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Establishing a protocol for building a pan-Canadian population-based monitoring system for early childhood development for children with health disorders - Canadian Children's Health in Context Study (CCHICS)

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Abstract

Introduction: Health disorders early in life have tremendous impact on children's developmental trajectories. Almost 80% of children with health disorders lack the developmental skills to take full advantage of school-based education relative to 27% of children without a health disorder. In Canada, there is currently a dearth of nationally representative data on the social determinants of early childhood development for children with health disorders. Evidence from Canada and other countries indicate that poorer developmental outcomes in typically-developing children are associated with lower socioeconomic status (SES). However, to date, it is not known whether this relationship is stronger among children with health disorders. The study's objectives are to estimate the prevalence and to investigate social determinants of developmental outcomes for young children with health disorders, using the Early Development Instrument (EDI).

Methods and analysis: Study objectives will be achieved through three steps. First, using existing (EDI data for 10 provinces and 2 territories collected from 2004-2015, we will investigate differences in developmental health outcomes among children with identified health disorders. Second, population-level EDI data will be linked with neighbourhood sociodemographic census data to explore associations between socioeconomic characteristics and rates of specific diagnoses among 5- and 6-year-olds, including trends over time. Third, for 3 of these 12 regions, additional health and/or education databases will be linked at an individual level. These data will be used to establish differences in EDI outcomes in relation to the age-of-onset of diagnosis, and presence of intervention or treatment.

Ethics and dissemination: Study methodologies have been approved by the Hamilton Integrated Research Ethics Board (HiREB). The results of the analyses of developmental health outcomes for children with health disorders combined with SES will have implications for both health service delivery and school-based intervention strategies. Results will contribute to a framework for public policy.

Keywords: Epidemiology, community child health, mental health, paediatrics, developmental neurology & neurodisability

Strengths and limitations of this study

- CCHICS will use population-level pan-Canadian data to monitor the developmental health of over 990,502 children, of which 155,858 have a health disorder.
- This study offers a broad overview of the developmental health vulnerabilities of children with health disorders across Canada, as well as over time, which allow for in-depth analyses of the social determinants of health.
- Linkages at the individual level between child development data and health and/or education administrative data in 3 provinces will allow for the exploration of factors contributing to the association between developmental health outcomes and SES.
- Asynchronous data collection cycles in provinces may be a limitation.
- Health disorders may be subject to over- or under-reporting which may differ by type of disorder or place of residence, therefore limiting interpretation.

INTRODUCTION

Early Childhood Trajectories

According to UNICEF, healthy development is a right for every child.[1] A *health disorder* i.e., a diagnosable medical condition early in life, has a tremendous impact on the developmental health trajectory of a child. Among otherwise healthy children, approximately one in four kindergartners (27%) lacks the developmental skills to take optimal advantage of school-based education.[2] Among children with identified special health needs at that age, this proportion rises to almost 80%. Having a health disorder in childhood often impacts trajectories of development throughout childhood, adolescence, and adulthood.[3] For instance, poor physical, mental, and socio-emotional development in childhood is linked to later school failure, unemployment, delinquency, and poor health in adulthood.[4, 5] Accordingly, providing additional support to children who are struggling can have protective effects that can set the child on a healthier trajectory,[4] provided we are able to identify those at risk. In environments rich with developmental opportunities and positive experiences, young children can flourish, regardless of their impairment, disease, or health condition.[6] Recent advances in understanding the developmental outcomes for children with health disorders indicate that difficulties are often confined to the areas of disability,[7] and, most importantly, that it is possible to experience a healthy developmental trajectory within a context of a health disorder.[8]

Children's health and socioeconomic gradients

The constellations of conditions in which children are born and grow are often referred to as *social determinants of health.*[5, 9] Social determinants of health include, among other things, income, social status, education, social support networks, as well as social and physical environments.[9] It has long been recognized that socioeconomic status (SES), usually conceptualized as a combination of income, education, and employment indicators, is strongly related to health, with lower SES associated

with both higher mortality and morbidity.[10-13] While not synonymous with social determinants, SES is one of their strongest correlates.[5] The disparities in health across SES are referred to as the *socioeconomic gradient,*[10] underscoring that difference in health outcomes is gradual and occurs across the full spectrum of SES. That is, individuals living in poverty have poorer outcomes when compared to those at the top of the SES hierarchy, but each increase in income is associated with an increase in positive outcomes. The gradient in health status across SES has been well described across a variety of conditions in both adult and child populations.[10, 14-16] Differences in SES at younger ages are particularly important for setting lifetime health trajectories.[17]

There is emerging evidence that low SES can negatively affect the speed of brain development.[18, 19] In this regard, societal inequities are likely to exert a stronger impact on children with health disorders than on those growing up without health disorders, henceforth referred to as "typically developing". Families of children with health disorders are also more likely to experience socio-economic disadvantage.[6, 17, 20, 21] Combined with additional social or economic risks (e.g., single parent family, low income), health disorders can significantly increase a child's odds for later negative outcomes.[22-24]

SES gradient may affect children with health disorders differently than typically-developing children.[25-32] Current research on children with health disorders has explored the association of SES factors with prevalence or with outcomes (such as academic achievement or behaviour), but not both, and usually for no more than one disorder/diagnosis at a time. This gap has been acknowledged,[33] in particular in the emerging pediatric literature focusing on children with special health care needs,[34, 35] as it limits comparability, and thus implications for further research and policy. Research in three Canadian provinces has shown that substantive differences in developmental health among typically-developing children at school entry are tied to SES.[19, 36-38] Little is known about the underlying

mechanisms of this association at the neighbourhood level,[39] and even less about whether this relationship is similar for children with health disorders.

Measuring Child Development at the Population Level

Until recently, Canada has lacked nationally representative data pertaining to social indicators of children's developmental health at school entry. Data collection initiatives implemented across most Canadian provinces and territories over the past decade have sought to address this gap, using the Early Development Instrument (EDI) to monitor trends in children's development across jurisdictions. The EDI is a teacher-completed checklist that measures children's developmental health at school entry in kindergarten in five domains: physical health and well-being, social competence, emotional maturity, language and cognitive development, and communication skills and general knowledge. It has been administered at the population level in most Canadian provinces and territories since 2004 (Table 1).[3, 40] EDI data are collected for each child individually and then aggregated at various levels to offer an assessment of developmental vulnerability in a given population. While the main purpose of the EDI is the assessment of child development, the questionnaire includes information on children's special needs, functional difficulties, and as of 2010, diagnoses. Participants with any of these comprise the sample of children with health disorders in the dataset. This approach reflects the non-categorical concept of illness.[41]

Table 1. *Canadian EDI Implementation Schedule from 2003/2004 to 2014/2015 with percentages and number of children with health disorders, as well as number of typically developing children for each implementation.*

	AB	BC	MB	NB	NL	NT	NS	ON	PEI	QC	SK	Y
2003/2004								13% 15643 103260				
2004/2005	18% 434 2015	13% 4622 30747	13% 1080 7307	9% 61 617						14% 230 1390	14% 429 2644	
2005/2006			18%	16%			15%			14%	15%	

