Improved outcomes associated with a pediatric clinical diabetes network: a population-based time-trend analysis in Ontario, Canada

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Abstract

Background: To determine the association of implementing a pediatric diabetes network on the risk of acute diabetes-related complications and on the socioeconomic (SES) and geographic disparities in these outcomes.

Methods: We conducted a population-based time trend analysis of children (< 18 years) with diabetes (n= 13 806) using health administrative databases in Ontario, Canada from 1996-2011. The relationship between network implementation and diabetes-related emergency department (ED) visits and hospitalizations was determined using linear mixed effects models with a Poisson link function.

Results: After network implementation in 2001, there was a significant decrease in the rates of ED-visits (17/100 to 10/100 children in 2011, P<0.001) and hospitalizations (8.8/100 to 5.0/100 children in 2011, P<0.001). This decrease was most significant for those in the lowest SES quintile and in urban areas. Compared with the highest SES, the lowest SES remained at higher risk of ED-visits (adjusted rate ratio [RR_{after}]1.77; 95% CI:1.55,2.03) and hospitalizations (RR_{after} 2.11; 95% CI:1.77,2.52) after network implementation. However, the yearly decrease in ED-visits and hospitalization rates for the lowest compared to the highest SES, shifted towards a decreasing disparity after network implementation (P<0.05). Before the network, geographic location was not associated with disease outcomes. After network implementation, the risk of ED-visits in urban areas was significantly lower compared to rural areas.

Interpretation: The establishment of a diabetes network is associated with better health outcomes, particularly for those of lower SES. Further work is needed to address the healthcare needs of those in rural areas.

Key words: Diabetes Mellitus, Type 1; Child; Child, Preschool; Adolescent; Health Services Research, Acute Complications, Socioeconomic Status, Disparities



Introduction

The incidence of type 1 diabetes mellitus in children is increasing at a rate of 3-5% per year, representing a growing public health burden (1). Acute complications, such as diabetic ketoacidosis (DKA) and severe hypoglycemia remain the leading cause of avoidable hospitalizations and emergency department (ED) visits among children with type 1 diabetes (2, 3). Regular access to specialized healthcare services is essential in preventing diabetes-related complications (4-7). Low socioeconomic status (SES) and remote geographic location may impede access to services (7-9). Various healthcare delivery models, including clinical networks, have developed to foster continuity of care and equitable access to specialized diabetes services (10). As the management of pediatric diabetes becomes more complex, access to specialized care is increasingly recognized as an important priority (11). However, except for a publicly reported audit from a pediatric diabetes network in the U.K, the effect of clinical networks has been described only in the adult diabetes population (12, 13). Further, the effect of diabetes networks on acute diabetes-related complications and on the SES and geographic disparities in these outcomes has not been evaluated.

In 2001, the Network of Ontario Pediatric Diabetes Programs was established to promote equitable distribution and timely access to quality diabetes care for all children in Ontario, Canada (14). The network, funded through the Ontario Ministry of Health, consists of 35 specialized pediatric diabetes centres. Each centre, at a minimum, provide access to a team consisting of physicians, nurses, dietitians and social workers with training in diabetes care (15). The workforce in these centres varies from generalists (family

physicians, pediatricians) to pediatric endocrinologists (academic centres) and all of the community centres are affiliated with one of the five academic pediatric centres (15). The overall goal of the network is to promote linkages between the centres, assist with the development and dissemination of resources and guidelines, provide support and infrastructure for implementing evidence-based care and for coordinating services, while promoting consistency in standards of practice through professional development. To date, accountability measures for the network have not included patient outcomes and are not publicly reported.

The objectives of our study were to determine whether implementation of a diabetes network was associated with 1) a decrease in the risk of acute diabetes-related complications, and 2) a reduction in the SES and geographic disparities in these outcomes.

Methods

Study design

We conducted a population-based time-trend analysis of the acute complications of diabetes using multiple linked health administrative databases from Ontario available at the Institute for Clinical Evaluative Sciences. This study was approved by both the Research Ethics Boards of Sunnybrook Health Sciences Centre and McGill University Health Centre.

