the Infant Toddler Checklist at 18 months and School Readiness as Measured by the Early Development Instrument

by

Kimberly Megan Nurse

A thesis submitted in conformity with the requirements
for the degree of Master of Science

Institute of Health Policy, Management and Evaluation
University of Toronto

Developmental Screening using the Infant Toddler Checklist at 18 months and School Readiness as Measured by the Early Development Instrument

Kimberly Megan Nurse

Master of Science

Institute of Health Policy, Management and Evaluation
University of Toronto

2021

ABSTRACT

Background: This study identified factors associated with a positive Infant Toddler Checklist (ITC) screen and examined the validity of the ITC in identifying vulnerability on the Early Development Instrument (EDI).

Methods: Multivariable regression models were used to identify the factors and examine the construct validity of the ITC. Screening test properties were used to evaluate the predictive validity of the ITC, using the EDI as the criterion measure.

Results: 10-13% of children had a positive ITC screen. Male sex, lower birthweight, income <$40,000 and having 2 or more siblings resulted in higher odds of a positive ITC screen. An association was found between a positive ITC screen and the Language & Cognitive Development and Communication Skills & General Knowledge EDI domains. The ITC had a high specificity of 88-95%.

Conclusion(s): We identified several risk factors for a positive ITC screen. The ITC accurately identified children not vulnerable on the EDI.

ACKNOWLEDGMENTS

Completing a Master of Science degree has been an enlightening and fulfilling experience that would not have been possible without the support of many individuals, especially amidst a global pandemic.

I would like to express my sincerest appreciation and gratitude to my supervisor Dr. Cornelia Borkhoff and the other members of my thesis committee, Dr. Patricia Parkin and Dr. Charles Keown-Stoneman for their guidance and support throughout this process. Dr. Borkhoff, thank you for your wonderful mentorship, encouragement and for sharing your expertise. Dr. Parkin, thank you for your thoughtful feedback and your passion and dedication towards improving child health and development. Dr. Keown-Stoneman, thank you for your patience and willingness to share your knowledge of biostatistics and answer any questions. It has been an honour and inspiration to have had the opportunity to learn from you all. I will treasure this experience and carry what I have learned throughout my research career.

I would also like to express my appreciation for the *TARGet Kids!* research team, the EDI team and the enrolled children and their families. A special thank you, to the *TARGet Kids!* principal investigators, Dr. Catherine Birken and Dr. Jonathon Maguire for their guidance and support and the research managers, Christine Kowal and Dalah Mason, research assistants, administrative assistant, Donna Whitely and post-doctoral fellow, Dr. Jessica Omand for their efforts and assistance. To the co-creator of the EDI, Dr. Magdalena Janus and the EDI research program coordinator, Dr. Caroline Reid-Westoby, thank you for your guidance and collaboration. I am also grateful for my peers and the professors at the Institute of Health Policy, Management and Evaluation (IHPME) for facilitating my intellectual growth and development over the years and making this an equally enjoyable experience.

Finally, this endeavor truly would not have been possible without the love and unwavering support I receive from my family. To my parents, Elvis and Cheryl, my sister, Vonetta and my grandmother, Leleith, thank you for imparting your knowledge, inspiring me and demonstrating what it means to persevere and be resilient. I am forever grateful for you. To my extended family and friends, thank you for the supportive Skype and Zoom calls during these unprecedented times. My gratitude to all!

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

AAP	American Academy of Pediatrics
ADHD	Attention Deficit/Hyperactivity Disorder
ASD	Autism Spectrum Disorder
ASQ-3	Ages & Stages Questionnaires, 3rd Edition
BAS-NV	British Ability Scales Naming Vocabulary
Bayley-III/ Bayley-3	Bayley Scales of Infant and Toddler Development, 3rd Edition
BDI	Battelle Developmental Inventory
BMI	Body Mass Index
BSID	Bayley Scales of Infant Development
CAD/CAN$	Canadian Dollar
CDC	Centers for Disease Control and Prevention
CDI-SF	MacArthur Communicative Development Inventories
CI	Confidence Interval
CPS	Canadian Paediatric Society
CSBS:DP	Communication and Symbolic Behaviour Scales: Developmental Profile
CSDH	Commission on Social Determinants of Health
DAS-II	Differential Ability Scales, 2nd Edition
DDST	Denver Developmental Screening Test

ECE	Early Childhood Educators
EDI	Early Development Instrument
EWCV	Enhanced Well-Child Visit
g coefficient	Generalizability Coefficient
IEP	Individual Education Plan
IPRC	Identification, Placement, and Review Committee
IRT	Item Response Theory
IT	Information Technology
ITC	Infant Toddler Checklist
JK	Junior Kindergarten
kg	kilograms
M-CHAT-R	Modified Checklist for Autism in Toddlers, Revised
MICE	Multiple Imputation by Chained Equation
NDDS	Nipissing District Developmental Screen
OCCS	Offord Centre for Child Studies
OHIP	Ontario Health Insurance Plan
OR	Odds Ratio
PDGMS	Peabody Developmental Gross Motor Scale
PEDS/ PEDS:DM	Parents' Evaluation of Developmental Status: Developmental Milestones
PKU	Phenylketonuria

PPVT	Peabody Picture Vocabulary Test
Q-CHAT	Quantitative Checklist for Autism in Toddlers
r	Pearson's Correlation Coefficient
R^2	Coefficient of Determination
SD	Standard Deviation
SDOH	Social Determinants of Health
SES	Socioeconomic Status
SK	Senior Kindergarten
TARGet Kids!	The Applied Research Group for Kids
UNICEF	United Nations International Children's Emergency Fund
USA	United States of America
USD	United States Dollar
VIF	Variance Inflation Factor
WHO	World Health Organization
WPPSI	Wechsler Preschool and Primary Scale of Intelligence
zBMI	Body Mass Index z-score

LIST OF APPENDICES

CHAPTER 1: INTRODUCTION

Early childhood is a critical period of brain development laying the foundation for an individual's overall health and well-being.[1] One framework for early childhood development can be divided into the following domains: socio-emotional, language/communication, cognitive and physical development.[1, 2] Within each domain are specific tasks deemed appropriate for children of a certain age based on the performance of the average child at said age.[3] Within a domain, when the task is performed and the skill acquired, it is considered a milestone.[3] Both genetic and environmental factors influence child development which may lead to developmental delay and/or disorder.[3, 4]

The Canadian Task Force on Preventive Health Care characterizes developmental delay in children as significant delay in one or more of the above mentioned domains.[5] A significant delay refers to a standard deviation of 1.5 or more below the expected norms of a child's performance at a particular age.[5] These delays may be transient or sustained; however, there is a higher risk of behavioural problems, functional impairments, and learning difficulties throughout life as a result of sustained developmental delay.[5]

Originating in childhood, a developmental disorder has been defined as a chronic condition that manifests as an impairment that is psychological, cognitive, communicative, or physical in nature.[6] Developmental disorders occur in up to 15% of young children.[6, 7] In children with various developmental disorders, communication delays are often first to present and lead to learning, emotional and behavioural difficulties.[8] Therefore, early identification of developmental delay followed by early intervention is essential for child health and has the potential to circumvent social-emotional problems.[9] As a result, the Canadian Paediatric Society (CPS) and American Academy of Pediatrics (AAP) recommend developmental screening in early childhood, using standardized tools.[8] In 2009, the Province of Ontario introduced the 18-month Enhanced Well-Child Visit (EWCV)[10] including the use of a developmental screening tool, as recommended by an expert panel of health care and public health professionals as well as researchers, and government ministers and directors.[8]

However, few studies have evaluated the association between early identification of developmental delay, using a standardized screening tool and later developmental outcomes.

Therefore, this thesis will seek to link two key provincial policy initiatives (the 18-month EWCV and the Early Development Instrument - EDI for all Kindergarten students in Ontario) by exploring the relationship between early child development at 18 months and school readiness at 4 to 6 years of age. This will be accomplished by identifying factors associated with a positive Infant Toddler Checklist (ITC) screen at 18 months, which occurs when either an expressive speech delay or other communication delay is present and by examining the construct and predictive validity of the ITC in identifying vulnerability on the EDI.

This study was conducted within The Applied Research Group for Kids (*TARGet Kids!* - www.targetkids.ca). *TARGet Kids!* is an ongoing open longitudinal cohort based in Toronto, Canada.[11] It is also the largest primary care practice-based research network in Canada. Children between 0 to 5 years of age are recruited and followed into adolescence. Data collected in *TARGet Kids!* includes anthropometric measures, baseline demographics based on the Canadian Community Health Survey questions, child growth and developmental measures as well as health behaviours. This cohort collects and links the data from early childhood with EDI data collected by the Offord Centre for Child Studies (OCCS). The OCCS is affiliated with McMaster Children's Hospital and McMaster University.

The following Chapter 2 consists of a review of the literature on factors associated with developmental concern or delay, an introduction to the 18-month EWCV and use of the ITC. It also includes a review of the literature on the determinants of school readiness, the use of the EDI and existing research examining early identification of developmental delay and later developmental outcomes. Chapter 3 presents the first study: *"Factors Associated with a Positive Screen on the Infant Toddler Checklist at the 18-Month Health Supervision Visit"* and Chapter 4, the second study: "*Developmental Screening using the Infant Toddler Checklist at 18 months and School Readiness as Measured by the Early Development Instrument"*. Chapter 5 concludes the dissertation with a discussion.

CHAPTER 2: REVIEW OF LITERATURE

This chapter presents a review of the literature on child development and health outcomes, the role and importance of well-child visits, in particular, the 18-month Enhanced Well-Child Visit (EWCV) and the assessment of developmental milestones. There are a number of developmental screening tools that can be completed by parents at the 18-month visit. For the purposes of this thesis, we focused on the Infant Toddler Checklist (ITC). This chapter also includes a review of the determinants of school readiness, the use of the Early Development Instrument (EDI) and existing research on early identification of developmental delay and later developmental outcomes.

2.1 Introduction

2.1.1 Child Development and Health Outcomes

Healthy development between birth to 3 years of age provides the foundation for future development and lifelong health and well-being.[12, 13] This is as a result of the brain's ability to rapidly form novel neural connections during this time and is shaped by an individual's early life experiences in addition to their genes.[14] A child's brain development is influenced by maternal health during pregnancy, exposure to infections and/or toxins, and experiences within their environment.[15] Vaccinations, newborn screening for conditions such as phenylketonuria (PKU) that are dangerous to the brain, nurturing care, access to healthy foods and stable housing along with reading, talking and playing with children aid in supporting early brain health.[15] The above factors that children are exposed to affect their health and development, across the life course and are broadly considered determinants of health.[16, 17]

The World Health Organization (WHO) has documented the importance of early child development, highlighting this period as a "window of opportunity" that could serve to improve individuals' health and equity.[1] They have categorized development in the following domains: physical, social/emotional and language/cognitive.[18] Whether a child receives nurturing care (care that is sensitive to their health and nutritional needs), early learning opportunities, responsive interactions, protection from threats and a stable environment that allows for emotional support and encourages development, greatly influences their developmental potential.[1]

In March 2005, the WHO established the Commission on Social Determinants of Health (CSDH) in the hopes of achieving global health equity by addressing social determinants of health (SDOH).[19, 20] As defined by WHO, health equity is "the absence of unfair and avoidable or remediable differences in health among population groups defined socially, economically, demographically or geographically".[21] Emphasis was placed on early child development and education in the Commission's recommendations as they noted that worldwide, approximately 200 million children were not achieving their full developmental potential.[20] Early child development is considered a determinant of health as children require nurturing, safe, supportive, and responsive living conditions to achieve their potential.[19, 21] These conditions are important for children's health and resiliency; their absence may leave children vulnerable to poor health and development in the future.[22] As noted by the Canadian Paediatric Society (CPS) and Centers for Disease Control and Prevention (CDC), chronic stressors or experiences in childhood, such as poverty, neglect or abuse and maternal mental health conditions (e.g., depression), trauma or stress may negatively affect lifelong developmental health and well-being.[5, 14, 15, 22, 23] Moreover, a discussion paper by Enns et al. noted that SDOH, for example socioeconomic status (SES), affect early child development.[24] They indicated that a portion of the inequalities related to SES, family composition and ethnicity highlighted areas requiring action and monitoring to improve child health and well-being.[24] Therefore, the field of healthcare and health indicators play an important role in child development as many families visit a health care professional routinely during pregnancy and throughout early childhood.[1, 24]

Resegue et al. conducted a retrospective study in Embu, São Paulo of 211 children followed from birth to up to 3 months to examine the association between presence of risk factors and developmental abnormalities during follow-up.[25] They found that history of perinatal asphyxia, low birthweight and young maternal age were associated with developmental abnormalities in infants.[25] Chiu et al. conducted a prospective, longitudinal cohort study in Taiwan including children birth to 18 months of age.[26] They found that breastfeeding for longer than 6 months seemed to have a protective effect on children in terms of risk of developmental delay (measured by items on the Denver Development Screening Test - DDST at 15 to 18 months) compared to those who were never breast-fed.[26] A review by Natsuaki et al. found that both maternal and paternal depression are risk factors that are environmental in nature and affect the neurobiological, emotional and behavioural development of children.[27] They also noted that maternal depression seemed to be a stronger risk factor than paternal depression for infants.[27]

A cross-sectional study by Schonhaut et al. in infants 8 or 18 months (corrected for postnatal age) examined the association between gestation age and risk of developmental delay using the Ages and Stages Questionnaires, 3rd Edition (ASQ-3) in Chile.[28] They used a convenience sample of 1,667 participants based on those who attended their routine follow up at the health center. Increased risk of developmental delay was found among children who were moderate to late preterm (32 to 36 weeks of gestation) and suggested that more research is needed to determine if this risk is transient or whether it persists throughout life and would require early intervention.[28] Additionally, Paiva et al. conducted a cross-sectional study of 136 infants 9 to 12 months of age to identify poverty levels in a low socioeconomic population in Recife, Pernambuco, Brazil and to examine its influence on the neuropsychomotor development of infants.[29] Child development was assessed using the Bayley Scales of Infant and Toddler Development, 3rd Edition (Bayley-III). They found that infants presenting with the highest frequency of suspected receptive communication delay were among families in the lowest quartile in terms of socioeconomic index.[29] Receptive communication and cognition were affected by parental unemployment.[29] Male infants also had a higher frequency of suspected receptive communication delay.[29] Further, Zhou et al. conducted a case-control study with 3,182 children to investigate characteristics of developmental delay in children 18 months of age in Beijing, China.[30] In this study, physicians completed a child developmental questionnaire (Denver Developmental Screening Test – DDST) and children were transferred to a tertiary hospital for developmental delay diagnosis.[30] Twenty-two children were found to have developmental delay, 15 of which were male. Further, children in families with low income, mothers with low levels of education and children small for gestational age were among the primary risk factors found to be associated with developmental delay.[30]

A study by Sanchez et al. compared children's language outcomes between those born less than 30 weeks gestational age (n=149) and those born at term (n=151).[31] This cohort study recruited participants from the Royal Women's Hospital and Frances Perry House (a private hospital) in Melbourne, Australia, within 2 weeks of their birth. The Bayley Scales of Infant and Toddler Development, 3rd Edition (Bayley-3) and the Communication and Symbolic Behaviour Scales: Developmental Profile – Infant Toddler Checklist (CSBS:DP-ITC) were used to assess development at 24 months.[31] They found that children born less than 30 weeks performed poorly on the social and symbolic composites of the CSBS:DP-ITC and the language scale of the Bayley-3, in particular, compared to those born at term. They also reported that male sex,

lower gestational age, hearing loss and multilingualism typically resulted in poorer language scores.[31]

Moreover, a study by Kerstjens et al. was conducted in the Netherlands as part of the Longitudinal Preterm Outcome Project focusing on preterm children's growth and development.[32] Children 43 to 49 months were included during their regularly scheduled visit at a preventive child health care centre.[32] Based on the 834 children in the final sample, they found male sex and the following three pregnancy or delivery-related maternal factors to be associated with increased risk of developmental delay, as measured by the ASQ: small for gestational age, pre-existing maternal obesity and multiple pregnancies.[32] Additionally, having more than four adverse childhood experiences has been associated with risk for development delay in at least one developmental area on the ASQ-3.[33] It has also been noted in a review by Allen that infants with multiple risk factors are at a greater risk of developmental delay.[34] Paediatric follow-up including developmental screening and early intervention programs are particularly important for these infants.[34]

Furthermore, Washbrook et al., noted that compared to children 4 to 5 years of age with native-born parents in Australia, Canada, the United Kingdom and the United States of America (USA), children of immigrants underperform in vocabulary tests.[35] Items from the Peabody Picture Vocabulary Test (PPVT) and the British Ability Scales Naming Vocabulary (BAS-NV) test were used to measure vocabulary and were scored on a "difficulty scale" by Item Response Theory (IRT) techniques.[35] This was particularly true if a language other than the official language of the above-mentioned countries was spoken in the child's home.[35] However, it was noted that overall, children of immigrants were not disadvantaged in terms of nonverbal cognitive domains and there were no notable differences in behaviour in the early years.[35]

Finally, Orri et al. conducted a population-based longitudinal study in Quebec, Canada focusing on early childhood factors and later developmental outcomes.[36] Across several studies, including children up to 8 years of age, parenting quality (maternal depression and/or harsh parenting), socioeconomic difficulties (low income and/or low maternal education) and maternal risky behaviour (alcohol and/or substance use during pregnancy) predicted poor cognitive outcomes as well as higher levels of internalizing (social withdrawal, anxiety and depression) and externalizing (hyperactivity-impulsivity, opposition and physical aggression) behaviours.[36]

2.1.2 Developmental Domains, Milestones and Delay

Child development can be determined by monitoring skill acquisition. These skills are referred to as developmental milestones, which exist across early childhood, are age specific and fall under one of the following four developmental domains: 1) Social/Emotional; 2) Language/ Communication; 3) Cognitive; 4) Movement/Physical Development.[37] Major milestones surrounding how a child learns, plays, speaks, moves and acts should be accomplished by 2, 4, 6, 9 and 18 months as well as 1 through 5 years of age.[37]

According to the CDC, the developmental milestones children should meet by 18 months of age, under the four developmental domains are as follows:

> Social/Emotional Domain: "Likes to hand things to others as play; May have temper tantrums; May be afraid of strangers; Shows affection to familiar people; Plays simple pretend, such as feeding a doll; May cling to caregivers in new situations; Points to show others something interesting; and Explores alone but with parent close by";
>
> Language/Communication Domain: "Says several single words; Says and shakes head "no"; and Points to show someone what they want";
>
> Cognitive Domain: "Knows what ordinary things are for; for example, telephone, brush, spoon; Points to get the attention of others; Shows interest in a doll or stuffed animal by pretending to feed; Points to one body part; Scribbles on their own; and Can follow 1-step verbal commands without any gestures; for example, sits when you say "sit down";
>
> Movement/Physical Development Domain: "Walks alone; May walk up steps and run; Pulls toys while walking; Can help undress themselves; Drinks from a cup; and Eats with a spoon".

The CDC also provides a reminder about general developmental and autism screening for children at 18 months.[2]

Recognizing that all children will not meet developmental milestones synchronously, if these milestones are not met within a specific age range, it could be indicative of, or raise

concerns about developmental delays or disorders that may negatively impact child development by leading to learning, emotional and behavioural difficulties.[8, 38] Communication delays are common and may be an early presentation of varied developmental disorders.[8] Other developmental delays and disorders include language delay, global developmental delay, autism spectrum disorder (ASD), intellectual disabilities and isolated expressive speech delay.[8] Identifying these delays followed by intervention in early childhood is imperative to circumvent socio-emotional problems and improve child health.[9, 38] Therefore, early and frequent developmental screening of young children has been proposed to assist in the identification of potential delay or need for further developmental evaluation.[38]

2.1.3 Developmental Surveillance, Screening and Screening Tools

Used to supplement the ongoing, non-standardized, observation of child development over time (developmental surveillance), developmental screening involves utilizing a standardized tool to detect concerns about development and potential developmental delay in populations where no overt indications of either are present.[39, 40] To ensure its effectiveness, the United States Department of Health and Human Resources recommends that developmental screening begins in early childhood and is repeated throughout the years from birth to age 5 using tools that are age appropriate in addition to being appropriate to the language and culture of a child.[38] These tools are not designed to capture the full range of development but rather distinguish those skills on the lower end of performance.[38] The ability of the tool to obtain accurate information impacts the care received and decisions made regarding a child's health and well-being.[41] Consequently, these tools typically have a sensitivity and specificity that are relatively high and are accurate in identifying developmental delay and if necessary, based on the screening results, are followed by a comprehensive evaluation process for confirmation of delay or disorder.[38, 42] Furthermore, the validity and reliability of screening tools depends on the population and language in which it is administered as well as its implementation procedures and how closely they are followed by the administrating individuals.[38]

Although developmental screening tools have been recommended by the Canadian Paediatric Society and the American Academy of Pediatrics,[8, 42-44] the Canadian Task Force on Preventive Health Care concluded that there was insufficient evidence to recommend developmental screening.[5] This is in part because screening may lead to over referral due to low

specificity/screening test accuracy and high false positives.[40] However, several developmental screening tools have been created to assess child development. In Canada, the most commonly used screening tools are the Nipissing District Developmental Screen (NDDS), Ages & Stages Questionnaires, 3rd Edition (ASQ-3), and Parents' Evaluation of Developmental Status: Developmental Milestones (PEDS/PEDS:DM).[43] The Infant Toddler Checklist (ITC) is a screening tool that is used in the USA, and one that *TARGet Kids!* has administered at ages 6 to 24 months since 2010. *TARGet Kids!* has also collected the 18-month NDDS since 2008, and the 18-month or 24-month ASQ-3 and 48-month or 60-month ASQ-3 since 2018.

The NDDS (now called the Looksee Checklist) is a 17-item parent-reported questionnaire with binary responses (yes/no) that was first developed in 1993 and revised in 2011. It was designed to monitor and promote child development in children 1 month to 6 years.[45-47] It is scored using flags with 1+NDDS flag signifying 1 or more "no" responses (i.e., child does not demonstrate the milestone) and 2+NDDS flag signifying 2 or more "no" responses.[8] Additionally, the current recommendation is a "one flag" rule indicating the need for further assessment or referral. There is no total score or subscale scores, therefore developmental level cannot be determined.[8] The administration time for this tool is less than 5 minutes. It is offered free of charge to health professionals in Canada but is for purchase in 10 languages including English, French, Spanish, Chinese, and Italian.[8, 45, 47]

The ASQ-3, a 30-item parent-reported questionnaire with 6 questions per area screened, was released in 2009. It was designed to identify socio-emotional and developmental delays in children 1 to 66 months of age.[48-50] It is scored using 5 raw scores (one for each area). Each score is compared to cut-off points to determine whether the child needs further assessment, monitoring/rescreening, or is doing well.[48] The administration time for this tool is 10 to 15 minutes and 2 to 3 minutes for scoring. It is available in several languages including English, Spanish, Arabic, Chinese, French, and Vietnamese. The English and Spanish starter kit for professional use includes 21 master questionnaires and scoring sheets, an ASQ-3 user's guide, a laminated ASQ-3 quick start guide and CD-ROM with questionnaires that can be printed at a cost of $295.00. When purchased individually, 21 master copies of the questionnaire that can be photocopied, scoring sheets and the CD-ROM cost $240.00 in English and Spanish and $175.00 in the other available languages; five sets of 4-page quick start guides cost $30.00 and the user's guide $55.00. The ASQ-3 materials kit, with approximately 20 engaging toys, books and other

items promoting child participation, costs $295.00 and the training DVD addressing screening, scoring and result interpretation costs $49.95.[48]

The PEDS:DM, released in 2007, is a 6 to 8 item (depending on the child's age) parent-reported questionnaire, used alongside the PEDS, which is a 10-item measure focusing on parental concern.[51-53] The PEDS:DM was designed to be used for developmental and behavioural screening in children from birth to 7-11 years of age.[53] It also includes supplemental measures for older children and specific populations. For example, the Modified Checklist for Autism in Toddlers - Revised (M-CHAT-R).[51, 52] A score at or below the 16th percentile indicates failure on an item, predicting difficulty in the specific domain.[54] The administration time for this tool is 7 minutes and 5 minutes for scoring. It is available in several languages including English, Spanish, Arabic, Chinese, French, Japanese, Korean, Punjabi, Swahili, Taiwanese, Tamil, and Thai.[55, 56] The cost of the PEDS:DM packages, available in English or Spanish vary from $299.00 to $439.00 United States dollars (USD) depending on its intended use.[57] The Pediatric and Public Health package ($299.00) includes the PEDS:DM laminated family book, 100 longitudinal recording forms, a scoring template, professional manual, dry erase marker, clip for page securement and binder for storage.[57] The Best Approach for Pediatric and Public Encounters package ($346.00) includes the PEDS:DM starter kit, 100 PEDS response forms, brief guide and scoring/interpretation for identifying when the PEDS should be collected and 100 PEDS:DM recording forms. When purchased individually, the PEDS:DM family book costs $130.00, recording form $57.00, professional manual $75.00 and the assessment level forms/booklet $86.00.[58] Additionally, the PEDS brief guide costs $5.00, manual $89.95, response form $19.50, scoring/interpretation forms $19.50; the complete set costs $42.00 and the discounted bulk order of 20 brief guides, 20 pads of 50 response forms and 20 pads of 50 score/interpretation forms to screen 1000 children costs $699.00.[59]

The ITC is a 1-page, 24-item, parent-completed, checklist that was developed in 2002 by Amy M. Wetherby & Barry M. Prizant and published by Paul H. Brookes publishing company incorporated.[60] It includes 7 subscales with 3 to 5 response options per question and one open question on parental concern regarding child development.[60] It was designed to detect communication delays in addition to ASD, developmental and language delays in children 6 to 24 months of age.[60] This checklist is part of the Communication and Symbolic Behaviour Scales (CSBS) and is a tool, with normative scores, that has been standardized and validated.[60] Scoring

is binary (concern or no concern) and 3 composite scores (expressive, symbolic, social) and a total score can be obtained from this tool.[60] Concern regarding expressive speech delay is based on an expressive speech composite score below the 10th percentile. Concern regarding other communication delay is based on a social composite, symbolic composite, or total score below the 10th percentile. Parent concern is based on parents reporting "yes" on the one open question and parents are invited to describe their concern in free text.[61] A positive ITC screen occurs when either an expressive speech delay or other communication delay is present.[61] The administration time for this tool is 5 minutes and the scoring time is 2 minutes.[62] It is free of charge for practitioners and it is available in several languages including English, Spanish, French, Slovenian, Chinese, German, and Swedish.[63] Additionally, available for purchase are the CSBS Manual for $66.95 USD and CSBS:DP-ITC and Easy-Score CD-ROM (with an accompanying user's guide and a result summary letter for families) enabling efficient scoring and interpretation for $99.95 USD.[64]

2.1.4 Developmental Screening Tools – Summary and Screening Test Properties

Box 1 presents a summary of the data and properties of the aforementioned developmental screening tools for developmental delay, including estimates of their criterion validity and reliability.

Cairney et al. and the CPS found that the NDDS had a low concurrent criterion validity using the Bayley Scales of Infant Development - BSID (3rd edition) as the criterion measure and a moderate test-retest reliability within a 2-week interval.[46, 65] Additionally, when compared to the ITC, van den Heuvel et al. found that the 1+NDDS flag had good sensitivity and poor specificity and the 2+NDDS flag had low to fair sensitivity and good specificity when identifying speech and communication delays. Both studies recommended that the NDDS should not be used on its own to screen for developmental delay.[8, 46]

Sheldrick et al., reported that the ASQ-3 had a low to moderate concurrent criterion validity using the Bayley Scales of Infant and Toddler Development, 3rd Edition (Bayley-III); the Battelle Developmental Inventory (BDI), 2nd Edition and the Differential Ability Scales, 2nd Edition (DAS-II) as the criterion measures.[41] Also, Squires et al. reported that the ASQ-3 had moderate to high test-retest reliability within a 2-week interval and interobserver reliability as completed by two administers who were independent to the test.[66]

Warren et al. reported that the PEDS has a low to moderate concurrent criterion validity based on clinical-diagnostic evaluation of ASD or developmental delay[67] while Vameghi et al. reported that the PEDS has a moderate to high test-retest reliability within a two to three week interval and Cronbach's alpha coefficent.[68] Sheldrick et al. reported that the PEDS:DM has a low to moderate concurrent criterion validity using the Bayley-III; the BDI, 2nd Edition and the DAS-II as the criterion measures.[41] Additionally, the PEDS:DM has a very high test-retest reliability within a two to four week interval and inter-method (parent-reported, interview or hands-on) reliability.[69]

Wetherby et al. carried out several validation studies of the ITC. They found that the ITC has moderate to strong criterion validity when screening for communication delays.[70-72] Children in a Behaviour Sample underwent a communication evaluation performed by a trained examiner, and included children performing in the bottom 10th percentile and a random selection of those with a negative ITC screen and/or parent concern.[70] The evaluation uses a set of systematic procedures that are standardized and designed to encourage a range of spontaneous behaviours within the provided structure.[70] The child is presented with various items such as a balloon, bubbles, and a jar with food and toys to entice communication and symbolic or constructive play. Children also receive gaze/point-following probes and their comprehension of a person's, body part or object's name is assessed.[70] Wetherby et al. also found that the ITC has a high to very high inter-rater reliability using a normative sample of 337 children.[70-72] Scores from 5 independent raters, using randomly selected videotapes of the Behaviour Sample, were compared to calculate inter-rater reliability, expressed using generalizability (g) coefficients.[71] The g coefficient was chosen to estimate this reliability as it "accounts for error other than individual differences or measurement error".[71]

Screening Tool	Age	Cost	Criterion Validity	Reliability
NDDS[8, 46, 65]	1 month to 6 years	Free of charge	**Low to Moderate** Bayley Scales of Infant Development, 3rd Edition: Sensitivity 29-68% and Specificity 58-88% ITC: Sensitivity 86-94% (1+ flag); 50-73% (2+ flag) and Specificity 63% (1+ flag) and 86-88% (2+ flag)	**Moderate** Test-retest Reliability: .62 (Spearman's rho)
ASQ-3[41, 48, 66, 73]	1 to 66 months (5.5 years)	Not free of charge	**Low to Moderate** Bayley Scales of Infant and Toddler Development, 3rd Edition, the Battelle Developmental Inventory, 2nd Edition and Differential Ability Scales, 2nd Edition: Sensitivity 24-60% and Specificity 89-92%	**Moderate to High** Test-retest Reliability: .75 to .82 Inter-observer Reliability: .43 to .69
PEDS[67, 68]	Birth to 8 years	Not free of charge	**Low to Moderate** Clinical-diagnostic evaluation of ASD: Sensitivity 57% and Specificity 41% Clinical-diagnostic evaluation of developmental delay: Sensitivity 41% and Specificity 89%	**Moderate to High** Test-retest Reliability: .87 Cronbach's alpha: .63
PEDS:DM[41, 53, 69]	Birth to 7-11 years	Not free of charge	**Low to Moderate** Bayley Scales of Infant and Toddler Development, 3rd Edition, the Battelle Developmental Inventory, 2nd Edition and Differential Ability Scales, 2nd Edition: Sensitivity 61-89% and Specificity 13-43%	**Very High** Test-retest Reliability: >90% Inter-method Reliability: 92%
ITC[70-72]	6 to 24 months	Free of charge	**Moderate to Strong** Infant-Toddler Checklist and Behavior Sample: Sensitivity 86-89% and Specificity 75-77%	**High to Very High** Inter-rater Reliability: .76 to .97 for composites and .92 to .97 for composites and total (*g* coefficients)

Box 1. Summary and Screening Test Properties of Developmental Screening Tools

2.1.5 Health Surveillance Visits and the 18-month Enhanced Well-Child Visit

Primary health care, especially in early childhood, should include health surveillance visits. These visits typically align with the immunization schedule and have been described as a "comprehensive health and development surveillance program focused on promoting healthy development for all children".[74] Consequently, they typically occur at the following times: 2 weeks (no immunization in Ontario); 1 month (no immunization in Ontario); 2 months; 4 months; 6 months; 9 months (no immunization in Ontario); 12 months; 15 months; 18 months; 2 years (no immunization in Ontario); 3 years (no immunization in Ontario); 4 years; 5 years; 6 years.[74-76] Developmental screening tools are completed by parents/caregivers during these visits to obtain an idea of a child's development and is the basis for discussion surrounding their development.[77] This provides the opportunity for infant growth and development to be monitored by primary care providers. Additional aims of these visits are to address any parental concerns, assess family health and interactions between parents and child, counsel families regarding nutrition, safety, development and community resources and identify risks or issues requiring action.[74]

The 18-month visit should be of particular focus as this age is crucial in terms of healthy child development. Children begin speaking and detection of early signs of communication issues become possible.[74] Detection of developmental delay or disorders such ASD during this time can make the difference for a child in terms of their future health and well-being.[74] This visit is also the last time primary care providers see almost all young children in their respective practices, outside of the recommended but optional health surveillance visits at 2 to 3 years of age. The remaining visits are usually for immunizations, which are required for school, at 4 years of age or older or when a child falls ill.[74, 76] The idea was brought forth to broaden the current 18-month well-child visit to include increased discussion regarding the enhancement of healthy child development, a deeper assessment of a child's development to date and provide families with information and referrals to assist with connecting to programs and services in their community.[74]

Accordingly, the 18-month EWCV was introduced in 2009 as recommended by an expert panel of health care and public health professionals, researchers and government ministers and directors in Ontario.[8] This visit includes a developmental evaluation (screening)

and review by parents and primary care providers, a discussion about healthy child development and behaviour between parents and primary care providers, timely referrals to required services, and parenting and community program information regarding promoting early learning and child development.[74] The Ontario Ministry of Health introduced a new Ontario Health Insurance Plan (OHIP) fee code, reimbursing primary care practitioners for a more in-depth 18-month visit as a means of encouraging the use of standardized developmental screening tools on all children.[43, 74, 77] The Ministry recommended using the NDDS and ensured that it would be available to practitioners free of charge.[74, 77] Therefore, the 18-month visit provides an opportunity to discuss and enhance the developmental health and well-being of children by establishing effective partnerships among primary care providers, parents and community services.[74, 77] Since its inception, the EWCV resulted in increased uptake of screening from 39% to 61% in 2017.[10] Guttman et al. noted that clinically important differences related to this screening included the fact that a greater proportion of children who lived in lower income neighbourhoods, rural areas and who were born to teenage mothers (less than 19 years of age) at the birth of their first child were not screened.[10] Additionally, screening was less likely to occur in very low birth weight infants.[10]

2.2 School Readiness

2.2.1 Determinants of School Readiness

Once defined based on a child's chronological age, specific skills and competencies, children's readiness to learn is multi-faceted and now broadly understood as the outcome of the early years. This is not solely based on cognitive skills but is a holistic concept including developmental areas such as cognitive, physical and socio-emotional. As children approach school age, their development has been influenced by their families, neighbourhood and the broader society.[16]