			2158 9513	125 659			229 1291			1548 9638	191 1089	
2006/2007			12% 1386 10128	10% 39 344						19% 262 1132	14% 219 1319	
2007/2008	13% 24 167	13% 5016 32197	13% 179 1239		11% 37 303		17% 77 379	10% 11997 103955	8% 88 1002	20% 176 700	16% 254 1326	
2008/2009			12% 1368 10148	12% 849 6147			13% 605 4222			15% 369 2150		
2009/2010		19% 8942 37301					20% 147 599				19% 4139 18181	26% 86 250
2010/2011	20% 14701 57980		17% 2006 9813		14% 156 932		20% 460 1835	16% 19641 105102				26% 90 250
2011/2012		20% 8228 33805			16% 329 1760	24% 141 440	20% 448 1749			20% 12747 52242	16% 87 451	25% 89 273
2012/2013			16% 2071 10802		14% 699 4134	23% 138 468	19% 1590 6804				19% 1474 6469	24% 95 304
2013/2014		17% 222 1055			16% 823 4237	23% 140 465	23% 314 1061					
2014/2015			16% 2106 11090			26% 153 442	19% 1582 6922	17% 22319 110400				

Note. Light blue cells indicate a partial provincial collection. Dark blue cells indicate a full provincial collection; if the dark blue box spans multiple years it means a province or territory completed the implementation in waves.

A population-level database of developmental outcomes in kindergarten (as measured by the EDI) has recently been created in a CIHR-funded project, referred to as the *Can*adian *N*eighbourhoods and *E*arly *C*hildhood *D*evelopment (CanNECD) Study.[42] The aim of the CanNECD Study was to establish a pan-Canadian database for monitoring children's developmental health and well-being.[35] This database merged pan-Canadian EDI data from 2004 to 2015, spanning 12 of the 13 Canadian provinces and territories, with the Canadian 2005 and 2010 Taxfiler data, as well as 2006 Census and 2011 National Household Survey data using children's postal codes.

The primary goal of the current study, named the *C*anadian *C*hildren's *H*ealth *i*n *C*ontext *S*tudy (CCHICS), is to investigate the impact of different health disorders diagnosed prior to kindergarten and socioeconomic disadvantage on children's developmental outcomes at school entry. Analysis of these data will provide an opportunity to interpret and disseminate findings on developmental outcomes and socioeconomic gradients at regional and provincial levels for children with different health disorders. CCHICS aims to establish the prevalence of health disorders and explore the social determinants of developmental outcomes for children with health disorders. CCHICS is guided by the following research questions:

1) For children diagnosed with health disorders, how do their developmental health outcomes, measured with the EDI in kindergarten, differ from those of typically-developing children, and do they vary depending on the type of disorder?

2) What is the association between prevalence rates of various health disorders in kindergarten and neighbourhood-level SES? Does this association vary across jurisdictions (e.g., provinces, health regions)?

3) What is the association between developmental outcomes as measured by the EDI and SES for children with health disorders? Is it the same as for children without health disorders?

4) In three provinces with the capacity to link EDI to administrative health and education data at the individual level (Manitoba, British Columbia (BC), Ontario), what are the factors contributing to the association between EDI outcomes and SES?

METHODS AND ANALYSIS

Data sources and variables

Developmental health at school entry data

The EDI is a measure of developmental health of kindergarten-age children, implemented at population levels in most jurisdictions in Canada.[3] It is a 103-item, teacher-completed survey of five domains of children's development: physical health and well-being; social competence; emotional maturity; language and cognitive development; and communication skills and general knowledge, further broken down into 16 subdomains (Table 2). Variables relevant to the research objectives are: age, sex, special needs status, functional impairments, a specific diagnosis, if any, and the mean scores for each (sub)domain. After receiving training, kindergarten teachers complete the EDI in the second half of the school year. The psychometric properties of the EDI have been extensively validated.[3, 43-45] The EDI is a reliable and cost-efficient method of assessing developmental health outcomes at the developmentally critical period of transition to school and has moderate to high predictive validity for later school achievement.[46, 47] The EDI is completed for each individual student and the results are aggregated to a group level (according to geographic or demographic criteria) for interpretation. The most common aggregations are at the neighbourhood, school district, and province/territory levels. The Offord Centre for Child Studies (OCCS), at McMaster University, is the national repository of the anonymized EDI data.

Table 2. *Domains and subdomains of the EDI*

Domains	**Subdomains**
Physical health and well-being	Physical readiness for the school day Physical independence Gross and fine motor skills
Social competence	Overall social competence Responsibility and respect Approaches to learning Readiness to explore new things
Emotional maturity	Prosocial and helping behaviour Anxious and fearful behaviour Aggressive behaviour Hyperactivity and inattention

Language and cognitive development	Basic literacy Interest in literacy/numeracy and memory Advanced literacy Basic numeracy
Communication skills and general knowledge	Communication skills and general knowledge

Derived measures. Health disorders. On the EDI, teachers report up to three diagnosed health conditions or impairments, based on information from a parent or health professional (Table 3). The first diagnosis listed is considered the "primary" one for statistical purposes. Teachers report on whether a child has a limitation that interferes with their ability to function in the classroom, with 11 categories provided (Table 4), and whether or not he/she has a special need. *Developmental health.* Mean scores for each of the five EDI domains, and for the 16 EDI subdomains will be used. Vulnerability on each domain, i.e., a score below the 10th percentile based on the population sample of over 160,000 Canadian kindergarten children, will also be used, in addition to *overall vulnerability* (0 = not vulnerable, 1 = vulnerable), which represents vulnerability in at least one of the five domains.[48] For each aggregate unit of analysis (e.g., neighbourhood, school district), child-level data are aggregated to represent the "percentage of vulnerable children" overall, and in a domain, for the given unit of analysis.

Table 3. *Diagnoses included on the EDI.*

DIAGNOSIS	CODE
Mental Health	
ADHD	1
Anxiety	2
Depression	3
Oppositional Defiant Disorder/Conduct Disorder	4
Other Mental Health Disorders	5
Developmental Disabilities	
Autism Spectrum Disorder (ASD – includes Autism, Asperger Syndrome, & Pervasive Developmental Disorder [PDD-NOS] not otherwise specified)	6
Developmentally Delayed/Global Delay	7
Down Syndrome/Other Genetic Developmental Disability	8
Fetal Alcohol Spectrum Disorder (FASD) or Alcohol-Related Neurodevelopmental Disorder (ARND)	9
Intellectual Delay (Mild or Moderate)	10
Rett's Disorder, Childhood Disintegrative Disorder [CDD]	11
Learning disorders (reading, writing, math)	12
Speech and Language Disorders	

Apraxia	13
Cleft Palate/Lip	14
Receptive or Expressive Language	15
Selective Mutism	16
Other Speech & Language Disorders	17
Sensory Disorders	
Blind/ Visually Impaired	18
Deaf/Hard of Hearing	19
Other Sensory	20
Motor Disorders	
Cerebral Palsy	21
Mitochondrial disease	22
Muscular Dystrophies	23
Spina Bifida	24
Other Motor Impairment	25
Other	
Acquired Brain Injury	26
Asthma	27
Cancer/ Leukemia/Brain Tumour	28
Cystic Fibrosis (CF)	29
Diabetes	30
Epilepsy/Seizures	31
Heart Problems/Stroke	32
Juvenile Rheumatoid Arthritis	33
Obesity	34
Phenylketonuria (PKU)/Other Metabolic	35
Tourette Syndrome	36
Other, not listed	37