We used the Ontario Diabetes Database (ODD), a validated population-based database, to identify all children (ages < 18 years) with a diabetes duration of at least 1 year, living in Ontario from April 1st,1996- March 31st,2011 (16). The database does not distinguish between type 1 and type 2 diabetes; however recent Canadian studies have shown that most individuals under age 20 with diabetes have type 1 diabetes (15, 17). Once cases enter the database, they remain until death or migration out of Ontario. Using a unique encoded identifier, records were linked to other administrative databases. These databases included the Registered Persons Database (demographic information); the Ontario Health Insurance Plan Database (OHIP) (physicians' billing claims) and; the Canadian Institute for Health Information Hospital Discharge Abstract Database (hospital admissions). Using the individual's postal code for each fiscal year of the study, records were linked to census data to determine neighborhood income quintiles and rural-urban status. Patients with invalid health insurance numbers and missing postal codes were excluded. Postal codes that are missing are excluded because the dissemination or enumerations areas in

which they are located are "unstable" neighbourhoods with frequent migration (student housing, long-term care homes).

Outcome measures

Outcomes were diabetes-related ED-visits and hospitalizations. ED-visits not resulting in hospitalizations were identified using OHIP physicians' service claims bearing a diagnostic code for diabetes (ICD-9 250) and indicating that the encounter occurred in the ED. Hospitalizations were identified as those with the most responsible diagnosis code for hyperglycemia (ICD-9 250.1), including DKA (ICD-9 250.2, ICD-10 10.1-14.1) and hyperosmolar hyperglycemic coma (ICD-9 250.3, ICD-10 10.0-14.0), and for hypoglycemia (ICD-9 251, ICD-10 E10.63-E14.63). ICD-10 codes were used for hospitalizations that occurred after 2001.

Explanatory variables

Our exposure was implementation of the diabetes network in 2001. The effect of the network was measured from 2001 to 2011. The following covariates were determined a priori: age, sex, SES and urban-rural status. Age was grouped into pre-school (1-4 years), school age (5-9 years), early adolescent (10-14 years), and late adolescent (15-18 years). SES was measured using neighborhood income quintiles derived from census-based median household income levels of an individual's neighborhood of residence enumeration (1996) or dissemination (2001) area (population 400-700). Geographic location of residence was categorized as urban (population ≥ 10, 000) versus rural. Age, SES and urban-rural status were assigned at the start of each fiscal year.

Analysis

We examined whether rates for diabetes-related ED-visits and hospitalizations changed significantly after network implementation. The numerator was the total number of episodes in each year and the denominator the total number of eligible persons in the ODD in that year.

We estimated the effect of network implementation on ED-visits and hospitalizations using the segmented regression analysis approach (18). We used generalized linear mixed effects models to assess the relationship between network implementation and annual diabetes-related ED-visit and hospitalization rates, respectively. We used aggregate data of annual crude rates for each level of SES, urban-rural status, sex and age. For each model, we used Poisson link and accounted for correlation (compound symmetry structure) within groups over the follow-up period. We determined population average adjusted rate ratios (aRR) by accounting for the number of individuals in each aggregate. For the base model, we created three variables: a continuous variable representing fiscal year (pre-network trend estimate), a dummy variable representing the network implementation (immediate network effect) and an interaction term between network implementation and fiscal year (difference between pre- and post-network trend estimate). We included all the covariates selected a priori and interaction terms between network implementation and SES as well as network implementation and geographic location to determine whether SES and geographic location modified the effect of the diabetes network.

To determine if there was a change in the trend of ED-visit or hospitalization annual rates post-network, and by SES and geographic location, we repeated the multivariate analysis with the addition of interaction terms between year, network implementation and SES, as well as year, network implementation and geographic location to the model. From these models, yearly predicted adjusted rates (modeled rates post-network implementation) and the projected adjusted rates (rates had the network not been implemented) were calculated using the means method which involved setting each confounder to its mean value. We calculated the difference in the predicted adjusted rates between the start of the network and 2011 using the marginal standardization method with confidence intervals (CI) determined by using the delta method (19). Statistical tests were two-sided with significance assigned at p < 0.05.

Statistical analyses were performed using SAS 9.4(SAS Institute, Cary, NC).

Results

There were 14,425 cases of established diabetes identified and of these, 13,806 had valid postal codes and were included in the final analysis.

ED-visits

Figure 1A presents the observed crude rates, as well as the trends in ED-visit rates with (predicted rates) and without (projected rates) network implementation. Pre-network, ED-visits remained unchanged (18/100 in 1996, 17/100 in 2001, p = 0.15 for trend). Post-network, visits decreased to 10 per 100 in 2011(p < 0.001 for trend). The decreasing trend

in ED-visits post-network was seen across SES quintiles and geographic locations (Figures 2A and 3A).

In the multivariate analysis, lower SES was associated with an increased risk of ED-visits which persisted post-network (Table 1). Post-network, those living in rural regions had a 20% increased risk of ED-visits compared to urban areas. Male gender was also associated with a decreased risk in the multivariate analysis (aRR 0.78; 95% CI 0.72,0.84).