In *TARGet Kids!*, the Fit for School, Fit for Life study investigates child health and school readiness in an ongoing prospective cohort study.[78] This study looks at child growth patterns using body mass index (BMI) and other health trajectories such as nutrition, cardiometabolic risk, health behaviours and development. *TARGet Kids!* Early Development Instrument (EDI) data was collected as part of this study from April 2014 to March 2020.[78] Since early health and developmental trajectories in children are imperative for successful

school transition, the Fit for School study will contribute to improving kindergarten outcomes through primary care practices.[78]

2.2.2 The Early Development Instrument (EDI): A Population-based Measure for Communities

The EDI is a 103-item survey developed in 1999, released in 2000 and modified in 2002 by the Offord Centre for Child Studies (OCCS) at McMaster University.[79, 80] As a holistic kindergarten teacher-completed measure of the developmental health of children between 3.5 to 6.5 years of age, it provides an indicator between early childhood and school-age that can be used to inform research and policy, along with other indicators, regarding early years outcomes and predictors of later development.[79] It assesses the skills and behaviours contributing to a child's school readiness across the 5 domains of child development.[79, 81] These developmental domains are 1) Physical Health & Well-Being (13 items), 2) Social Competence (26 items), 3) Emotional Maturity (28 items), 4) Language & Cognitive Development (26 items) and 5) Communication Skills & General Knowledge (8 questions).[79, 81] In 2014, the Ontario Ministry of Education mandated collection of the EDI in the public school system throughout the province every 3 years, in year-two of kindergarten (i.e., Senior Kindergarten).[78]

With the exception of the Communication Skills & General Knowledge domain, each domain is divided into subdomains representing behaviours and skills used to explore a child's strengths and weaknesses.[82] The Physical Health & Well-being subdomains include gross and fine motor skills, physical independence and physical readiness for the school day.[82, 83] The Social Competence subdomains include responsibility and respect for adult authority, readiness to explore new things, approach to learning curiosity and overall social competence.[82, 83] The Emotional Maturity subdomains include pro-social and helpful behaviour (thinking prior to acting, concentration, ability to age-appropriately address feelings, and ability to express empathy), aggressive behaviour, anxious and fearful behaviour and inattentive and hyperactive behaviour.[82, 83] The Language & Cognitive Development subdomains include basic literacy, basic numeracy and advanced literacy as well as interest in literacy/numeracy and memory.[82, 83] In general, the Communication Skills & General Knowledge domain includes skills for socially appropriate communication, storytelling, symbolic use of language and some knowledge regarding life and the world.[83]

Sample EDI questions asked in each domain are as follows: In the Physical Health & Well-Being domain, “Would you say that this child is well coordinated (moves without running into things or tripping over things)?”; in the Social Competence domain, “Would you say that this child is able to follow one-step instructions?”; in the Emotional Maturity domain “Would you say that this child comforts a child who is crying or upset?”; in the Language & Cognitive Development domain, “Would you say that this child is able to read simple words?”; and in the Communication Skills & General Knowledge domain, “How would you rate this child’s ability to tell a story?”.[79]

The format of the EDI is as follows: page 1 includes child demographic variables (date of birth, sex, postal code, first language, language status, French or other immersion status, student status, special needs status, class assignment and EDI date of completion); pages 2 through 8 include questions regarding the 5 domains, which form the results, and special concerns (skills/problems); pages 8 and 9 include questions about children’s pre-kindergarten experience (early intervention, preschool and child care).[84]

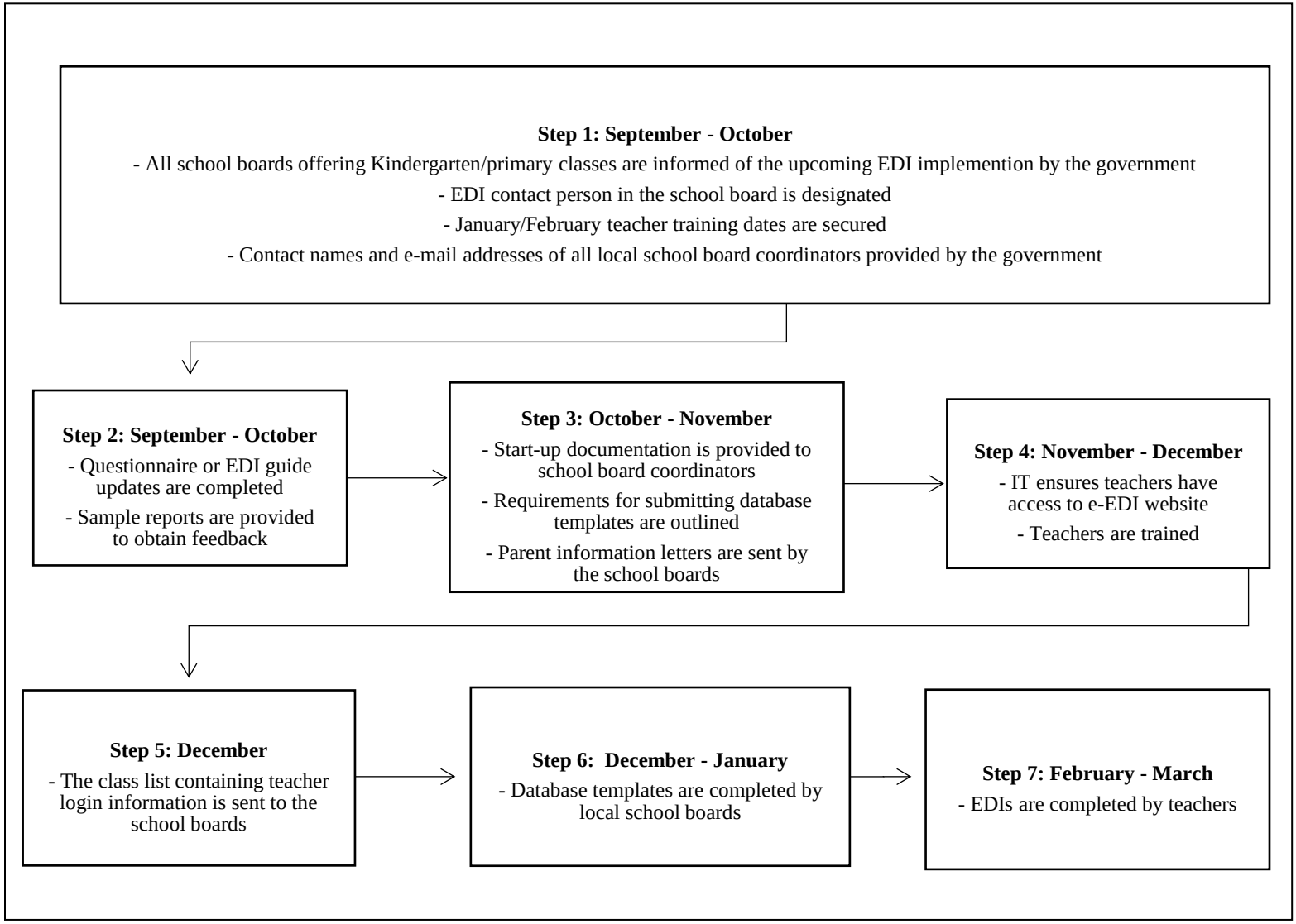
2.2.3 EDI Validity and Reliability

Available in both English and French and on an electronic EDI platform, this population-level research tool is a validated instrument that is predictive of child well-being, social relationships and academic achievement.[79, 81, 82] Janus & Offord reported consistent low to moderate relationships when concurrent criterion validity of the EDI was determined in comparison with parent interviews about child behaviour as well as direct language tests.[81] The Pearson correlations of the Language & Cognitive Development and Communication Skills & General Knowledge domains with the Peabody Picture Vocabulary Test – PPVT (0.31 and 0.47, respectively) were used to assess concurrent criterion validity.[81] The inter-rater reliability of the EDI as determined by comparing correlations between kindergarten teachers and early childhood educators (ECE) and between teachers and parents ranged from 0.53 to 0.80 and 0.36 to 0.64, respectively.[81] All correlations were significant.[81]

2.2.4 EDI Implementation Process

Typically, the EDI is implemented in the second half of the second year of kindergarten (i.e., Senior Kindergarten) as the teacher will be familiar with the students and can efficiently

complete the instrument after allowing children time to assimilate to the school environment and catch up to their peers. This ensures that only those deemed vulnerable based on the instrument truly are and still demonstrate some weakness prior to starting grade school.[79] However, in *TARGet Kids!*, the EDI was implemented every year for both Junior and Senior Kindergarten between 2015 and 2020. **Box 2** includes a detailed description of the EDI implementation process by the OCCS.[82]



Box 2. EDI Implementation Process

2.2.5 EDI Scoring and Normative Data

The EDI is scored by providing children with a score on each of the 5 developmental domains. Each child's scores are then averaged and grouped to obtain an overview of children's developmental status across schools, cities, provinces/states and countries and can be beneficial to educators, researchers and government.[79] More specifically, in the Physical Health & Well-being domain, 10 questions are answered on a 5-point scale ranging from excellent to very poor or never to always.[81] The answers are scored in intervals of 2.5 (10, 7.5, 5, 2.5, 0), with 10 being the best and 0 the worst. Three questions in this domain are scored as "yes" (10) and "no" (0).[81] Furthermore, all answers are scored on a 3-point scale (10 – often or very true, 5 – sometimes or somewhat true, and 0 – never or not true) for the Social Competence and Emotional Maturity domains.[81] All scores in the Language & Cognitive Development domain are scored on a 2-point scale (10 – "yes" and 0 – "no") according to whether a child possess a skill.[81] Seven answers in the Communication Skills & General Knowledge domain are scored on a 5-point scale from very poor (0) to excellent (10) in intervals of 2.5 and the remaining answer is scored on a 3-point scale (10 – often, 5 – sometimes and 0 – never). However, the EDI has no total score as the domains are not cumulative. This facilitates the identification of the specific area(s) in which a child is experiencing difficulty.[82]

The distribution of scores was derived from the baseline collection of EDI data, which is a site's (school's) first full implementation of the EDI (collected over one or several years).[82] The cut-off scores for children are as follows: 1) "On Track" refers to a score above the 25th percentile of baseline scores; 2) "At Risk" refers to a score between the 10th and 25th percentile of baseline scores and 3) "Vulnerable" refers to a score below the 10th percentile, based on the Ontario Normative population, in any of the 5 domains.[81, 82] Janus & Offord found that approximately 27% of Canadian children were vulnerable in at least one of the 5 domains.[82] More specifically, 34% of male and 20% of female children were vulnerable in at least one of the 5 domains.[85]

2.2.6 Global EDI Collection

In Canada, the EDI was first collected and tested for cultural validity in North York, Ontario in 1998.[79, 80] It has since been implemented in 12 of 13 provinces and territories in Canada, with the exception being Nunavut. Data have been collected for 1.1 million children across the country.[79, 85]

Internationally, the EDI has been implemented, piloted or in planning stages in 32 countries including the United States of America, Mexico, Chile, Australia, Brazil, Peru, Ireland, Scotland, Estonia, Jordan, Kyrgystan, Vietnam, Jamaica, Trinidad, Sweden, Netherlands, Germany, Italy, Greece, Moldova, Kosovo, Pakistan, Ethiopia, Malawi, Mozambique, South Korea, Hong Kong, Cambodia, Philippines, Indonesia, New Zealand and Barbados.[79]

2.3 Early Identification of Developmental Delay and Later Developmental Outcomes

In the literature, studies have been conducted that compare early identification screening tools such as the ITC and the Quantitative Checklist for Autism in Toddlers (Q-CHAT)[86] as well as the ITC and the MacArthur Communicative Development Inventories (CDI-SF)[87] for construct validation purposes. Other available studies include the use of developmental screening tools in those who already have a diagnosis such as ASD at 12 to 24 months[88] in addition to using the EDI to predict later development outcomes in grade school.[89] However, few studies have examined the relationship between early identification of developmental delay using a standardized screening tool and later developmental outcomes. A study by Crowe et al. examined the relationship between the BSID scores during the first 2 years of life and cognitive and motor performance at 4.5 years as measured by the Wechsler Preschool and Primary Scale of Intelligence (WPPSI) and the Peabody Developmental Gross Motor Scale (PDGMS), respectively.[90] The sample of children used were identified as "biologically high risk" at birth.[90] At 12 months, the BSID mental scale scores were related to motor and cognitive measure scores in preschool children and at 24 months, BSID scores were related to cognitive measure scores only.[90] However, the correlation coefficients had small magnitudes suggesting that caution should be applied when the BSID is used to predict later preschool performance.[90]

Additionally, a study by Borkhoff et al. in *TARGet Kids!* evaluated the association between a positive ITC screen at 18 months and 1) parent-reported developmental diagnosis at 3 to 10 years, and 2) parent-reported school concern and 3) parent-reported receipt of additional school resources.[91] Of the final sample of 540 children, 48 (8.9%) had a positive ITC screen and at follow-up, 26 (4.8%) had a parent-reported developmental disorder. They found that the odds of children with a positive ITC screen at 18 months with a later parent-reported developmental diagnosis was 4.75 times that for children with a negative ITC screen. In addition, a positive ITC screen was associated with an increased odds of later parent-reported school concern for development and receipt of additional school resources. The reported screening test properties of the ITC screen at the 18-month visit, using parent-reported developmental diagnosis at 3 to 10 years as the criterion measure were: 31% sensitivity, 92% specificity, false positive rate of 8%, positive predictive value of 17% and a negative predictive value of 96%. The reported screening test properties of parent concern alone, using parent-reported developmental diagnosis at 3 to 10 years as the criterion measure were: 42% sensitivity, 95% specificity, false positive rate of 5%, positive predictive value of 31% and negative predictive value of 97%. Finally, the reported screening test properties of the ITC screen or parent concern, using parent-reported developmental diagnosis at 3 to 10 years as the criterion measure were: 50% sensitivity, 89% specificity, false positive rate of 11%, positive predictive value of 19% and negative predictive value of 97%. These findings demonstrated that in Canadian children, the ITC may be a promising tool for developmental screening.[91]

2.4 Summary of Review of Literature

Optimizing early child development is a priority for Ontario's child health and educational systems. This research links two key provincial policy initiatives to improve children's developmental outcomes: 18-month developmental screening (the provincially supported 18-month EWCV) and age 4 to 6 years assessment of school readiness (the provincially supported EDI in all Kindergarten students in Ontario). Earlier identification of developmental delay can lead to improvements in the health outcomes and well-being of children. However, few studies have evaluated factors associated with developmental concern or delay using a standardized screening tool as well as the association between early identification of developmental delay using a standardized screening tool and later developmental outcomes. Therefore, this thesis will identify factors associated with a positive Infant Toddler Checklist (ITC) screen, laying the

groundwork for the examination of the association between the ITC and school readiness as measured by the Early Development Instrument (EDI).

2.5 Search Strategy and Criteria

This literature review was conducted by searching MEDLINE (1950-current), to identify citations related to 1) factors associated with child development and developmental concern or delay and 2) evaluating the association between early identification of developmental delay and later developmental outcomes. An asterisk (*) was used to truncate words and yield maximum search results.

The first search began with a series of searches combining search lines and phrases. The first combination was “risk factors” AND “child development”. This was limited to “all infant (birth to 23 months)”, then further specified by AND “healthy child*” to obtain studies in which the participants were healthy children as is the case in this study. Twenty-three results were obtained for review. The second combination was “risks factors” AND “developmental concern” OR “developmental delay*”. This was limited to “all infant (birth to 23 months)”, then further specified by AND “developmental screen*” to obtain studies that used or were related to developmental screening. Twenty-six results were obtained for review. The third combination was “risk factors” AND “infant toddler checklist”, which yielded 2 results. The fourth combination was “determinants of health” AND “child development” and was further limited to “all infant (birth to 23 months)”. Twenty-two results were obtained for review. The fifth combination was “determinants of health” AND “developmental concern” OR “developmental delay*”. This was further limited to “all infant (birth to 23 months)”. Two results were obtained for review. The sixth combination was “determinants of health” AND “infant toddler checklist”. No results were yielded (see **Appendix A** for the MEDLINE search strategy).

Specific phrases were also searched. These included: “risk factors associated with child development”; “risk factors associated with developmental concern”; “risk factors associated with developmental delay*”; “factors associated with child development”; “factors associated with developmental concern” and “factors associated with developmental delay*”. Fourteen results were obtained for review (see **Appendix A** for the MEDLINE search strategy).

Overall, this search yielded 4,926 articles. As detailed above, after further specification and limitation, 89 articles were selected for review. Subsequent to title and abstract review, 23 citations were identified as potentially relevant and acquired for full article review. Of the identified 23 citations, 6 dealt with risk factors related to child development, 9 related to risk factors of developmental concern or delay and 8 determinants of health in relation to child development.

The second search began with the phrase “early identification of developmental delay*”. The next phrase searched was “later developmental outcomes” followed by “infant toddler checklist” and “early development instrument”. Finally, a series of searches were carried out combining search lines/phrases, however, no results were yielded. These combinations were as follows: “early identification of developmental delay*” AND “later developmental outcomes”; “early identification of developmental delay*” AND “early development instrument”; “infant toddler checklist” AND “early development instrument”; “later developmental outcomes” AND “infant toddler checklist”; and “later developmental outcomes” AND “early development instrument” (see **Appendix A** for the MEDLINE search strategy).

Overall, this search yielded 138 articles. Subsequent to title and abstract review, 35 citations were identified as potentially relevant and acquired for full article review. Of the identified 35 citations, 8 dealt with early identification of developmental delay, 6 with later developmental outcomes, 10 with the ITC and 11 with the EDI.

The search field codes used (.tw, kf and .mp) indicated which fields the database should search and are defined as follows: tw – title and abstract, kf – key word/heading word and mp or multi-purpose – title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier.[92]

CHAPTER 3: FACTORS ASSOCIATED WITH A POSITIVE SCREEN ON THE INFANT TODDLER CHECKLIST AT THE 18-MONTH HEALTH SUPERVISION VISIT

ABSTRACT

Background: Children's health and development is determined based on biological and genetic factors in addition to the physical, social and economic environments they experience. Characteristics such as male sex, low birthweight, low level of parent education, non-European ethnicity, low socioeconomic status, family composition and family history of mental health concern are known risk factors for developmental delay. No previous study has examined child, sociodemographic and family factors associated with a positive Infant Toddler Checklist (ITC) screen at the 18-month health supervision visit.

Objective: The study objective was to identify child, sociodemographic and other family factors associated with a positive ITC screen at the 18-month visit.

Methods: A cross-sectional study of healthy Canadian children seen in primary care through the *TARGet Kids!* practice-based research network in Toronto, Canada was conducted. Parents completed standardized questionnaires and the 24-item ITC at the 18-month visit. An ITC screen is positive if there is concern for expressive speech delay and/or other communication delay. Multivariable logistic regression models were used to examine risk factors associated with a positive ITC screen.

Results: Of the 2,188 children (1,193 males, 995 females) in the study sample, 285 (13%) had a positive ITC screen. We found evidence of an association between male sex, lower birthweight, family income less than $40,000 compared to $150,000 or more and having 2 or more siblings and a positive ITC screen. Male sex (adjusted odds ratio [aOR] 1.74, 95% CI (1.19, 2.55), p=0.004), family income less than $40,000 compared to $150,000 or more (aOR 4.16, 95% CI (2.25, 7.70), p=<0.0001), and having 2 or more siblings (aOR 2.05, 95% CI (1.18, 3.58), p=0.011) resulted in higher odds of a positive ITC screen. As birthweight increased, the odds of a positive ITC screen was lower (aOR 0.58, 95% CI (0.44, 0.75), p=<0.0001).

Conclusion(s): Among healthy urban children seen by a primary care provider at the 18-month visit, we identified several risk factors for a positive ITC screen. These findings will be of importance for clinicians, parents and policy makers as children who may be at risk of having a positive ITC screen should be closely monitored and early intervention may be beneficial.

3.1 Introduction

Early childhood is a critical time in human development. Overall health and well-being throughout life is predicated on healthy early child development in the physical, social/emotional and language/cognitive developmental domains.[18] External influences in early childhood affect brain development.[20] Therefore, a child's health and developmental trajectories are directly influenced by the complex interaction between biological and environmental factors.[16] This interaction begins in utero, is influenced by the quality of maternal nutrition, and continues through to birth and the early years of life.[20]

Determinants of health are factors individuals are exposed to that affect their health and development across the life course as well as that of their communities.[16, 17] These include an individual's characteristics (e.g., age, sex, genetics) and behaviours; the physical environment (e.g., access to and condition of places of work and living as well as basic nutritional needs), social environment (e.g., social status and support networks, race/ethnicity) and economic environment (e.g., income, access to health services).[17] These environments interact with each other and individuals at multifaceted levels of influence.[16]

The social and economic factors within the determinants of health are referred to as social determinants of health (SDOH).[93] Social determinants are of particular importance for child development and include: living conditions; family sociodemographics; access to green spaces; a safe neighbourhood; interpersonal relationship between children, parents and peers; school and daycare learning environments and socio-political context.[16] Inequalities in children's health status may arise as a result of variations in their determinants of health that range from a micro-level (parents' knowledge of health services) to macro-level (social and economic factors).[93, 94] Further, the health and developmental outcomes of children, occur along a social gradient. Therefore, children have better outcomes if their family and caregivers are further up the socioeconomic spectrum.[94] The concept of the social gradient in health has been demonstrated in the Whitehall Studies by Marmot et al.[95, 96] These studies incorporated varying employment grades (a measure of social class) of British civil servants and illustrated a stepwise relationship with mortality rates.[95-97]

In Canada, screening for developmental delay is recommended at the 18-month health supervision visit. The Infant Toddler Checklist (ITC) is a screening tool developed to identify children who have or are at risk for developing a communication impairment, including expressive speech delay and other communication disorders such as autism spectrum disorder (ASD). The purpose of this study was to identify child, sociodemographic and other family factors associated with a positive ITC screen at the 18-month visit. Identifying these factors at an earlier age may be beneficial as early intervention can improve an individual's lifelong health and well-being.

3.2 Methods

3.2.1 Participants and Study Design

This was a cross-sectional study of healthy children between 16 and 23 months of age. Children were included in the study if they had an 18-month *TARGet Kids!* (The Applied Research Group for Kids[13]) health supervision visit and a parent-completed ITC screen (the outcome). Parents also completed age-specific standardized *TARGet Kids!* questionnaires to capture data on important predictors including sociodemographic information.[98]

TARGet Kids! exclusion criteria are: children with associated health conditions affecting growth (e.g., failure to thrive, cystic fibrosis); a chronic health condition (except for asthma and high functioning autism); severe developmental delay; an unscheduled visit; and families not able to communicate in English. For the purpose of this study, children were also excluded if they were missing ITC data at baseline.

Ethics approval was obtained from the Research Ethics Board at the Hospital for Sick Children and Unity Health, Toronto. Administrative approval was also given by the University of Toronto's Office of Research Ethics (RIS Protocol Reference # 39292). Participation in the study was voluntary, parents/guardians could opt out of completing the ITC and standardized *TARGet Kids!* questionnaires.

3.2.2 Variables

3.2.2.1 Predictor Variables

The following variables were examined as potential predictors and subsequently included in the analysis based on their relationship with developmental concern, developmental delay or developmental diagnosis in previous literature: Child Factors (age at ITC (months), sex and birthweight (kg)); Sociodemographic Factors (maternal ethnicity, maternal education, family income in Canadian dollars (self-reported) and family immigration status); and Other Family Factors (siblings and family history of developmental concern (in mother, father and sibling)). To obtain this information, children's parents/guardians completed the standardized *TARGet Kids!* questionnaires.

More specifically, maternal ethnicity was determined based on geographical regions identified by the United Nations.[99] It was initially categorized into 9 categories: European (Eastern European (e.g., Polish, Russian, Croatian), Western European (e.g., English, French, Portuguese), Australian or New Zealander); East Asian (Chinese, Korean or Japanese); Southeast Asian (e.g., Vietnamese, Malaysian, Filipino or Oceania (e.g., Samoan, Fijian)); South Asian (e.g., East Indian, Pakistani, Sri Lankan or Indian-Caribbean); West Asian/North African (West Asian (e.g., Iranian, Afghan, Palestinian) or North African (e.g., Moroccan, Algerian, Egyptian, Sudanese)); African and Caribbean (East African (e.g., Ethiopian, Kenyan, Somali), Middle African (e.g., Cameroonian, Chadian, Congolese), Southern African (e.g., Botswana, South African), Western African (e.g., Ghanaian, Nigerian, Guinean) or Caribbean Region (e.g., Jamaican, Guyanese, Trinidadian/Tobagonian)); Latin American (e.g., Argentinean, Costa Rican, Mexican); Indigenous (North American Indigenous (Inuit, Métis, First Nations)) and Mixed (if parents responded with two or more ethnic groups) and later categorized as European and Non-European. Maternal education was determined based on parent-reported highest level of educational attainment. Family income was collected in the following 4 categories: less than $40,000; $40,000 to $79,999; $80,000 to $149,999 and $150,000 and greater. The lowest and the lower middle income categories approximate Toronto, Canada's low income cut-off (CAD $44,266 [$32,684] for a 4-person household) and the median family income (CAD $82,859 [$61,180] for a 4-person household).[100] Family immigration status was divided into 3 categories: non-immigrants, immigrants from

industrialized regions and immigrants from non-industrialized regions base on UNICEF's World Regions.[101] This was determined based on responses to the questions: "Where were your child's biological parents born?" and "Where was your child born?" If either parent or the child was not born in Canada, the child was considered to be from an immigrant family and the child was classified as a 'non-industrialized immigrant' if at least one parent was from a non-industrialized country. Additionally, siblings refer to the number of siblings a child has, categorized as zero, one or two or more. Finally, family history of developmental concern included Autism Spectrum Disorder (ASD), Attention-Deficit/Hyperactivity Disorder (ADHD), or learning disability in the mother, father, or siblings.

3.2.2.2 Outcome Variable

The 24-item ITC, a developmental screening tool, was completed at the 18-month health supervision visit in *TARGet Kids!*. The outcome was a positive ITC screen, which refers to concern for expressive speech delay (defined as an expressive speech composite score below the 10th percentile) and/or other communication delay (defined as a social composite, symbolic composite, or total score below the 10th percentile).[60, 102]

3.2.2.3 Other Variables (Demographic Characteristics)

Gestational age and body mass index z-score (zBMI) were also included as participant demographic characteristics. Gestational age was collected via the standardized *TARGet Kids!* questionnaires. In terms of child zBMI, anthropometric measurements were collected by trained research assistants. Height/length (m) and weight (kg) were used to calculate BMI (kg/m^2). BMI was then standardized by age and sex according to the World Health Organization (WHO) growth standards to obtain a zBMI. zBMI scores from the sample population were further categorized into 5 weight categories, according to the WHO growth standards: underweight (BMI z-score [zBMI] <-2), healthy-weight ($-2 \leq z \leq 1$), at-risk-of-overweight ($1 < z \leq 2$), overweight ($2 < z \leq 3$), and obese ($z > 3$).[103]

3.2.3 Statistical Analysis

3.2.3.1 Data Review & Cleaning

Prior to data analysis, all variables in the dataset were examined for missing, implausible, or duplicate values. Subsequent to merging the data, participants were retained or excluded based on the eligibility criteria. The distribution of all continuous variables was examined based on visual inspection of boxplots, histograms and Q-Q plots as well as the Kolmogorov-Smirnov test to determine normality. Non-normal continuous variables were identified based on visual analysis and a statistically significant ($p<0.05$) Kolmogorov-Smirnov test, as the sample size was greater than 2,000.

Histograms revealed a symmetric and normal distribution for birthweight and zBMI. Box plots also revealed a symmetric distribution and data were aligned to the diagonal with minimal deviations in the Q-Q plots. The values for skewness and kurtosis were as follows: birthweight (-0.51 and 1.15) and zBMI (0.03 and 0.49) and the Kolmogorov-Smirnov test was significant for both birthweight and zBMI ($p<0.0100$). Although the Kolmogorov-Smirnov test value would suggest that our sample provided evidence to reject the null hypothesis that the data were normally distributed, based on visual inspection the data approximate a normal distribution. In addition, histograms revealed a non-symmetric distribution for age at ITC. Box plots also revealed a non-symmetric distribution and data deviated from the diagonal in the Q-Q plots**.** The values for skewness and kurtosis were 1.71 and 4.41, respectively. The Kolmogorov-Smirnov test was significant ($p<0.0100$) suggesting that our sample provided evidence to reject the null hypothesis that the data were normally distributed. However, Central Limit Theorem states that regardless of the populations probability distribution, if the sample size is large enough, the average calculated will approximate a normal distribution.[104]

3.2.3.2 Participant Characteristics

The continuous variables (age at ITC, birthweight (kg) and zBMI) were described by mean and standard deviation (SD). The remainder of the variables: sex; maternal ethnicity; maternal education; family income; family immigration status; siblings; family history of developmental concern (in mother, father, or siblings) and the 5 components of the ITC were categorical and described as frequencies and percentages. Results were also stratified by ITC screen status.

3.2.3.3 Primary Objective: Unadjusted & Adjusted Logistic Regression Analysis

To determine the association between the potential predictors and a positive ITC screen at the 18-month visit [binary outcome], unadjusted and adjusted logistic regression analyses were used. Unadjusted logistic regression models were used to compare each potential predictor (child age at ITC, sex, birthweight, maternal ethnicity, maternal education, family income, family immigration status, siblings and family history of developmental concern) with the outcome. The unadjusted logistic regression model was built using the following equation: **$\text{Log } (p_i/(1-p_i)) = \log(\text{odds of a positive ITC screen}) = \beta_0 + \beta_1 * \text{predictor}_i$.**

The adjusted logistic regression model included all potential predictors regardless of statistical significance.[105] The equation for the adjusted logistic regression model was: **$\text{Log } (p_i/(1-p_i)) = \log(\text{odds of a positive ITC screen}) = \beta_0 + \beta_1X_1 + \beta_2X_2 + \beta_3X_3 + \ldots + \beta_kX_k$.** Where k, is the number of regression parameters in the model. The 4 key assumptions of the final model were verified. The model fit was assessed using the c-statistic and Hosmer-Lemeshow Goodness-of-Fit test. Multicollinearity was assessed and deemed present with a variance inflation factor (VIF) >4. If multicollinearity was present, a stepwise variable reduction based on clinical guidance was conducted in order to remove collinear variables. The presence of influential outliers was assessed by examining the Pearson/Deviance residual and DFBeta plots. The assumption of independence was not formally tested; however, only a single ITC visit per subject was kept in the data. Therefore, it was assumed that observations were independent.

3.2.3.4 Level of Significance and Software

A $p<0.05$ level of significance was used for all hypothesis tests, and statistical tests were two-sided. All statistical analyses were conducted using SAS 9.4 statistical software (SAS Institute, Cary, North Carolina).[106]

3.3 Results

3.3.1 Participant Flow

A total of 2,998 children were eligible participants, with a visit at 16 to 23 months of age. Of those eligible, 810 (27%) were excluded as they were missing ITC data at baseline. The total

number of participants with a parent-completed ITC screen was 2,188 (73%), of which, 285 (13%) had a positive ITC screen and 1,903 (87%) had a negative ITC screen **(Figure 3)**.

3.3.2 Descriptive Statistics

Table 1 summarizes the baseline characteristics of children in *TARGet Kids!* with (n=2188) and without (n=810) an ITC. Children with an ITC, compared to those without an ITC, were younger (mean (SD) age at ITC 18.2 months (1.0) vs. 19.0 months (2.0)), had a lower mean (SD) zBMI (0.2 (1.1) vs. 0.9 (18.0)), had a higher percentage of mothers with European ethnicity (n=1192 (62%) vs. n=295 (53%)) and had a lower percentage with a low family income (<$ 40,000: n=192 (9%) vs. n=48 (20%)). Otherwise, children in *TARGet Kids!* with an ITC appeared similar to children who did not have an ITC. We also found that there was a higher rate of missing data among all variables in children without an ITC.

Table 2 summarizes the overall participant characteristics as well as participant characteristics by ITC screen status. Participant characteristics and health behaviours differed based on status. Children with a positive ITC screen, compared to those with a negative ITC screen, had a similar age at ITC (mean (SD) 18.3 months (1.1) vs. 18.2 months (1.0)), were mostly male (n=193 (68%) vs. n=1000 (53%)) and had a slightly lower mean (SD) birthweight (3.1 (0.7) vs. 3.3 (0.6)). Children with a positive ITC screen, compared to those with a negative ITC screen, also had a lower percentage of mothers with European ethnicity (n=121 (48%) vs. n=1071 (64%)), a lower percentage of mothers with a College/University education (n=249 (90%) vs. n=1747 (94%)), a higher percentage with a lower family income (<$ 40,000: n=57 (21%) vs. n=135 (7%); $40,000 – $79,999: n=54 (20%) vs. n=242 (13%)) and a lower percentage with a higher family income ($80,000 – $149,999: n=80 (29%) vs. n=630 (34%); ≥$150,000: n=85 (31%) vs. n=839 (46%)). Children with a positive ITC screen, compared to those with a negative ITC screen, had a lower percentage of families with an industrialized immigrant status (n=17 (9%) vs. n=183 (15%)) and a higher percentage of families with a non-industrialized immigrant status (n=85 (46%) vs. n=356 (29%)). Of children with a positive ITC screen, a lower percentage had no siblings, a similar percentage had one sibling and a higher percentage had 2 or more siblings, compared to those with a negative ITC screen (0: n=134 (48%) vs. n=975 (53%); 1: n=107 (38%) vs. n=688 (37%); 2 or more: n=39 (14%) vs. n=193 (10%)). Children with a positive ITC screen had a slightly higher percentage of family history of

developmental concern (n=29 (11%) vs. n=178 (10%)). Finally, children with a positive ITC screen, compared to those with a negative ITC screen had a higher percentage of parent concern (n=59 (21%) vs. n=90 (5%)).

3.3.3 Analysis

Table 3 depicts unadjusted and adjusted logistic regression models for the association between the potential predictors and the primary outcome (a positive ITC screen). In the adjusted model (complete case analysis n=1129), evidence of an association was found between sex, birthweight (kg), family income less than $40,000 compared to $150,000 or more, and having 2 or more siblings and a positive ITC screen. Male sex (adjusted odds ratio [aOR] 1.74, 95% CI (1.19, 2.55), p=0.004), family income less than $40,000 compared to $150,000 or more (aOR 4.16, 95% CI (2.25, 7.70), p=<0.0001), and having 2 or more siblings (aOR 2.05, 95% CI (1.18, 3.58), p=0.011) resulted in higher odds of a positive ITC screen. Additionally, as birthweight increased, the odds of a positive ITC screen was lower (aOR 0.58, 95% CI (0.44, 0.75), p=<0.0001). The adjusted model equation was: **Log (pi/(1-pi)) = log (odds of a positive ITC screen)** = 1.10 + (-0.14 × age at ITC) + (0.56 × male) + (-0.55 × birthweight) + (0.30 × Non-European ethnicity) + (0.22 × maternal education) + (1.43 × family income <$40,000) + (0.26 × family income $40,000 - $79,999) + (0.27 × family income $80,000 -$149,999) + (-0.11 × immigrant, industrialized) + (0.31 × immigrant, non-industrialized) + (0.34 × one sibling) + (0.72 × two or more siblings) + (0.10 × family history of developmental concern).