Table 4. *Functional impairments included on the EDI.*

Does this child have a problem that influences his/her ability to function in a classroom?
a. 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

The EDI database contains data for over 990,502 kindergarten children, of whom 155,858 (15.7%) have either an identified special need (yes/no), a functional impairment (out of 11), or a diagnosis (up to 3 out of a possible 37; see Table 3) of a health disorder. The newly-developed linkage between EDI and databases containing neighbourhood-level socio-demographic variables offers an opportunity to investigate the degree of impact of socioeconomic disadvantage on children with health disorders. Furthermore, the linking of the individual records from the EDI–SES databases with existing health and educational administrative databases in three out of the 12 jurisdictions will allow us to replicate and validate, on a subsample, the robustness of the patterns found for population-level data, by including health diagnoses occurring after kindergarten, treatment and service data, and individual-level indicators of SES.

Neighbourhood-level socio-economic status

The measures of neighbourhood-level SES applied in this study are based on the methodology established for the CanNECD Study.[42] Socio-economic and demographic information will come from the 2006 Canadian Census and 2011 National Household Survey, as well as the 2005 and 2010 Taxfiler data. Geographic regions have been established for the CanNECD Study. The criteria and boundaries maintain existing geographical, social, and neighbourhood boundaries, where possible.[42]

The traditional conceptualizations of SES usually rely on indicators of income, education, and occupation, and these will be used in our models, following the establishment of a new SES index for the CanNECD study.[49] Building on the methodology in the CanNECD Study,[42] additional SES and demographic indicators will be used in the analyses, including measures of wealth, poverty, lone parenthood, unemployment, residential dwelling/type of housing, residential stability, occupation, education, immigration, and language diversity.

Individual-level health/education data linkages

For three provinces, provincial EDI datasets will be linked with other population-wide databases at the individual level. Different combinations of data sources (e.g. health, education) will be used to cross-validate different health disorders in childhood (i.e. examine the concordance of diagnosis from EDI and administrative datasets) and to examine children's developmental trajectories after kindergarten.[50, 51] 1) Manitoba: The Manitoba Centre for Health Policy (MCHP) houses the Population Research Data Repository, a collection of de-identified administrative, survey, clinical, and registry databases for the entire province. 2) British Columbia: Population Data BC (PopDataBC) houses provincial administrative databases from the Ministries that hold data relevant to this study (Health and Education); and 3) Ontario: The Education and Accountability Office (EQAO) database contains standard grade tests and children's special education needs, and the Institute for Clinical and Evaluative Science (ICES) data holdings include information on variables similar to Manitoba and BC. These data will be linked with individual-level EDI data.

Patient and public involvement

The project's methodology is based on a secondary data analysis, therefore we did not involve patients or the public in the development of the research questions. Notwithstanding, considering the relevance of the study to public health, policy-makers and advisors are members of our team.

Data access and security

The CCHICS database will be hosted on a secure network at the OCCS at McMaster University in Hamilton, Ontario, Canada. A secure platform is a crucial tool for creating accessibility to the database by other interested researchers and thus increasing the opportunities for future linkages and knowledge mobilization. We are committed to expand the utilization of the databases we create, therefore, researchers wishing to gain access to the CCHICS database are invited to submit a short application outlining the researcher's background and providing a brief description of the proposed project. Upon

approval, the anonymized, neighbourhood-aggregated dataset can be downloaded from a secure server at the OCCS.

The individual-level linkages in Manitoba will occur at MCHP and analyses will be conducted by one of their analysts. CCHICS researchers will only receive results and will not have access to the linked data. As for the linkages in BC and Ontario, the various establishments will link and de-identify the data before providing access to the local CCHICS investigators.

Analysis plan

The planned analyses are designed to address each of the research questions outlined above. The statistical analyses will take place once the databases have been prepared (EDI/SES) or access approved (individual-level databases). Building on the methods developed for the CanNECD Study, we will statistically model the additive and multiplicative associations between the SES and demographic variables and developmental outcomes for children with health disorders. Results of these analyses will be particularly valuable for research dissemination and knowledge translation purposes for specific regions, and within different health disorder subpopulations, as they will allow, for the first time, the ability to explore SES-related factors that are associated with positive development outcomes for children with health disorders.

Research Question 1. Developmental outcomes in kindergarten for children with health disorders.

The health information reported on the EDI will be used to create several groups. First, the *typically-developing* reference group will be identified, comprising children without any diagnosed health disorders, specials needs, or functional impairments. Second, the *health disorder* group will be identified as children with any diagnosed health disorder, specials needs, or functional impairments. This group will be further subdivided into those with specific disorders (e.g. autism spectrum disorder (ASD), attention deficit hyperactivity disorder (ADHD), cerebral palsy (CP), etc.) and categories of disorders (e.g.

mental health, developmental delay, speech and language, etc.). Where possible with administrative databases, the conditions will be categorized using the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10).

The analyses will focus on EDI scores at the domain- and subdomain-level as outcomes. Diagnostic subgroups of children with specific disorders (e.g. ASD, ADHD, CP, etc.) will be compared with the reference group and then with each of the other groups (i.e. ASD compared to ADHD, and so forth). We will also compare children with only a diagnosis to those with a diagnosis and either a second diagnosis, a special needs designation, teacher-reported functional concerns, or all of the above.

Research Question 2. Association of the prevalence of health disorders and SES. Our analyses aim to identify the combinations of SES factors that are most strongly associated with the prevalence of health disorders for: 1) the pan-Canadian context, 2) different regions (i.e. provincial, health regions, neighbourhoods), and 3) with various subpopulations and health groups (e.g. boys compared to girls, ASD vs other developmental disorders, single vs. co-morbid disorders, etc.). The association between the identified SES factors and prevalence (overall prevalence and prevalence of specific disorders) will be tested for main and interaction effects, after controlling for the child-level variables (gender, age, English-as-a-Second-Language) available from the EDI. The first model to be tested will be that of the selected SES variables and the prevalence of health disorders. Next, the multiplicative associations of the SES variables will be added to the model. Finally, child-level variables and geographic-unit variables will be added to the model as covariates at the different levels of clustering. These analyses will be performed for each province/territory in the study.

Research Question 3. Child developmental outcomes and SES indices. We will statistically model associations between the SES composite indicators and developmental health outcomes using EDI vulnerability rates for each of the five domains, as well as overall vulnerability rates, for children with

health disorders in order to replicate the findings for typically developing children. The relationship between the SES index variables identified in the CanNECD Study and the EDI mean scores for children with health disorders will also be examined,[42] and the most strongly correlated neighbourhood-level SES index variables will be used as neighbourhood-level covariates. The relationship between the SES variables and each of the outcomes will be tested for main and interaction effects. These analyses will be repeated for each jurisdiction and each disorder with an adequate sample size.