In the multivariate analysis, we found a significant difference in the overall pre- and postnetwork trend estimates, with a significant decrease in the long-term trend in annual rates
post-network compared to trends pre-network (Table 2). This decrease was statistically
significant within the highest SES (Q5), lowest SES (Q1) and urban areas. Although
SES-disparities persisted post-network, the relative yearly decrease in ED-visits in the
lowest compared to the highest SES shifted towards a decreasing disparity (Figure 2A).
Further, the absolute difference in the predicted adjusted rates between Q1 and Q5 in
2011 (5.2%; 95% CI: 3.29%,7.14%) was significantly less than in 2001 (9.3%; 95% CI:
6.12%,12.50%) (Difference: -4.0 %; 95% CI -0.2%, - 8.0%, p<0.05).

Hospitalizations

Pre-network, hospitalizations had remained unchanged (8.4/100 in 1996; 8.8/100 in 2001, p=0.18 for trend) (Figure 1B). Post-network, rates decreased to 5.0/100 in 2011 (p<0.001 for trend). As demonstrated in Figure 1B, had the network not been implemented, hospitalization rates would have increased over time. This decreasing trend in

hospitalizations post-network was seen across SES quintiles and urban areas (Figures 2B and 3B).

In the multivariate analysis, hospitalization rates increased with decreasing SES quintile, pre- and post-network (Table 1). There were no geographic disparities. Other associations included males (aRR_{male} 0.71; 95% CI 0.64,0.78) and older age (10-14 y.o., aRR 1.67; 95% CI:1.23,2.27 and 15-18 y.o., aRR 1.91; 95%CI:1.41,2.59, compared to 1-4 y.o. age respectively).

The network was associated with a 6 % per year decrease in the long-term trend in hospitalization rates compared to a 3% per year increase pre-network (Table 2). This decrease was significant within the middle and lowest SES as well as within urban areas.

As with ED-visits, the relative yearly decrease in hospitalizations in the lowest compared to the highest SES, shifted towards a decreasing disparity (Figure 2B); where the absolute difference in the predicted adjusted rates between Q1 and Q5 decreased from 7.8% (95% CI 5.4%,10.1%) in 2001to 3.1% (95% CI 1.7%,4.5%) in 2011 (Difference: -4.7%; 95% CI -1.8%, -7.6%, p<0.05).

Interpretation

In this population-based study, efforts of a diabetes network to standardize and improve access to specialized pediatric diabetes care were associated with better health outcomes, particularly for those of lower SES. Our work extends previous findings that have

highlighted the importance of comprehensive ambulatory care in preventing acute diabetes-related complications (7, 20). Further, our findings are consistent with those of another pediatric diabetes network in the U.K., that has demonstrated improvements in care delivery with implementation of a network model (21). In a recent audit report, the network reported an increase in the proportion of children that received all recommended care processes, from 4.1% in 2009/10 to 16% in 2013/14 (21).

Research in other pediatric chronic diseases have also shown the positive effect clinical networks can have on care delivery and outcomes (22). One example, a pediatric inflammatory bowel disease network, has reported improvements in care processes as well as an increase in the proportion of patients in remission at follow-up (23, 24). Although these networks may differ with respect to structure, governance, and accountability mechanisms, results support our findings that clinical networks are associated with improved care delivery and outcomes.

Our finding that those of low SES are most at risk of diabetes-related ED-visits and hospitalizations within a universal access system supports previous Ontario research (25, 26). Lower income families may be limited in purchasing glucometer strips, potentially leading to reduced glucose monitoring frequency and an increased risk of poor outcomes (27). Transportation costs or restrictions in taking time off work may limit lower income families' abilities to attend diabetes care visits, resulting in missed opportunities for education and guidance (4, 7).

Post-network, we found a significant trend towards decreasing SES-disparities. Children of lower SES had the greatest improvement in outcomes, suggesting that the network was most successful in possibly increasing access to effective care for these patients. Older Canadian data found that visits for primary care were 15% higher in low versus high SES populations, but an inverse gradient was seen with specialist visits (28). Arguably, primary care delivery is more accessible in terms of distance and scheduling than specialized care (28). Thus, by providing more accessible diabetes care, the network may have reduced some barriers. In addition, the network promoted more equitable availability of other diabetes professionals such as dietitians and nurses which may have had additional benefits for those of lower SES.