To assess the final model fit, the Hosmer-Lemeshow Goodness-of-Fit test was not significant (χ^2 = 6.85 (df8) p=0.553), indicating no evidence of poor model fit. The c-statistic was 0.715 indicating the model had acceptable discrimination (**Appendix B - Figure 1**). Additionally, there was no evidence of multicollinearity (no VIF >4) identified between any of the predictors included in the final model (**Appendix B - Table 1**). The distribution of the variables in the equation were not sparse based on the odds ratio estimates and their confidence intervals, therefore the model was not overspecified. Influential outliers were examined using Pearson/Deviance residuals and DFBetas (**Appendix B - Figure 2**). A few outliers existed in the final model. Due to the fact that there were few, these observations were kept in the final model.

3.4 Discussion

In this study, we identified that 13% of healthy urban children had a positive ITC screen at the 18-month health supervision visit. This prevalence of a positive ITC screen in our sample was slightly higher than the expected 10th percentile cut-off. Male sex, lower birthweight, family income less than $40,000 compared to $150,000 or more, as well as having 2 or more siblings were associated with a positive ITC screen. These results suggest that there are several important risk factors for a positive ITC screen that primary care providers should consider when screening for developmental delay in early childhood.

The strengths of this study included prospective data collection from a real-world setting. We also examined a number of child, sociodemographic and family factor variables using logistic regression models. Furthermore, our study utilized a large sample size providing statistical power and reliable results.

Limitations of this study include that causality cannot be determined due to the cross-sectional design. Additionally, our study participants were recruited from primary care practices in Toronto, Canada and may not be representative of children in other settings. Our sample had a relatively higher maternal education and family income, however, the level of income is similar to women of childbearing age in Toronto.[100] Although this was a multi-ethnic cohort, maternal ethnicity was predominantly European, which may limit the generalizability of our findings. Also, we used the ITC as our measure of developmental concern; the ITC is a screening tool rather than a formal developmental assessment. Finally, a complete case analysis was used. Therefore, a portion of the sample was removed due to missing or incomplete data.

The findings of our study were similar to those found by previous investigators:[25, 29, 31, 32] Paiva et al. conducted a cross-sectional study of 136 infants 9 to 12 months of age to identify and examine the influence of poverty levels in a low socioeconomic population on the neuropsychomotor development of infants in Brazil.[29] Child development was assessed using the Bayley Scales of Infant and Toddler Development Screening Test, 3rd Edition (Bayley-III). Male infants had a higher frequency of suspected receptive communication delay and infants presenting with the highest frequency of suspected receptive communication delay were found among families in the lowest quartile in terms of socioeconomic index.[29] Paiva et al. noted that

19 children (12%) were not in attendance for the evaluation (screening) even after being called a second time, which rendered the study sample size 136.[29]

A longitudinal community-based cohort study conducted by Kerstjens et al. focused on preterm children's growth and development in the Netherlands.[32] Children 43 to 49 months were included during their regularly scheduled visit at a preventive child health care centre.[32] Based on the 834 children in the final sample, they also found that male sex was associated with increased risk of developmental delay as measured by the Ages and Stages Questionnaire.[32] Kerstjens et al. noted that parent-reported screening tools were used to measure developmental outcomes rather than neuropsychologic tests, citing that in high-risk populations, developmental screeners are deemed reliable measures.[32] Many complex factors may have contributed to a moderately preterm birth, increasing the difficulty of assessing variables separately.[32] Additionally, the study may have been underpowered to identify associations for some rare pregnancy outcomes and the generalizability of the results may be reduced as the children not included in the analyses often had mothers born outside of The Netherlands.[32]

Resegue et al. conducted a retrospective study of 211 children in Embu, São Paulo. Children were followed from birth to up to 3 months and low birthweight was found to be associated with developmental abnormalities during follow-up.[25] They noted that the generalizability of their study may be affected as most preterm follow-up cohorts are hospitalized babies, babies from wards in several institutions or from outpatient clinics where as theirs were from a multidisciplinary clinic, making it difficult to compare to other studies.[25]

A cohort study by Sanchez et al. in Melbourne, Australia compared children's language outcomes between those born less than 30 weeks gestational age (n=149) and those born at term (n=151).[31] They found that children's performance was poor on the social and symbolic composites on the Communication and Symbolic Behaviour Scales: Developmental Profile (CSBS:DP) and on the language scale of the Bayley Scales of Infant and Toddler Development, 3rd Edition (Bayley-3) at 2 years, if they were born less than 30 weeks gestation.[31] They also found that male sex was associated with language outcomes that were worse at 2 years.[31] Sanchez et al. noted that their study may have been underpowered to detect associations as there was low medical complexity in the preterm cohort.[31] Additionally, less sensory input while in hospital as a result of preterm birth may have influenced the association with poorer language

outcomes at 2 years of age.[31] Further, they noted that the Bayley-3 typically underestimated developmental delay due to its poor sensitivity.[31]

Our study differed from the above listed studies as it was conducted in Ontario, Canada, we included infants 18 months of age and had a large sample size (n=1129). However, similarities between our study and the ones listed above include: our cross-sectional study design, which was similar to that of Paiva et al.; the use of the CSBS:DP by Sanchez et al. or a similar developmental screening tool by Kerstjens et al. to assess concern for or risk of developmental delay and the fact that children were included in the study by Kerstjens et al. subsequent to attending their regularly scheduled visit at a preventive child health care centre.

Our study demonstrated that child, sociodemographic and family factors are associated with a positive ITC screen identified at a child's 18-month health supervision visit. This is of importance for clinicians, parents and policy makers as children who may be at risk of having a positive ITC screen should be closely monitored and if delay is identified, prompt referrals to early intervention would be beneficial in improving their health and well-being. Future research may examine this association using additional factors related to child health or in a population with a broader range of family income, ethnicity and education status.

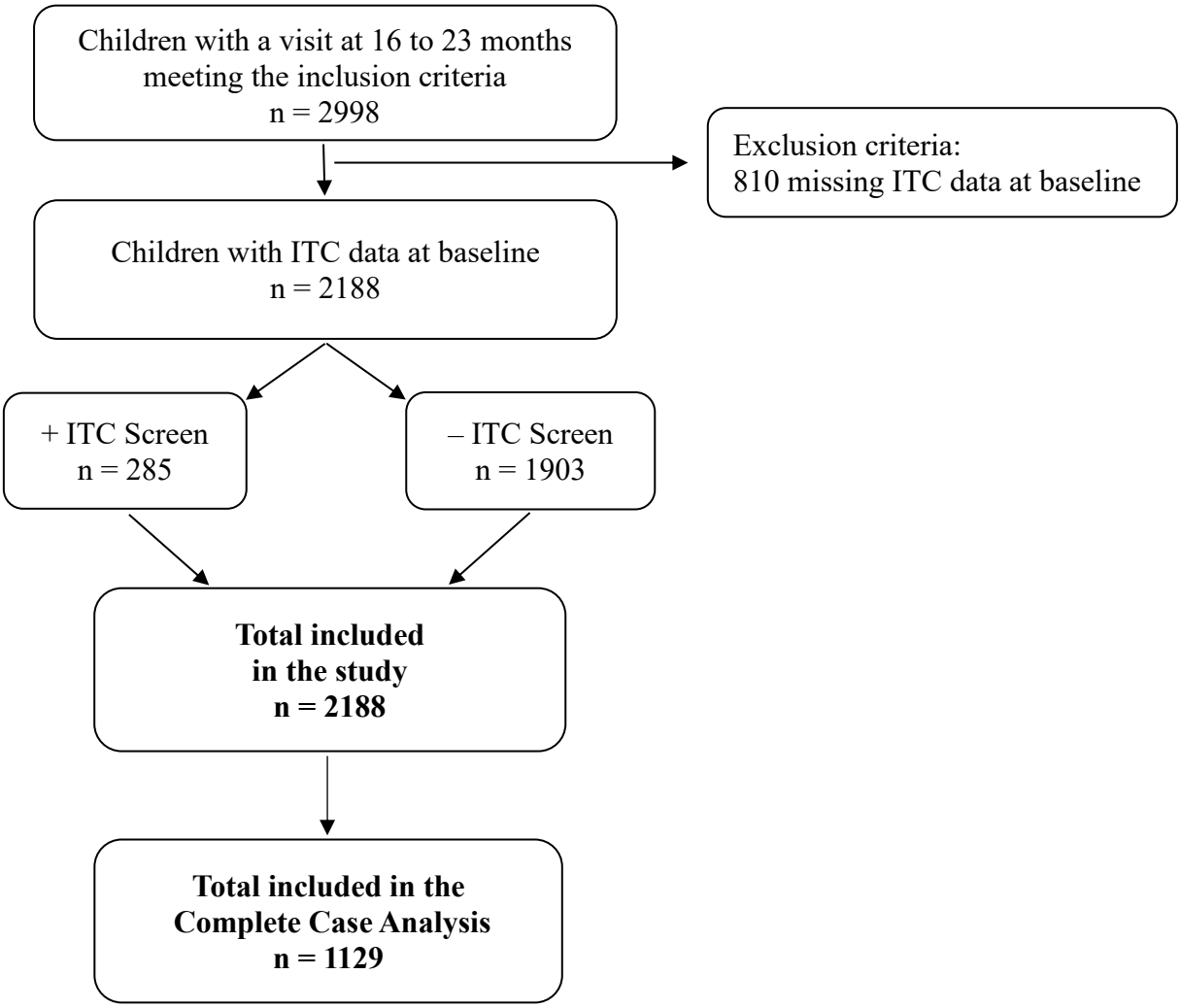


Figure 3. Study Participant Flow Chart (n=2188)

Table 1. Baseline Characteristics of Children in *TARGet Kids!* with an ITC (N=2188) and Baseline Characteristics of Children in *TARGet Kids!* without an ITC (N=810)

Characteristics		Children with an ITC		Children without an ITC
N		**2188**		**810**
Child Factors	*n*		*n*	
Age at ITC (months), Mean (SD)	2188	18.2 (1.0)		19.0 (2.0)
Sex, n (%)				
Male	2188	1193 (54.5)	805	404 (50.2)
Female		995 (45.5)		401 (49.8)
Gestational Age, n (%)				
<32 weeks	2089	24 (1.2)	595	7 (1.2)
32-36 weeks		256 (12.2)		78 (13.1)
≥37 weeks		1809 (86.6)		510 (85.7)
Birthweight (kg), Mean (SD) & n (%)		3.2 (0.6)		3.2 (0.7)
<1.25 kg		17 (0.8)		8 (1.2)
1.25 - 2.5 kg	2099	218 (10.4)	656	71 (10.8)
2.5 - 4.0 kg		1688 (80.4)		521 (79.4)
>4.0 kg		176 (8.4)		56 (8.6)
zBMI, Mean (SD) & n (%)		0.2 (1.1)		0.9 (18.0)
Underweight (z <–2)		59 (2.7)		17 (2.2)
Healthy weight (–2≤ z ≤1)	2158	1640 (76.0)	785	565 (72.0)
At Risk of Overweight (1< z ≤2)		355 (16.5)		141 (18.0)
Overweight (2< z ≤3)		86 (4.0)		52 (6.6)
Obese (z >3)		18 (0.8)		10 (1.2)
Sociodemographic Factors				
Maternal Ethnicity, n (%)				
European	1925	1192 (61.9)	555	295 (53.1)
Non-European		733 (38.1)		260 (46.9)
Maternal Education, n (%)				
Primary/High School	2133	137 (6.4)	565	27 (11.0)
College/University		1996 (93.6)		218 (89.0)
Self-reported Family Income, CAN$, n (%)				
<$ 40,000		192 (9.0)	240	48 (20.0)
$40,000 – $79,999	2122	296 (14.0)		33 (13.8)
$80,000 – $149,999		710 (33.5)		68 (28.3)
$150,000+		924 (43.5)		91 (37.9)
Family Immigration Status, n (%)				
Canadian-born	1421	780 (54.9)	222	96 (43.2)
Immigrant, industrialized		200 (14.1)		32 (14.4)
Immigrant, non-industrialized		441 (31.0)		94 (42.4)
Other Family Factors				
Siblings, n (%)				
0	2136	1109 (51.9)	243	130 (53.5)
1		795 (37.2)		83 (34.2)
2+		232 (10.9)		30 (12.3)
Family History of Developmental Concern, n (%)	2082		515	
Yes		207 (9.9)		50 (9.7)
No		1875 (90.1)		465 (90.3)

Abbreviations: BMI = Body Mass Index; ITC = Infant Toddler Checklist; SD = Standard Deviation

Table 2. Overall Study Participant Characteristics (N=2188) and Participant Characteristics for the Total Sample by ITC Screen Status

Characteristics		All Participants	ITC Screen	
			Positive	Negative
N		**2188**	**285**	**1903**
Child Factors	*n*			
Age at ITC (months), Mean (SD)	2188	18.2 (1.0)	18.3 (1.1)	18.2 (1.0)
Sex, n (%)				
Male	2188	1193 (54.5)	193 (67.7)	1000 (52.5)
Female		995 (45.5)	92 (32.3)	903 (47.5)
Gestational Age, n (%)				
<32 weeks	2089	24 (1.2)	6 (2.2)	18 (1.0)
32-36 weeks		256 (12.2)	52 (19.2)	204 (11.2)
≥37 weeks		1809 (86.6)	213 (78.6)	1596 (87.8)
Birthweight (kg), Mean (SD) & n (%)		3.2 (0.6)	3.1 (0.7)	3.3 (0.6)
<1.25 kg		17 (0.8)	6 (2.2)	11 (0.6)
1.25 - 2.5 kg	2099	218 (10.4)	46 (17.0)	172 (9.4)
2.5 - 4.0 kg		1688 (80.4)	200 (73.8)	1488 (81.4)
>4.0 kg		176 (8.4)	19 (7.0)	157 (8.6)
zBMI, Mean (SD) & n (%)		0.2 (1.1)	0.2 (1.2)	0.2 (1.1)
Underweight (z <–2)		59 (2.7)	9 (3.2)	50 (2.6)
Healthy weight (–2≤ z ≤1)	2158	1640 (76.0)	210 (74.7)	1430 (76.2)
At Risk of Overweight (1< z ≤2)		355 (16.5)	45 (16.0)	310 (16.5)
Overweight (2< z ≤3)		86 (4.0)	15 (5.4)	71 (3.8)
Obese (z >3)		18 (0.8)	2 (0.7)	16 (0.9)
Sociodemographic Factors				
Maternal Ethnicity, n (%)				
European	1925	1192 (61.9)	121 (47.6)	1071 (64.1)
Non-European		733 (38.1)	133 (52.4)	600 (35.9)
Maternal Education, n (%)				
Primary/High School	2133	137 (6.4)	28 (10.1)	109 (5.9)
College/University		1996 (93.6)	249 (89.9)	1747 (94.1)
Self-reported Family Income, CAN$, n (%)				
<$ 40,000		192 (9.0)	57 (20.6)	135 (7.3)
$40,000 – $79,999	2122	296 (14.0)	54 (19.6)	242 (13.1)
$80,000 – $149,999		710 (33.5)	80 (29.0)	630 (34.1)
$150,000+		924 (43.5)	85 (30.8)	839 (45.5)
Family Immigration Status, n (%)				
Canadian-born	1421	780 (54.9)	81 (44.3)	699 (56.4)
Immigrant, industrialized		200 (14.1)	17 (9.3)	183 (14.8)
Immigrant, non-industrialized		441 (31.0)	85 (46.4)	356 (28.8)
Other Family Factors				
Siblings, n (%)				
0	2136	1109 (51.9)	134 (47.9)	975 (52.5)
1		795 (37.2)	107 (38.2)	688 (37.1)
2+		232 (10.9)	39 (13.9)	193 (10.4)
Family History of Developmental Concern, n (%)	2082			
Yes		207 (9.9)	29 (10.7)	178 (9.8)
No		1875 (90.1)	243 (89.3)	1632 (90.2)

ITC Variables				
Positive ITC Screen, n (%)				
Expressive Speech Delay	2188	176 (8.0)	176 (61.8)	0
Other Communication Delay		176 (8.0)	176 (61.8)	0
Parent-concern, n (%)	2188	149 (6.8)	59 (20.7)	90 (4.7)
Positive ITC Screen or Parent-concern, n (%)	2188	375 (17.1)	285 (100)	90 (4.7)

*Frequency and percentage are used to represent all categorical variables.
Continuous variables are represented as Mean (SD).
Abbreviations: BMI = Body Mass Index; ITC = Infant Toddler Checklist; SD = Standard Deviation

Table 3. Logistic Regression Models for the Association between the Potential Predictor Variables and the Primary Outcome Variable (a positive ITC screen) (Total N=2188; Complete Case Analysis n=1129)

Predictor Variables		Unadjusted OR (95% CI)	p-value		Adjusted OR (95% CI)	p-value
	n			*n*		
Age at ITC (months)	2188	1.10 (0.98, 1.25)	0.105	1129	0.87 (0.72, 1.06)	0.172
Sex: Male (ref = female)	2188	**1.89 (1.46, 2.47)**	**<.0001**	1129	**1.74 (1.19, 2.55)**	**0.004**
Birthweight (kg)	2099	**0.64 (0.53, 0.78)**	**<.0001**	1129	**0.58 (0.44, 0.75)**	**<.0001**
Maternal Ethnicity: Non-European (ref = European)	1925	**1.96 (1.50, 2.56)**	**<.0001**	1129	1.35 (0.85, 2.15)	0.199
Maternal Education: Primary/High School (ref = College/University)	2133	**1.80 (1.17, 2.79)**	**0.008**	1129	1.25 (0.64, 2.45)	0.521
Income: <$40,000 (ref = $150,000+)	2122	**4.17 (2.85, 6.11)**	**<.0001**	1129	**4.16 (2.25, 7.70)**	**<.0001**
Income: $40,000 – $79,999 (ref = $150,000+)	2122	2.20 (1.52, 3.19)	0.157	1129	1.30 (0.71, 2.38)	0.396
Income: $80,000 – $149,999 (ref = $150,000+)	2122	**1.25 (0.91, 1.73)**	**0.0004**	1129	1.31 (0.82, 2.08)	0.255
Family Immigration Status: Immigrant, industrialized (ref = Canadian-born)	1421	**0.80 (0.46, 1.39)**	**0.029**	1129	0.89 (0.48, 1.66)	0.719
Family Immigration Status: Immigrant, non-industrialized (ref = Canadian-born)	1421	**2.06 (1.48, 2.87)**	**<.0001**	1129	1.36 (0.84, 2.21)	0.215
Siblings: 1 (ref = 0)	2136	1.13 (0.86, 1.49)	0.630	1129	1.40 (0.93, 2.11)	0.103
Siblings: 2+ (ref = 0)	2136	1.47 (1.00, 2.17)	0.086	1129	**2.05 (1.18, 3.58)**	**0.011**
Family History of Developmental Concern: Yes (ref = no)	2082	1.09 (0.72, 1.66)	0.671	1129	1.10 (0.59, 2.04)	0.762

Abbreviations: CI = confidence interval; OR = odds ratio
Bold = statistically significant findings at p<0.05
Income = Self-reported Family Income (CAN$)
*c-statistic = 0.715; Hosmer-Lemeshow Goodness-of-Fit test chi-square (χ^2) = 6.85 (df8) (p=0.553)

CHAPTER 4: DEVELOPMENTAL SCREENING USING THE INFANT TODDLER CHECKLIST AT 18 MONTHS AND SCHOOL READINESS AS MEASURED BY THE EARLY DEVELOPMENT INSTRUMENT

ABSTRACT

Background: In previous research, a positive Infant Toddler Checklist (ITC) screen at the 18-month visit was strongly associated with later parent-reported developmental diagnosis. No previous study has evaluated the association between a positive ITC screen with the teacher-completed Early Development Instrument (EDI).

Objectives: The primary objective of this study was to examine the construct validity of the ITC by evaluating the association between a positive ITC screen at the 18-month visit and school readiness as measured by EDI overall vulnerability among Junior Kindergarten and Senior Kindergarten children at 4 to 6 years (using logistic regression). The secondary objectives of this study were to: 1) examine the construct validity of the ITC by evaluating the association between a positive ITC screen at the 18-month visit and school readiness as measured by the mean score of each of the 5 EDI domains at 4 to 6 years (using linear regression), and 2) examine the predictive criterion validity of the ITC screen at the 18-month visit, using overall vulnerability on the EDI as the criterion measure (using screening test properties).

Methods: A prospective cohort study was conducted. Parents completed the 24-item ITC at the 18-month visit and teachers completed the EDI when the child was 4 to 6 years of age. An ITC screen is positive if there is concern for expressive speech delay and/or other communication delay. Children were considered vulnerable on the EDI if at least one of the 5 domains was below the 10th percentile. Multivariable regression models were used to examine the associations between the ITC and EDI. Bootstrap resampling was used because of skewed EDI data. Missing covariate data were addressed using multiple imputation. Screening test properties were calculated to address the final secondary objective.

Results: The final sample included 293 participants (157 males, 136 females) with a mean (SD) age at EDI of 5.3 (0.6) years. Of the 293, 30 (10%) participants had a positive ITC screen and 54 (18%) participants had overall vulnerability on the EDI. We found no evidence of an

association between a positive ITC screen and overall vulnerability on the EDI, subsequent to adjusting for the following *a priori* selected covariates: age at EDI, sex, birthweight, maternal ethnicity, family income, siblings and family history of developmental concern (adjusted odds ratio [aOR] 1.27 95% CI (0.46, 3.50), p=0.645). In the adjusted linear and hierarchical regression models, there was evidence of an association between a positive ITC screen and the Language & Cognitive Development domain (Beta coefficient [β]=-0.62, 95% CI (-1.25, -0.18), p=0.046). There was also evidence of an association between a positive ITC screen and the Communication Skills & General Knowledge domain (β=-1.08, 95% CI (-2.10, -0.17), p=0.036). Additionally, the ITC had high to very high specificity or true negative rates ranging from 88% to 95% and high negative predictive values (83% to 84%).

Conclusion(s): This study demonstrates evidence of an association between a positive ITC screen and the Language & Cognitive Development as well as Communication Skills & General Knowledge domains relating to school readiness, after adjusting for child, sociodemographic and other family factors. The ITC accurately identified children who were not vulnerable on the EDI. Therefore, the ITC is useful for "ruling in" overall vulnerability on the EDI and children with a positive ITC screen should be monitored further to ensure their readiness for school at 4 to 6 years. Earlier identification of developmental delay can lead to improvements in children's readiness for school as well as their overall health and well-being. Therefore, these results contribute to the literature and are meaningful for children and their families, clinicians and policy makers.

4.1 Introduction

Developmental disorders occur in up to 15% of young children.[6,7] However, only 30% of children with developmental delay are diagnosed prior to starting school.[107] Delayed development occurs when a child does not reach important developmental milestones in certain domains (e.g., speech and language skills) within an expected period of time.[108] Identifying children with developmental delay in infancy followed by early intervention in a timely manner is vital to child health and has the potential to circumvent social-emotional problems and improve the readiness of children for school.[9]

Developmental screening in early childhood is recommended by several leading professional organizations, including the Canadian Paediatric Society and American Academy of Pediatrics[42-44] and optimizing early childhood is a priority for Ontario's Ministry of Health and Education.[43, 74, 81, 109] However, few studies have evaluated the association between early identification of developmental delay using a standardized screening tool and later developmental outcomes. In a recent study by *TARGet Kids!* (The Applied Research Group for Kids), the odds of children with a positive ITC screen at 18 months with a parent-reported developmental diagnosis at 3 to 10 years was 4.75 times that for children with a negative ITC screen.[91] No previous study has evaluated the association between a positive ITC screen with the teacher-completed Early Development Instrument (EDI).

The primary objective of this study was to examine the construct validity of the ITC by evaluating the association between a positive ITC screen at the 18-month visit and school readiness as measured by EDI overall vulnerability among Junior Kindergarten (JK) and Senior Kindergarten (SK) children at 4 to 6 years (using logistic regression). The secondary objectives of this study were to: 1) examine the construct validity of the ITC by evaluating the association between a positive ITC screen at the 18-month visit and school readiness as measured by the mean score of each of the 5 EDI domains at 4 to 6 years (using linear regression), and 2) examine the predictive criterion validity of the ITC screen at the 18-month visit, using overall vulnerability on the EDI as the criterion measure (using screening test properties).

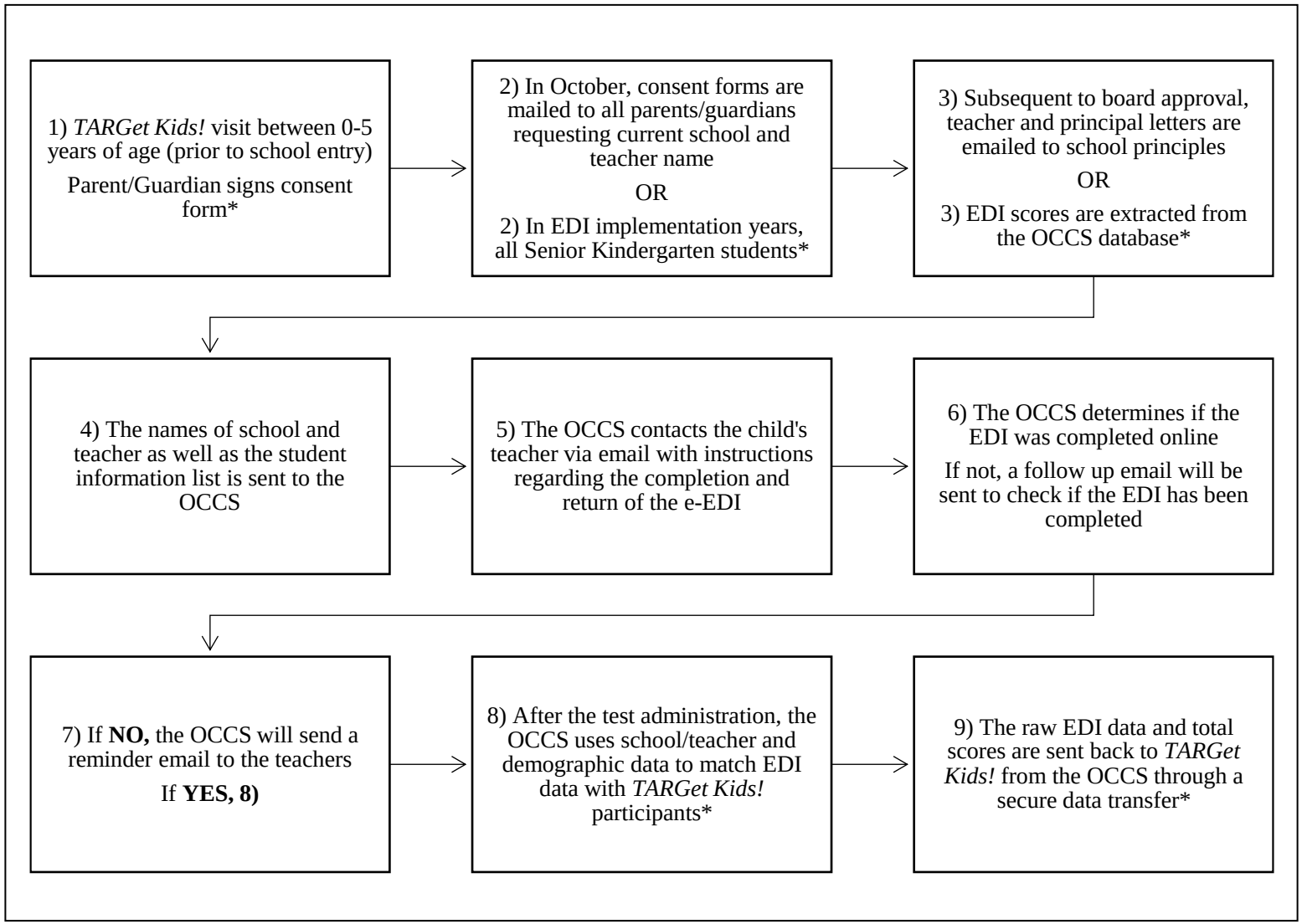
4.2 Methods

4.2.1 Study Design and Population

This prospective cohort study included healthy children between 16 to 23 months old. Children were included in the study if they had at least two visits: 1) an 18-month *TARGet Kids!* health supervision visit,[98] where the parent-completed ITC screen (the predictor) was completed and 2) an EDI visit and a teacher-completed EDI (the outcome), measured at 4 to 6 years. **Box 4** depicts the EDI recruitment process within *TARGet Kids!*.[78] Participant demographics were collected at the health supervision visits using the standardized *TARGet Kids!* questionnaires.

TARGet Kids! exclusion criteria are: children with associated health conditions affecting growth (e.g., failure to thrive, cystic fibrosis); a chronic health condition except for asthma and high functioning autism; severe developmental delay; an unscheduled visit and families who were not fluent in English. For the purpose of this study, children with a parent-report of developmental diagnosis at baseline (index visit); a gestational age less than 32 weeks and a birthweight less than 1.25 kilograms (kg) were also excluded.

Ethics approval was obtained from the Research Ethics Board at the Hospital for Sick Children and Unity Health Toronto. Administrative approval was also given by the University of Toronto's Office of Research Ethics (RIS Protocol Reference # 39292). Participation in the study was voluntary, parents/guardians could opt out of completing the ITC and standardized *TARGet Kids!* questionnaires and teachers could opt out of completing the EDI. However, no additional time was set aside for teachers to complete the EDI unless it was a provincial implementation year.



Box 4. *TARGet Kids!* Recruitment Process
*Alternative stream of participant recruitment
Abbreviations: OCCS – Offord Centre for Child Studies

4.2.2 Variables

4.2.2.1 Parent-reported Developmental Screening using the ITC at 18 months

The 24-item ITC, a developmental screening tool, is completed at the 18-month health supervision visit in *TARGet Kids!*. The primary predictor was a positive ITC screen, which refers to concern for expressive speech delay (defined as an expressive speech composite score below the 10th percentile) and/or concern for other communication delay (defined as a social composite, symbolic composite, or total score below the 10th percentile).

For this study, we examined the 5 components of the ITC: positive ITC screen; concern for expressive speech delay; concern for other communication delay; positive parent concern alone (determined by a parent-reported response of "Yes" to the question: "Do you have any concerns about your child's development?") and positive ITC screen or positive parent concern.

4.2.2.2 Teacher-reported EDI Outcomes at 4 to 6 years of age

School readiness was measured by using the EDI in children 4 to 6 years in JK and SK. The EDI is a validated, 103-item teacher-completed measure, assessesing children's skills and behaviours according to 5 domains (Language & Cognitive Development, Physical Health & Well-being, Social Competence, Emotional Maturity and Communication Skills & General Knowledge).

The *primary outcome* was overall vulnerability (binary variable), represented by vulnerability in at least one of the 5 EDI domains (children who score below the 10th percentile cut-off of the Ontario Baseline population).

The *secondary outcome* was school readiness as measured by the mean continuous score of each of the 5 EDI domains. The Language & Cognitive Development as well as the Communication Skills & General Knowledge domains were of particular importance for this study. A mean score of 8 or more indicates that the child is reaching or almost reaching all the developmental expectations in a particular subdomain, performs strongly in the corresponding portion of the school day and is proficient with fine and gross motor skills.[110, 111]

4.2.2.3 Other Variables (Child and Family Characteristics)

The following child and family characteristics were collected: Age at ITC (months); Age at EDI (years); Child Factors (sex, gestational age, birthweight (kg), body mass index z-score (zBMI), class type (JK or SK) and special needs); Sociodemographic Factors (maternal ethnicity, maternal education and family income in Canadian dollars (self-reported)); and Other Family Factors (siblings and family history of developmental concern (in mother, father, or siblings)). To obtain this information, children's parents/guardians completed the standardized *TARGet Kids!* questionnaires, developed based on the Canadian Community Health Survey.[98, 112]

Child factors included age and sex. Child age is correlated with the 5 domains of the EDI and younger age at school entry was found to contribute significantly to being unready for school.[81] On average, the developmental scores of girls are higher than boys in Kindergarten as developmental outcomes have a steeper gradient in boys compared to girls.[113] Children who were low or very low birthweight and who were small for gestational age have higher vulnerability on the EDI, compared to normal birthweight or normal/large for gestational age.[114]

Sociodemographic factors associated with vulnerability on the EDI include maternal education. Maternal education has been found to affect children's mathematics and reading skills in the first year of school.[17] Children with fewer risk factors (lower maternal education, lower income, use of social assistance and having a home language other than English) were more likely to have better reading and cognitive skills upon commencing Kindergarten.[115] Family income was collected in the following 4 categories: less than $40,000; $40,000 to $79,999; $80,000 to $149,999 and $150,000 and greater. The lowest and the lower middle income categories approximate Toronto, Canada's low income cut-off (CAD $44,266 [$32,684] for a 4-person household) and the median family income (CAD $82,859 [$61,180] for a 4-person household).[100]

Other family factors that we included were families with a large number of children in the home (multiple siblings), which has been correlated with poorer emotional maturity and social competence (2 domains of the EDI).[16] Additionally, in terms of family history of developmental concern (including Autism Spectrum Disorder – ASD, Attention-Deficit/ Hyperactivity Disorder (ADHD), or learning disability in the mother, father, or siblings), ASD and ADHD have been found to be "highly inheritable neurodevelopmental disorders".[116, 117]

Over 50% of children with ADHD have a learning disability that is usually specific to writing, reading and math deficits in early speech/communication.[118]

The results of the study in Chapter 3, identifying factors associated with a positive ITC screen influenced the *a priori* selected covariates. Of the variables listed above, gestational age, zBMI, special needs and maternal education were not included as covariates in the model but were described in participant characteristics. Gestational age was not included as it is typically a similar variable to birthweight in this cohort. zBMI was not included as it was determined not to be an important covariate. Special needs was not included as it strongly correlated with the EDI alone.[82] Prior to 2018, the EDI special needs definition was as follows: "A child may have special needs due to a diagnosis provided by medical or health practitioners in the community or a child may have special education needs, meaning the child: has been identified as exceptional by an Identification, Placement, and Review Committee (IPRC) and is required to have an Individual Education Plan (IEP) or has not been identified by an IPRC but requires an IEP or is receiving special education programs and/or services even though they may not yet have an IEP".[82, 119] Finally, maternal education was not included as there was no evidence of an association with the ITC based on the results of our Chapter 3 and we have included family income.

4.2.3 Statistical Analysis

4.2.3.1 Data Review & Cleaning

Prior to data analysis, all variables in the dataset were examined for missing, unrealistic, or duplicate values. Subsequent to merging the data, participants were retained or excluded from the analysis based on the inclusion and exclusion criteria, respectively. The distribution of all continuous variables was examined based on visual inspection of boxplots, histograms and Q-Q plots as well as the Shapiro-Wilk test to determine normality. Non-normal continuous variables were identified based on visual analysis and a statistically significant ($p<0.05$) Shapiro-Wilk test.