Research Question 4. Case study provinces: Impact of timing of diagnosis and presence of comorbidities on the association between outcomes and SES. For three provinces (BC, Manitoba, and Ontario), children's EDI data will be linked at an individual-level with administrative health and education databases which include diagnostic information and age-of-onset of first diagnosis. These data will be used to search for unique behaviour functioning characteristics, measured by the EDI, among children who were, for the respective disorders, first diagnosed at a relatively younger or older age, and those with co-morbidities (i.e., for children with more than one disorder). The availability of individual-level measures of poverty in BC and Manitoba will also allow us to determine whether the patterns observed using area-level measures of SES are replicated at the individual level.[37] As with Research Question 3, we will statistically test the main and interaction effects between SES factors and EDI overall vulnerability rates, including the interaction between SES and age of diagnosis, and (separately) the interaction between SES and the existence of co-morbidities.

Ethics and dissemination

CCHICS has been approved by the Hamilton Integrated Research Ethics Board (HiREB) and the University of Manitoba Health Research Ethics Board. Participant confidentiality is protected as the EDI, Census, and Taxfiler data for this study are aggregated to the neighbourhood level and hosted in a secure database system.

The team of investigators maximizes the relevance of the findings to different communities of practice (academic, clinical, education, and policy) and the reach to diverse health-oriented groups. Currently, results from each EDI implementation are disseminated to participating communities and school districts and have been incorporated by governments and agencies as an indicator of children's health and well-being.[52, 53] We have a large network of collaborators from other universities and jurisdictions, whose interests intersect with our program and may, at an appropriate time, join the team of investigators. Relationships are already well established with many study stakeholders (e.g., clinicians and educators) through various relationships of the investigators. This will facilitate mobilization of the knowledge generated through this research and translate it to various audiences (e.g., clinicians, educators, policy-makers, researchers, community groups, and parents) through four major mechanisms: practitioner/community networks, education and knowledge dissemination networks, policy-makers, and data accessibility.

DISCUSSION

Few data sources provide the opportunity to researchers to examine the combined association between early childhood health disorder and socioeconomics in relation to children's early developmental outcomes. CCHICS is a novel approach to do so at a pan-Canadian population level. As such, it will generate new knowledge, which will contribute to the science of child development, and will be of immediate use and application in community contexts. The sociodemographic neighbourhood factors associated with the prevalence of particular disorders that we expect to find will support public health community efforts to improve access and integration of early identification services in neighbourhoods. The integrated knowledge base resulting from this project will establish: 1) a population-based prevalence of health disorders by jurisdiction, thus allowing future monitoring of health and developmental trajectories of children with these disorders; 2) the extent to which socioeconomic disadvantage affects developmental outcomes for children with health disorders; 3) the

degree of impact of SES on child development for different types of health disorders; and 4) the factors that contribute to the mechanism of association between SES and development that can contribute to our understanding of interventions and supports for children with health disorders.

In this study our goal is to identify SES and social factors, if any, that contribute to 'unfair and unnecessary inequities' in children's developmental health outcomes for those with health disorders.[5] Identifying these inequities is the first step towards developing strategies to flatten the socioeconomic gradients.[5] By flattening these gradients, we can improve the overall health status of children, so that society can move toward the goal of achieving *equity from the start.* Our research will allow us to compare social gradients across jurisdictions, health disorder subgroups, and groups with associated functional impairments. Our Pan-Canadian data allow for comparisons that would be otherwise impossible due to small frequencies of specific health disorders in any given jurisdiction, and if each province or territory had their own, incommensurable indicator of developmental health outcome. Moreover, population-level data, and specifically EDI data, have guided action and progress toward improving early childhood development in Canada and Australia,[54, 55] and have transformed early childhood systems in parts of the United States.[56] Our methodology and findings will have instant relevance to research in these countries, as well as others that use EDI data on a regular basis.

This approach of examining children with health disorders will also help contribute new knowledge and make meaningful differences at a policy level, as well as for children in the classroom. Despite scattered evidence of educational and health sectors adopting policies reflecting the growing knowledge about actions that will assist in optimizing developmental outcomes (e.g., introduction of full-day learning in Ontario and BC, enhanced billing codes for the 18-month well-baby visit in Ontario), provincial policy innovation is inconsistent across Canada, and there is no federal policy framework for the early years. The results of our study, with their direct relevance to early identification and detection

policies, both in the health and education sectors, have a high potential for a direct impact on policies supporting optimal development for children with health disorders.

Limitations

Despite many advantages (such as geographic breadth and sample size), our study has limitations. With the exception of the administrative databases in Manitoba, BC, and Ontario, the diagnostic information is based on parent information, not on administrative diagnostic codes. Health disorders may be subject to over- or under-reporting which may differ by type of disorder or even place of residence. These limitations will be addressed by exploring concordance between EDI and health databases in Manitoba, BC, and Ontario. However, until data are available to researchers in the remaining provinces, these limitations cannot be easily overcome in population-based studies. Another potential limitation is the small number of cases of certain disorders which may limit the analyses possible by the SES indicators, and by the five EDI domains and 16 sub-domains; aggregation of measures may be necessary in these cases. In addition, our definition of 'primary' diagnosis as the first listed disorder is somewhat arbitrary and may require additional sensitivity analyses. Finally, it is important to note that while this study uses the neighbourhood-level SES to examine the impact of sociodemographic factors on child development, it does not commit the ecological fallacy as it does not make inferences about the individual children's SES based on neighbourhood SES.

Conclusion

CCHICS offers an important opportunity to investigate developmental outcomes in children at risk that are not commonly included or available in sufficient numbers in sample-based research on children with health problems. This study also provides a unique and timely opportunity to utilize existing resources and methods to monitor the prevalence of health disorders at a population level. Establishing the pattern of the SES gradient is needed for designing early interventions, for policy-level

decision-making regarding the type and location of services, and for understanding the necessary conditions for optimal developmental trajectories of children with health disorders.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Title of manuscript: Establishing a protocol for building a pan-Canadian population-based monitoring system for early childhood development for children with health disorders - Canadian Children's Health in Context Study (CCHICS)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-5
Objectives	3	State specific objectives, including any prespecified hypotheses	7
Methods			
Study design	4	Present key elements of study design early in the paper	1, 11
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	1, 6, 7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	11
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	13-15
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-12
Bias	9	Describe any efforts to address potential sources of bias	N/A
Study size	10	Explain how the study size was arrived at	11
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	13-15
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	13
		(*b*) Describe any methods used to examine subgroups and interactions	13
		(*c*) Explain how missing data were addressed	N/A

		(*d*) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	N/A
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15*	Report numbers of outcome events or summary measures	N/A
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	N/A
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17, 18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16-18
Generalisability	21	Discuss the generalisability (external validity) of the study results	N/A
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Cover letter, p. 6

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Establishing a protocol for building a pan-Canadian population-based monitoring system for early childhood development for children with health disorders - Canadian Children's Health in Context Study (CCHICS)

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Establishing a protocol for building a pan-Canadian population-based monitoring system for early childhood development for children with health disorders - Canadian Children's Health in Context Study (CCHICS)

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Abstract

Introduction: Health disorders early in life have tremendous impact on children's developmental trajectories. Almost 80% of children with health disorders lack the developmental skills to take full advantage of school-based education relative to 27% of children without a health disorder. In Canada, there is currently a dearth of nationally representative data on the social determinants of early childhood development for children with health disorders. Evidence from Canada and other countries indicate that poorer developmental outcomes in typically-developing children are associated with lower socioeconomic status (SES). However, to date, it is not known whether this relationship is stronger among children with health disorders. The study's objectives are to estimate the prevalence and to investigate social determinants of developmental outcomes for young children with health disorders, using the Early Development Instrument (EDI).