Pre-network there were no geographic disparities in outcomes, which contrasts with previous literature in adults (8, 9). This suggests that either gaps in service delivery within rural areas existed but other factors such as SES may have been a stronger driver of complication risk or alternatively access to specialized diabetes care may not have been an important gap in rural areas as patients travelled to urban centres to receive care. Post-network, there was an increasing geographic-disparity in ED-visit rates and a significant decrease in ED-visits and hospitalizations within urban areas but not in rural areas, suggesting that the network may have improved care more in urban areas as compared to rural areas. The reason for these findings is unclear and may be related to differential implementation of diabetes care between rural and urban centres; however, future research should more closely examine this disparity.

Our study has several limitations. Administrative data did not allow us to control for factors such as haemoglobin A1c (HbA1c) (29) and education level (30), which are known to contribute to complication risk. Further, we could not measure the effect of the network on HbA1c. Ambulatory care use was not assessed since some pediatric subspecialists are salaried and their "shadow" billings data may not be complete. Availability of additional resources may vary between centres, including 24-hour support, physician type (endocrinologist, pediatrician) or access to mental health services, which may result in differing outcomes within the network. Also, improvements in outcomes occurring over time could have taken place independent of the network and be due to an increase in the supply of pediatric endocrinologists or advancements in diabetes management, including insulin pump therapy. However, recent studies of Ontario children on insulin pumps suggest no significant association on selected outcomes with diabetes centre resources, including physician type (31). Further, several populationbased studies have demonstrated that despite improvements in HbA1c, trends for diabetes-related hospitalizations among children with diabetes have remained stable over a similar time period (1995-2009(32), 1993-2004(33), 2005-2010(34)). Although, we could not capture treatment modalities with administrative data, it is unlikely that advancements in care, much of which rely on more intensive management, would have had a greater impact on outcomes for lower income children (31, 35). Previous Ontario studies have shown that low income children were less likely to be on pumps and those on pumps and of lower income had an increased risk of DKA compared to higher income children (31, 35).

Within a universal access health system, the establishment of a diabetes network was associated with improvements in diabetes-related ED-visit and hospitalization rates as well as with decreasing SES disparities in these outcomes. This has implications for health policy efforts in other jurisdictions that are aimed at improving the quality of care for pediatric diabetes populations. Future work should include comparative effectiveness studies of the differing models of care within the network including cost-effectiveness analyses.



Abbreviations

aRR-adjusted Rate Ratio

CI- Confidence Intervals

DKA- Diabetic Ketoacidosis

ED- Emergency Department

ICD-9, 10-International Classification of Diseases, Ninth Revision, Tenth Revision

ODD- Ontario Diabetes Database

OHIP- Ontario Health Insurance Plan

Contributors' Statement

Meranda Nakhla conceptualized and designed the study, provided oversight of the analysis and interpreted the data, drafted the initial manuscript, and approved the final manuscript as submitted.

Elham Rahme conceptualized and designed the study, provided oversight of the analysis and interpreted the data, critically reviewed and revised the manuscript, and approved the final manuscript as submitted.

Marc Simard contributed to the study conception and design, carried out the analysis, contributed to interpretation of the data, critically reviewed and revised the manuscript, and approved the final manuscript as submitted.

Astrid Guttmann conceptualized and designed the study, provided oversight of the analysis and interpreted the data, critically reviewed and revised the manuscript, and approved the final manuscript as submitted.

All authors are accountable for all aspects of the study.

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Conflicts of Interest

The authors have no conflicts of interest to disclose.

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Figure 1. Crude rate, white square; projected adjusted rates (without network implementation), dotted line; predicted adjusted rates (with network implementation), solid line.

Figure 2. Crude rate Q1 (low SES), white squares; projected adjusted rates Q1 (low SES), dotted line; predicted adjusted rates Q1 (low SES), black squares; crude rate Q5 (high SES), white circles; projected adjusted rates Q5 (high SES), dashed line; predicted adjusted rates Q5 (high SES), black circles.

Figure 3. Crude rate rural, white squares; projected adjusted rates rural, dotted line; predicted adjusted rural, black squares; crude rate urban, white circles; projected adjusted rates urban, dashed line; predicted adjusted rates urban, black circles.