Histograms revealed a symmetric and bell-shaped distribution for birthweight and zBMI. Box plots also revealed a symmetric distribution and data were aligned to the diagonal with minimal deviations in the Q-Q plots. The values for skewness and kurtosis were as follows:

birthweight (-0.03 and 0.42) and zBMI (-0.08 and 0.35). Furthermore, the Shapiro-Wilk test was not significant for birthweight (p=0.288). This suggests that our sample did not provide evidence to reject the null hypothesis that the data were normally distributed. However, the Shapiro-Wilk test was significant for zBMI (p=0.025), suggesting that our sample provided evidence to reject the null hypothesis that the data were normally distributed. In addition, histograms revealed a non-symmetric distribution for age at ITC and age at EDI. Box plots also revealed a non-symmetric distribution and data deviated from the diagonal in the Q-Q plots**.** The values for skewness and kurtosis were as follows: age at ITC (2.00 and 6.35) and age at EDI (-0.18 and -1.18). The Shapiro-Wilk tests were significant for both age at ITC and age at EDI ($p<0.0001$) suggesting that our sample provided evidence to reject the null hypothesis that the data were normally distributed. However, Central Limit Theorem states that regardless of the populations probability distribution, if the sample size if large enough, the average calculated will approximate a normal distribution.[104]

Furthermore, histograms revealed a non-symmetric distribution for the continuous scores of each of the 5 EDI domains (secondary outcomes). Box plots also revealed a non-symmetric distribution and data deviated from the diagonal in the Q-Q plots. The values for skewness and kurtosis for each variable were as follows: the Language & Cognitive Development domain (-1.71 and 2.82); the Physical Health & Wellbeing domain (-1.03 and 0.57), the Social Competence domain (-1.45 and 1.82), the Emotional Maturity domain (-1.09 and 1.02) and the Communication Skills & General Knowledge domain (-1.10 and 0.42). The Shapiro-Wilk tests were significant for all of the above listed continuous variables ($p<0.0001$) suggesting that our sample provided evidence to reject the null hypothesis that the data were normally distributed. In the adjusted and unadjusted analyses, bootstrap resampling was used to address the skewed EDI data (*see section 4.3.4*).

4.2.3.2 Participant Characteristics

The continuous variables (age at ITC, age at EDI, birthweight (kg) and zBMI) were described by mean and standard deviation (SD). The mean scores of the 5 EDI domains were also represented by mean and standard deviation (SD). The remainder of the variables: sex; gestational age; maternal ethnicity; maternal education; family income; siblings; family history of developmental concern (in mother, father, or siblings); class type; special needs; the

components of the ITC and EDI overall vulnerability were categorical and described as frequencies and percentages. Results were also reported based on ITC screen status.

4.2.3.3 Primary Objective: Unadjusted & Adjusted Logistic Regression Analysis

To examine the construct validity of the ITC, unadjusted and adjusted logistic regression analyses were used to evaluate the association between a positive ITC screen at the 18-month visit and overall vulnerability on the EDI at 4 to 6 years [binary outcome]. Unadjusted logistic regression models were used to compare each *a priori* selected covariate (child age at EDI, sex, birthweight, maternal ethnicity, family income, siblings and family history of developmental concern) with the outcome. The univariable logistic regression model was built using the following equation: $\mathbf{Log\ (p_i/(1\text{-}p_i)) = log\ (odds\ of\ overall\ vulnerability) = \beta_0 + \beta_1 * predictor_i.}$

The full multivariable logistic regression model included all *a priori* selected covariates regardless of statistical significance.[105] The equation for the multivariable logistic regression model adjusting for the identified covariates was: $\mathbf{Log\ (p_i/(1\text{-}p_i)) = log\ (odds\ of\ overall\ vulnerability) = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \ldots + \beta_k X_k.}$ Where k, is the number of regression parameters in the model. The 4 key assumptions of the final model were verified. The model fit was assessed using the c-statistic and Hosmer-Lemeshow Goodness-of-Fit test. Multicollinearity was assessed and deemed present with a variance inflation factor (VIF) >4. If multicollinearity was present, a stepwise variable reduction based on clinical guidance was conducted in order to remove collinear variables. The presence of influential outliers was assessed by examining the Pearson/Deviance residual and DFBeta plots. The assumption of independence was not formally tested; however, only a single ITC and EDI visit per subject was kept in the data. Therefore, it was assumed that observations were independent.

4.2.3.4 Secondary Objective: Correlation, Unadjusted & Adjusted Linear Regression Analysis

To determine whether the ITC is correlated with the EDI, a correlation matrix assessing Pearson correlations between a positive ITC screen; expressive speech delay; other communication delay; parent concern alone and a positive ITC screen or parent concern and overall vulnerability on the EDI as well as between a positive ITC screen; expressive speech delay; other communication delay; parent concern alone and a positive ITC screen or parent concern and each of the 5 EDI domains was conducted.

Additionally, to examine the construct validity of the ITC, unadjusted and adjusted linear regression analyses were used to evaluate the association between a positive ITC screen at the 18-month visit (binary predictor) and school readiness, as measured by the mean score of the Language & Cognitive Development and Communication Skills & General Knowledge domains at 4 to 6 years (continuous outcome). A simple linear regression model was built in the form of: $\boldsymbol{\mu}$ **EDI score**$_{|\text{ITC screen}} = \beta_0 + \beta_1$***positive ITC screen.** Parameter estimates ($\hat{\beta}_0$ and $\hat{\beta}_1$) and their standard errors were determined using the method of least squares estimation and the proportion of variation in each domain that was explained by the ITC screen (independent variable) was determined using the coefficient of determination (R^2).

Multivariable linear regression models and a hierarchical linear regression analysis were constructed to evaluate and describe the relationship between the primary predictor (ITC screen) and the secondary outcome (school readiness, as measured by the Language & Cognitive Development as well as the Communication Skills & General Knowledge domains) subsequent to adjusting for confounding variables. *A priori* selected covariates (child age at EDI, sex, birthweight, maternal ethnicity, family income, siblings and family history of developmental concern) were included in the model. A VIF >4 was considered as evidence of *multicollinearity* and, if necessary, one of the two collinear variables were removed based on statistical significance and clinical relevance. Therefore, the final model was built with the ITC and the 7 covariates listed above, using the following equation: $\boldsymbol{\mu}_{\text{EDI}|\text{positive ITC screen + Participant Characteristics}} = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \ldots + \beta_k X_k$.

The proportion of variation in the outcome variable (school readiness) explained by the predictors in the final model was determined using R^2. The 4 assumptions of the final model were verified to ensure they were not violated. Skewness, kurtosis, plots (i.e., histogram and Q-Q plots) and tests for normality (Shapiro-Wilks) were analyzed to determine *normality of the residuals*. Studentized residuals were used to analyze any influential outliers that could skew the regression line (those greater than 2 were identified for further analysis). Observations were defined as influential outliers by using Cook's distance. *Linearity and homoscedasticity* were assessed through visual analysis of studentized residual plots versus predicted values. If a violation existed, the residuals (y axis) were plotted versus each independent variable (x axis) to determine if the violation was due to an independent variable relationship. If necessary, variables were bootstrapped to ensure no normality or homoscedasticity violation. *Independence*

was not formally tested; however, the residuals were assumed to be independent based on the study design.

Additionally, 5 multivariable linear regression models were used to examine the association between the 5 components of the ITC (positive ITC screen, expressive speech delay, other communication delay, positive parent-reported concern alone, and positive ITC screen or parent concern), the predictors, and the mean score of the each of the 5 EDI domains (the outcomes). The *a priori* selected covariates adjusted for included: child age at EDI; sex; birthweight; maternal ethnicity; family income; siblings and family history of developmental concern.

4.2.3.5 Secondary Objective: Predictive Criterion Validity of the ITC

To examine the predictive criterion validity of the ITC screen at the 18-month visit, using overall vulnerability on the EDI as the criterion measure, the screening test properties sensitivity, specificity, false positives, and positive and negative predictive values were calculated along with 95% confidence intervals (CIs). All 5 ITC components were examined. The ITC screen status is based on concern for expressive speech delay and/or concern for other communication delay however, the rationale for including them as separate components is as follows: expressive speech delay at 18 months is transient ("late bloomers") in many children and by school age (4 to 6 years) the child may no longer have language or communication difficulties. Additionally, children with other communication delays may be at risk for more persistent developmental difficulties.

4.2.3.6 Level of Significance and Software

A $p<0.05$ level of significance or a null hypothesis (H_0) value not contained in the bootstrapped 95% CI was used for all hypothesis tests. Two-sided p-values were used. The maximum rate of missing data for any covariate was 17%. Multiple imputation by chained equation (MICE) was used for missing covariate data and bootstrap resampling was used to adjust for skewed EDI domain scores. More specifically, a random imputation and bootstrap combination was used.[120] A bootstrap sample was taken, one imputation was run on the sample to estimate the imputation model and a model was produced.[120, 121] Subsequently, a complete case analysis was conducted

1 to 3 times.[120, 121] All statistical analyses were conducted using SAS 9.4 statistical software (SAS Institute, Cary, North Carolina)[106] and R version 4.0.3.[122]

4.3 Results

4.3.1 Participant Flow

A total of 2,998 children were eligible participants, with a visit at 16 to 23 months of age. Of those eligible, 32 (1.1%) were excluded for a gestational age less than 32 weeks, 9 (0.3%) were excluded for a birthweight less than 1.25 kg and 36 (1.2%) were excluded for a developmental diagnosis at baseline. Of the 2,921 remaining, 2,124 (73%) had ITC data at baseline. 263 (12%) had a positive ITC screen and 1,861 (88%) had a negative ITC screen. Subsequent to excluding 428 (20%) participants who were not yet 4 years old and therefore not eligible for a follow-up visit (n=1696), 208 (12%) participants had a positive ITC screen and 1,488 (88%) had a negative ITC screen. Additionally, 818 (48%) participants had no follow-up visit at 4 to 6 years of age (n=878), of which 91 (10%) had a positive ITC screen and 787 (90%) had a negative ITC screen. Finally, 585 (67%) children with a follow-up visit at 4 to 6 years of age were excluded as the EDI was not yet collected in *TARGet Kids!*. The final sample had 293 participants, 30 (10%) had a positive ITC screen and 263 (90%) had a negative ITC screen **(Figure 5)**.

4.3.2 Participant Characteristics

Table 4 summarizes the overall study participant characteristics as well as depicts participant characteristics by ITC screen status. Participant characteristics and health behaviours differed based on status. Children with a positive ITC screen, compared to those with a negative ITC screen, had a similar age at EDI (age: mean (SD) 5.2 years (0.6) vs. 5.3 years (0.6)), were mostly male (n=19 (63%) vs. n=138 (53%)) and included a higher percentage of children with special needs (n=4 (13%) vs. n=7 (3%)).

Of the 293 included in the final sample, 125 (43%) were in Junior Kindergarten and 168 (57%) in Senior Kindergarten. In addition, 54 (18%) of children were identified as having overall vulnerability pertaining to school readiness (primary outcome), of which 9 (30%) had a positive ITC screen and 45 (17%) had a negative ITC screen.

Finally, the mean (SD) of the Language & Cognitive Development domain (secondary outcome) was 8.0 (1.8) in children with a positive ITC screen and 8.9 (1.4) in children with a negative ITC screen. The mean (SD) of the Physical Health & Well-being domain (secondary outcome) was 8.3 (1.6) in children with a positive ITC screen and 8.8 (1.2) in children with a negative ITC screen. The mean (SD) of the Social Competence domain (secondary outcome) was 7.8 (2.4) in children with a positive ITC screen and 8.6 (1.6) in children with a negative ITC screen. The mean (SD) of the Emotional Maturity domain (secondary outcome) was 7.5 (1.9) in children with a positive ITC screen and 8.1 (1.5) in children with a negative ITC screen. The mean (SD) of the Communication Skills & General Knowledge domain (secondary outcome) was 6.8 (2.7) in children with a positive ITC screen and 8.3 (2.1) in children with a negative ITC screen.

4.3.3 Primary Analysis: Construct Validity of the ITC (Logistic Regression)

Table 5 depicts unadjusted and adjusted logistic regression models for the association between the primary predictor (a positive ITC screen) and the primary outcome (overall vulnerability) using *a priori* selected covariates (n=293). In the multivariable model, no evidence of an association was found between a positive ITC screen and overall vulnerability on the EDI (adjusted odds ratio [aOR] 1.27, 95% CI (0.46, 3.50), p=0.645). However, male sex (aOR 2.13, 95% CI (1.05, 4.29), p=0.035) and having a family income of less than $40,000 compared to $150,000 or more (aOR 6.67, 95% CI (1.58, 28.16), p=0.010) resulted in higher odds of overall vulnerability. The adjusted model equation was: **Log (pi/(1-pi)) = log (odds of overall vulnerability)** = -1.07 + (0.24 × ITC screen status) + (-0.29 × age at EDI) + (0.75 × male) + (0.09 × birthweight) + (0.49 × Non-European ethnicity) + (1.90 × family income <$40,000) + (-0.07 × family income $40,000 - $79,999) + (-0.70 × family income $80,000 - $149,999) + (0.65 × 1 sibling) + (0.08 × 2 or more siblings) + (-0.16 × family history of developmental concern).

To assess the final model fit, the Hosmer-Lemeshow Goodness-of-Fit test was not significant (χ^2 = 2.85 (df8) p=0.943), indicating no evidence of poor model fit. The c-statistic was 0.717 indicating the model had acceptable discrimination (**Appendix C - Figure 1**). Additionally, there was no evidence of multicollinearity (no VIF >4) identified between any of the predictors included in the final model (**Appendix C - Table 1**). The distribution of the

variables in the equation were not sparse based on the odds ratio estimates and their confidence intervals, therefore the model was not overspecified. Influential outliers were examined using Pearson/Deviance residuals and DFBetas (**Appendix C - Figure 2**). Based on visual inspection, a few outliers existed in the final model. Due to the fact that there were few outliers, they were kept in the final model.

4.3.4 Secondary Analysis: Construct Validity of the ITC (Correlation & Linear Regression)

Table 6a depicts a correlation matrix to assess Pearson correlations (r) conducted between the ITC and overall vulnerability and the 5 domains on the EDI. Evidence of correlations were identified between a positive ITC screen and each of the 5 EDI domains: Language & Cognitive Development (r=-0.18, p=0.002); Physical Health & Well-being (r=-0.12, p=0.045); Social Competence (r=-0.14, p=0.020); Emotional Maturity (r=-0.13, p=0.028); Communication Skills & General Knowledge (r=-0.21, p=0.0004). Evidence of correlations were identified between expressive speech delay and each of the 5 EDI domains: Language & Cognitive Development (r=-0.22, p=0.0002); Physical Health & Well-being (r=-0.19, p=0.001); Social Competence (r=-0.15, p=0.008); Emotional Maturity (r=-0.17, p=0.004); Communication Skills & General Knowledge (r=-0.28, p<0.0001). Evidence of correlations were identified between other communication delay and the Language & Cognitive Development (r=-0.13, p=0.022); Social Competence (r=-0.15, p=0.009) and Communication Skills & General Knowledge (r=-0.14, p=0.018) EDI domains. Evidence of correlations were identified between parent concern and the Language & Cognitive Development (r=-0.15, p=0.012) and Physical Health & Well-being (r=-0.16, p=0.007) EDI domains. Finally, evidence of correlations were identified between a positive ITC screen or parent concern and overall vulnerability on the EDI as well as each of the 5 EDI domains: Overall Vulnerability (r=0.13, p=0.031); Language & Cognitive Development (r=-0.21, p=0.0003); Physical Health & Well-being (r=-0.17, p=0.004); Social Competence (r=-0.13, p=0.022); Emotional Maturity (r=-0.13, p=0.024); Communication Skills & General Knowledge (r=-0.18, p=0.002). Moreover, all the EDI variables (overall vulnerability and 5 domains) were also significantly correlated with each other (p<0.05) **(Table 6b)**.

Table 7a & 7b depict unadjusted and adjusted linear regression models for the association between the primary predictor (a positive ITC screen) and the secondary outcome (school readiness as measured by the mean score on the Language & Cognitive Development

and Communication Skills & General Knowledge EDI domains, respectively) using *a priori* selected covariates.

In the adjusted model, evidence of an association was found between a positive ITC screen and the Language & Cognitive Development domain (Beta coefficient [β]=-0.62, 95% CI (-1.25, -0.18), p=0.046). Additionally, child age at EDI (β=0.93, 95% CI (0.61, 1.22), p<0.002), male sex (β=-0.50, 95% CI (-0.77, -0.18), p<0.002), and having a family income less than $40,000 compared to $150,000 or more (β=-1.23, 95% CI (-2.01, 0.14), p=0.008) were statistically significant predictors associated with school readiness. The final model equation was: $\mu_{\text{EDI|positive ITC screen + Participant Characteristics}} = 4.51 + (-0.62 \times \text{positive ITC screen}) + (0.93 \times \text{age at EDI}) + (-0.50 \times \text{male}) + (-0.10 \times \text{birthweight}) + (0.01 \times \text{Non-European ethnicity}) + (-1.23 \times \text{family income <\$40,000}) + (-0.33 \times \text{family income \$40,000 - \$79,999}) + (0.17 \times \text{family income \$80,000 - \$149,999}) + (0.07 \times \text{1 sibling}) + (-0.28 \times \text{2 or more siblings}) + (0.15 \times \text{family history of developmental concern})$. On average, 22% of the variation in school readiness was explained by a positive ITC screen (adjusted $R^2 = 0.217$) (**Table 7a**).

Similarly, in the adjusted model, evidence of an association was found between a positive ITC screen and the Communication Skills & General Knowledge domain (β=-1.08, 95% CI (-2.10, -0.17), p=0.036). Additionally, child age at EDI (β=1.10, 95% CI (0.70, 1.50), p<0.002), male sex (β=-0.42, 95% CI (-0.83, 0.07), p=0.046) and having a family income less than $40,000 compared to $150,000 or more (β=-2.01, 95% CI (-3.75, 0.11), p=0.030) were predictors associated with school readiness. The final model equation was: $\mu_{\text{EDI|positive ITC screen + Participant Characteristics}} = 2.82 + (-1.08 \times \text{positive ITC screen}) + (1.10 \times \text{age at EDI}) + (-0.42 \times \text{male}) + (0.04 \times \text{birthweight}) + (-0.15 \times \text{Non-European ethnicity}) + (-2.01 \times \text{family income <\$40,000}) + (-0.58 \times \text{family income \$40,000 - \$79,999}) + (0.10 \times \text{family income \$80,000 - \$149,999}) + (-0.24 \times \text{1 sibling}) + (-0.45 \times \text{more than 2 siblings}) + (0.19 \times \text{family history of developmental concern})$. On average, 15% of the variation in school readiness was explained by a positive ITC screen (adjusted $R^2 = 0.147$) (**Table 7b**).

The assumptions of the models with the Language & Cognitive Development and the Communication Skills & General Knowledge domains were tested, and there was no evidence of multicollinearity between the variables as no VIF was greater than 4 (**Appendix D - Table 1 & 2**). However, the normality of the residuals and the homoscedasticity assumptions were

violated for both domains (**Appendix D - Figure 1 & 3**). Residual plots were used to verify linearity (**Appendix D - Figure 2 & 4**). One influential outlier observation was identified with a Cook's distance of 2.16 therefore, they were kept in the analysis. The histogram showed that the data were negatively skewed. Skewness and kurtosis values for the model with the Language & Cognitive Development domain were -1.33 and 2.17, respectively and the Shapiro-Wilk test was significant ($p<0.0001$). Additionally, skewness and kurtosis values for the model with the Communication Skills & General Knowledge domain were -1.06 and 0.76, respectively and the Shapiro-Wilk test was significant ($p<0.0001$). To address this, analyses with the EDI domains were bootstrapped with 500 resamples. This provided accurate 95% confidence intervals for both the unadjusted and adjusted linear regressions by taking multiple subsamples with replacement observations. Additionally, due to missing data in some covariates, multiple imputation was conducted for the multivariable analyses.

Table 8a & 8b depict adjusted hierarchical linear regression models for the association between the primary predictor (a positive ITC screen) and the secondary outcome (school readiness as measured by the mean score on the Language & Cognitive Development and Communication Skills & General Knowledge EDI domains, respectively) using *a priori* selected covariates.

After accounting for child age at EDI, sex and birthweight (model 1); maternal ethnicity, family income, siblings and family history of developmental concern (model 2) and a positive ITC screen (model 3), there was evidence of an association between a positive ITC screen and school readiness as measured by the mean score of the Language & Cognitive Development domain (β=-0.62, 95% CI (-1.25, -0.18), p=0.046). On average, model 3 explained the most variance in school readiness (adjusted $R^2 = 0.217$) compared to model 2 (adjusted $R^2 = 0.209$) and model 1 (adjusted $R^2 = 0.164$) (**Table 8a**).

Similarly, after accounting for child age at EDI, sex and birthweight (model 1); maternal ethnicity, family income, siblings and family history of developmental concern (model 2) and a positive ITC screen (model 3), there was evidence of an association between a positive ITC screen and school readiness as measured by the mean score of the Communication Skills & General Knowledge domain (β=-1.08, 95% CI (-2.10, -0.17), p=0.036). On average, model 3

explained the most variance in school readiness (adjusted $R^2 = 0.147$) compared to model 2 (adjusted $R^2 = 0.130$) and model 1 (adjusted $R^2 = 0.092$) (**Table 8b**).

Table 9 depicts multivariable linear regression models for the association between the 5 components of the ITC (a positive ITC screen, expressive speech delay, other communication delay, positive parent-reported concern alone and a positive ITC screen or parent concern) and the mean scores of each of the 5 EDI domains. Subsequent to adjusting for the *a priori* selected covariates, evidence of an association was found between a positive ITC screen and the Language & Cognitive Development domain (β=-0.62, 95% CI (-1.25, -0.18), p=0.046) and between a positive ITC screen and the Communication Skills & General Knowledge domain (β=-1.08, 95% CI (-2.10, -0.17), p=0.036). Further, evidence of an association was found between concern for expressive speech delay and the Language & Cognitive Development domain (β=-1.22, 95% CI (-2.11, -0.58), p=0.008), concern for expressive speech delay and the Physical Health & Well-being domain (β=-0.75, 95% CI (-1.43, 0.06), p=0.032), concern for expressive speech delay and the Emotional Maturity domain (β=-1.00, 95% CI (-1.80, -0.23), p=0.014), concern for expressive speech delay and the Communication Skills & General Knowledge domain (β=-2.35, 95% CI (-3.63, -1.32), p<0.002) and a positive ITC screen or parent concern and the Language & Cognitive Development domain (β=-0.63, 95% CI (-1.17, -0.19), p=0.018). Finally, evidence of an association was found between a positive ITC screen or parent concern and the Physical Health & Well-being domain (β=-0.43, 95% CI (-0.89, -0.01), p=0.080) and between a positive ITC screen or parent concern and the Communication Skills & General Knowledge domain (β=-0.79, 95% CI (-1.67, -0.06), p=0.056), as the null hypothesis (H_0) value was not contained in the bootstrapped 95% CI.

Table 10 is a summary table depicting the unadjusted and adjusted linear and logistic regression models for the association between a positive ITC screen and school readiness as measured by the 5 EDI domains and overall vulnerability. Subsequent to adjusting for the following *a priori* selected covariates: child age at EDI (years); child sex; birthweight (kg); maternal ethnicity; family income; siblings and family history of developmental concern, evidence of an association was found between a positive ITC screen and the Language and Cognitive Development domain (β=-0.62, 95% CI (-1.25, -0.18), p=0.046) and between a positive ITC screen and the Communication Skills & General Knowledge domain (β=-1.08, 95% CI (-2.10, -0.17), p=0.036).

4.3.5 Secondary Analysis: Predictive Criterion Validity of the ITC

Table 11 depicts the screening test properties of the ITC at the 18-month visit, using overall vulnerability on the EDI as the criterion measure. A sensitivity of 16.7% (95% CI (7.9, 29.3)), specificity of 91.2% (95% CI (86.9, 94.5)), false positive rate 8.8% (95% CI (5.4, 13.4)), positive predictive value 30.0% (95% CI (17.2, 46.9)) and negative predictive value 82.9% (95% CI (81.0, 82.1)) was found.

Further, the screening test properties of concern for expressive speech delay, using overall vulnerability on the EDI as the criterion measure were: sensitivity 11.1% (95% CI (4.2, 22.6)); specificity 95.4% (95% CI (91.9, 97.7)); false positive rate 4.6% (95% CI (2.3, 8.2)); positive predictive value 35.3% (95% CI (17.4, 58.5)) and negative predictive value 82.6% (95% CI (81.2, 84.0)) and the screening test properties of concern for other communication delay, using overall vulnerability on the EDI as the criterion measure were: sensitivity 11.1% (95% CI (4.2, 22.6)); specificity 94.6% (95% CI (90.9, 97.1)); false positive rate 5.4% (95% CI (2.9, 9.3)); positive predictive value 31.6% (95% CI (14.2, 23.4)) and negative predictive value 82.5% (95% CI (81.0, 83.9)).

The screening test properties of parent concern alone on the ITC, using overall vulnerability on the EDI as the criterion measure were: sensitivity 11.1% (95% CI (4.2, 22.6)); specificity 95.0% (95% CI (91.4, 97.4)); false positive rate 5.0% (95% CI (2.6, 8.8)); positive predictive value 33.3% (95% CI (16.4, 56.0)) and negative predictive value 82.6% (95% CI (81.1, 84.0)).

Finally, the screening test properties of the ITC screen or parent concern on the ITC, using overall vulnerability on the EDI as the criterion measure were: sensitivity 24.1% (95% CI (13.5, 37.6)); specificity 87.5% (95% CI (82.6, 91.4)); false positive rate 12.6% (95% CI (8.5, 17.9)); positive predictive value 30.2 (95% CI (19.5, 43.6)) and negative predictive value 83.6% (95% CI (81.3, 85.7)).

4.4 Discussion

In this study, we found no evidence that a positive ITC screen (primary predictor) was associated with overall vulnerability on the EDI (primary outcome). Low, inverse, Pearson correlations were found between several of the 5 components of the ITC and overall

vulnerability and/or each of the 5 EDI domains. Evidence of construct validity was found between a positive ITC screen and the Language & Cognitive Development EDI domain (secondary outcome) and between a positive ITC screen and the Communication Skills & General Knowledge EDI domain (secondary outcome). Further, evidence of an association was found between concern for expressive speech delay on the ITC and the Language & Cognitive Development EDI domain; concern for expressive speech delay on the ITC and the Physical Health & Well-being EDI domain; concern for expressive speech delay on the ITC and the Emotional Maturity EDI domain; concern for expressive speech delay on the ITC and the Communication Skills & General Knowledge EDI domain as well as a positive ITC screen or parent concern on the ITC and the Language & Cognitive Development EDI domain; a positive ITC screen or parent concern on the ITC and the Physical Health & Well-being EDI domain; and a positive ITC screen or parent concern on the ITC and the Communication Skills & General Knowledge EDI domain. Additionally, we found evidence of predictive criterion validity. The ITC was found to accurately identify children who were not vulnerable on the EDI as it had a high to very high specificity ranging from 88% to 95%.

There are a few possible explanations for our findings. The absence of an association between a positive ITC screen and overall vulnerability on the EDI may be explained by the small sample size, particularly of those who have a positive ITC screen in our sample. Additionally, the low sensitivity may be explained by the long duration between the completion of the ITC (at 18-months) and the EDI (between 4 to 6 years of age), as new developmental concerns may arise between 18 months and 4 to 6 years. This would be the most informative explanation of our study findings as some developmental delays are transient, while others persist throughout the life course.[5] Therefore, ongoing developmental screening and surveillance from 18 months to preschool age may enhance the sensitivity of the ITC.

The strengths of this study include that the data collection was prospective, recruitment was from a real-world setting and validated instruments were used for data collection at 18 months and 4 to 6 years. Our data set also included several child, sociodemographic and family factor variables, which provided relevant covariates that were adjusted for in the linear and logistic regression models. Furthermore, our study utilized advanced statistical methods, including bootstrap resampling the negatively skewed EDI data and multiple imputation by chained equation to address missing covariate data.

Alongside the strengths, this study had a few limitations. Family income was high and maternal ethnicity was predominantly European in our sample, which may limit the generalizability of our findings. However, while the prevalence of 18% for overall vulnerability on the EDI was less than that found in Canadian children,[82, 85] the prevalence of a positive ITC screen in our sample was at the expected 10th percentile cut-off. This study also had a small sample size of 293, which may have affected the power to detect statistically significant associations.

The findings of our study compared favourably with those of previous findings by Wetherby et al. and Borkhoff et al. with a few minor differences as discussed below. Wetherby et al. conducted several validation studies of the ITC in children 6 to 24 months of age. A high specificity of 75% to 77% was found when screening for communication delays based on 364 children evaluated with a Behaviour Sample.[70-72] Wetherby et al. also found that the ITC has a high to very high inter-rater reliability (g=.76 to .97 for composites and g=.92 to .97 for composites and total) using a normal sample of 337 children.[70-72] Additionally, a *TARGet Kids!* study by Borkhoff et al. evaluated the association between a positive ITC screen at 18 months and 1) parent-reported developmental diagnosis at 3 to 10 years, and 2) parent-reported school concern and 3) parent-reported receipt of additional school resources.[91] The final sample was 540 children of which 48 (9.8%) had a positive ITC screen. They found that the odds of children with a positive ITC screen at 18 months with a later parent-reported developmental diagnosis was 4.75 times that for children with a negative ITC screen.[91] Evidence of construct validity was also found as a positive ITC screen was associated with an increased odds of later parent-reported school concern for development and receipt of additional school resources.[91] The reported screening test properties of the ITC screen at the 18-month visit were: a sensitivity of 31% to 50% and specificity of 89% to 95%. Borkhoff et al. noted that the outcomes were measured using a parent-reported developmental assessment rather than a standardized one.[91] Furthermore, the generalizability of the findings may be limited as maternal education and family income were high. However, the prevalence of a positive ITC was close to the expected 10th percentile cut-off in their sample.[91]

Our study differed from the studies by Wetherby et al. as we studied infants 18 months of age and they studied infants 6 to 24 months. We also had a smaller sample size of 293 compared to 364 and 337 and a lower sensitivity. Additionally, sample bias may have been

introduced in the Wetherby et al. studies as they sampled children with a positive and negative ITC screen. However, our study was similar as a standardized assessment of developmental outcomes was used. Our study was similar to that of Borkhoff et al. as both studies included infants 18 months of age at the time of ITC screening, and later outcomes. However, they differ in that our study used standardized assessments (the EDI) to obtain outcome data and the study by Borkhoff et al. used parent-reported developmental diagnosis at 3 to 10 years of age and the overall sample size used is smaller in our study (293 compared to 540).

Early identification of developmental delay can lead to improvements in the health outcomes and well-being of children. Developmental screening is currently recommended in Canada at the 18-month Enhanced Well-Child Visit (EWCV). Therefore, this is the ideal visit to screen for developmental delay using the ITC. This study's results reinforce the need to focus on child, sociodemographic and family factors as they affect the relationship between a positive ITC screen and a child's readiness for school. The results of this study can be used to inform subsequent analyses as they support the use of the ITC as a developmental screening tool to identify those who may be vulnerable overall in terms of school readiness at 4 to 6 years of age. Future studies may consider obtaining a larger sample size to better understand if an association exists between a positive ITC screen and overall vulnerability on the EDI and between a positive ITC screen and the 5 developmental domains on the EDI.