Methods and analysis: Study objectives will be achieved through three steps. First, using existing (EDI data for 10 provinces and 2 territories collected from 2004-2015, we will investigate differences in developmental health outcomes among children with identified health disorders. Second, population-level EDI data will be linked with neighbourhood sociodemographic census data to explore associations between socioeconomic characteristics and rates of specific diagnoses among 5- and 6-year-olds, including trends over time. Third, for 3 of these 12 regions, additional health and/or education databases will be linked at an individual level. These data will be used to establish differences in EDI outcomes in relation to the age-of-onset of diagnosis, and presence of intervention or treatment.

Ethics and dissemination: Study methodologies have been approved by the Hamilton Integrated Research Ethics Board (HiREB). The results of the analyses of developmental health outcomes for children with health disorders combined with SES will have implications for both health service delivery and school-based intervention strategies. Results will contribute to a framework for public policy.

Keywords: Epidemiology, community child health, mental health, paediatrics, developmental neurology & neurodisability

Strengths and limitations of this study

- CCHICS will use population-level pan-Canadian data to monitor the developmental health of over 990,502 children, of which 155,858 have a health disorder.
- This study offers a broad overview of the developmental health vulnerabilities of children with health disorders across Canada, as well as over time, which allow for in-depth analyses of the social determinants of health.
- Linkages at the individual level between child development data and health and/or education administrative data in 3 provinces will allow for the exploration of factors contributing to the association between developmental health outcomes and SES.
- Asynchronous data collection cycles in provinces may be a limitation.
- Health disorders may be subject to over- or under-reporting which may differ by type of disorder or place of residence, therefore limiting interpretation.

INTRODUCTION

Early Childhood Trajectories

According to UNICEF, healthy development is a right for every child.[1] A *health disorder* i.e., a diagnosable medical condition early in life, has a tremendous impact on the developmental health trajectory of a child. Among otherwise healthy children, approximately one in four kindergartners (27%) lacks the developmental skills to take optimal advantage of school-based education.[2] Among children with identified special health needs at that age, this proportion rises to almost 80%. Having a health disorder in childhood often impacts trajectories of development throughout childhood, adolescence, and adulthood.[3] For instance, poor physical, mental, and socio-emotional development in childhood is linked to later school failure, unemployment, delinquency, and poor health in adulthood.[4, 5] Accordingly, providing additional support to children who are struggling can have protective effects that can set the child on a healthier trajectory,[4] provided we are able to identify those at risk. In environments rich with developmental opportunities and positive experiences, young children can flourish, regardless of their impairment, disease, or health condition.[6] Recent advances in understanding the developmental outcomes for children with health disorders indicate that difficulties are often confined to the areas of disability,[7] and, most importantly, that it is possible to experience a healthy developmental trajectory within a context of a health disorder.[8]

Children's health and socioeconomic gradients

The constellations of conditions in which children are born and grow are often referred to as *social determinants of health.*[5, 9] Social determinants of health include, among other things, income, social status, education, social support networks, as well as social and physical environments.[9] It has long been recognized that socioeconomic status (SES), usually conceptualized as a combination of income, education, and employment indicators, is strongly related to health, with lower SES associated

with both higher mortality and morbidity.[10-13] While not synonymous with social determinants, SES is one of their strongest correlates.[5] The disparities in health across SES are referred to as the *socioeconomic gradient,*[10] underscoring that difference in health outcomes is gradual and occurs across the full spectrum of SES. That is, individuals living in poverty have poorer outcomes when compared to those at the top of the SES hierarchy, but each increase in income is associated with an increase in positive outcomes. The gradient in health status across SES has been well described across a variety of conditions in both adult and child populations.[10, 14-16] Differences in SES at younger ages are particularly important for setting lifetime health trajectories.[17]

There is emerging evidence that low SES can negatively affect the speed of brain development.[18, 19] In this regard, societal inequities are likely to exert a stronger impact on children with health disorders than on those growing up without health disorders, henceforth referred to as "typically developing". Families of children with health disorders are also more likely to experience socio-economic disadvantage.[6, 17, 20, 21] Combined with additional social or economic risks (e.g., single parent family, low income), health disorders can significantly increase a child's odds for later negative outcomes.[22-24]

SES gradient may affect children with health disorders differently than typically-developing children.[25-32] Current research on children with health disorders has explored the association of SES factors with prevalence or with outcomes (such as academic achievement or behaviour), but not both, and usually for no more than one disorder/diagnosis at a time. This gap has been acknowledged,[33] in particular in the emerging pediatric literature focusing on children with special health care needs,[34, 35] as it limits comparability, and thus implications for further research and policy. Research in three Canadian provinces has shown that substantive differences in developmental health among typically-developing children at school entry are tied to SES.[19, 36-38] Little is known about the underlying

mechanisms of this association at the neighbourhood level,[39] and even less about whether this relationship is similar for children with health disorders.

Measuring Child Development at the Population Level

Until recently, Canada has lacked nationally representative data pertaining to social indicators of children's developmental health at school entry. Data collection initiatives implemented across most Canadian provinces and territories over the past decade have sought to address this gap, using the Early Development Instrument (EDI) to monitor trends in children's development across jurisdictions. The EDI is a teacher-completed checklist that measures children's developmental health at school entry in kindergarten in five domains: physical health and well-being, social competence, emotional maturity, language and cognitive development, and communication skills and general knowledge. It has been administered at the population level in most Canadian provinces and territories since 2004 (Table 1).[3, 40] EDI data are collected for each child individually and then aggregated at various levels to offer an assessment of developmental vulnerability in a given population. While the main purpose of the EDI is the assessment of child development, the questionnaire includes information on children's special needs, functional difficulties, and as of 2010, diagnoses. Participants with any of these comprise the sample of children with health disorders in the dataset. This approach reflects the non-categorical concept of illness.[41]

Table 1. *Canadian EDI Implementation Schedule from 2003/2004 to 2014/2015 with percentages and number of children with health disorders, as well as number of typically developing children for each implementation.*

	AB	BC	MB	NB	NL	NT	NS	ON	PEI	QC	SK	Y
2003/2004								13% 15643 103260				
2004/2005	18% 434 2015	13% 4622 30747	13% 1080 7307	9% 61 617						14% 230 1390	14% 429 2644	
2005/2006			18%	16%			15%			14%	15%	

			2158 9513	125 659			229 1291			1548 9638	191 1089	
2006/2007			12% 1386 10128	10% 39 344						19% 262 1132	14% 219 1319	
2007/2008	13% 24 167	13% 5016 32197	13% 179 1239		11% 37 303		17% 77 379	10% 11997 103955	8% 88 1002	20% 176 700	16% 254 1326	
2008/2009			12% 1368 10148	12% 849 6147			13% 605 4222			15% 369 2150		
2009/2010		19% 8942 37301					20% 147 599				19% 4139 18181	26% 86 250
2010/2011	20% 14701 57980		17% 2006 9813		14% 156 932		20% 460 1835	16% 19641 105102				26% 90 250
2011/2012		20% 8228 33805			16% 329 1760	24% 141 440	20% 448 1749			20% 12747 52242	16% 87 451	25% 89 273
2012/2013			16% 2071 10802		14% 699 4134	23% 138 468	19% 1590 6804				19% 1474 6469	24% 95 304
2013/2014		17% 222 1055			16% 823 4237	23% 140 465	23% 314 1061					
2014/2015			16% 2106 11090			26% 153 442	19% 1582 6922	17% 22319 110400				

Note. Light blue cells indicate a partial provincial collection. Dark blue cells indicate a full provincial collection; if the dark blue box spans multiple years it means a province or territory completed the implementation in waves.

A population-level database of developmental outcomes in kindergarten (as measured by the EDI) has recently been created in a CIHR-funded project, referred to as the *Can*adian *N*eighbourhoods and *E*arly *C*hildhood *D*evelopment (CanNECD) Study.[42] The aim of the CanNECD Study was to establish a pan-Canadian database for monitoring children's developmental health and well-being.[35] This database merged pan-Canadian EDI data from 2004 to 2015, spanning 12 of the 13 Canadian provinces and territories, with the Canadian 2005 and 2010 Taxfiler data, as well as 2006 Census and 2011 National Household Survey data using children's postal codes.

The primary goal of the current study, named the *C*anadian *C*hildren's *H*ealth *i*n *C*ontext *S*tudy (CCHICS), is to investigate the impact of different health disorders diagnosed prior to kindergarten and socioeconomic disadvantage on children's developmental outcomes at school entry. Analysis of these data will provide an opportunity to interpret and disseminate findings on developmental outcomes and socioeconomic gradients at regional and provincial levels for children with different health disorders. CCHICS aims to establish the prevalence of health disorders and explore the social determinants of developmental outcomes for children with health disorders. CCHICS is guided by the following research questions:

1) For children diagnosed with health disorders, how do their developmental health outcomes, measured with the EDI in kindergarten, differ from those of typically-developing children, and do they vary depending on the type of disorder?

2) What is the association between prevalence rates of various health disorders in kindergarten and neighbourhood-level SES? Does this association vary across jurisdictions (e.g., provinces, health regions)?

3) What is the association between developmental outcomes as measured by the EDI and SES for children with health disorders? Is it the same as for children without health disorders?

4) In three provinces with the capacity to link EDI to administrative health and education data at the individual level (Manitoba, British Columbia (BC), Ontario), what are the factors contributing to the association between EDI outcomes and SES?

METHODS AND ANALYSIS

Data sources and variables

Developmental health at school entry data

The EDI is a measure of developmental health of kindergarten-age children, implemented at population levels in most jurisdictions in Canada.[3] It is a 103-item, teacher-completed survey of five domains of children's development: physical health and well-being; social competence; emotional maturity; language and cognitive development; and communication skills and general knowledge, further broken down into 16 subdomains (Table 2). Variables relevant to the research objectives are: age, sex, special needs status, functional impairments, a specific diagnosis, if any, and the mean scores for each (sub)domain. After receiving training, kindergarten teachers complete the EDI in the second half of the school year. The psychometric properties of the EDI have been extensively validated.[3, 43-45] The EDI is a reliable and cost-efficient method of assessing developmental health outcomes at the developmentally critical period of transition to school and has moderate to high predictive validity for later school achievement.[46, 47] The EDI is completed for each individual student and the results are aggregated to a group level (according to geographic or demographic criteria) for interpretation. The most common aggregations are at the neighbourhood, school district, and province/territory levels. The Offord Centre for Child Studies (OCCS), at McMaster University, is the national repository of the anonymized EDI data.

Table 2. *Domains and subdomains of the EDI*

Domains	**Subdomains**
Physical health and well-being	Physical readiness for the school day Physical independence Gross and fine motor skills
Social competence	Overall social competence Responsibility and respect Approaches to learning Readiness to explore new things
Emotional maturity	Prosocial and helping behaviour Anxious and fearful behaviour Aggressive behaviour Hyperactivity and inattention

Language and cognitive development	Basic literacy Interest in literacy/numeracy and memory Advanced literacy Basic numeracy
Communication skills and general knowledge	Communication skills and general knowledge

Derived measures. Health disorders. On the EDI, teachers report up to three diagnosed health conditions or impairments, based on information from a parent or health professional (Table 3). The first diagnosis listed is considered the "primary" one for statistical purposes. Teachers report on whether a child has a limitation that interferes with their ability to function in the classroom, with 11 categories provided (Table 4), and whether or not he/she has a special need. *Developmental health.* Mean scores for each of the five EDI domains, and for the 16 EDI subdomains will be used. Vulnerability on each domain, i.e., a score below the 10th percentile based on the population sample of over 160,000 Canadian kindergarten children, will also be used, in addition to *overall vulnerability* (0 = not vulnerable, 1 = vulnerable), which represents vulnerability in at least one of the five domains.[48] For each aggregate unit of analysis (e.g., neighbourhood, school district), child-level data are aggregated to represent the "percentage of vulnerable children" overall, and in a domain, for the given unit of analysis.

Table 3. *Diagnoses included on the EDI.*

DIAGNOSIS	CODE
Mental Health	
ADHD	1
Anxiety	2
Depression	3
Oppositional Defiant Disorder/Conduct Disorder	4
Other Mental Health Disorders	5
Developmental Disabilities	
Autism Spectrum Disorder (ASD – includes Autism, Asperger Syndrome, & Pervasive Developmental Disorder [PDD-NOS] not otherwise specified)	6
Developmentally Delayed/Global Delay	7
Down Syndrome/Other Genetic Developmental Disability	8
Fetal Alcohol Spectrum Disorder (FASD) or Alcohol-Related Neurodevelopmental Disorder (ARND)	9
Intellectual Delay (Mild or Moderate)	10
Rett's Disorder, Childhood Disintegrative Disorder [CDD]	11
Learning disorders (reading, writing, math)	12
Speech and Language Disorders	

Apraxia	13
Cleft Palate/Lip	14
Receptive or Expressive Language	15
Selective Mutism	16
Other Speech & Language Disorders	17
Sensory Disorders	
Blind/ Visually Impaired	18
Deaf/Hard of Hearing	19
Other Sensory	20
Motor Disorders	
Cerebral Palsy	21
Mitochondrial disease	22
Muscular Dystrophies	23
Spina Bifida	24
Other Motor Impairment	25
Other	
Acquired Brain Injury	26
Asthma	27
Cancer/ Leukemia/Brain Tumour	28
Cystic Fibrosis (CF)	29
Diabetes	30
Epilepsy/Seizures	31
Heart Problems/Stroke	32
Juvenile Rheumatoid Arthritis	33
Obesity	34
Phenylketonuria (PKU)/Other Metabolic	35
Tourette Syndrome	36
Other, not listed	37

Table 4. *Functional impairments included on the EDI.*

Does this child have a problem that influences his/her ability to function in a classroom?
a. 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

The EDI database contains data for over 990,502 kindergarten children, of whom 155,858 (15.7%) have either an identified special need (yes/no), a functional impairment (out of 11), or a diagnosis (up to 3 out of a possible 37; see Table 3) of a health disorder. The newly-developed linkage between EDI and databases containing neighbourhood-level socio-demographic variables offers an opportunity to investigate the degree of impact of socioeconomic disadvantage on children with health disorders. Furthermore, the linking of the individual records from the EDI–SES databases with existing health and educational administrative databases in three out of the 12 jurisdictions will allow us to replicate and validate, on a subsample, the robustness of the patterns found for population-level data, by including health diagnoses occurring after kindergarten, treatment and service data, and individual-level indicators of SES.