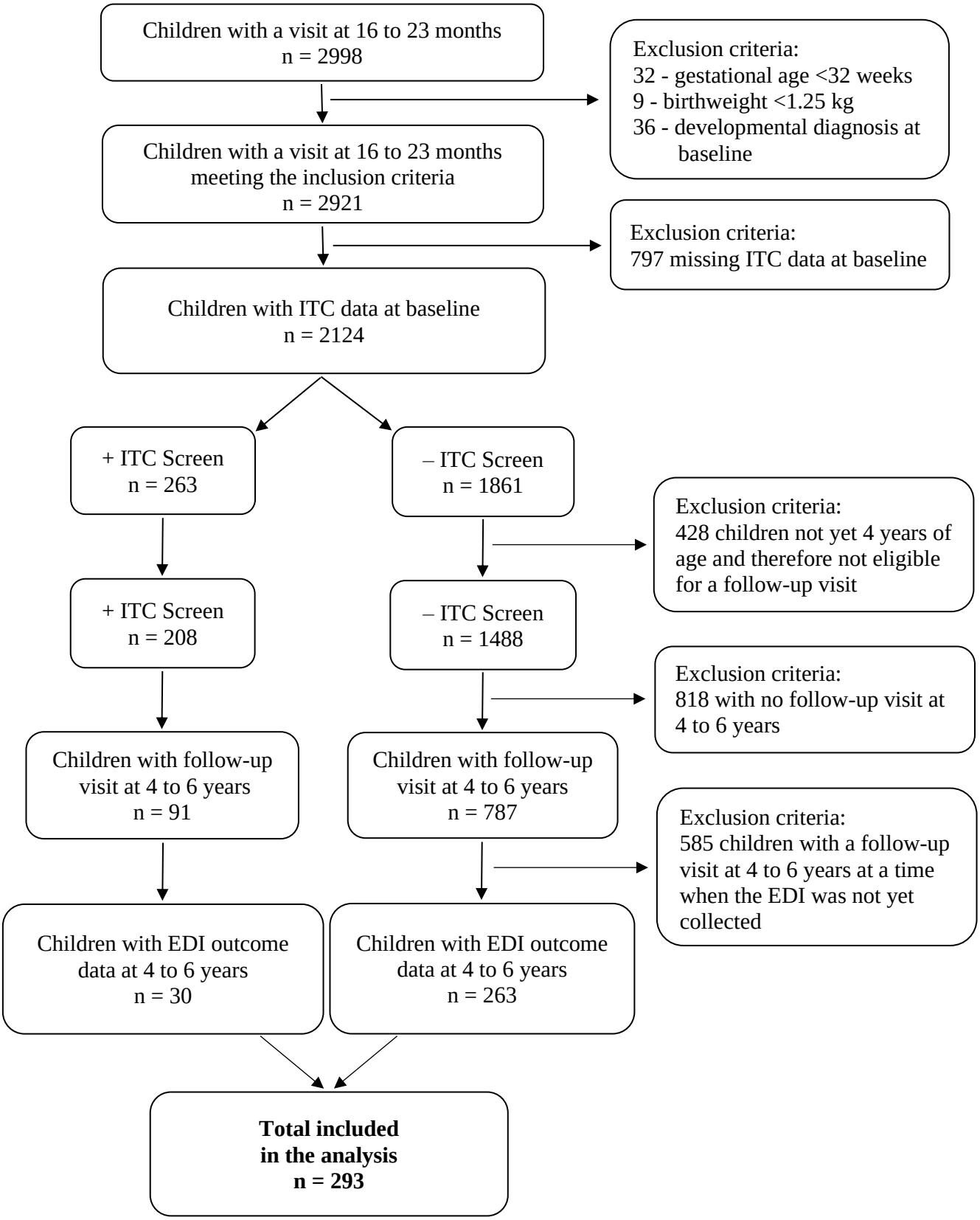


Figure 5. Study Participant Flow Chart (n=293)

Table 4. Overall Study Participant Characteristics (N=293) and Participant Characteristics for the Total Sample by ITC Screen Status

Characteristics		All Participants	ITC Screen	
			Positive	Negative
N		**293**	**30**	**263**
Child Factors	*n*			
Sex, n (%)				
Male	293	157 (53.6)	19 (63.3)	138 (52.5)
Female		136 (46.4)	11 (36.7)	125 (47.5)
Gestational Age, n (%)				
32-36 weeks	262	28 (10.7)	5 (21.7)	23 (9.6)
≥37 weeks		234 (89.3)	18 (78.3)	216 (90.4)
Birthweight (kg), Mean (SD) & n (%)		3.3 (0.6)	3.0 (0.6)	3.3 (0.6)
1.25 - 2.5 kg	268	24 (9.0)	4 (17.4)	20 (8.1)
2.5 - 4.0 kg		222 (82.8)	18 (78.3)	204 (83.3)
>4.0 kg		22 (8.2)	1 (4.3)	21 (8.6)
zBMI, Mean (SD) & n (%)		0.1 (1.1)	0.5 (1.2)	0.1 (1.1)
Underweight (z <–2)		8 (2.9)	0	8 (3.2)
Healthy weight (–2≤ z ≤1)	273	214 (78.4)	17 (73.9)	197 (78.8)
At Risk of Overweight (1< z ≤2)		43 (15.8)	4 (17.3)	39 (15.6)
Overweight (2< z ≤3)		5 (1.8)	1 (4.4)	4 (1.6)
Obese (z >3)		3 (1.1)	1 (4.4)	2 (0.8)
Sociodemographic Factors				
Maternal Ethnicity, n (%)				
European	244	184 (75.4)	12 (57.1)	172 (77.1)
Non-European		60 (24.6)	9 (42.9)	51 (22.9)
Maternal Education, n (%)				
Primary/High School	269	10 (3.7)	2 (8.3)	8 (3.3)
College/University		259 (96.3)	22 (91.7)	237 (96.7)
Self-reported Family Income, CAN$, n (%)				
<$ 40,000		10 (3.7)	3 (12.5)	7 (2.9)
$40,000 – $79,999	269	27 (10.0)	6 (25.0)	21 (8.6)
$80,000 – $149,999		96 (35.7)	6 (25.0)	90 (36.7)
$150,000+		136 (50.6)	9 (37.5)	127 (51.8)
Other Family Factors				
Siblings, n (%)				
0	266	134 (50.4)	11 (45.8)	123 (50.8)
1		107 (40.2)	10 (41.7)	97 (40.1)
2+		25 (9.4)	3 (12.5)	22 (9.1)
Family History of Developmental Concern, n (%)	288			
Yes		33 (11.5)	2 (6.7)	31 (12.0)
No		255 (88.5)	28 (93.3)	227 (88.0)
Baseline (ITC Variables)				
Age at ITC (months), Mean (SD)	293	18.2 (0.9)	18.1 (1.1)	18.2 (0.9)
Positive ITC Screen, n (%)				
Expressive Speech Delay	293	17 (5.8)	17 (56.7)	0
Other Communication Delay		19 (6.5)	19 (63.3)	0
Parent-concern, n (%)	293	18 (6.1)	5 (16.7)	13 (4.9)

Positive ITC Screen or Parent-concern, n (%)	293	43 (14.7)	30 (100)	13 (4.9)
Follow-Up (EDI Variables)				
Age at EDI (years), Mean (SD)	293	5.3 (0.6)	5.2 (0.6)	5.3 (0.6)
Class Type, n (%)				
Junior Kindergarten	293	125 (42.7)	15 (50.0)	110 (41.8)
Senior Kindergarten		168 (57.3)	15 (50.0)	153 (58.2)
Special Needs, n (%)				
Yes	292	11 (3.8)	4 (13.3)	7 (2.7)
No		281 (96.2)	26 (86.7)	255 (97.3)
Language & Cognitive Development Mean (SD)	293	8.8 (1.5)	8.0 (1.8)	8.9 (1.4)
Physical Health & Well-being Mean (SD)	293	8.7 (1.3)	8.3 (1.6)	8.8 (1.2)
Social Competence Mean (SD)	293	8.5 (1.7)	7.8 (2.4)	8.6 (1.6)
Emotional Maturity Mean (SD)	293	8.1 (1.6)	7.5 (1.9)	8.1 (1.5)
Communication Skills & General Knowledge Mean (SD)	293	8.2 (2.3)	6.8 (2.7)	8.3 (2.1)
Overall Vulnerability, n (%)				
Yes	293	54 (18.4)	9 (30.0)	45 (17.1)
No		239 (81.6)	21 (70.0)	218 (82.9)

*Frequency and percentage are used to represent all categorical variables.
Continuous variables are represented as Mean (SD).
Abbreviations: BMI = Body Mass Index; EDI = Early Development Instrument; ITC = Infant Toddler Checklist; SD = Standard Deviation

Table 5. Logistic Regression Models for the Association between the Primary Predictor (a positive ITC screen) and the Primary Outcome (Overall Vulnerability) (n=293)

Predictors	Unadjusted OR (95% CI)	p-value	Adjusted OR (95% CI)	p-value
Positive ITC Screen: Yes (ref = no)	2.08 (0.89, 4.83)	0.090	1.27 (0.46, 3.50)	0.645
Age at EDI (years)	0.73 (0.43, 1.23)	0.234	0.75 (0.43, 1.31)	0.311
Sex: Male (ref = female)	**2.16 (1.15, 4.04)**	**0.016**	**2.13 (1.05, 4.29)**	**0.035**
Birthweight (kg)	0.92 (0.52, 1.61)	0.765	1.09 (0.59, 2.03)	0.782
Maternal Ethnicity: Non-European (ref = European)	1.77 (0.86, 3.65)	0.122	1.64 (0.66, 4.06)	0.287
Income: <$40,000 (ref = $150,000+)	**6.66 (1.75, 25.37)**	**0.002**	**6.67 (1.58, 28.16)**	**0.010**
Income: $40,000 – $79,999 (ref = $150,000+)	1.01 (0.35, 2.92)	0.514	0.93 (0.31, 2.84)	0.904
Income: $80,000 – $149,999 (ref = $150,000+)	**0.46 (0.20, 1.03)**	**0.002**	0.50 (0.22, 1.14)	0.100
Siblings: 1 (ref = 0)	1.77 (0.90, 3.48)	0.223	1.91 (0.86, 4.21)	0.111
Siblings: 2+ (ref = 0)	1.23 (0.38, 4.00)	0.890	1.08 (0.30, 3.89)	0.908
Family History of Developmental Concern: Yes (ref = no)	0.96 (0.38, 2.45)	0.930	0.85 (0.30, 2.39)	0.756

Abbreviations: CI = confidence interval; OR = odds ratio
Bold = statistically significant findings at $p<0.05$
Income = Self-reported Family Income (CAN$)
*c-statistic = 0.717; Hosmer-Lemeshow Goodness-of-Fit test chi-square (χ^2) = 2.85 (df8) (p=0.943)

Table 6a. Pearson Correlation Matrix for the Association between the ITC and Overall Vulnerability and the 5 Domains on the EDI

	Overall Vulnerability	Language & Cognitive Development	Physical Health & Well-being	Social Competence	Emotional Maturity	Communication Skills & General Knowledge
Positive ITC Screen	0.10	-0.18*	-0.12*	-0.14*	-0.13*	-0.21*
Expressive Speech Delay	0.11	-0.22*	-0.19*	-0.15*	-0.17*	-0.28*
Other Communication Delay	0.09	-0.13*	-0.05	-0.15*	-0.08	-0.14*
Parent Concern	0.10	-0.15*	-0.16*	-0.09	-0.08	-0.06
Positive ITC Screen or Parent Concern	0.13*	-0.21*	-0.17*	-0.13*	-0.13*	-0.18*

*p<0.05

Table 6b. Pearson Correlation Matrix for the Association between Overall Vulnerability and the 5 Domains on the EDI

	1	2	3	4	5	6
1. Overall Vulnerability	1.00	-0.50*	-0.64*	-0.66*	-0.62*	-0.50*
2. Language & Cognitive Development	-0.50*	1.00	0.53*	0.55*	0.46*	0.68*
3. Physical Health & Well-being	-0.64*	0.53*	1.00	0.58*	0.53*	0.63*
4. Social Competence	-0.66*	0.55*	0.58*	1.00	0.75*	0.58*
5. Emotional Maturity	-0.62*	0.46*	0.53*	0.75*	1.00	0.45*
6. Communication Skills & General Knowledge	-0.50*	0.68*	0.63*	0.58*	0.45*	1.00

*p<0.05

Table 7a. Linear Regression Models for the Association between the Primary Predictor (a positive ITC screen) and Secondary Outcome (mean score of the Language & Cognitive Development domain) (n=293)

Predictors	Unadjusted β coefficient Estimate (95% CI)	p-value	Adjusted β coefficient Estimate (95% CI)	p-value
Positive ITC Screen: Yes (ref = no)	**-0.88 (-1.55, -0.17)**	**0.014**	**-0.62 (-1.25, -0.18)**	**0.046**
Age at EDI (years)	**0.96 (0.64, 1.27)**	**<0.002**	**0.93 (0.61, 1.22)**	**<0.002**
Sex: Male (ref = female)	**-0.56 (-0.87, -0.24)**	**<0.002**	**-0.50 (-0.77, -0.18)**	**<0.002**
Birthweight (kg)	0.01 (-0.39, 0.26)	0.660	-0.10 (-0.48, 0.18)	0.650
Maternal Ethnicity: Non-European (ref = European)	-0.33 (-0.88, 0.09)	0.290	0.01 (-0.48, 0.46)	0.900
Income: <$40,000 (reference = $150,000+)	**-1.37 (-2.37, 0.36)**	**0.020**	**-1.23 (-2.01, 0.14)**	**0.008**
Income: $40,000 – $79,999 (reference = $150,000+)	-0.37 (-1.19, 0.57)	0.376	-0.33 (-1.18, 0.41)	0.464
Income: $80,000 – $149,999 (reference = $150,000+)	0.17 (-0.17, 0.51)	0.258	0.17 (-0.17, 0.47)	0.230
Siblings: 1 (ref = 0)	0.02 (-0.41, 0.38)	0.746	0.07 (-0.32, 0.40)	0.622
Siblings: 2+ (ref = 0)	-0.08 (-0.64, 0.73)	0.526	-0.28 (-1.04, 0.36)	0.514
Family History of Developmental Concern: Yes (ref = no)	0.12 (-0.27, 0.50)	0.506	0.15 (-0.19, 0.49)	0.376

Adjusted R^2 (adjusted coefficient of determination) = 0.217
Abbreviations: β = Beta; CI = confidence interval
Bold = statistically significant findings at p<0.05
Adjusted for child age at EDI in years, child sex, birthweight (kg), maternal ethnicity, self-reported family income (CAN$), siblings and family history of developmental concern including ASD, ADHD, or learning disability in mother, father or siblings. All covariates were measured at baseline except child age which was at follow-up and family history of developmental concern which was derived from across all visits up until age 3.

Table 7b. Linear Regression Models for the Association between the Primary Predictor (a positive ITC screen) and Secondary Outcome (mean score of the Communication Skills & General Knowledge domain) (n=293)

Predictors	Unadjusted β coefficient Estimate (95% CI)	p-value	Adjusted β coefficient Estimate (95% CI)	p-value
Positive ITC Screen: Yes (ref = no)	**-1.54 (-2.51, -0.47)**	**0.004**	**-1.08 (-2.10, -0.17)**	**0.036**
Age at EDI (years)	**1.15 (0.69, 1.60)**	**<0.002**	**1.10 (0.70, 1.50)**	**<0.002**
Sex: Male (ref = female)	**-0.53 (-1.02, -0.07)**	**0.028**	**-0.42 (-0.83, 0.07)**	**0.046**
Birthweight (kg)	0.15 (-0.54, 0.54)	0.244	0.04 (-0.54, 0.43)	0.728
Maternal Ethnicity: Non-European (ref = European)	-0.53 (-1.29, 0.05)	0.250	-0.15 (-0.87, 0.44)	0.836
Income: <$40,000 (reference = $150,000+)	**-1.96 (-3.60, 0.87)**	**0.028**	**-2.01 (-3.75, 0.11)**	**0.030**
Income: $40,000 – $79,999 (reference = $150,000+)	-0.69 (-1.70, 0.41)	0.178	-0.58 (-1.61, 0.40)	0.282
Income: $80,000 – $149,999 (reference = $150,000+)	0.10 (-0.53, 0.58)	0.576	0.10 (-0.46, 0.56)	0.562
Siblings: 1 (ref = 0)	-0.30 (-1.00, 0.18)	0.540	-0.24 (-0.91, 0.23)	0.630
Siblings: 2+ (ref = 0)	-0.21 (-0.90, 1.05)	0.364	-0.45 (-1.46, 0.60)	0.378
Family History of Developmental Concern: Yes (ref = no)	0.18 (-0.57, 0.92)	0.662	0.19 (-0.51, 0.89)	0.534

Adjusted R^2 (adjusted coefficient of determination) = 0.147
Abbreviations: β = Beta; CI = confidence interval
Bold = statistically significant findings at p<0.05
Adjusted for child age at EDI in years, child sex, birthweight (kg), maternal ethnicity, self-reported family income (CAN$), siblings and family history of developmental concern including ASD, ADHD, or learning disability in mother, father or siblings. All covariates were measured at baseline except child age which was at follow-up and family history of developmental concern which was derived from across all visits up until age 3.

Table 8a. Hierarchical Linear Regression Models for the Association between the Primary Predictor (a positive ITC screen) and Secondary Outcome (mean score of the Language & Cognitive Development domain) (n=293)

Predictors	Model 1		Model 2		Model 3	
	Adjusted β coefficient Estimate (95% CI)	**p-value**	**Adjusted β coefficient Estimate (95% CI)**	**p-value**	**Adjusted β coefficient Estimate (95% CI)**	**p-value**
Age at EDI (years)	**0.95 (0.65, 1.25)**	**<0.002**	**0.98 (0.71, 1.31)**	**<0.002**	**0.93 (0.61, 1.22)**	**<0.002**
Sex: Male (ref = female)	**-0.53 (-0.82, -0.24)**	**0.002**	**-0.53 (-0.82, -0.24)**	**0.002**	**-0.50 (-0.77, -0.18)**	**<0.002**
Birthweight (kg)	-0.05 (-0.40, 0.18)	0.928	-0.10 (-0.49, 0.16)	0.778	-0.10 (-0.48, 0.18)	0.650
Maternal Ethnicity: Non-European (ref = European)			-0.11 (-0.68, 0.25)	0.974	0.01 (-0.48, 0.46)	0.900
Income: <$40,000 (reference = $150,000+)			**-1.41 (-2.25, 0.02)**	**0.010**	**-1.23 (-2.01, 0.14)**	**0.008**
Income: $40,000 – $79,999 (reference = $150,000+)			-0.38 (-1.18, 0.49)	0.322	-0.33 (-1.18, 0.41)	0.464
Income: $80,000 – $149,999 (reference = $150,000+)			0.17 (-0.15, 0.51)	0.294	0.17 (-0.17, 0.47)	0.230
Siblings: 1 (ref = 0)			0.05 (-0.35, 0.38)	0.682	0.07 (-0.32, 0.40)	0.622
Siblings: 2+ (ref = 0)			-0.14 (-0.71, 0.63)	0.424	-0.28 (-1.04, 0.36)	0.514
Family History of Developmental Concern: Yes (ref = no)			0.21 (-0.08, 0.64)	0.288	0.15 (-0.19, 0.49)	0.376
Positive ITC Screen: Yes (ref = no)					**-0.62 (-1.25, -0.18)**	**0.046**
Adjusted R^2	0.164		0.209		0.217	

Abbreviations: β = Beta; CI = confidence interval; R^2 = coefficient of determination
Bold = statistically significant findings at p<0.05
Model 1: Adjusted for child age at EDI in years, child sex and birthweight (kg)
Model 2: Adjusted for maternal ethnicity, self-reported family income (CAN$), siblings and family history of developmental concern including ASD, ADHD, or learning disability in mother, father or siblings
Model 3: Adjusted for a positive ITC screen
All covariates were measured at baseline except child age which was at follow-up and family history of developmental concern which was derived from across all visits up until age 3.

Table 8b. Hierarchical Linear Regression Models for the Association between the Primary Predictor (a positive ITC screen) and Secondary Outcome (mean score of the Communication Skills & General Knowledge domain) (n=293)

Predictors	Model 1		Model 2		Model 3	
	Adjusted β coefficient Estimate (95% CI)	**p-value**	**Adjusted β coefficient Estimate (95% CI)**	**p-value**	**Adjusted β coefficient Estimate (95% CI)**	**p-value**
Age at EDI (years)	**1.14 (0.67, 1.62)**	**<0.002**	**1.16 (0.75, 1.66)**	**<0.002**	**1.10 (0.70, 1.50)**	**<0.002**
Sex: Male (ref = female)	**-0.50 (-1.00, -0.03)**	**0.040**	**-0.47 (-0.91, 0.01)**	**0.042**	**-0.42 (-0.83, 0.07)**	**0.046**
Birthweight (kg)	0.08 (-0.57, 0.45)	0.350	-0.02 (-0.63, 0.36)	0.596	0.04 (-0.54, 0.43)	0.728
Maternal Ethnicity: Non-European (ref = European)			-0.29 (-1.21, 0.24)	0.790	-0.15 (-0.87, 0.44)	0.836
Income: <$40,000 (reference = $150,000+)			**-1.95 (-3.52, 0.68)**	**0.024**	**-2.01 (-3.75, 0.11)**	**0.030**
Income: $40,000 – $79,999 (reference = $150,000+)			-0.69 (-1.64, 0.38)	0.178	-0.58 (-1.61, 0.40)	0.282
Income: $80,000 – $149,999 (reference = $150,000+)			0.09 (-0.48, 0.62)	0.626	0.10 (-0.46, 0.56)	0.562
Siblings: 1 (ref = 0)			-0.30 (-0.99, 0.23)	0.540	-0.24 (-0.91, 0.23)	0.630
Siblings: 2+ (ref = 0)			-0.25 (-0.99, 1.07)	0.290	-0.45 (-1.46, 0.60)	0.378
Family History of Developmental Concern: Yes (ref = no)			0.27 (-0.31, 1.02)	0.438	0.19 (-0.51, 0.89)	0.534
Positive ITC Screen: Yes (ref = no)					**-1.08 (-2.10, -0.17)**	**0.036**
Adjusted R^2	0.092		0.130		0.147	

Abbreviations: β = Beta; CI = confidence interval; R^2 = coefficient of determination
Bold = statistically significant findings at p<0.05
Model 1: Adjusted for child age at EDI in years, child sex and birthweight (kg)
Model 2: Adjusted for maternal ethnicity, self-reported family income (CAN$), siblings and family history of developmental concern including ASD, ADHD, or learning disability in mother, father or siblings
Model 3: Adjusted for a positive ITC screen
All covariates were measured at baseline except child age which was at follow-up and family history of developmental concern which was derived from across all visits up until age 3.

Table 9. Multivariable Linear Regression Models for the Association between the 18-month Infant Toddler Checklist-based Screening and the Mean Scores of each of the 5 EDI Domains (n=293)

	EDI Domains									
	Language & Cognitive Development[c]		**Physical Health & Well-being[c]**		**Social Competence[c]**		**Emotional Maturity[c]**		**Communication Skills & General Knowledge[c]**	
Predictors[ab]	**β coefficient Estimate (95% CI)**	***P***	**β coefficient Estimate (95% CI)**	***P***	**β coefficient Estimate (95% CI)**	***P***	**β coefficient Estimate (95% CI)**	***P***	**β coefficient Estimate (95% CI)**	***P***
Positive ITC Screen	**-0.62 (-1.25, -0.18)**	**0.046**	-0.28 (-0.86, 0.32)	0.278	-0.55 (-1.48, 0.28)	0.262	-0.50 (-1.16, 0.07)	0.170	**-1.08 (-2.10, -0.17)**	**0.036**
Expressive Speech Delay	**-1.22 (-2.11, -0.58)**	**0.008**	**-0.75 (-1.43, 0.06)**	**0.032**	-0.94 (-2.06, 0.27)	0.104	**-1.00 (-1.80, -0.23)**	**0.014**	**-2.35 (-3.63, -1.32)**	**<0.002**
Other Communication Delay	-0.43 (-1.19, 0.29)	0.276	-0.03 (-0.72, 0.71)	0.988	-0.70 (-1.85, 0.40)	0.288	-0.17 (-1.01, 0.62)	0.778	-0.79 (-2.10, 0.33)	0.306
Parent Concern	-0.64 (-1.30, 0.07)	0.054	-0.59 (-1.27, 0.12)	0.074	-0.41 (-1.45, 0.56)	0.424	-0.33 (-1.08, 0.39)	0.348	-0.25 (-1.31, 0.80)	0.710
Positive ITC Screen or Parent Concern	**-0.63 (-1.17, -0.19)**	**0.018**	**-0.43 (-0.89, -0.01)**	**0.080**	-0.42 (-1.13, 0.19)	0.300	-0.35 (-0.88, 0.18)	0.200	**-0.79 (-1.67, -0.06)**	**0.056**

[a]Reference = no concern

[b]Each row shows results from 5 separate models.

[c]Adjusted for child age at EDI in years, child sex, birthweight (kg), maternal ethnicity, self-reported family income (CAN$), siblings and family history of developmental concern including ASD, ADHD, or learning disability in mother, father or siblings. All covariates were measured at baseline except child age which was at follow-up and family history of developmental concern which was derived from across all visits up until age 3.

Abbreviations: β = Beta; CI = confidence interval

Bold = statistically significant findings at $p<0.05$, or H_0 value not contained in the bootstrapped 95% CI.

Table 10. Summary of Unadjusted and Adjusted Linear and Logistic Regression Models for the Association between a Positive ITC Screen and School Readiness (n=293)

EDI Variables	Unadjusted β/OR	p-value	Adjusted β/OR	p-value
Overall Vulnerability, OR (95% CI)	2.08 (0.89, 4.83)	0.090	1.40 (0.52, 3.78)	0.509
Language & Cognitive Development domain, β (95% CI)	**-0.88 (-1.55, -0.17)**	**0.014**	**-0.62 (-1.25, -0.18)**	**0.046**
Physical Health & Well-being domain, β (95% CI)	-0.49 (-1.11, 0.11)	0.106	-0.28 (-0.86, 0.32)	0.278
Social Competence domain, β (95% CI)	-0.76 (-1.64, 0.06)	0.082	-0.55 (-1.48, 0.28)	0.262
Emotional Maturity domain, β (95% CI)	**-0.67 (-1.30, 0.06)**	**0.052**	-0.50 (-1.16, 0.07)	0.170
Communication Skills & General Knowledge domain, β (95% CI)	**-1.54 (-2.51, -0.47)**	**0.004**	**-1.08 (-2.10, -0.17)**	**0.036**

Abbreviations: β = Beta; CI = confidence interval; OR = odds ratio
Bold = statistically significant findings at $p<0.05$
Adjusted for child age at EDI in years, child sex, birthweight (kg), maternal ethnicity, self-reported family income (CAN$), siblings and family history of developmental concern including ASD, ADHD, or learning disability in mother, father or siblings. All covariates were measured at baseline except child age which was at follow-up and family history of developmental concern which was derived from across all visits up until age 3.

Table 11. Screening Test Properties of the ITC compared with Overall Vulnerability on the EDI (n=293)

	Overall Vulnerability on the EDI at Follow-up		
ITC Screen	**Yes**	**No**	
Positive	9	21	30
Negative	45	218	263
	54	239	293
Sensitivity (95% CI), %	16.7 (7.9, 29.3)		
Specificity (95% CI), %	91.2 (86.9, 94.5)		
False Positives (95% CI), %	8.8 (5.4, 13.4)		
Positive Predictive Value (95% CI), %	30.0 (17.2, 46.9)		
Negative Predictive Value (95% CI), %	82.9 (81.0, 82.1)		
Expressive Speech Delay	**Yes**	**No**	
Positive	6	11	17
Negative	48	228	276
	54	239	293
Sensitivity (95% CI), %	11.1 (4.2, 22.6)		
Specificity (95% CI), %	95.4 (91.9, 97.7)		
False Positives (95% CI), %	4.6 (2.3, 8.2)		
Positive Predictive Value (95% CI), %	35.3 (17.4, 58.5)		
Negative Predictive Value (95% CI), %	82.6 (81.2, 84.0)		
Other Communication Delay	**Yes**	**No**	
Positive	6	13	19
Negative	48	226	274
	54	239	293
Sensitivity (95% CI), %	11.1 (4.2, 22.6)		
Specificity (95% CI), %	94.6 (90.9, 97.1)		
False Positives (95% CI), %	5.4 (2.9, 9.3)		
Positive Predictive Value (95% CI), %	31.6 (14.2, 23.4)		
Negative Predictive Value (95% CI), %	82.5 (81.0, 83.9)		
Parent Concern	**Yes**	**No**	
Positive	6	12	18
Negative	48	227	275
	54	239	293
Sensitivity (95% CI), %	11.1 (4.2, 22.6)		
Specificity (95% CI), %	95.0 (91.4, 97.4)		
False Positives (95% CI), %	5.0 (2.6, 8.8)		
Positive Predictive Value (95% CI), %	33.3 (16.4, 56.0)		
Negative Predictive Value (95% CI), %	82.6 (81.1, 84.0)		

ITC Screen or Parent Concern	Yes	No	
Positive	13	30	43
Negative	41	209	250
	54	239	293
Sensitivity (95% CI), %	24.1 (13.5, 37.6)		
Specificity (95% CI), %	87.5 (82.6, 91.4)		
False Positives (95% CI), %	12.6 (8.5, 17.9)		
Positive Predictive Value (95% CI), %	30.2 (19.5, 43.6)		
Negative Predictive Value (95% CI), %	83.6 (81.3, 85.7)		

CI = confidence interval
An ITC screen is positive if there is concern for: 1) expressive speech delay and/or 2) other communication delay.
Parent concern is positive if parents respond with a "Yes" to the question: "Do you have any concerns about your child's development?"

CHAPTER 5: DISCUSSION

The aims of this thesis were to: 1) identify factors associated with a positive ITC screen at the 18-month health supervision visit and 2) examine the construct and predictive criterion validity of developmental screening using the Infant Toddler Checklist (ITC) at 18 months. These objectives were accomplished by carrying out two sets of analyses. In the first analysis, we examined the factors associated with a positive ITC screen and in the second analysis, we examined the construct validity of the ITC and the predictive criterion validity of the ITC, using the Early Development Instrument (EDI) as the criterion measure. This Discussion will follow the recommendations for a Structured Discussion.[123]

5.1 Principal Findings

In the first analysis, we found evidence of an association between male sex, lower birthweight, family income less than CAD $40,000 compared to CAD $150,000 or more and having 2 or more siblings and a positive ITC screen. Male sex, having a family income of less than CAD $40,000 compared to CAD $150,000 or more and having 2 or more siblings resulted in higher odds of a positive ITC screen. Additionally, as birthweight increased, the odds of a positive ITC screen decreased.

The findings from the first analysis were used to inform the covariates included in the second analysis examining the construct and predictive criterion validity of the ITC, using the EDI as the criterion measure. The purpose of this study was to analyze the association between the ITC screen at 18 months of age and school readiness as measured by the EDI at 4 to 6 years of age. In this study, we found no evidence that a positive ITC screen (primary predictor) was associated with overall vulnerability on the EDI (primary outcome). Low, inverse, Pearson correlations were found between several of the 5 components of the ITC and overall vulnerability and/or each of the 5 EDI domains. Evidence of construct validity was found between a positive ITC screen and the Language & Cognitive Development EDI domain (secondary outcome) and between a positive ITC screen and the Communication Skills & General Knowledge EDI domain (secondary outcome). Furthermore, evidence of an association was found between concern for expressive speech delay on the ITC and the Language & Cognitive Development EDI domain, concern for expressive speech delay on the ITC and the

Physical Health & Well-being EDI domain, concern for expressive speech delay on the ITC and the Emotional Maturity EDI domain, concern for expressive speech delay on the ITC and the Communication Skills & General Knowledge EDI domain, a positive ITC screen or parent concern on the ITC and the Language & Cognitive Development EDI domain, a positive ITC screen or parent concern on the ITC and the Physical Health & Well-being EDI domain and a positive ITC screen or parent concern on the ITC and the Communication Skills & General Knowledge EDI domain. Additionally, the ITC was found to have a high to very high specificity ranging from 88% to 95% and low false positive of 5% to 13%, suggesting that it accurately identifies children who were not vulnerable on the EDI.

5.2 Strengths and Limitations

The strengths of the first study (Chapter 3): "*Factors Associated with a Positive Screen on the Infant Toddler Checklist at the 18-Month Health Supervision Visit"* included the fact that the data collection was prospective and recruitment was from a real-world setting. Due to the large amount of *TARGet Kids!* data available, our data set included several child, sociodemographic and family factor variables in the logistic regression models. Our study also utilized a large sample size providing statistical power and reliable results.

Alongside the strengths, this study had a few limitations. Maternal education and family income were high and maternal ethnicity was predominantly European in our cohort. This may limit the generalizability of our findings. Additionally, compared to Sanchez et al.,[31] only one developmental screening tool was used to determine developmental concern. Given the low sensitivity of the ITC, using more than one tool and ongoing surveillance and screening may increase identification of children with concern for developmental delay. Finally, a complete case analysis was used. Therefore, a portion of the sample was removed due to missing or incomplete data.

The strengths of the second study (Chapter 4):*"Developmental Screening using the Infant Toddler Checklist at 18 months and School Readiness as Measured by the Early Development Instrument"* included the fact that the data collection was prospective, recruitment was from a real-world setting and validated instruments were used for data collection at 18 months and 4 to 6 years. The *TARGet Kids!* dataset provided several relevant covariates that were adjusted for in the linear and logistic regression models. Further, our study utilized

advanced statistical methods, including bootstrapping the skewed EDI domains and multiple imputation by chained equation to address covariate data that was missing.

However, this study also had a few limitations. These included the fact that family income was high and maternal ethnicity was predominantly European, which may limit the generalizability of our findings. However, while the prevalence of 18% for overall vulnerability on the EDI was less than that of Canadian children,[82, 85] the prevalence of a positive ITC screen in our sample was at the expected 10th percentile cut-off. This study also had a small sample size of 293, which may have affected the power to detect associations. Finally, the low sensitivity suggested that it is not as useful for identifying those at risk of overall vulnerability on the EDI.

5.3 Possible Mechanisms & Explanations for Findings

There are a few possible explanations for our study findings. Other child, sociodemographic and family factors may be associated with a positive ITC screen. Additionally, in relation to the construct and predictive validity of the ITC, the absence of an association between a positive ITC screen and overall vulnerability on the EDI may be explained by the small sample size, particularly of those who have a positive ITC screen in our sample (n=30). The low sensitivity may be explained by the long duration between the completion of the ITC (at 18-months) and the EDI (between 4 to 6 years of age), as new developmental concerns that arise between 18 months and 4 to 6 years are not accounted for.

5.4 Practice and Policy Implications

Our study demonstrates that child, sociodemographic and family factors are associated with developmental concern identified at a child's 18-month health supervision visit. This is of importance for clinicians, parents and policy makers as children who may be at risk of having a positive ITC screen or developmental concern should be closely monitored and early intervention may be beneficial. This study's results also reinforce the need to focus on these factors as they affect the relationship between a positive ITC screen and a child's readiness for school.

Further, early identification of developmental delay can lead to improvements in the health outcomes and well-being of children. Developmental screening is currently recommended in Canada at the 18-month EWCV,[8] therefore, this is the ideal visit to screen for

developmental delay using the ITC. The ITC at 18 months had high to very high specificity ranging from 88% to 95% suggesting that most children with a negative ITC will demonstrate school readiness at 4 to 6 years. Additionally, with its focus on speech and language, communication disorders and ASD, the ITC may be a strong candidate for screening at the 18-month visit.

5.5 Future Research

Future studies may consider including other child, sociodemographic and family factors to examine their association with an ITC screen at 18 months of age. Additionally, this study could be replicated in a larger population with broader ranges of family income, ethnicity and education status to better understand the associations between a positive ITC screen at 18 months of age and school readiness at 4 to 6 years of age. Finally, a longitudinal study could be conducted, screening for developmental delay at the 18-month health supervision visit as well as at several ages leading up to 4 years. This would provide a comprehensive history of developmental concern prior to school entry and assist in understanding the relationship between developmental screening in early childhood and developmental outcomes at school age (4 to 6 years).

REFERENCES

1. Improving health in early childhood to safeguard development outcomes: World Health Organization 2020 [Available from: https://www.who.int/activities/improving-health-in-early-childhood-to-safeguard-development-outcomes.
2. Your Child at 18 Months (11/2 Yrs): Centers for Disease Control and Prevention 2008 [Available from: https://www.cdc.gov/ncbddd/actearly/pdf/checklists/CDC_-LTSAE-Checklists-with-Tips-18months-P.pdf.
3. Bellman M, Byrne O, Sege R. Developmental assessment of children. BMJ. 2013;346:e8687.
4. Rutter M, Redshaw J. Annotation: Growing up as a Twin: Twin-Singleton Differences in Psychological Development. Journal of Child Psychology and Psychiatry. 1991;32(6):885-95.
5. Canadian Task Force on Preventive Health Care. Recommendations on screening for developmental delay. CMAJ. 2016;188(8):579-87.
6. Boyle CA, Decoufle P, Yeargin-Allsopp M. Prevalence and health impact of developmental disabilities in US children. Pediatrics. 1994;93(3):399-403.
7. Rosenberg SA, Zhang D, Robinson CC. Prevalence of developmental delays and participation in early intervention services for young children. Pediatrics. 2008;121(6):e1503-9.
8. van den Heuvel M, Borkhoff CM, Koroshegyi C, Zabih W, Reijneveld SA, Maguire JL, et al. Diagnostic accuracy of developmental screening in primary care at the 18-month health supervision visit: a cross-sectional study. CMAJ OPEN. 2016;4(4):E634-E40.
9. American Academy of Pediatrics CoCwD. The pediatrician's role in development and implementation of an Individual Education Plan (IEP) and/or an Individual Family Service Plan (IFSP). Pediatrics. 1999;104:124-7.
10. Guttmann A, Saunders NR, Kumar M, Gandhi S, Diong C, MacCon K, et al. Implementation of a Physician Incentive Program for 18-Month Developmental Screening in Ontario, Canada. The Journal of Pediatrics. 2020:1-8.
11. TARGet Kids! The Applied Research Group 2020 [Available from: https://www.targetkids.ca/.
12. What Is Early Childhood Development? A Guide to the Science Center on the Developing Child: Harvard University 2020 [Available from: https://developingchild.harvard.edu/guide/what-is-early-childhood-development-a-guide-to-the-science/.
13. A Science-Based Framework for Early Childhood Policy: Using Evidence to Improve Outcomes in Learning, Behavior, and Health for Vulnerable Children2007. Available from: https://developingchild.harvard.edu/resources/a-science-based-framework-for-early-childhood-policy/.
14. Early Childhood Development Unicef2017 [Available from: https://www.unicef.org/early-childhood-development.
15. Child Development: Early Brain Development Centers for Disease Control and Prevention; 2020 [Available from: https://www.cdc.gov/ncbddd/childdevelopment/early-brain-development.html.
16. Maggi S, Irwin LJ, Siddiqi A, Hertzman C. The social determinants of early child development: an overview. J Paediatr Child Health. 2010;46(11):627-35.
17. Determinants of Health: World Health Organization 2017 [Available from: https://www.who.int/news-room/q-a-detail/determinants-of-health.

18. Social determinants of Health - Early Child Development: World Health Organization 2020 [Available from: https://www.who.int/social_determinants/themes/earlychilddevelopment/en/.
19. Irwin LG, Siddiqi A, Hertzman C. The Equalizing Power of Early Child Development: From the Commission on Social Determinants of Health to Action. Child Health and Education.1(3):146-61.
20. Closing the gap in a generation: Health equity through action on the social determinants of health. 2008.
21. Social determinants of health: World Health Organization 2021 [Available from: https://www.who.int/health-topics/social-determinants-of-health#tab=tab_3.
22. Early Child Development: Canadian Paediatric Society; 2020 [Available from: https://www.cps.ca/en/strategic-priorities/early-child-development.
23. InBrief: The Impact of Early Adversity on Children's Development2007. Available from: https://developingchild.harvard.edu/resources/inbrief-the-impact-of-early-adversity-on-childrens-development/.
24. Enns JE, Brownell M, Janus M, Guhn M. Early Childhood Development in Canada: Current State of Knowledge and Future Directions 2019. Available from: https://edi.offordcentre.com/the-state-of-early-child-development-in-canada/.
25. Resegue R, Puccini RF, Silva EM. Risk factors associated with developmental abnormalities among high-risk children attended at amultidisciplinary clinic. Sao Paulo Medical Journal. 2008;126(1):4-10.
26. Chiu WC, Liao HF, Chang PJ, Chen PC, Chen YC. Duration of breast feeding and risk of developmental delay in Taiwanese children: a nationwide birthcohort study. Paediatric and Perinatal Epidemiology. 2011;25(6):519-27.
27. Natsuaki MN, Shaw DS, Neiderhiser JM, Ganiban JM, Harold GT, Reiss D, et al. Raised by depressed parents: is it an environmental risk? Clinical Child & Family Psychology Review. 2014;17(4):357-67.
28. Schonhaut L, Armijo I, Perez M. Gestational age and developmental risk in moderately and late preterm and early term infants. Pediatrics. 2015;135(4):e835-41.
29. Paiva GS, Lima AC, Lima MC, Eickmann SH. The effect of poverty on developmental screening scores among infants. Sao Paulo Medical Journal. 2010;128(5):276-83.
30. Zhou WJ, Liang AM, Wang FZ, Cui WH, Wang XY, Liu QM, et al. Epidemiological study on developmental delay of 18-month-old children from four districts/counties in Beijing (Abstract). Yi Xue Ban/Journal of Peking University. 2013;45(2):211-6.
31. Sanchez K, Spittle AJ, Cheong JL, Thompson DK, Doyle LW, Anderson PJ, et al. Language in 2-year-old children born preterm and term: a cohort study. Archives of Disease in Childhood. 2019;104(7):647-52.
32. Kerstjens JM, de Winter AF, Sollie KM, Bocca-Tjeertes IF, Potijk MR, Reijneveld SA, et al. Maternal and pregnancy-related factors associated with developmental delay in moderately preterm-born children. Obstetrics & Gynecology. 2013;121(4):727-33.
33. McKelvey LM, Conners Edge NA, Fitzgerald S, Kraleti S, Whiteside-Mansell L. Adverse childhood experiences: Screening and health in children from birth to age 5. Families, Systems, & Health. 2017;35(4):420-9.
34. Allen MC. The high-risk infant. Pediatric Clinics of North America. 1993;40(3):479-90.
35. Washbrook E, Waldfogel J, Bradbury B, Corak M, Ghanghro AA. The Development of Young Children of Immigrants in Australia, Canada, the United Kingdom and the United States. Child Dev. 2012;83(5):1591-607.

36. Orri M, Boivin M, Chen C, Ahun MN, Geoffroy M-C, Ouellet-Morin I, et al. Cohort Profile: Quebec Longitudinal Study of Child Development (QLSCD). Social Psychiatry and Psychiatric Epidemiology. 2020.
37. Learn the Signs. Act Early: Milestones Centers for Disease Control and Prevention; 2020 [Available from: https://www.cdc.gov/ncbddd/actearly/milestones/index.html.
38. BIRTH TO 5: WATCH ME THRIVE! A COMPENDIUM OF SCREENING MEASURES FOR YOUNG CHILDREN U.S. Department of Health and Human Services: Centers for Disease Control and Prevention; 2014 [Available from: https://www.cdc.gov/ncbddd/actearly/pdf/BIRTH-TO-5-WATCH-ME-THRIVE-P.pdf.
39. Dosman CF, Andrews D, Goulden KJ. Evidence-based milestone ages as a framework for developmental surveillance. Paediatr Child Health 2012;17(10):561-8.
40. Parkin PC. Screening for Developmental Delay in Early Childhood 2016 - Canadian Task Force on Preventive Health Care (CTFPHC) 2016 [Available from: https://canadiantaskforce.ca/wp-content/uploads/2016/09/ctfphcdevelopmental-delayslide-deck160516final.pdf.
41. Sheldrick RC, Marakovitz S, Garfinkel D, Carter AS, Perrin EC. Comparative Accuracy of Developmental Screening Questionnaires. JAMA Pediatr. 2020.
42. American Academy of Pediatrics CoCwD, Section on Developmental Behavioral Pediatrics, Bright Futures Steering Committee, Medical Home Initiatives for Children with Special Needs Project Advisory Committee. Identifying infants and young children with developmental disorders in the medical home: an algorithm for developmental surveillance and screening. Pediatrics. 2006;118:405-20.
43. Williams R, Clinton J, Canadian Paediatric Society EYTF. Early Years Task Force. Getting it right at 18 months: in support of an enhanced well-baby visit. Paediatr Child Health. 2011;16:647-54.
44. Workgroup CoPaAMBFPS. 2016 recommendations for preventive pediatric health care. Pediatrics. 2016;137:25-7.
45. FAQ Looksee checklist NDDS2020 [Available from: https://www.lookseechecklist.com/en/faq.
46. Cairney J, Clinton J, Veldhuizen S, Rodrigues C, Missiuns C, Wade T, et al. Evaluation of the revised Nipissing District Developmental Screening (NDDS) tool for use in general population samples of infants and children. BMC Pediatrics. 2016;16(42):1-8.
47. Early Childhood Measurement and Evaluation Tool Review - NDDS: Community-University Partnership for the Study of Children, Youth, and Families; 2011 [Available from: https://www.ualberta.ca/-/media/ualberta/faculties-and-programs/centres-institutes/community-university-partnership/resources/tools---screening/nddsmay-2012.pdf.
48. ASQ-3: Product Details: Paul H. Brookes Publishing Co., Inc.; 2020 [Available from: https://agesandstages.com/products-pricing/asq3/.
49. Brookes Publishing and Phreesia Partner to Expand Delivery of the ASQ-3 Screening Tool: Ages & Stages Questionnaires; 2020 [Available from: https://agesandstages.com/phreesia-and-brookes-publishing-partnership/.
50. Introduction to ASQ Online 2019 [Available from: https://agesandstages.com/wp-content/uploads/2019/05/Introduction-to-ASQ-Online_2019.pdf.
51. PEDS Tools Online: PEDS, PEDS:DM, PEDS:DM-AL: PEDS TEST; 2018 [Available from: https://pedstest.com/AboutOurTools/OnlineScreening.html.
52. PEDS PEDS PEDS:DM PEDS:DM-AL: PEDS TEST; 2018 [Available from: https://pedstest.com/AboutOurTools/.

53. Parents' Evaluation of Developmental Status - Developmental Milestones (PEDS:DM): PEDS TEST; 2018 [Available from: https://pedstest.com/AboutOurTools/LearnAboutPEDSDM/.
54. What is PEDS Developmental Milestones (PEDS:DM©)? : PEDS TEST; 2018 [Available from: https://pedstest.com/AboutOurTools/LearnAboutPEDSDM/IntroductionToPEDSDM.html.
55. PEDS Tools In Other Languages: PEDS TEST; 2018 [Available from: https://pedstest.com/Translations/PEDSinOtherLanguages.html.
56. Help for PEDS Users: PEDS TEST; 2018 [Available from: https://pedstest.com/AboutOurTools/LearnAboutPEDSDM/HelpForPEDSUsers.html#:~:text=You%20can%20use%20PEDS%20and,the%20PEDS%20Combined%20Recording%20Form).
57. PEDS DM Packages PEDStest.com: Frances Page Glascoe; 2016 [Available from: https://www.pedstestshop.com/product-category/peds-dm-packages/.
58. PEDS DM Single Items PEDStest.com: Frances Page Glascoe; 2016 [Available from: https://www.pedstestshop.com/product-category/peds-dm-single-items/.
59. PEDS Products PEDStest.com: Frances Page Glascoe; 2016 [Available from: https://www.pedstestshop.com/product-category/peds-products/.
60. Wetherby A, Prizant B. The Infant Toddler Checklist from the Communication and Symbolic Behavior Scales. Baltimore: Brookes Publishing2014.
61. Wetherby AM, Prizant BM. CSBS DP Infant-Toddler Checklist Paul H. Brookes Publishing Co., Inc 2002 [Available from: https://brookespublishing.com/wp-content/uploads/2012/06/csbs-dp-itc.pdf.
62. Pierce K, Carter C, Weinfeld M, Desmond J, Hazin R, Bjork R, et al. Detecting, Studying, and Treating Autism Early: The One-Year Well-Baby Check-Up Approach. Journal of Paediatrics 2011;159(3):458-65.
63. Charman T. Infant/Toddler Checklist. In: Volkmar F.R. (eds) Encyclopedia of Autism Spectrum Disorders. . Springer, New York, NY. 2013.
64. Wetherby AM, Prizant BM. Communication and Symbolic Behavior Scales Developmental Profile (CSBS DP) Infant-Toddler Checklist and Easy-Score: Paul H. Brookes Publishing Co., Inc.; 2020 [Available from: https://products.brookespublishing.com/Communication-and-Symbolic-Behavior-Scales-Developmental-Profile-CSBS-DP-Infant-Toddler-Checklist-and-Easy-Score-P41.aspx#:~:text=The%20CSBS%20DP%E2%84%A2%20Infant,children%20ages%206%E2%80%9324%20months.
65. Zwaigenbaum L, Brian JA, Ip A. Early detection for autism spectrum disorder in young children. Paediatrics & Child Health. 2019;24(7):424-32.
66. Squires J, Twombly E, Bricker D, Potter L. Excerpted from: ASQ-3 User's Guide - PSYCHOMETRIC STUDIES OF ASQ, THIRD EDITION. 2009.
67. Warren R, Kenny M, Fitzpatrick-Lewis D, Ali MU, Rice M, Bayer A, et al. Screening and Treatment for Developmental Delay in Early Childhood (ages 1-4): Systematic Review McMaster University, Hamilton Ontario Canada2015 [Available from: https://canadiantaskforce.ca/wp-content/uploads/2016/05/screening-and-treatment-for-dev-delay-in-early-childhood-ages-1-4-plus-add-finaljan-4-2016-.pdf.
68. Vameghi R, Sajedi f, Shahshahani S, Biglarian A. Validity and Reliability Determination of Parents Evaluation of Developmental Status (PEDS) in 4-60 Months old Children in Tehran. Iranian Rehabilitation Journal. 2015;13(2).
69. PEDS:DM Validation: PEDS TEST; 2018 [Available from: https://pedstest.com/static/research/peds-dm-

validation.html#:~:text=The%20PEDS%3ADM%20has%20strong,2%20to%204%20week%20interval.
70. Wetherby AM, Brosnan-Maddox S, Peace V, Newton L. Validation of the Infant-Toddler Checklist as a Broadband Screener for Autism Spectrum Disorders from 9 to 24 Months of Age. Autism. 2008;12(5):487-511.
71. Wetherby AM, Allen L, Cleary J, Kublin K, Goldstein H. Validity and Reliability of the Communication and Symbolic Behavior Scales Developmental Profile With Very Young Children. Journal of Speech, Language, and Hearing Research. 2002;45(6):1202-18.
72. Wetherby AM, Goldstein H, Cleary J, Allen L, Kublin K. Early Identification of Children With Communication Disorders: Concurrent and Predictive Validity of the CSBS Developmental Profile. 2003;16(2):161-74.
73. Squires J, Bricker D. Ages & Stages Questionnaires®: Third Edition (ASQ®-3)
A Parent-Completed Child Monitoring System for Social-Emotional Behaviors 2017 [Available from: https://agesandstages.com/wp-content/uploads/2017/10/ASQ-3-At-a-Glance.pdf.
74. Getting it right at 18 months ... making it right for a lifetime report of the Expert Panel on the 18 Month Well Baby Visit. [S.l.]: Ministry of Children and Youth Services; 2005. Available from: http://myaccess.library.utoronto.ca/login?url=http://books.scholarsportal.info/uri/ebooks/ebooks2/ogdc/2014-02-24/2/279196.
75. Publicly Funded Immunization Schedules for Ontario Ministry of Health and Long-Term Care; 2016 [Available from: http://www.health.gov.on.ca/en/pro/programs/immunization/docs/immunization_schedule.pdf.
76. Ontario's Routine Immunization Schedule: Government of Ontario; [Available from: http://www.health.gov.on.ca/en/public/programs/immunization/static/immunization_tool.html.
77. Your child's enhanced 18-month well-baby visit: Ontario Ministry of Children, Community and Social Services; 2020 [Available from: http://www.children.gov.on.ca/htdocs/English/earlychildhood/health/your_enhanced_18-month.aspx.
78. Birken CS, Omand JA, Nurse KM, Borkhoff CM, Koroshegyi C, Lebovic G, et al. Fit for School Study protocol: early child growth, health behaviours, nutrition, cardiometabolic risk and developmental determinants of a child's school readiness, a prospective cohort. BMJ Open. 2019;9(11):e030709.
79. What is the EDI? : Early Development Instrument; 2019 [Available from: https://edi.offordcentre.com/about/what-is-the-edi/.
80. History of the EDI: Early Development Instrument; 2019 [Available from: https://edi.offordcentre.com/about/history-of-the-edi/.
81. Janus M, Offord DR. Development and psychometric properties of the Early Development Instrument (EDI): A measure of children's school readiness. Canadian Journal of Behavioural Science. 2007;39(1):1-22.
82. EARLY DEVELOPMENT INSTRUMENT Interpretation Toolkit: Offord Centre for Child Studies [Available from: https://edi-offordcentre.s3.amazonaws.com/uploads/2019/03/EDI-interpretation-toolkit.pdf.
83. Domains and Subdomains: Early Development Instrument; 2019 [Available from: https://edi.offordcentre.com/researchers/domains-and-subdomains/.
84. EARLY DEVELOPMENT INSTRUMENT
A Population-Based Measure for Communities Ontario 2017/2018 Offord Centre for Child Studies 2017 [Available from: https://edi-offordcentre.s3.amazonaws.com/uploads/2019/01/EDI-ON-ENG-2018.pdf.

85. EDI: Early Development Instrument Early Development Instrument; 2019 [Available from: https://edi.offordcentre.com/.
86. Devescovi R, Monasta L, Bin M, Bresciani G, Mancini A, Carrozzi M, et al. A Two-Stage Screening Approach with I-TC and Q-CHAT to Identify Toddlers at Risk for Autism Spectrum Disorder within the Italian Public Health System. 2020;10(3):1-12.
87. Vehkavuoria S, Stoltb S. Screening language skills at 2;0. Infant Behavior and Development. 2018;50:174-9.
88. Wetherby A, Woods J, Allen J, Cleary J, Dickinson H, Lord C. Early indicators of autism spectrum disorders in the second year of life. J Autism Dev Disord. 2004;34(5):473-93.
89. Duncan R, Duncan G, Stanley L, Aguilar E, Halfonc N. The kindergarten Early Development Instrument predicts third grade academic proficiency. Early Childhood Research Quarterly. 2020;53:287-300.
90. Crowe T, Deitz J, Bennett F. The relationship between the Bayley Scales of Infant Development and preschool gross motor and cognitive performance. Am J Occup Ther. 1987;41(6):374-8.
91. Borkhoff CM, Atalla M, Bayoumi I, Birken CS, Maguire JL, Parkin PC, et al. Screening using the Infant Toddler Checklist at 18 months and later developmental outcomes. 2020.
92. What Does .Mp Stand For? What Fields Does .Mp Search? 2015 [Available from: https://wkhealth.force.com/ovidsupport/s/article/What-does-mp-stand-for-What-fields-does-mp-search-1490023372318#:~:text=MP%20stands%20for%20multi%2Dpurpose,The%20fields%20searched%20by%20a%20.
93. Social Determinants of Health and Health Inequalities Government of Canada; 2020 [Available from: https://www.canada.ca/en/public-health/services/health-promotion/population-health/what-determines-health.html.
94. Moore TG, McDonald M, Carlon L, O'Rourke K. Early childhood development and the social determinants of health inequities. Health Promotion International. 2015;30(2):ii102 - ii5.
95. Marmot MG, Smith GD, Standsfeld S, Patel C, North F, Head J, et al. Health inequalities among British civil servants: the Whitehall II study. THE LANCET. 1991;337(8754):1387-93.
96. Marmot MG, Rose G, Shipley M, Hamilton PJS. Employment grade and coronary heart disease in British civil servants. Journal of Epidemiology and Community Health. 1978;32:244-9.
97. Lucyk K, McLaren L. Taking stock of the social determinants of health: A scoping review. PLoS ONE. 2017.
98. Carsley S, Borkhoff CM, Maguire JL, Birken CS, Khovratovich M, McCrindle B, et al. Cohort Profile: The Applied Research Group for Kids (TARGet Kids!). International Journal of Epidemiology. 2015:776–88.
99. Appendix C: comparison of ethnic origins disseminated in 2006, 2001 and 1996 Ottawa, Ontario: Statistics Canada; 2008 [
100. Distribution of total income by census family type and age of older partner, parent or individual: Statistics Canada 2020 [Available from: https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1110001201&pickMembers%5B0%5D=1.19&cubeTimeFrame.startYear=2016&cubeTimeFrame.endYear=2018&referencePeriods=20160101%2C20180101.
101. Unicef: Information by country and programme 2014.
102. Wetherby A, Prizant BM. Communication and Symbolic Behavior Scales Developmental Profile Infant/Toddler Checklist. 2001.

103. WHO Child Growth Standards: Methods and development: Length/height-for-age, weight-for-age, weight-for-length, weight-for-height and body mass index-for-age WHO2021 [Available from: http://www.who.int/childgrowth/publications/technical_report_pub/en/.
104. Pagano M, Gauvreau K. Principles of Biostatistics. Second ed. CA, USA: Brooks/Cole; 2000.
105. Harrell FE. Regression Modeling Strategies: With Applications to Linear Models, Logistic Regression, and Survival Analysis New York: Wiley; 2001.
106. Overview of SAS 9.4: SAS Institute Inc; 2020 [Available from: https://documentation.sas.com/?cdcId=pgmsascdc&cdcVersion=9.4_3.5&docsetId=whatsnew&docsetTarget=n17cszme3e52b4n1ooe3710fnuec.htm&locale=en.
107. Tomblin JB, Records NL, Buckwalter P, Zhang X, Smith E, O'Brien M. Prevalence of specific language impairment in kindergarten children. Journal of speech, language, and hearing research: JSLHR. 1997;40(6):1245-60.
108. American Academy of Pediatrics CoCwD. Developmental surveillance and screening of infants and young children. Pediatrics. 2001;108(1):192-6.
109. Ontario's enhanced 18-month well-baby visit Information for physicians & other health professionals: Ontario Ministry of Children, Community and Social Services 2017 [Available from: http://www.children.gov.on.ca/htdocs/English/earlychildhood/health/enhanced_18-month.aspx.
110. EDI in Ontario Early Development Instrument2019 [Available from: https://edi.offordcentre.com/partners/canada/edi-in-ontario/.
111. How to Interpret EDI Results Early Development Instrument2019 [Available from: https://edi.offordcentre.com/researchers/how-to-interpret-edi-results/.
112. Canadian Community Health Survey, Cycle 2.2, Nutrition (2004): Income-Related Household Food Security in Canada: Health Canada; 2008 [Available from: https://www.canada.ca/en/health-canada/services/food-nutrition/food-nutrition-surveillance/health-nutrition-surveys/canadian-community-health-survey-cchs/canadian-community-health-survey-cycle-2-2-nutrition-2004-income-related-household-food-security-canada-health-canada-2007.html.
113. Webb S, Duku E, Brownell M, Enns J, Forer B, Guhn M, et al. Sex differences in the socioeconomic gradient of children's early development. SSM - Population Health. 2007;10:2352-8273.
114. Santos R, Brownell M, Ekuma O, Mayer T, Soodeen RA. The Early Development Instrument (EDI) in Manitoba: Linking Socioeconomic Adversity and Biological Vulnerability at Birth to Children's Outcomes at Age 5 In University of Manitoba Faculty of Medicine2012 [Available from: http://mchp-appserv.cpe.umanitoba.ca/reference/MCHP_EDI_Report_WEB.pdf.
115. Janus M, Duku E. The School Entry Gap: Socioeconomic, Family, and Health Factors Associated with Children's School Readiness to Learn. Early Education and Development. 2007;18:375-403.
116. Rommelse NN, Franke B, Geurts HM, Hartman CA, Buitelaar JK. Shared heritability of attention-deficit/hyperactivity disorder and autism spectrum disorder. Eur Child Adolesc Psychiatry. 2010;19(3):281-95.
117. Faraone S, Larsson H. Genetics of attention deficit hyperactivity disorder. Molecular Psychiatry. 2019:562-75.
118. Austin M. ADHD and Learning Disorders, Autism and More 2020 [Available from: https://www.gracepointwellness.org/3-adhd/article/13874-adhd-and-learning-disorders-autism-and-more.

119. 2019: Early Development Instrument; Children with special needs [Available from: https://edi.offordcentre.com/about/children-with-special-needs/.
120. Shao J, Sittter R. Bootstrap for Imputed Survey Data. 1996;19(91-453):1278-88.
121. Bootstrapped confidence intervals for the parameters of a linear model applied to multiply imputed data 2013 [Available from: https://stats.stackexchange.com/questions/56136/bootstrapped-confidence-intervals-for-the-parameters-of-a-linear-model-applied-t/.
122. The R Project for Statistical Computing: The R Foundation; [Available from: https://www.r-project.org/.
123. Docherty M, Smith R. The case for structuring the discussion of scientific papers. BMJ. 1999;318(7193):1224-5.

APPENDICES

Appendix A: MEDLINE Search Strategies

Search Strategy 1

The search terms used in Ovid MEDLINE and the number of hits obtained from each search are listed below. The search was conducted on literature published between 1950 to current (2020).

1. risk factors.mp AND child development.mp (3987)
    - risk factors.mp AND child development.mp limited to "all infant (birth to 23 months)" (2210)
        - risk factors.mp AND child development.mp limited to "all infant (birth to 23 months)" AND healthy child*.mp (23)
2. risks factors.mp AND developmental concern.mp OR developmental delay*.mp (817)
    - risk factors.mp AND developmental concern.mp OR developmental delay*.mp limited to "all infant (birth to 23 months)" (497)
        - risk factors.mp AND developmental concern.mp OR developmental delay*.mp limited to "all infant (birth to 23 months)" AND developmental screen*.mp (26)
3. risk factors.mp AND infant toddler checklist.mp (2)
4. determinants of health.mp AND child development.mp (98)
    - determinants of health.mp AND child development.mp limited to "all infant (birth to 23 months)" (22)
5. determinants of health.mp AND developmental concern.mp OR developmental delay*.mp (8)
    - determinants of health.mp AND developmental concern.mp OR developmental delay*.mp limited to "all infant (birth to 23 months)" (2)
6. determinants of health.mp AND infant toddler checklist.mp (0)
7. risk factors associated with child development.tw, kf (1)
8. risk factors associated with child development.mp (1)†
9. risk factors associated with developmental concern.tw, kf (0)
10. risk factors associated with developmental concern.mp (0)†
11. risk factors associated with developmental delay*.tw, kf (1)
12. risk factors associated with developmental delay*.mp (1)†
13. factors associated with child development.tw, kf (4)
14. factors associated with child development.mp (4)†
15. factors associated with developmental concern.tw, kf (2)
16. factors associated with developmental concern.mp (2)†
17. factors associated with developmental delay*.tw, kf (6)
18. factors associated with developmental delay*.mp (6)†

Total number of search results: 4,926

Search Strategy 2

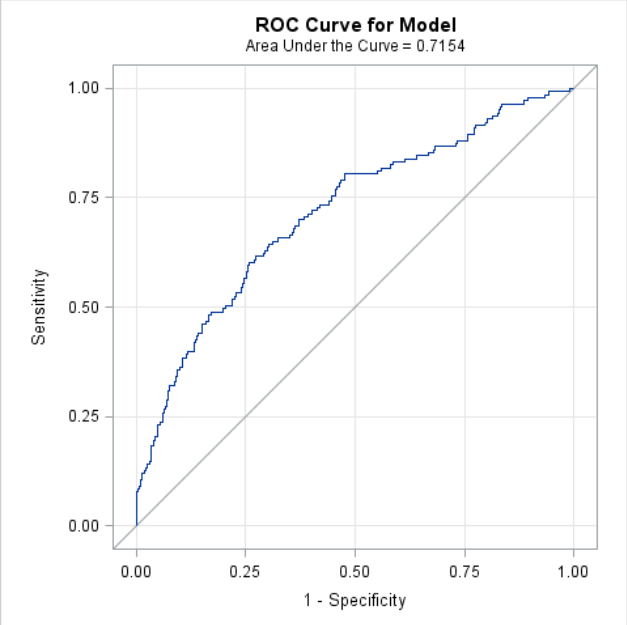
The search terms used in Ovid MEDLINE and the number of hits obtained from each search are listed below. The search was conducted on literature published between 1950 to current (2020).

1. early identification of developmental delay*.tw, kf (17)
2. early identification of developmental delay*.mp (17)†
3. later developmental outcomes.tw, kf (34)
4. later developmental outcomes.mp (34)†
5. infant toddler checklist.tw, kf (32)
6. infant toddler checklist.mp (32)†
7. infant toddler checklist/ (0)
8. early development instrument.tw, kf (55)
9. early development instrument.mp (55)†
10. early development instrument/ (0)
11. 2 and 4 (0)
    - early identification of developmental delay*.tw, kf AND later developmental outcomes.tw, kf.
12. 2 and 9 (0)
    - early identification of developmental delay*.tw, kf AND early development instrument.tw, kf.
13. 3 and 5 (0)
    - early identification of developmental delay*.mp AND later developmental outcomes.mp
14. 3 and 10 (0)
    - early identification of developmental delay*.mp AND early development instrument.mp
15. 6 and 9 (0)
    - infant toddler checklist.tw, kf AND early development instrument.tw, kf
16. 7 and 9 (0)
    - infant toddler checklist.mp AND early development instrument.mp
17. 4 and 6 (0)
    - later developmental outcomes.tw, kf AND infant toddler checklist.tw, kf
18. 5 and 7 (0)
    - later developmental outcomes.mp AND infant toddler checklist.mp
19. 4 and 9 (0)
    - later developmental outcomes.mp AND early development instrument.mp

Total number of search results: 138

†Note: The same results and articles were yielded when using search strategy codes .tw (title and abstract), kf (key word/heading word) and .mp (multi-purpose: title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier).[92]

Appendix B: Model Diagnostics for the Association between the Potential Predictor Variables and the Primary Outcome Variable (a positive ITC screen)



*χ^2 6.85, df8, p=0.553

Figure 1. ROC Curve for a Positive ITC Screen

Table 1. Variance Inflation Factors for Potential Predictor Variables based on a Positive ITC Screen to Assess Multicollinearity

Predictors	Variance Inflation Factors
Age at ITC (years)	1.01061
Sex	1.00750
Birthweight (kg)	1.02598
Maternal Ethnicity	1.44931
Maternal Education	1.12061
Family Income	1.28142
Family Immigration Status	1.44830
Siblings	1.00687
Family History of Developmental Concern	1.02821

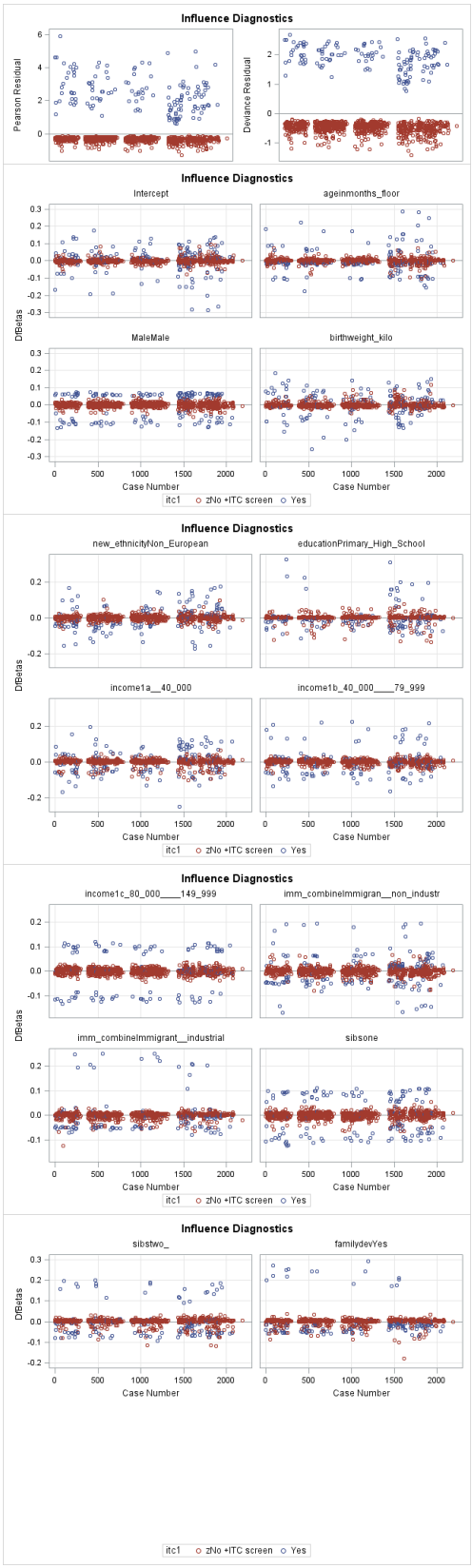
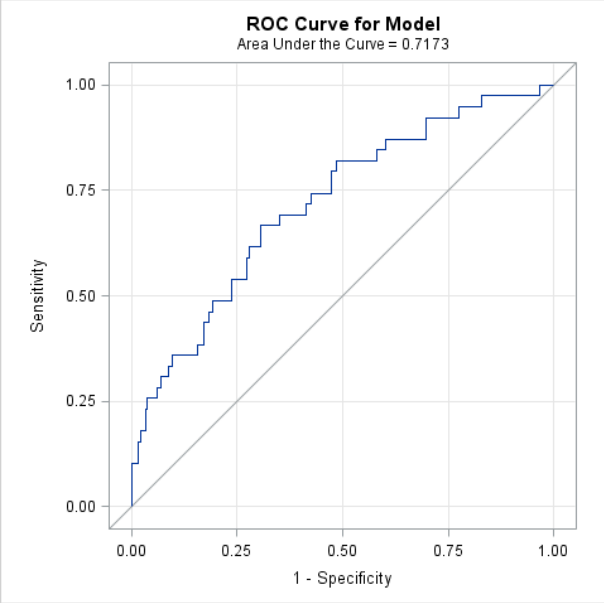


Figure 2. Pearson Residuals and DFBetas for the Predictor Variables in the Logistic Regression Model

Appendix C: Model Diagnostics for the Association between the Primary Predictor (a positive ITC screen) and Primary Outcome (Overall Vulnerability)



*χ^2 2.85, df 8, p = 0.943

Figure 1. ROC Curve for Overall Vulnerability

Table 1. Variance Inflation Factors for Potential Predictor Variables based on Overall Vulnerability to Assess Multicollinearity

Predictors	Variance Inflation Factors
ITC Screen	1.08185
Age at EDI (years)	1.03266
Sex	1.03001
Birthweight (kg)	1.04389
Maternal Ethnicity	1.12059
Family Income	1.13277
Siblings	1.00920
Family History of Developmental Concern	1.03976

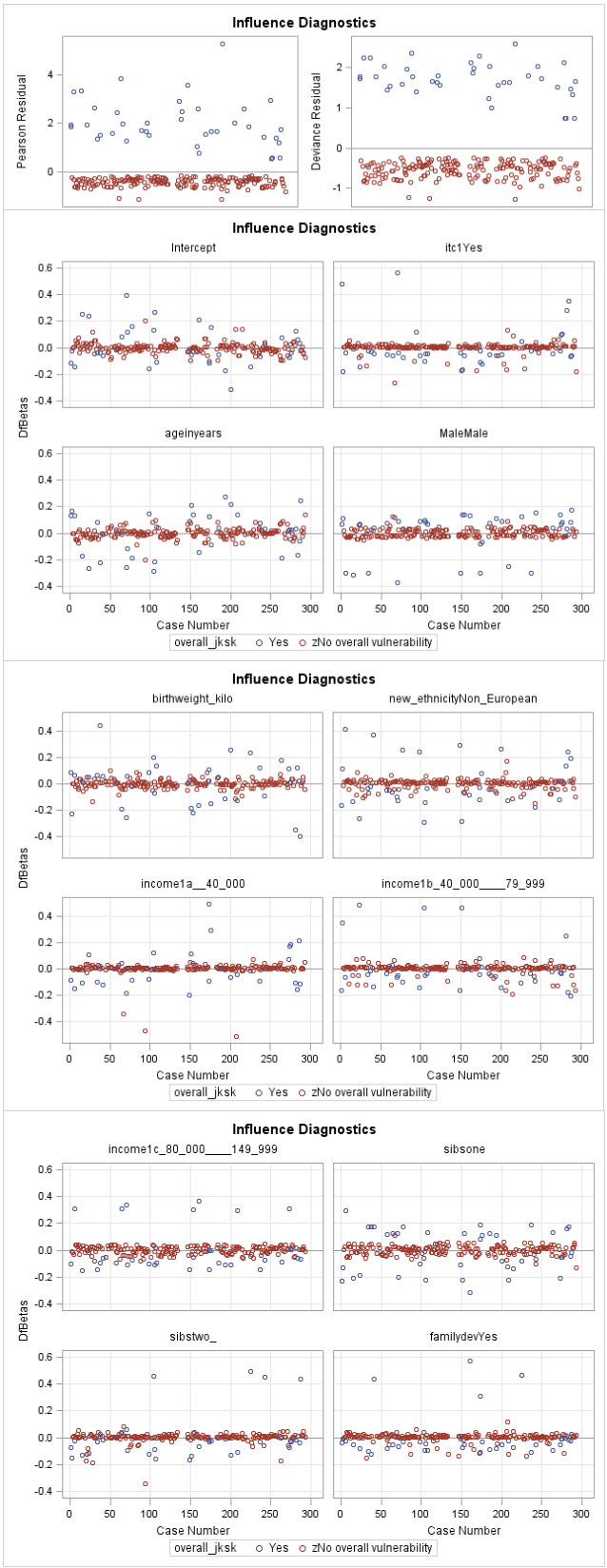


Figure 2. Pearson Residuals and DFBetas for the Predictor Variables in the Logistic Regression Model