Neighbourhood-level socio-economic status

The measures of neighbourhood-level SES applied in this study are based on the methodology established for the CanNECD Study.[42] Socio-economic and demographic information will come from the 2006 Canadian Census and 2011 National Household Survey, as well as the 2005 and 2010 Taxfiler data. Geographic regions have been established for the CanNECD Study. The criteria and boundaries maintain existing geographical, social, and neighbourhood boundaries, where possible.[42]

The traditional conceptualizations of SES usually rely on indicators of income, education, and occupation, and these will be used in our models, following the establishment of a new SES index for the CanNECD study.[49] Building on the methodology in the CanNECD Study,[42] additional SES and demographic indicators will be used in the analyses, including measures of wealth, poverty, lone parenthood, unemployment, residential dwelling/type of housing, residential stability, occupation, education, immigration, and language diversity.

Individual-level health/education data linkages

For three provinces, provincial EDI datasets will be linked with other population-wide databases at the individual level. Different combinations of data sources (e.g. health, education) will be used to cross-validate different health disorders in childhood (i.e. examine the concordance of diagnosis from EDI and administrative datasets) and to examine children's developmental trajectories after kindergarten.[50, 51] 1) Manitoba: The Manitoba Centre for Health Policy (MCHP) houses the Population Research Data Repository, a collection of de-identified administrative, survey, clinical, and registry databases for the entire province. 2) British Columbia: Population Data BC (PopDataBC) houses provincial administrative databases from the Ministries that hold data relevant to this study (Health and Education); and 3) Ontario: The Education and Accountability Office (EQAO) database contains standard grade tests and children's special education needs, and the Institute for Clinical and Evaluative Science (ICES) data holdings include information on variables similar to Manitoba and BC. These data will be linked with individual-level EDI data.

Patient and public involvement

The project's methodology is based on a secondary data analysis, therefore we did not involve patients or the public in the development of the research questions. Notwithstanding, considering the relevance of the study to public health, policy-makers and advisors are members of our team.

Data access and security

The CCHICS database will be hosted on a secure network at the OCCS at McMaster University in Hamilton, Ontario, Canada. A secure platform is a crucial tool for creating accessibility to the database by other interested researchers and thus increasing the opportunities for future linkages and knowledge mobilization. We are committed to expand the utilization of the databases we create, therefore, researchers wishing to gain access to the CCHICS database are invited to submit a short application outlining the researcher's background and providing a brief description of the proposed project. Upon

approval, the anonymized, neighbourhood-aggregated dataset can be downloaded from a secure server at the OCCS.

The individual-level linkages in Manitoba will occur at MCHP and analyses will be conducted by one of their analysts. CCHICS researchers will only receive results and will not have access to the linked data. As for the linkages in BC and Ontario, the various establishments will link and de-identify the data before providing access to the local CCHICS investigators.

Analysis plan

The planned analyses are designed to address each of the research questions outlined above. The statistical analyses will take place once the databases have been prepared (EDI/SES) or access approved (individual-level databases). Building on the methods developed for the CanNECD Study, we will statistically model the additive and multiplicative associations between the SES and demographic variables and developmental outcomes for children with health disorders. Results of these analyses will be particularly valuable for research dissemination and knowledge translation purposes for specific regions, and within different health disorder subpopulations, as they will allow, for the first time, the ability to explore SES-related factors that are associated with positive development outcomes for children with health disorders.

Research Question 1. Developmental outcomes in kindergarten for children with health disorders.

The health information reported on the EDI will be used to create several groups. First, the *typically-developing* reference group will be identified, comprising children without any diagnosed health disorders, specials needs, or functional impairments. Second, the *health disorder* group will be identified as children with any diagnosed health disorder, specials needs, or functional impairments. This group will be further subdivided into those with specific disorders (e.g. autism spectrum disorder (ASD), attention deficit hyperactivity disorder (ADHD), cerebral palsy (CP), etc.) and categories of disorders (e.g.

mental health, developmental delay, speech and language, etc.). Where possible with administrative databases, the conditions will be categorized using the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10).

The analyses will focus on EDI scores at the domain- and subdomain-level as outcomes. Diagnostic subgroups of children with specific disorders (e.g. ASD, ADHD, CP, etc.) will be compared with the reference group and then with each of the other groups (i.e. ASD compared to ADHD, and so forth). We will also compare children with only a diagnosis to those with a diagnosis and either a second diagnosis, a special needs designation, teacher-reported functional concerns, or all of the above.

Research Question 2. Association of the prevalence of health disorders and SES. Our analyses aim to identify the combinations of SES factors that are most strongly associated with the prevalence of health disorders for: 1) the pan-Canadian context, 2) different regions (i.e. provincial, health regions, neighbourhoods), and 3) with various subpopulations and health groups (e.g. boys compared to girls, ASD vs other developmental disorders, single vs. co-morbid disorders, etc.). The association between the identified SES factors and prevalence (overall prevalence and prevalence of specific disorders) will be tested for main and interaction effects, after controlling for the child-level variables (gender, age, English-as-a-Second-Language) available from the EDI. The first model to be tested will be that of the selected SES variables and the prevalence of health disorders. Next, the multiplicative associations of the SES variables will be added to the model. Finally, child-level variables and geographic-unit variables will be added to the model as covariates at the different levels of clustering. These analyses will be performed for each province/territory in the study.

Research Question 3. Child developmental outcomes and SES indices. We will statistically model associations between the SES composite indicators and developmental health outcomes using EDI vulnerability rates for each of the five domains, as well as overall vulnerability rates, for children with

health disorders in order to replicate the findings for typically developing children. The relationship between the SES index variables identified in the CanNECD Study and the EDI mean scores for children with health disorders will also be examined,[42] and the most strongly correlated neighbourhood-level SES index variables will be used as neighbourhood-level covariates. The relationship between the SES variables and each of the outcomes will be tested for main and interaction effects. These analyses will be repeated for each jurisdiction and each disorder with an adequate sample size.

Research Question 4. Case study provinces: Impact of timing of diagnosis and presence of comorbidities on the association between outcomes and SES. For three provinces (BC, Manitoba, and Ontario), children's EDI data will be linked at an individual-level with administrative health and education databases which include diagnostic information and age-of-onset of first diagnosis. These data will be used to search for unique behaviour functioning characteristics, measured by the EDI, among children who were, for the respective disorders, first diagnosed at a relatively younger or older age, and those with co-morbidities (i.e., for children with more than one disorder). The availability of individual-level measures of poverty in BC and Manitoba will also allow us to determine whether the patterns observed using area-level measures of SES are replicated at the individual level.[37] As with Research Question 3, we will statistically test the main and interaction effects between SES factors and EDI overall vulnerability rates, including the interaction between SES and age of diagnosis, and (separately) the interaction between SES and the existence of co-morbidities.