Appendix D: Model Diagnostics for the Association between the Primary Predictor (a positive ITC screen) and Secondary Outcomes (mean score of the Language & Cognitive Development and Communication Skills & General Knowledge domains)

Table 1. Variance Inflation Factors for Potential Predictor Variables based on the Language & Cognitive Development Domain to Assess Multicollinearity

Predictors	Variance Inflation Factors
ITC screen	1.08185
Age at EDI (years)	1.03266
Sex	1.03001
Birthweight (kg)	1.04389
Maternal Ethnicity	1.12059
Family Income	1.13277
Siblings	1.00920
Family History of Developmental Concern	1.03976

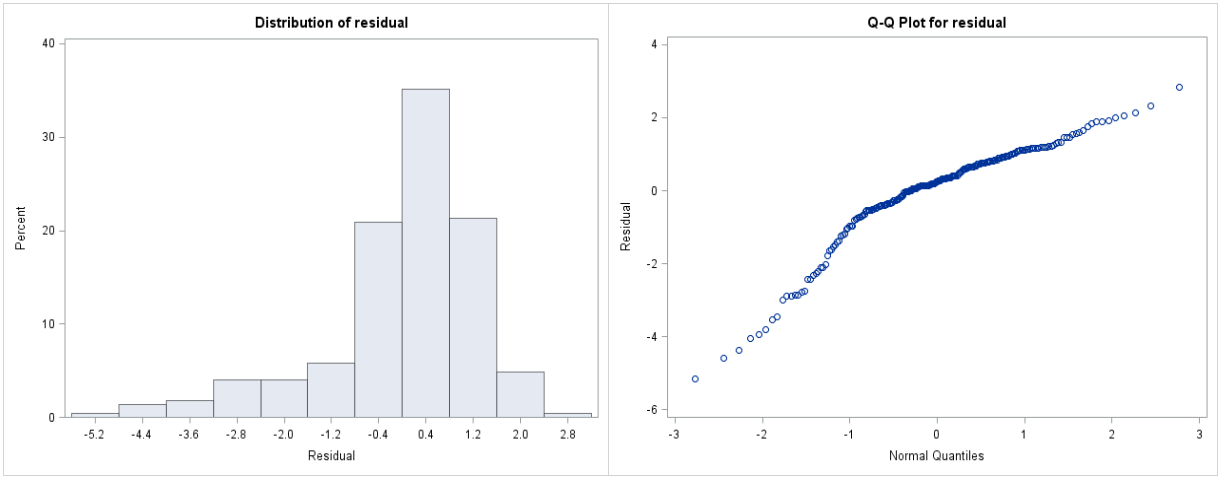


Figure 1. Normality of Residuals for the Language & Cognitive Development Domain
*Skewness = -1.33; Kurtosis = 2.17 (where -1 to +1 = normality); Shapiro-Wilk p<0.0001

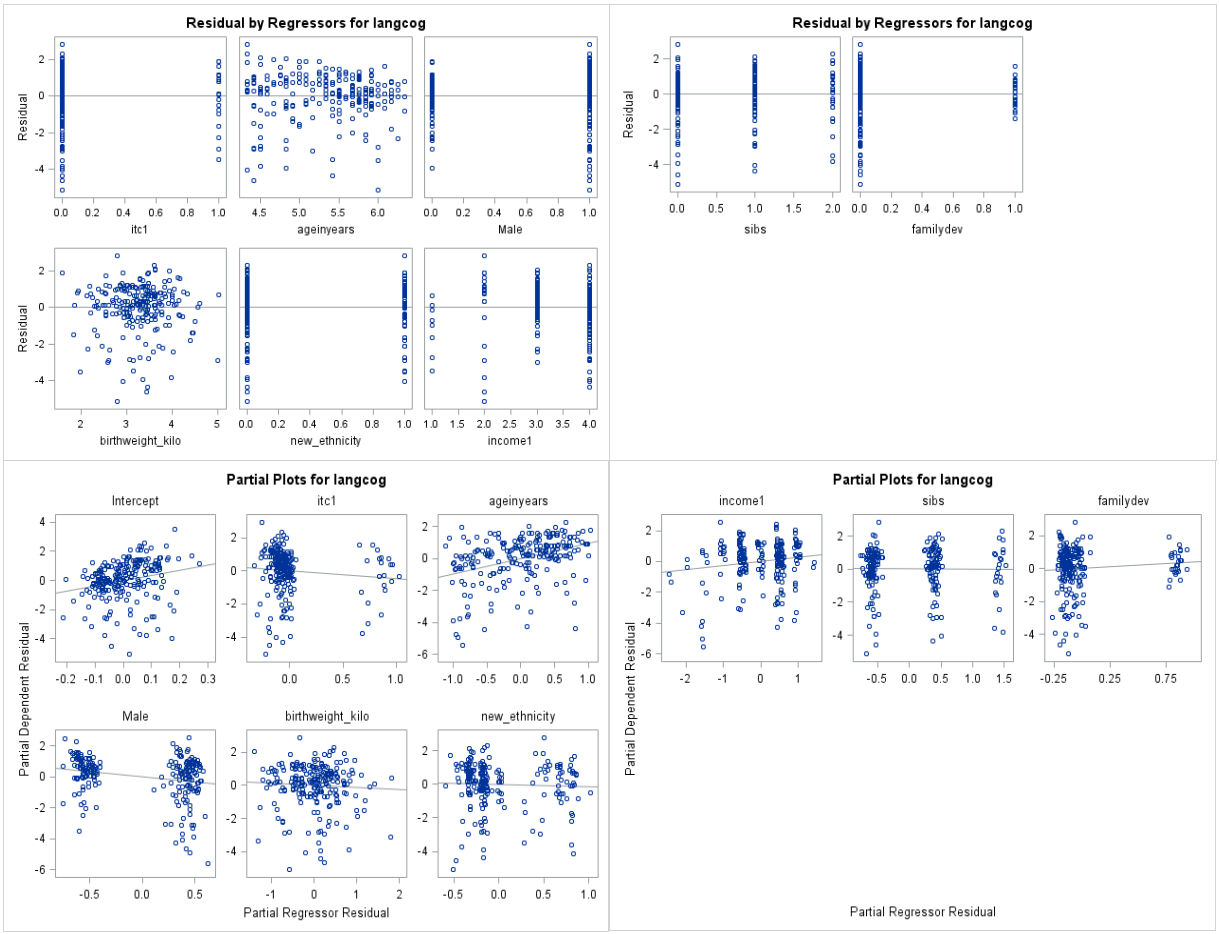


Figure 2. Language & Cognitive Development Domain Residuals and Partial Plots to Assess Homoscedasticity and Straight Line (Linear) Relationship

Table 2. Variance Inflation Factors for Potential Predictor Variables based on the Communication Skills & General Knowledge Domain to Assess Multicollinearity

Predictors	Variance Inflation Factors
ITC screen	1.08185
Age at EDI (years)	1.03266
Sex	1.03001
Birthweight (kg)	1.04389
Maternal Ethnicity	1.12059
Family Income	1.13277
Siblings	1.00920
Family History of Developmental Concern	1.03976

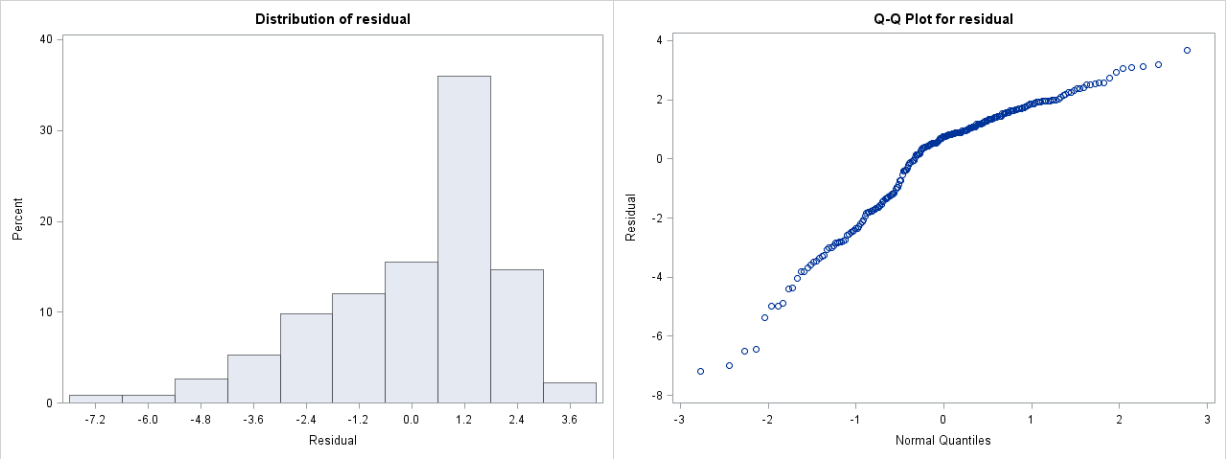


Figure 3. Normality of Residuals for the Communication Skills & General Knowledge Domain
*Skewness = -1.06; Kurtosis = 0.76 (where -1 to +1 = normality); Shapiro-Wilk p<0.0001

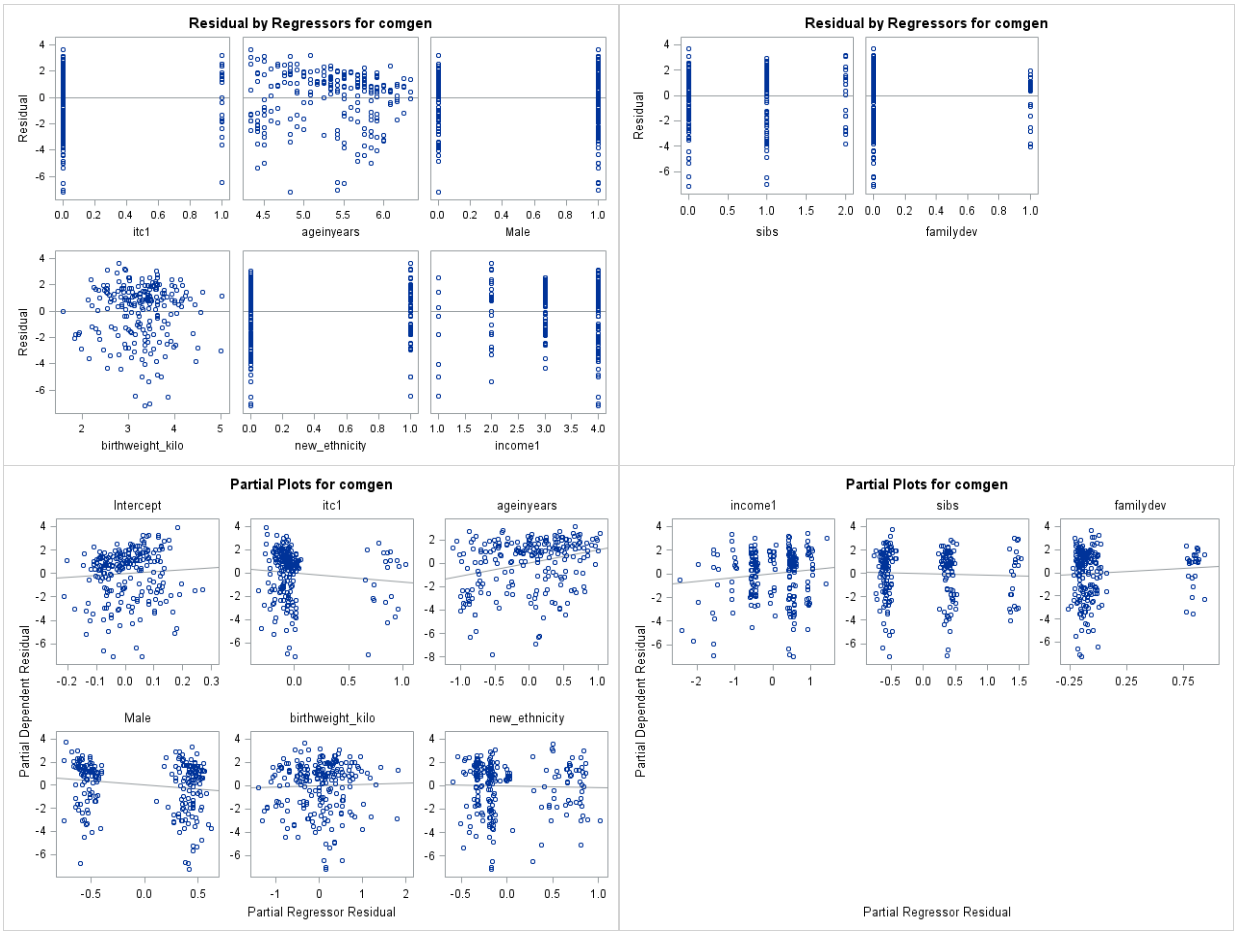


Figure 4. Communication Skills & General Knowledge Domain Residuals and Partial Plots to Assess Homoscedasticity and Straight Line (Linear) Relationship

Appendix E: Research Ethics Board Approval

UNIVERSITY OF TORONTO

OFFICE OF THE VICE-PRESIDENT, RESEARCH AND INNOVATION

RIS Protocol Number: 39292

Approval Date: 30-Apr-20

PI Name: Ms Cornelia Borkhoff

Division Name:

Dear Ms Cornelia Borkhoff:

Re: Your TAHSN-approved research ethics protocol entitled, "Optimizing Early Child Development: Association between the Infant Toddler Checklist (ITC) & School Readiness as measured by the Early Development Instrument (EDI)"

The University has conducted an Administrative review of the TAHSN REB-approved protocol titled above, and has granted approval to the attached until 2021-03-08.

Please be reminded of the following points:

- An annual Renewal must be submitted for ongoing research. Renewals should be submitted between 15 and 30 days prior to the current expiry date.
- A Protocol Completion Report (PCR) is required when research under the protocol involving the University has been completed.
- If your research is funded by a third party, please contact the assigned Research Funding Officer in Research Services to ensure that your funds are released.

Best wishes for the successful completion of your research.

Protocol #:21103					
Status:Admin Review approve	Version:0001	Sub Version:0000	Approved On:30-Apr-20	Expires On:8-Mar-21	Page of 1

OFFICE OF RESEARCH ETHICS
McMurrich Building, 12 Queen's Park Crescent West, 2nd Floor, Toronto, ON M5S 1S8 Canada
Tel: +1 416 946-3273 ● Fax: +1 416 946-5763 ● ethics.review@utoronto.ca ● http://www.research.utoronto.ca/for-researchers-administrators/ethics

Appendix F: *TARGet Kids!* Study – Standardized Questionnaires (2013)

Office use only
ID_____
(write on page 2 now)
OHIP_____

Participant Information

Nutrition and Health Questionnaire – Initial Visit

(This sheet to be stored separately from study data)

Date: _____2013
Month Day Year

1. Please provide contact information for you, your child, and your child's doctor. **You will only be contacted if your responses need to be clarified.**

   a) **Your name:** _____ **Phone #:** _____ - _____ - _____
   (First) (Last)
   Your relationship to the child:
   - ☐ Biological mother
   - ☐ Biological father
   - ☐ Adoptive mother
   - ☐ Adoptive father
   - ☐ Other: _____

   b) **Your child's name:** _____
   (First) (Last)

   c) **Your child's doctor's name:** Dr. _____
   (Initial) (Last)

2. Your postal code: ___ ___ ___ ___ ___ ___

3. Your child's date of birth: _____
   Month Day Year

4. Your child's gender:
   - ☐ Female
   - ☐ Male

5. What language do you speak **most often** at home?
   - ☐ English
   - ☐ French
   - ☐ Other – *Specify*_____

6. Would you like to receive TARGet Kids! updates, newsletters or brochures via email?
   - ☐ Yes Email _____
   - ☐ No

ID

Answer these questions for mother AND father ➔	Mother	Father
7. Where were your child's **biological parents** born?	_____ Country	_____ Country
8. If not born in Canada, what year did parents move here? *(e.g. 1979, 2001, 2012)*	_____	_____
9. What is the current age of the child's parents?	_____years	_____years
10. Are the child's parents currently employed?	☐ No ☐ Yes Is mother: ☐ Part time employed ☐ Full time employed ☐ On parental leave ☐ Other_____	☐ No ☐ Yes Is father: ☐ Part time employed ☐ Full time employed ☐ On parental leave ☐ Other_____

11. What is the immigration status of your child?
- ☐ Canadian Citizen
- ☐ Landed Immigrant
- ☐ Refugee
- ☐ International adoptee

The following questions are about the child being assessed with this questionnaire.

12. a) What was the biological mother's weight prior to her pregnancy? _____ ☐ pounds ☐ kg

b) What was biological mother's weight at the end of her pregnancy? _____ ☐ pounds☐ kg
(i.e. weight before baby was born)

13. During the pregnancy was child's biological mother diagnosed with any of the following?

Gestational Diabetes	☐No	☐Yes
High Blood Pressure	☐No	☐Yes
Anemia	☐No	☐Yes

14. Did your child's **biological mother** take <u>any medications</u> prescribed by a doctor **during her pregnancy**?
- ☐ Yes— **Please explain** _____
- ☐ No
- ☐ Child is adopted (unknown)

15. a) Did your child's **biological mother** take <u>any vitamins</u> or supplements **during her pregnancy?**

- ☐ No – **Skip to question 16**
- ☐ Prenatal multi-vitamin
- ☐ Iron
- ☐ Vitamin D
- ☐ Other – **Please explain** _____
- ☐ Child is adopted (unknown)

b) On a **TYPICAL DAY**, how much did she take?

	Dose/Quantity		**# days per week**
Prenatal multivitamin	_____	Tablet(s)	_____
Iron	_____	Tablet(s)	_____
Vitamin D *(ex: 400 IU, 1000 IU, 2000 IU)*	_____	IU	_____
Other	_____		_____

16. Please check all non-prescribed medications and substances that your child's **biological mother** took during her pregnancy.
- ☐ Cold/flu medication
- ☐ Cigarettes
- ☐ Alcohol
- ☐ Other— **Please explain** _____
- ☐ None
- ☐ Child is adopted (unknown)

17. Please specify **the diet for your child's biological mother** during her pregnancy. Please check all that apply.
- ☐ Red meat (beef, veal, pork, lamb etc)
- ☐ Poultry (chicken, turkey, duck etc)
- ☐ Fish (salmon, halibut, haddock, cod, tuna etc)
- ☐ Shellfish (lobster, crab, shrimp etc.)
- ☐ Eggs
- ☐ Milk
- ☐ Fruits
- ☐ Vegetables
- ☐ Cheese
- ☐ Yogurt
- ☐ Margarine
- ☐ Honey
- ☐ Vegetarian: did not eat red meat, poultry, fish or shellfish
- ☐ Vegan: did not eat red meat, poultry, fish, shellfish, eggs, dairy or honey
- ☐ Child is adopted (unknown)

Questions about your child's health

18. Where was your child born?_____ (Country)

19. What was your child's birth weight? _____Pounds _____Ounces (OR _____Grams)

20. What was your child's gestational age at birth:
- ☐ >41 weeks gestation
- ☐ 38-41 weeks gestation
- ☐ 37 weeks gestation
- ☐ 36 weeks gestation
- ☐ 35 weeks gestation
- ☐ 34 weeks gestation
- ☐ 33 weeks gestation
- ☐ 32 weeks gestation
- ☐ <32 weeks gestation

21. **What were the ethnic or cultural origins of your child's ancestors?**
An ancestor is usually more distant than a grandparent.

You can provide more than one answer.

Biological Mother	**Biological Father**
☐ Eastern European (Polish, Russian, Croatian, etc)	☐ Eastern European (Polish, Russian, Croatian, etc)
☐ Western European (English, French, Portuguese, etc)	☐ Western European (English, French, Portuguese, etc)
☐ East Asian (Chinese)	☐ East Asian (Chinese)
☐ East Asian (Korean)	☐ East Asian (Korean)
☐ East Asian (Japanese)	☐ East Asian (Japanese)
☐ South Asian (East Indian, Pakistani, Sri Lankan, etc)	☐ South Asian (East Indian, Pakistani, Sri Lankan, etc)
☐ Southeast Asian (e.g. Vietnamese, Malaysian, Filipino, etc)	☐ Southeast Asian (e.g. Vietnamese, Malaysian, Filipino, etc)
☐ West Asian (e.g. Iranian, Afghan, Palestinian, etc)	☐ West Asian (e.g. Iranian, Afghan, Palestinian, etc)
☐ East African (e.g. Ethiopian, Kenyan, Somali, etc)	☐ East African (e.g. Ethiopian, Kenyan, Somali, etc)
☐ Middle African (e.g. Cameroonian, Chadian, Congolese, etc)	☐ Middle African (e.g. Cameroonian, Chadian, Congolese, etc)
☐ Northern African (e.g. Moroccan, Algerian, Egyptian, Sudanese, etc)	☐ Northern African (e.g. Moroccan, Algerian, Egyptian, Sudanese, etc)
☐ Southern African (e.g. Botswana, South African, etc)	☐ Southern African (e.g. Botswana, South African, etc)
☐ Western African (e.g. Ghanaian, Nigerian, Guinean, etc)	☐ Western African (e.g. Ghanaian, Nigerian, Guinean, etc)
☐ Latin American (e.g. Argentinean, Costa Rican, Mexican, etc)	☐ Latin American (e.g. Argentinean, Costa Rican, Mexican, etc)
☐ Caribbean Region (e.g. Jamaican, Trinidadian/Tobagonian, etc)	☐ Caribbean Region (e.g. Jamaican, Trinidadian/Tobagonian, etc)
☐ Indian-Caribbean (e.g. Guyana with origins in India)	☐ Indian-Caribbean (e.g. Guyana with origins in India)
☐ North American Aboriginal (Inuit, Métis, First Nations, etc)	☐ North American Aboriginal (Inuit, Métis, First Nations, etc)
☐ Oceania (e.g. Samoan, Fijian, etc)	☐ Oceania (e.g. Samoan, Fijian, etc)
☐ Australian or New Zealander	☐ Australian or New Zealander
☐ Other (please specify) _____	☐ Other (please specify) _____

☐ Unknown: Child is adopted

Office use only
ID_____
(write on page 2 now)
OHIP_____

Participant Information

Nutrition and Health Questionnaire *(0 to 3 years old)*

(This sheet to be stored separately from study data)

Date: _____2013
Month Day Year

1. Please provide contact information for you, your child, and your child's doctor. **You will only be contacted if your responses need to be clarified.**

   a) **Your name:** _____ **Phone #:** _____ - _____ - _____
   (First) (Last)

   Your relationship to the child:
   - ☐ Biological mother
   - ☐ Biological father
   - ☐ Adoptive mother
   - ☐ Adoptive father
   - ☐ Other: _____

   b) **Your child's name:** _____
   (First) (Last)

   c) **Your child's doctor's name:** Dr. _____
   (Initial) (Last)

2. Your postal code: ___ ___ ___ ___ ___ ___

3. Your child's date of birth: _____
   Month Day Year

4. Your child's gender:
   - ☐ Female
   - ☐ Male

5. What language do you speak **most often** at home?
   - ☐ English
   - ☐ French
   - ☐ Other – *Specify*_____

6.(-) Would you like to receive TARGet Kids! updates, newsletters or brochures via email?
   - ☐ Yes Email _____
   - ☐ No

ID

7 Has your child's biological **family** (including parents, grandparents, aunts, uncles, or siblings) been diagnosed with:

Diagnosed	None	Mother	Father	Sibling	Grandparent, aunt or uncle
Multiple Sclerosis	☐	☐	☐	☐	☐
Diabetes	☐	☐	☐	☐	☐
Osteoporosis	☐	☐	☐	☐	☐
Heart disease	☐	☐	☐	☐	☐
Hypertension	☐	☐	☐	☐	☐
High cholesterol	☐	☐	☐	☐	☐
Cancer	☐	☐	☐	☐	☐
Asthma	☐	☐	☐	☐	☐
Depression / Anxiety	☐	☐	☐	☐	☐
Stroke	☐	☐	☐	☐	☐
Alcohol/ Drugs Problem	☐	☐	☐	☐	☐
ADHD	☐	☐	☐	☐	☐
Autism	☐	☐	☐	☐	☐
Learning Disability	☐	☐	☐	☐	☐
Overweight/Obesity	☐	☐	☐	☐	☐

7.1 Has anyone in your child's biological **family** (including parents, grandparents, aunts, uncles, or siblings) been diagnosed with the following conditions at an **early age** (before 55 for men before 65 for women):

Yes	No	
☐	☐	Heart attack
☐	☐	Treated angina
☐	☐	Coronary artery bypass surgery
☐	☐	Coronary angioplasty
☐	☐	Stroke
☐	☐	Sudden cardiac death

8. Which of the following best describes your child's living arrangements?
- ☐ Lives with 2 parents in the same household
- ☐ Lives with 1 parent only
- ☐ Lives alternating with 2 parents in different households
- ☐ Other— **Please explain** _____

9. Aside **from the child being assessed with this questionnaire**, please list the **date of birth** for **other** children you have
- ☐ No other children
- ☐ Birth dates _____ _____ _____ _____ _____ _____

Year/month/day Year/month/day Year/month/day Year/month/day Year/month/day Year/month/day

10. Do you consider your child to be healthy?
- ☐ Yes
- ☐ No

11. Has **your child** been diagnosed with any of the following conditions? Please check ALL that apply.
- ☐ Asthma
- ☐ Diabetes
- ☐ Eczema or Atopic Dermatitis
- ☐ Attention Deficit Hyperactivity Disorder
- ☐ Autism or Autism Spectrum Disorder
- ☐ Learning problem
- ☐ Developmental delay (e.g. speech and language delay, gross motor delay)
- ☐ Obesity / Overweight
- ☐ Allergies
- ☐ Inflammatory bowel disease
- ☐ Cancer
- ☐ Other-Please explain_____
- ☐ **None**

12. Has **your child** been ill within the past month?
- ☐ Yes— **Please explain**_____
- ☐ No

13. Please check all non-prescribed medications or substances that your child has taken **in the past month.**
- ☐ Cold/flu medication
- ☐ Other - Please explain_____
- ☐ None

14. Was your child given, within the last 3 months, any traditional remedies or cosmetics that are not sold in a regular drugstore or are homemade?
- ☐ Yes
- ☐ No

15. Has your child ever had wheezing or whistling in the chest at any time in the past?
- ☐ Yes
- ☐ No (if you answered "no" please skip to question 16)

15.1 How many attacks of wheezing has your child had in the last 12 months?
☐ None ☐ 1 to 3 ☐ 4 to 12 ☐ More than 12

15.2 In the last 12 months, how often, on average, has your child's sleep been disturbed due to wheezing?
☐ Never woken with wheezing ☐ Less than one night per week ☐ One or more nights per week

15.3 In the last 12 months, has your child's chest sounded wheezy during or after exercise?
☐ Yes ☐ No

15.4 In the last 12 months, has wheezing ever been severe enough to limit your child's speech to only one or two words at a time between breaths?
☐ Yes ☐ No

15.5. Does your child use asthma medication such as inhalers?
☐ Yes, every day ☐ Daily for > 1 month in the past year ☐ Daily for < 1 month in the past year ☐ No

15.6. During the past 12 months, how many times has your child gone to a hospital emergency room for a wheezing episode?
☐ None
☐ How many times? _____

16. Does any member of your household smoke cigarettes?
- ☐ Yes
- ☐ No

17. Has your child ever broken a bone?
- ☐ Yes— How many previous fractures? _____ Fracture type(s):_____
- ☐ No

18. a) Does **your child** take any vitamins or supplements regularly?

- ☐ No – Skip to question 19
- ☐ Vitamin D
- ☐ Iron (e.g. Ferinsol, Palafer)
- ☐ Multivitamin
- ☐ Multivitamin with iron
- ☐ Calcium
- ☐ Other – **Please explain** _____

b) On a **TYPICAL DAY**, how much does your child take?

	Dose/Quantity		**# days per week**
e.g. Vitamin D	*400 IU*		*5*
Vitamin D *(ex: 400 IU, 1000 IU, 2000 IU)*	_____	IU	_____
Iron (e.g. Ferinsol, Palafer)	_____	ml	_____
Multivitamin	_____	tablet(s)	_____
Multivitamin with iron	_____	tablet(s)	_____
Calcium	_____	tablet(s)	_____
Other	_____		_____

19. Does **your child** regularly take any prescribed medications?
- ☐ Yes – Which ones? _____
- ☐ No

Questions about breastfeeding

20. Has your child ever been breastfed?
- ☐ Yes
- ☐ No – skip to Question 21

b) Is your child **currently** breastfeeding?
- ☐ Yes
- ☐ No— At what age did you stop breastfeeding? _____ months

c) How long did you ***exclusively*** breastfeed (only give breast milk) your child?_____ months

d) Did your child receive Vitamin D drops when breastfed?

- ☐ Yes - _____ # days per week
- ☐ No – Skip to question 20f)

e) Have you stopped giving Vitamin D to your child?
- ☐ Yes →**what age** did you **stop**? _____ months
- ☐ No

f) Did your child's **mother** take <u>any vitamins</u> or supplements **while breastfeeding?**

- ☐ No – skip to question 21
- ☐ Prenatal multi-vitamin or multi-vitamin
- ☐ Iron
- ☐ Vitamin D
- ☐ Other – **Please explain** _____

g) On a **TYPICAL DAY**, how much did she take?

	Dose/Quantity		**# days per week**
Prenatal multivitamin	_____	Tablet(s)	_____
Iron	_____	Tablet(s)	_____
Vitamin D *(ex: 400 IU, 1000 IU, 2000 IU)*	_____	IU	_____
Other	_____		_____

21. Which scenario **best describes** your child **in the first year of life**?
- ☐ My child received infant formula 80-100% of the time (was exclusively formula fed).
- ☐ My child received breast milk 80-100% of the time (was exclusively breastfed).
- ☐ My child received both breast milk and formula equally.

22. For how long has your child received infant formula? _____ months

23. On a typical day, does your child **currently drink from**:

	Yes	No
Bottle	☐	☐
Cup (open, no lid)	☐	☐
Sippy cup (lid and spout)	☐	☐

24. Does your child use a bottle during **the day**?
- ☐ Yes—No— At what age did you stop bottle use? _____ months.
- ☐ My child has never used the bottle (breast to cup)

25. Does your child use a bottle **in bed**?
- ☐ Never
- ☐ Occasionally
- ☐ Most of the time

26. In a typical week, besides parents, who usually feeds your child? **Check all that apply**
- ☐ Other family members (ex. grandparents)
- ☐ Licensed child care provider
- ☐ Home child care provider (not licensed)
- ☐ Nanny or babysitter
- ☐ No one else
- ☐ Other— Please explain_____

27. Please specify **your child's diet for the past 3 days. Please check all that apply.**
- ☐ Breast milk
- ☐ Infant formula
- ☐ Infant cereal
- ☐ Red meat (beef, veal, pork, lamb, etc.)
- ☐ Poultry (chicken, turkey, duck, etc.)
- ☐ Fish (salmon, halibut, haddock, cod, tuna, etc.)
- ☐ Shellfish (lobster, crab, shrimp, etc.)
- ☐ Eggs
- ☐ Milk
  - ☐ Skim
  - ☐ 1%
  - ☐ 2%
  - ☐ Homo
- ☐ Fruits
- ☐ Vegetables
- ☐ Cheese
- ☐ Yogurt
- ☐ Margarine
- ☐ Honey
- ☐ Grain products (bread, bagel, bun, cereal, pasta, rice, roti, tortillas, etc.)
- ☐ Fast Food
- ☐ Vegetarian: does not eat red meat, poultry, fish or shellfish
- ☐ Vegan: does not eat red meat, poultry, fish, shellfish, eggs, dairy or honey

28. **Circle how many cups of each drink your child has <u>currently in a typical day, if none then circle 0</u>**
(1 cup=8 ounces=250 ml)

Cow's milk Skim	0	½	1	2	3	4	5+	
Cow's milk 1%	0	½	1	2	3	4	5+	
Cow's milk 2%	0	½	1	2	3	4	5+	
Cow's milk Homo (Whole Milk 3%)		0	½	1	2	3	4	5+
Infant formula	0	½	1	2	3	4	5+	
Infant cereal	**0**	**¼**	**½**	**¾**	**1**	**2**	**3+**	
Soy milk	0	½	1	2	3	4	5+	
Other milk (rice, goat etc)	0	½	1	2	3	4	5+	
100% Juice (apple, orange etc)	0	½	1	2	3	4	5+	
Sweetened drinks (Kool aid, Sunny D, etc.)	0	½	1	2	3	4	5+	
Tea	0	½	1	2	3	4	5+	
Soda or Pop	0	½	1	2	3	4	5+	

29. At what age **did you introduce**:

a) Infant cereal	Age introduced _____ months	**OR**	☐	Not yet introduced
b) Cows milk	Age introduced _____ months	**OR**	☐	Not yet introduced
c) Juice	Age introduced _____ months	**OR**	☐	Not yet introduced

30. Circle how many **servings** of each food your child has in a typical day. *(Ex: 2 pieces of a Kit Kat bar, or a mini bag of chips)*

Sweets or candy	0	½	1	2	3	4	5+
Chips or Fried snacks	0	½	1	2	3	4	5+

31. a) "Within the past 12 months we worried whether our food would run out before we got money to buy more". Was that often true, sometimes true, or never true for (you/your household) **in the last 12 months**?

☐ Often true
☐ Sometimes true
☐ Never true

b) "Within the past 12 months the food we bought just didn't last and we didn't have money to get more." Was that often true, sometimes true or never true for (you/your household) **in the last 12 months**?

☐ Often true
☐ Sometimes true
☐ Never true

32. In a typical week, how many times does your family eat the evening meal together? _____ days

Questions about <u>screen time</u> (time spent in a room with the TV, video/DVD on, or using a computer, tablet or cell phone)

33. **How many** of the following are in your home **(please indicate exact number)**:Televisions _____

DVD/video players _____

Computers _____

Video game consuls (e.g. Playstation, Xbox, Nintendo Wii) _____

Handheld devices (e.g. iPhones, iPads, Tablets, Nintendo DS videogame) _____

34. Is there a television in your child's bedroom?

☐ Yes— **If yes,** does your child share a bedroom with parents or siblings? ☐ Yes ☐ No
☐ No

35. On a **TYPICAL WEEKDAY** how many minutes did your child spend awake in a room with:

The television on: _____minutes

Videos or a DVD on: _____minutes

Playing the computer: _____minutes

Playing video game consuls *(e.g. Playstation, Xbox, Nintendo Wii)* _____minutes

Playing handheld devices *(e.g. IPhones, IPads, Tablets, Nintendo DS videogame)* _____minutes

36. On a **TYPICAL WEEKDAY**, which meals did your child eat in a room with a screen device (television, computer, tablet etc.) on:

Breakfast	☐Yes	☐No
Lunch	☐Yes	☐No
Dinner	☐Yes	☐No
A snack	☐Yes	☐No

37. On a **TYPICAL WEEKEND DAY**, how many minutes did your child spend awake in a room with:

The television on:	_____minutes
Videos or a DVD on:	_____minutes
Playing the computer:	_____minutes
Playing video game consuls *(e.g. Playstation, Xbox, NIntendo WII)*	_____minutes
Playing handheld devices *(e.g. IPhones, IPads, Tablets, NIntendo DS)*	_____minutes

38. On a **TYPICAL WEEKEND DAY**, which meals did your child eat in a room with a screen device on (television, computer, tablet etc.)

Breakfast	☐Yes	☐No
Lunch	☐Yes	☐No
Dinner	☐Yes	☐No
A snack	☐Yes	☐No

39. Do you have household rules about watching television/videos/DVD?
- ☐ Yes
- ☐ No

40. On a **TYPICAL WEEKDAY**, how much time did **YOU** spend:

a. Watching television? (not videos/DVDs)	_____minutes
b. Watching videos or DVDs	_____minutes
c. Using the computer (not for work)?	_____minutes
d. Playing video games	_____minutes
e. Playing handheld devices *(e.g. IPhones, IPads, Tablets, NIntendo DS)*	_____minutes

41. On a **TYPICAL WEEKEND DAY**, how much time did **YOU** spend:

a. Watching television? (not videos/DVDs)	_____minutes
b. Watching videos or DVDs	_____minutes
c. Using the computer (not for work)?	_____minutes
d. Playing video games	_____minutes
e. Playing handheld devices *(e.g. IPhones, IPads, Tablets, NIntendo DS)*	_____minutes

Questions about your child's sleep

42.a) How many hours does your child usually spend sleeping in a 24 hour period? _____hours

b) On a typical day, how long does your child spend in sleep during the day (naps)? _____minutes

c) On a typical night, how many times does your child wake up during the night: _____

d) On a typical day, how long does it take to put your child to sleep in the evening: _____ minutes

43. During the past week, how many days did you or other family members read to your child _____ # days/week

In the following questions we will be asking about your childcare arrangement.

44. Do you use any form of child care (besides your child's parent)?
- ☐ Yes, continue to Question 45
- ☐ No (e.g. I take care of my child at home full time) – skip to question 50

45. What type of arrangement do you use? (please choose one answer)
- ☐ Care in someone else's home by a non-relative (e.g. neighbor)
- ☐ Care by a relative (e.g. grandparent, aunt,)
- ☐ Care in child's home by a non-relative (e.g. nanny or babysitter)

- ☐ Daycare (centre or home-based)
- ☐ Child is home alone

46. How many hours per week do you use this method of childcare? _____ hours

47. Is this a home-based daycare? Yes No

48. Is this an Early Childhood Center (ECC) or affiliated with an Early Childhood Center? Yes No

49. Is the person providing this care licensed by the government or approved by a family daycare agency? Yes No

Questions about your child's activities

50.Is your child currently in a preschool program? Yes No

51. How many hours did your child attend preschool during **last week**? _____ hours
- ☐ N/A (child is not at preschool program)

52. On a **TYPICAL WEEKDAY**, how much time does your child spend outside or in a gymnasium for 'recess' or 'unstructured free play **during child care?** _____ minutes
- ☐ N/A (not in a child care setting)

53. On a **TYPICAL WEEKDAY**, how much time does your child spend outside or in a gymnasium for 'recess' or 'unstructured free play **during preschool program?** _____ minutes
- ☐ N/A (not in preschool program)

54. **Aside from time in child care and preschool**, on a **TYPICAL WEEKDAY**, how much time does your child spend outside in 'unstructured free play'? _____ minutes

The following questions are about your child's physical activity. Being active can include:

Infants (0 to 1 year)
- Tummy time
- Reaching or grasping balls or other toys
- Playing or rolling on the floor
- Crawling around the home

Toddlers 1-3 years
- Any activity that gets kids moving
- Climbing stairs and moving around the home
- Playing outside and exploring their environment
- Crawling, brisk walking, running of dancing

55. On a **typical day**, how long is your child physically active? _____minutes

56. Over a **typical/usual week**, on how many days is your child physically active for a total of at least 180 minutes per day? (Add up all the time your child spends in physical activity each day) _____days

57. When you or a caregiver are going for a walk with your child, how often does your child ride in a stroller or wagon? **Circle the best answer:**

Never 25% of the time 50% of the time 75% of the time Always

58. On a **typical weekday**, how much time does your child spend in a stroller? _____minutes

59. On a **typical weekday**, how much time does your child spend as a passenger in a motor vehicle (eg. a car, bus)? _____ minutes

60. On a **typical weekday**, how much time does your child spend in organized physical activities (ex. swimming, soccer, gymnastics, etc.)?

None <1/2 hour ½ hour 1 hour 1 ½ hour 2 hours >2 hours

61. On a **typical weekend day**, how much time does your child spend in organized physical activities (ex. swimming, soccer, gymnastics, etc.)?

None <1/2 hour ½ hour 1 hour 1 ½ hour 2 hours >2 hours

62. Do **you** do physical activity in your leisure time (not as part of your job)?

☐ Yes _____ times per ☐week for ☐0-15 min
☐ No ☐month ☐16-30 min
☐31-60 min
☐More than one hour

Questions about sun exposure

63. On a **TYPICAL** day, how much time did your child spend outside?

<1h 1h 2h 3h 4h 5h 6h >7h

64. In the summer, how often does your child play outside for at least 15 min with minimal clothing (without a shirt on or wearing only bathing suit)?

Never 1d/week 2d/week 3d/week 4d/week 5d/week 6d/week Everyday

65. When your child is outside in the summer, how often do you apply sun block to your child's exposed skin?

Never 25% of the time 50% of the time 75% of the time Always

The following questions are about respiratory infections.

66.a) Has your child had an Influenza (flu) Like Illness in the last 12 months? (Influenza Like Illness is *the sudden onset of fever and cough and one or more of the following symptoms: sore throat, muscle aches, joint pain, or weakness. Nausea and or vomiting may also be present.)*

☐ Yes how many times? _____
☐ No

b) Has your child received the Seasonal Influenza vaccine this year?

☐ Yes
☐ No

c) How many colds (cough or runny nose) has your child had in the past 12 months?

☐ None
☐ Number of times _____

d) How many pneumonias has your child had in the past 12 months?

☐ None
☐ Number of times _____

The following questions are about your child's dental care

67. (-) When was the last time your child was seen by a dental professional? _____ months ago

☐ N/A (child has never been seen a dental professional)

68. (-) How many dental cavities has you child had? (please circle one) n/a 0 1 2 3 4 5 >5

69. (-) What was your total family income before taxes last year?

☐ Less than $10,000
☐ $10,000 to $19,999
☐ $20,000 to $29,999
☐ $30,000 to $39,999
☐ $40,000 to $49,999
☐ $50,000 to $59,999
☐ $60,000 to $79,999
☐ $80,000 to $99,999
☐ $100,000 to $149,999
☐ $150,000 to $199,999
☐ $200,000 to $299,999
☐ $300,000 to $499,999
☐ $500,000 or more

70. (-) How many adults and children did this income support? _____

71. (14) What is the highest level of education completed by mother?
- ☐ No certificate, diploma or degree
- ☐ High school certificate or equivalent
- ☐ Apprenticeship or trades certificate or diploma
- ☐ College, CEGEP or other non-university certificate or diploma
- ☐ University certificate, diploma or degree

72. a) Do you live in a house OR apartment ? (please circle one)

b) When was your current home built?
- ☐ 1940s or before
- ☐ 1950s
- ☐ 1960s
- ☐ 1970s
- ☐ 1980s
- ☐ 1990s
- ☐ 2000 or later

73. Within the last 2 years, have you had any renovations done on the interior of your home?
- ☐ Yes
- ☐ No

74. Do you notice peeling paint, paint chips, or dust from paint in your home?
- ☐ Yes
- ☐ No

75. Do you or anyone in your household have a job or hobby that involves exposure to:

Yes	No	
☐	☐	Lead (e.g. construction work, home renovation/repair, furniture refinishing, working with firearms, or arts/crafts work involving ceramics, stained glass, metals or color pigments etc.)
☐	☐	Cadmium (e.g. Mining, smelting, welding etc.)
☐	☐	Mercury (e.g. factories that make products containing mercury such as batteries, thermometers, sphygmomanometers, pressure gauges other measuring devices, electric switches, chlor-akali manufacturing, artisanal gold mining etc.)

OFFICE USE ONLY

ID Number

Parent Measured: Mom Dad

	Child	Parent	
Weight (kg)			
Height (m)			Height Taken □ Standing □ Supine
Waist Circumference (cm)			
Blood Pressure		N/A	

Skin Type: I II III IV V VI

Please list the last time the child consumed a meal or snack: _____ AM / PM

Please list the last time the child consumed a drink (except for water):_____ AM / PM

Time of blood sample collection: _____ AM / PM

Appendix G: Infant Toddler Checklist (ITC)

CSBS DP Infant-Toddler Checklist

ID:_____ Date:_____

Instructions for caregivers: This Checklist is designed to identify different aspects of development in infants and toddlers. Many behaviors that develop before children talk may indicate whether or not a child will have difficulty learning to talk. This Checklist should be completed by a caregiver when the child is between **6 and 24 months of age** to determine whether a referral for an evaluation is needed. The caregiver may be either a parent or another person who nurtures the child daily. Please check all the choices that best describe your child's behavior. If you are not sure, please choose the closest response based on your experience. **Children at your child's age are not necessarily expected to use all the behaviors listed.**

Emotion and Eye Gaze

1. Do you know when your child is happy and when your child is upset? ❒ Not Yet ❒ Sometimes ❒ Often
2. When your child plays with toys, does he/she look at you to see if you are watching? ❒ Not Yet ❒ Sometimes ❒ Often
3. Does your child smile or laugh while looking at you? ❒ Not Yet ❒ Sometimes ❒ Often
4. When you look at and point to a toy across the room, does your child look at it? ❒ Not Yet ❒ Sometimes ❒ Often

Communication

5. Does your child let you know that he/she needs help or wants an object out of reach? ❒ Not Yet ❒ Sometimes ❒ Often
6. When you are not paying attention to your child, does he/she try to get your attention? ❒ Not Yet ❒ Sometimes ❒ Often
7. Does your child do things just to get you to laugh? ❒ Not Yet ❒ Sometimes ❒ Often
8. Does your child try to get you to notice interesting objects—just to get you to look at the objects, not to get you to do anything with them? ❒ Not Yet ❒ Sometimes ❒ Often

Gestures

9. Does your child pick up objects and give them to you? ❒ Not Yet ❒ Sometimes ❒ Often
10. Does your child show objects to you without giving you the object? ❒ Not Yet ❒ Sometimes ❒ Often
11. Does your child wave to greet people? ❒ Not Yet ❒ Sometimes ❒ Often
12. Does your child point to objects? ❒ Not Yet ❒ Sometimes ❒ Often
13. Does your child nod his/her head to indicate *yes*? ❒ Not Yet ❒ Sometimes ❒ Often

Sounds

14. Does your child use sounds or words to get attention or help? ❒ Not Yet ❒ Sometimes ❒ Often
15. Does your child string sounds together, such as *uh oh, mama, gaga, bye bye, bada*? ❒ Not Yet ❒ Sometimes ❒ Often
16. About how many of the following consonant sounds does your child use: *ma, na, ba, da, ga, wa, la, ya, sa, sha*? ❒ None ❒ 1–2 ❒ 3–4 ❒ 5–8 ❒ over 8

Words

17. About how many different words does your child use meaningfully that you recognize (such as *baba* for bottle; *gaggie* for doggie)? ❒ None ❒ 1–3 ❒ 4–10 ❒ 11–30 ❒ over 30
18. Does your child put two words together (for example, *more cookie, bye bye Daddy*)? ❒ Not Yet ❒ Sometimes ❒ Often

Understanding

19. When you call your child's name, does he/she respond by looking or turning toward you? ❒ Not Yet ❒ Sometimes ❒ Often
20. About how many different words or phrases does your child understand without gestures? For example, if you say "where's your tummy," "where's Daddy," "give me the ball," or "come here," without showing or pointing, your child will respond appropriately. ❒ None ❒ 1–3 ❒ 4–10 ❒ 11–30 ❒ over 30

Object Use

21. Does your child show interest in playing with a variety of objects? ❒ Not Yet ❒ Sometimes ❒ Often
22. About how many of the following objects does your child use appropriately: cup, bottle, bowl, spoon, comb or brush, toothbrush, washcloth, ball, toy vehicle, toy telephone? ❒ None ❒ 1–2 ❒ 3–4 ❒ 5–8 ❒ over 8
23. About how many blocks (or rings) does your child stack? **Stacks** ❒ None ❒ 2 blocks ❒ 3–4 blocks ❒ 5 or more
24. Does your child pretend to play with toys (for example, feed a stuffed animal, put a doll to sleep, put an animal figure in a vehicle)? ❒ Not Yet ❒ Sometimes ❒ Often

Do you have any concerns about your child's development? ❒ yes ❒ no If yes, please describe on back.

CSBS DP Infant-Toddler Checklist. Retrieved from https://brookespublishing.com/wp-content/uploads/2012/06/csbs-dp-itc.pdf

CSBS DP Infant-Toddler Checklist: Screening Report

Child's name: _____ *Date filled out:* _____

Date of birth: _____

Chronological age[1]: _____

[1]If child is 4 or more weeks premature, use corrected age. Calculate chronological age by subtracting Date of birth from Date the Checklist was filled out.

Checklist Results

Predictor	Raw Score		Standard Score[a,b]	Percentile Rank[b]	Concern[c]
Emotion and Eye Gaze					
Communication					
Gestures					
SOCIAL COMPOSITE					
Sounds					
Words					
SPEECH COMPOSITE					
Understanding					
Object Use					
SYMBOLIC COMPOSITE					
TOTAL					

[a] The standard scores are based on a mean of 10 and SD of 3 for the Composite Scores and a mean of 100 and SD of 15 for the Total Score. (Refer to the *CSBS DP Manual, First Normed Edition*, for standard scores and tables of norms.)

[b] Criterion levels for concern are set at more than 1.25 SD below the mean as follows: Standard Scores at or below 6 for the Composite Scores and 81 for the Total Score; Percentiles at or below 10. (Refer to the *CSBS DP Manual, First Normed Edition,* for standard scores, percentiles, and tables of norms.)

[c] After filling in Standard Score and Percentile Rank, if below criterion level, write *Yes* in the Concern box. If at or above criterion level, leave blank. A child should be referred for an evaluation if the Social Composite, Symbolic Composite, or the Total Score is below criterion level. A child should be monitored carefully if the Speech Composite is below criterion level; administer a Checklist again in 3 months, and if the child's scores remain below criterion level, refer for a developmental evaluation.

Recommendation

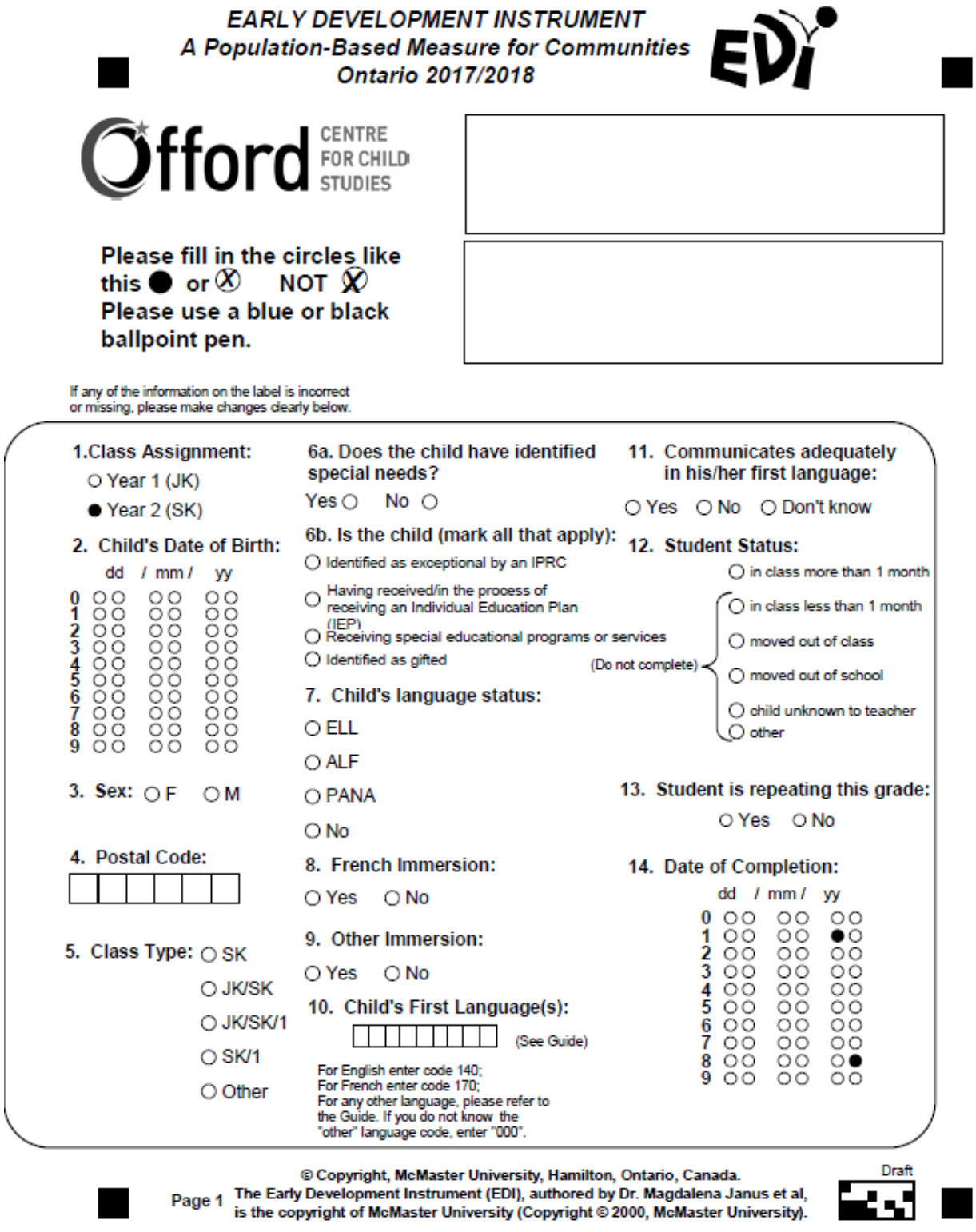
Based on the information provided on the Infant-Toddler Checklist and the results shown above, the following recommendation is made at this time (check one):

- ❒ This child currently communicates as expected for his or her age. Because new skills are emerging each month, it is important to monitor this child's development by asking the child's caregiver to complete the Checklist again in 3 months.
- ❒ This child should be carefully monitored. Re-administer the Checklist in 3 months to determine if a developmental evaluation will become advisable.
- ❒ This child should be referred for a developmental evaluation.

Cut-off Scores for the CSBS DP Infant-Toddler Checklist

		COMPOSITES			TOTAL
		Social	Speech	Symbolic	
6 months	*No Concern*	8 to 26	2 to 14	3 to 17	13 to 57
	Concern	0 to 7	0 to 1	0 to 2	0 to 12
7 months	*No Concern*	8 to 26	2 to 14	3 to 17	14 to 57
	Concern	0 to 7	0 to 1	0 to 2	0 to 13
8 months	*No Concern*	8 to 26	4 to 14	4 to 17	16 to 57
	Concern	0 to 7	0 to 3	0 to 3	0 to 15
9 months	*No Concern*	9 to 26	4 to 14	4 to 17	18 to 57
	Concern	0 to 8	0 to 3	0 to 3	0 to 17
10 months	*No Concern*	12 to 26	5 to 14	5 to 17	23 to 57
	Concern	0 to 11	0 to 4	0 to 4	0 to 22
11 months	*No Concern*	13 to 26	5 to 14	6 to 17	25 to 57
	Concern	0 to 12	0 to 4	0 to 5	0 to 24
12 months	*No Concern*	14 to 26	6 to 14	7 to 17	28 to 57
	Concern	0 to 13	0 to 5	0 to 6	0 to 27
13 months	*No Concern*	15 to 26	6 to 14	8 to 17	29 to 57
	Concern	0 to 14	0 to 5	0 to 7	0 to 28
14 months	*No Concern*	16 to 26	7 to 14	9 to 17	33 to 57
	Concern	0 to 15	0 to 6	0 to 8	0 to 32
15 months	*No Concern*	18 to 26	7 to 14	10 to 17	35 to 57
	Concern	0 to 17	0 to 6	0 to 9	0 to 34
16 months	*No Concern*	18 to 26	7 to 14	11 to 17	36 to 57
	Concern	0 to 17	0 to 6	0 to 10	0 to 35
17 months	*No Concern*	18 to 26	7 to 14	11 to 17	37 to 57
	Concern	0 to 17	0 to 6	0 to 10	0 to 36
18 months	*No Concern*	18 to 26	8 to 14	11 to 17	38 to 57
	Concern	0 to 17	0 to 7	0 to 10	0 to 37
19 months	*No Concern*	18 to 26	8 to 14	11 to 17	38 to 57
	Concern	0 to 17	0 to 7	0 to 10	0 to 37
20 months	*No Concern*	19 to 26	8 to 14	12 to 17	39 to 57
	Concern	0 to 18	0 to 7	0 to 11	0 to 38
21 months	*No Concern*	19 to 26	9 to 14	12 to 17	40 to 57
	Concern	0 to 18	0 to 8	0 to 11	0 to 39
22 months	*No Concern*	19 to 26	9 to 14	12 to 17	40 to 57
	Concern	0 to 18	0 to 8	0 to 11	0 to 39
23 months	*No Concern*	19 to 26	9 to 14	13 to 17	42 to 57
	Concern	0 to 18	0 to 8	0 to 12	0 to 41
24 months	*No Concern*	19 to 26	10 to 14	13 to 17	42 to 57
	Concern	0 to 18	0 to 9	0 to 12	0 to 41
		Social	Speech	Symbolic	TOTAL

Appendix H: Early Development Instrument (EDI)



EARLY DEVELOPMENT INSTRUMENT
A Population-Based Measure for Communities
Ontario 2017/2018

Offord CENTRE FOR CHILD STUDIES

Please fill in the circles like this ● or ⊗ NOT ✗
Please use a blue or black ballpoint pen.

If any of the information on the label is incorrect or missing, please make changes clearly below.

1. Class Assignment:
○ Year 1 (JK)
● Year 2 (SK)

2. Child's Date of Birth:
dd / mm / yy

3. Sex: ○ F ○ M

4. Postal Code:

5. Class Type: ○ SK ○ JK/SK ○ JK/SK/1 ○ SK/1 ○ Other

6a. Does the child have identified special needs?
Yes ○ No ○

6b. Is the child (mark all that apply):
○ Identified as exceptional by an IPRC
○ Having received/in the process of receiving an Individual Education Plan (IEP)
○ Receiving special educational programs or services
○ Identified as gifted

7. Child's language status:
○ ELL
○ ALF
○ PANA
○ No

8. French Immersion:
○ Yes ○ No

9. Other Immersion:
○ Yes ○ No

10. Child's First Language(s):
(See Guide)
For English enter code 140;
For French enter code 170;
For any other language, please refer to the Guide. If you do not know the "other" language code, enter "000".

11. Communicates adequately in his/her first language:
○ Yes ○ No ○ Don't know

12. Student Status:
○ in class more than 1 month
(Do not complete)
○ in class less than 1 month
○ moved out of class
○ moved out of school
○ child unknown to teacher
○ other

13. Student is repeating this grade:
○ Yes ○ No

14. Date of Completion:
dd / mm / yy

Page 1

Draft

EARLY DEVELOPMENT INSTRUMENT A Population-Based Measure for Communities Ontario 2017/2018. Retrieved from https://edi-offordcentre.s3.amazonaws.com/uploads/2019/01/EDI-ON-ENG-2018.pdf

Section A - Physical Well-being

1. About how many regular days (see Guide) has this child been absent since the beginning of school in the fall?

Number of days absent: ☐☐.☐☐

Since the start of school in the fall, has this child sometimes (more than once) arrived:	yes	no	don't know
2. over- or underdressed for school-related activities	○	○	○
3. too tired/sick to do school work	○	○	○
4. late	○	○	○
5. hungry	○	○	○

Would you say that this child:	yes	no	don't know
6. is independent in washroom habits most of the time	○	○	○
7. shows an established hand preference (right vs. left or vice versa)	○	○	○
8. is well coordinated (i.e., moves without running into or tripping over things)	○	○	○

How would you rate this child's:	very good/ good	average	poor/ very poor	don't know
9. proficiency at holding a pen, crayons, or a brush	○	○	○	○
10. ability to manipulate objects	○	○	○	○
11. ability to climb stairs	○	○	○	○
12. level of energy throughout the school day	○	○	○	○
13. overall physical development	○	○	○	○

Section B - Language and Cognitive Skills

How would you rate this child's:	very good/ good	average	poor/ very poor	don't know
1. ability to use language effectively in English	○	○	○	○
2. ability to listen in English	○	○	○	○
3. ability to tell a story	○	○	○	○
4. ability to take part in imaginative play	○	○	○	○
5. ability to communicate own needs in a way understandable to adults and peers	○	○	○	○
6. ability to understand on first try what is being said to him/her	○	○	○	○
7. ability to articulate clearly, without sound substitutions	○	○	○	○

Would you say that this child:	yes	no	don't know
8. knows how to handle a book (e.g., turn a page)	○	○	○
9. is generally interested in books (pictures and print)	○	○	○
10. is interested in reading (inquisitive/curious about the meaning of printed material)	○	○	○
11. is able to identify at least 10 letters of the alphabet	○	○	○
12. is able to attach sounds to letters	○	○	○
13. is showing awareness of rhyming words	○	○	○
14. is able to participate in group reading activities	○	○	○
15. is able to read simple words	○	○	○
16. is able to read complex words	○	○	○
17. is able to read simple sentences	○	○	○
18. is experimenting with writing tools	○	○	○
19. is aware of writing directions in English (left to right, top to bottom)	○	○	○
20. is interested in writing voluntarily (and not only under the teacher's direction)	○	○	○
21. is able to write his/her own name in English	○	○	○
22. is able to write simple words	○	○	○

Section B - Language and Cognitive Skills

Would you say that this child:	yes	no	don't know
23. is able to write simple sentences	○	○	○
24. is able to remember things easily	○	○	○
25. is interested in mathematics	○	○	○
26. is interested in games involving numbers	○	○	○
27. is able to sort and classify objects by a common characteristic (e.g., shape, colour, size)	○	○	○
28. is able to use one-to-one correspondence	○	○	○
29. is able to count to 20	○	○	○
30. is able to recognize numbers 1 - 10	○	○	○
31. is able to say which number is bigger of the two	○	○	○
32. is able to recognize geometric shapes (e.g., triangle, circle, square)	○	○	○
33. understands simple time concepts (e.g., today, summer, bedtime)	○	○	○
34. demonstrates special numeracy skills or talents	○	○	○
35. demonstrates special literacy skills or talents	○	○	○
36. demonstrates special skills or talents in arts	○	○	○
37. demonstrates special skills or talents in music	○	○	○
38. demonstrates special skills or talents in athletics/dance	○	○	○
39. demonstrates special skills or talents in problem solving in a creative way	○	○	○
40. demonstrates special skills or talents in other areas *If yes, please specify:* _____	○	○	○

Section C - Social and Emotional Development

How would you rate this child's:	very good/ good	average	poor/ very poor	don't know
1. overall social/emotional development	○	○	○	○
2. ability to get along with peers	○	○	○	○

Below is a list of statements that describe some of the feelings and behaviours of children. For each statement, please fill in the circle that best describes this child now or within the past six months.

Would you say that this child:	often or very true	sometimes or somewhat true	never or not true	don't know
3. plays and works cooperatively with other children at the level appropriate for his/her age	○	○	○	○
4. is able to play with various children	○	○	○	○
5. follows rules and instructions	○	○	○	○
6. respects the property of others	○	○	○	○
7. demonstrates self-control	○	○	○	○
8. shows self-confidence	○	○	○	○
9. demonstrates respect for adults	○	○	○	○
10. demonstrates respect for other children	○	○	○	○
11. accepts responsibility for actions	○	○	○	○
12. listens attentively	○	○	○	○
13. follows directions	○	○	○	○
14. completes work on time	○	○	○	○
15. works independently	○	○	○	○
16. takes care of school materials	○	○	○	○
17. works neatly and carefully	○	○	○	○
18. is curious about the world	○	○	○	○
19. is eager to play with a new toy	○	○	○	○
20. is eager to play a new game	○	○	○	○
21. is eager to play with/read a new book	○	○	○	○

Section C - Social and Emotional Development

Would you say that this child:	often or very true	sometimes or somewhat true	never or not true	don't know
22. is able to solve day-to-day problems by him/herself	○	○	○	○
23. is able to follow one-step instructions	○	○	○	○
24. is able to follow class routines without reminders	○	○	○	○
25. is able to adjust to changes in routines	○	○	○	○
26. answers questions showing knowledge about the world (e.g., leaves fall in the autumn, apple is a fruit, dogs bark)	○	○	○	○
27. shows tolerance to someone who made a mistake (e.g., when a child gives a wrong answer to a question posed by the teacher)	○	○	○	○
28. will try to help someone who has been hurt	○	○	○	○
29. volunteers to help clear up a mess someone else has made	○	○	○	○
30. if there is a quarrel or dispute will try to stop it	○	○	○	○
31. offers to help other children who have difficulty with a task	○	○	○	○
32. comforts a child who is crying or upset	○	○	○	○
33. spontaneously helps to pick up objects which another child has dropped (e.g., pencils, books)	○	○	○	○
34. will invite bystanders to join in a game	○	○	○	○
35. helps other children who are feeling sick	○	○	○	○
36. is upset when left by parent/guardian	○	○	○	○
37. gets into physical fights	○	○	○	○
38. bullies or is mean to others	○	○	○	○
39. kicks, bites, hits other children or adults	○	○	○	○
40. takes things that do not belong to him/her	○	○	○	○
41. laughs at other children's discomfort	○	○	○	○
42. can't sit still, is restless	○	○	○	○
43. is distractible, has trouble sticking to any activity	○	○	○	○
44. fidgets	○	○	○	○
45. is disobedient	○	○	○	○

Section C - Social and Emotional Development

Would you say that this child:	often or very true	sometimes or somewhat true	never or not true	don't know
46. has temper tantrums	○	○	○	○
47. is impulsive, acts without thinking	○	○	○	○
48. has difficulty awaiting turn in games or groups	○	○	○	○
49. cannot settle to anything for more than a few moments	○	○	○	○
50. is inattentive	○	○	○	○
51. seems to be unhappy, sad, or depressed	○	○	○	○
52. appears fearful or anxious	○	○	○	○
53. appears worried	○	○	○	○
54. cries a lot	○	○	○	○
55. is nervous, high-strung, or tense	○	○	○	○
56. is incapable of making decisions	○	○	○	○
57. is shy	○	○	○	○
58. sucks a thumb/finger	○	○	○	○

Section D - Special Concerns

1. Does the student have a problem that influences his/her ability to participate in a regular classroom? (based on parent information, medical diagnosis, and/or teacher observation)

○ yes ○ no ○ don't know (If answered no/don't know go to question 5)

If YES above, please mark all that apply.
Please base your answers on teacher observation or medical diagnosis and/or parent/guardian information.

	YES Observed	YES Parent Info/Medical Diagnosis	YES Both
2a. physical disability	○	○	○
b. visual impairment	○	○	○
c. hearing impairment	○	○	○
d. speech impairment	○	○	○
e. learning disability	○	○	○
f. emotional problem	○	○	○
g. behavioural problem	○	○	○
h. home environment/ problems at home	○	○	○
i. chronic medical/health problems	○	○	○
j. unaddressed dental needs	○	○	○
k. other *(if known, print below)*	○	○	○

3. If the child has received a diagnosis or identification by a doctor or psychological professional please indicate. You can indicate up to three diagnoses. If there are more than three, please write in the "other" box. Please do not use children's names. **(see the Guide for codes)**

If Other, please specify: _____

Draft

Section D - Special Concerns con't

		yes	no	don't know
4.	Is the child receiving any school based support(s) (e.g. educational assistant, equipment)?	○	○	○
5.	a. Is the child currently receiving further assessment?	○	○	○
	b. Is the child currently on a wait list to receive further assessment?	○	○	○
	c. Do you feel that this child needs further assessment?	○	○	○

If yes, please specify: _____

Section E - Additional Questions

To the best of your knowledge, please mark all that apply to this child:

		yes	no	don't know
1.	Did this child attend an early intervention program *Specify if known, please print:*	○	○	○
2.	On a regular basis, has this child been in non-parental care prior to kindergarten entry	○	○	○

If yes, please specify type of care arrangement (please refer to Guide for examples):

2a. Centre-based, within our school building	○	2e. Child's home, relative	○
2b. Centre-based, in the community	○	2f. Pre-school/Nursery School	○
2c. Home-based child care	○	2g. Other/don't know	○
2d. Child's home, non-relative	○		○

		full-time	part-time	don't know
2h.	If yes to question 1, was this arrangement:	○	○	○

		yes	no	don't know
3.	Did this child attend other community learning programs (e.g. language classes, religion classes, cultural programs, music classes, sports, etc.)	○	○	○
4.	Did this child attended Year 1 (JK):	○	○	○

5. On a regular basis, does this child attend non-parental care in the mornings **before** school:	yes	no	don't know
	^ ○	^ ○	^ ○

If yes, please specify type of care arrangement (please refer to Guide for examples):

5a. Centre based, within our school building	○	5e. Child's home, relative	○
5b. Centre based, in the community	○	5f. Other/don't know	○
5c. Home based child care	○		
5d. Child's home, non-relative	○		

6. How does this child get dropped off **before** school (Please refer to Guide for examples):

6a. By school bus	○
6b. By parent/guardian	○
6c. From school based child-care	○
6d. Other	○

7. On a regular basis, does this child attend non-parental care **after** school:	yes	no	don't know
	^ ○	^ ○	^ ○

If yes, please specify type of care arrangement (please refer to Guide for examples):

7a. Centre based, within our school building	○	7e. Child's home, relative	○
7b. Centre based, in the community	○	7f. Other/don't know	○
7c. Home based child care	○		
7d. Child's home, non-relative	○		

8. How does this child get picked up **after** school (Please refer to Guide for examples):

8a. By school bus	○
8b. By parent/guardian	○
8c. From school based child-care	○
8d. Other	○

If you have any comments about this child and her/his readiness for school, list them below, please print.

Draft