Ethics and dissemination

CCHICS has been approved by the Hamilton Integrated Research Ethics Board (HiREB) and the University of Manitoba Health Research Ethics Board. Participant confidentiality is protected as the EDI, Census, and Taxfiler data for this study are aggregated to the neighbourhood level and hosted in a secure database system.

The team of investigators maximizes the relevance of the findings to different communities of practice (academic, clinical, education, and policy) and the reach to diverse health-oriented groups. Currently, results from each EDI implementation are disseminated to participating communities and school districts and have been incorporated by governments and agencies as an indicator of children's health and well-being.[52, 53] We have a large network of collaborators from other universities and jurisdictions, whose interests intersect with our program and may, at an appropriate time, join the team of investigators. Relationships are already well established with many study stakeholders (e.g., clinicians and educators) through various relationships of the investigators. This will facilitate mobilization of the knowledge generated through this research and translate it to various audiences (e.g., clinicians, educators, policy-makers, researchers, community groups, and parents) through four major mechanisms: practitioner/community networks, education and knowledge dissemination networks, policy-makers, and data accessibility.

DISCUSSION

Few data sources provide the opportunity to researchers to examine the combined association between early childhood health disorder and socioeconomics in relation to children's early developmental outcomes. CCHICS is a novel approach to do so at a pan-Canadian population level. As such, it will generate new knowledge, which will contribute to the science of child development, and will be of immediate use and application in community contexts. The sociodemographic neighbourhood factors associated with the prevalence of particular disorders that we expect to find will support public health community efforts to improve access and integration of early identification services in neighbourhoods. The integrated knowledge base resulting from this project will establish: 1) a population-based prevalence of health disorders by jurisdiction, thus allowing future monitoring of health and developmental trajectories of children with these disorders; 2) the extent to which socioeconomic disadvantage affects developmental outcomes for children with health disorders; 3) the

degree of impact of SES on child development for different types of health disorders; and 4) the factors that contribute to the mechanism of association between SES and development that can contribute to our understanding of interventions and supports for children with health disorders.

In this study our goal is to identify SES and social factors, if any, that contribute to 'unfair and unnecessary inequities' in children's developmental health outcomes for those with health disorders.[5] Identifying these inequities is the first step towards developing strategies to flatten the socioeconomic gradients.[5] By flattening these gradients, we can improve the overall health status of children, so that society can move toward the goal of achieving *equity from the start.* Our research will allow us to compare social gradients across jurisdictions, health disorder subgroups, and groups with associated functional impairments. Our Pan-Canadian data allow for comparisons that would be otherwise impossible due to small frequencies of specific health disorders in any given jurisdiction, and if each province or territory had their own, incommensurable indicator of developmental health outcome. Moreover, population-level data, and specifically EDI data, have guided action and progress toward improving early childhood development in Canada and Australia,[54, 55] and have transformed early childhood systems in parts of the United States.[56] Our methodology and findings will have instant relevance to research in these countries, as well as others that use EDI data on a regular basis.

This approach of examining children with health disorders will also help contribute new knowledge and make meaningful differences at a policy level, as well as for children in the classroom. Despite scattered evidence of educational and health sectors adopting policies reflecting the growing knowledge about actions that will assist in optimizing developmental outcomes (e.g., introduction of full-day learning in Ontario and BC, enhanced billing codes for the 18-month well-baby visit in Ontario), provincial policy innovation is inconsistent across Canada, and there is no federal policy framework for the early years. The results of our study, with their direct relevance to early identification and detection

policies, both in the health and education sectors, have a high potential for a direct impact on policies supporting optimal development for children with health disorders.

Limitations

Despite many advantages (such as geographic breadth and sample size), our study has limitations. With the exception of the administrative databases in Manitoba, BC, and Ontario, the diagnostic information is based on parent information, not on administrative diagnostic codes. Health disorders may be subject to over- or under-reporting which may differ by type of disorder or even place of residence. These limitations will be addressed by exploring concordance between EDI and health databases in Manitoba, BC, and Ontario. However, until data are available to researchers in the remaining provinces, these limitations cannot be easily overcome in population-based studies. Another potential limitation is the small number of cases of certain disorders which may limit the analyses possible by the SES indicators, and by the five EDI domains and 16 sub-domains; aggregation of measures may be necessary in these cases. In addition, our definition of 'primary' diagnosis as the first listed disorder is somewhat arbitrary and may require additional sensitivity analyses. Finally, it is important to note that while this study uses the neighbourhood-level SES to examine the impact of sociodemographic factors on child development, it does not commit the ecological fallacy as it does not make inferences about the individual children's SES based on neighbourhood SES.

Conclusion

CCHICS offers an important opportunity to investigate developmental outcomes in children at risk that are not commonly included or available in sufficient numbers in sample-based research on children with health problems. This study also provides a unique and timely opportunity to utilize existing resources and methods to monitor the prevalence of health disorders at a population level. Establishing the pattern of the SES gradient is needed for designing early interventions, for policy-level

decision-making regarding the type and location of services, and for understanding the necessary conditions for optimal developmental trajectories of children with health disorders.

Authors' Contributions: MJ and MB conceived the study. MJ, MB, TB, CB, RC, ED, MAF, BF, SG, JWG, MG, JLM, HM, JP, RS contributed to the study design and planning. CRW prepared the first draft of the manuscript with MJ reviewing and amending early draft versions; MJ & CRW finalised the manuscript. BF, MG, & ED provided statistical expertise guiding the analytic plan. MJ, MB, BF, ED & MG developed the neighbourhood SES index. All authors (MJ, MB, CRW, TB, CB, RC, ED, MAF, BF, SG, JWG, MG, JLM, HM, JP, RS) edited and contributed to the final version of the manuscript and gave final approval to the submitted version. All authors (MJ, MB, CRW, TB, CB, RC, ED, MAF, BF, SG, JWG, MG, JLM, HM, JP, RS) will participate in the interpretation of findings and the drafting of manuscripts.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Title of manuscript: Establishing a protocol for building a pan-Canadian population-based monitoring system for early childhood development for children with health disorders - Canadian Children's Health in Context Study (CCHICS)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-5
Objectives	3	State specific objectives, including any prespecified hypotheses	7
Methods			
Study design	4	Present key elements of study design early in the paper	1, 11
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	1, 6, 7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	11
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	13-15
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-12
Bias	9	Describe any efforts to address potential sources of bias	N/A
Study size	10	Explain how the study size was arrived at	11
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	13-15
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	13
		(*b*) Describe any methods used to examine subgroups and interactions	13
		(*c*) Explain how missing data were addressed	N/A

		(*d*) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	N/A
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15*	Report numbers of outcome events or summary measures	N/A
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	N/A
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17, 18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16-18
Generalisability	21	Discuss the generalisability (external validity) of the study results	N/A
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Cover letter, p. 6

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.