Table 1-Risk of diabetes-related ED-visits and hospitalizations by SES and geographic locations before and after network implementation (n=13 806)

	Pre-	Network	Post-Ne	etwork	Difference
	Adjusted		Adjusted		
_	RR	95%CI	RR	95%CI	p-value*
ED-VISITS					
SES					
Q1 (Lowest)	1.60	1.36 1.89	1.77	1.55 2.03	0.25
Q2	1.49	1.26 1.75	1.48	1.28 1.70	0.94
Q3	1.20	1.02 1.41	1.25	1.09 1.44	0.64
Q4	1.14	0.97 1.34	1.23	1.07 1.41	0.39
Q5 (highest)	1.00	-	1.00	-	-
Geographic location					
Rural	0.93	0.80 1.07	1.20	1.06 1.34	0.001
Urban	1.00	-	1.00	-	-
HOSPITALIZATIONS					
SES					
Q1 (Lowest)	2.40	1.91 3.03	2.11	1.77 2.52	0.31
Q2	1.76	1.38 2.24	1.73	1.44 2.08	0.90
Q3	1.47	1.16 1.87	1.44	1.19 1.74	0.89
Q4	1.21	0.95 1.54	1.33	1.11 1.60	0.47
Q5 (Highest)	1.00		1.00	-	-
Geographic location					
Rural	0.92	0.75 1.12	0.93	0.80 1.10	0.86
Urban	1.00	-	1.00	-	-

^{*}p-value represents significance testing of difference in adjusted RRs before and after implementation of diabetes network

Other variables in the multivariate model: Sex, age group, fiscal year, dummy variable network implementation, fiscal year* network implementation, SES* network implementation, geographic location*network implementation

Table 2- Adjusted annual trend in diabetes-related ED-visits and hospitalizations before and after network implementation

	Pre-Network Adjusted			Post-Network Adjusted		
ED MCIEC	RR	95%CI	RR	95%CI	p-value*	
ED-VISITS Overall						
Overan	0.99	0.97 1.01	0.94	0.93 0.95	< 0.001	
SES	0.55	0.57	V.5	0.50	0.001	
Q1	1.01	0.97 1.06	0.94	0.92 0.96	0.009	
Q2	0.98	0.94 1.03	0.95	0.93 0.97	0.27	
Q3	0.95	0.91 0.99	0.94	0.92 0.96	0.69	
Q4	0.99	0.95 1.03	0.93	0.92 0.95	0.04	
Q5	0.99	0.95 1.04	0.93	0.91 0.96	0.04	
Geographic location						
Rural	1.01	0.96 1.06	0.96	0.94 0.98	0.17	
Urban	0.98	0.96 1.00	0.94	0.93 0.95	0.001	
HOSPITALIZATIONS						
Overall						
	1.03	1.01 1.06	0.94	0.93 0.95	< 0.001	
SES						
Q1	1.03	0.97 1.09	0.93	0.91 0.95	0.01	
Q2	1.03	0.97 1.10	0.96	0.93 0.98	0.08	
Q3	1.08	1.01 1.15	0.93	0.90 0.95	0.005	
Q4	1.00	0.94 1.07	0.96	0.93 0.99	0.28	
Q5	1.04	0.96 1.12	0.95	0.92 0.98	0.07	
Geographic location						
Rural	0.96	0.89 1.03	0.97	0.94 1.01	0.87	
Urban	1.05	1.01 1.08	0.94	0.93 0.95	< 0.001	

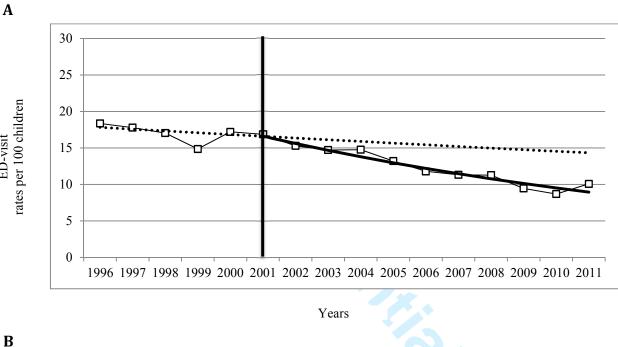
Abbreviations: RR, rate ratio; CI, Confidence Interval

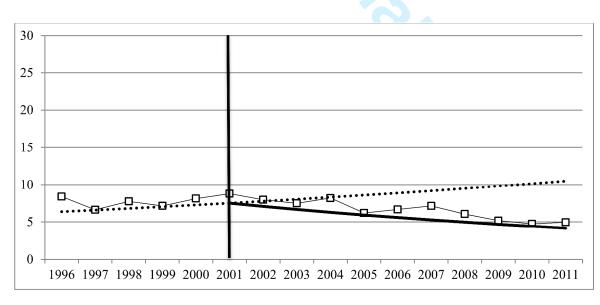
Other variables in the model: Sex, Age group; and interaction terms fiscal year*network implementation*SES and fiscal year*network implementation*geographic location

^{*} p-value represents significance testing of difference in adjusted year trends before and after implementation of diabetes network

rates per 100 children

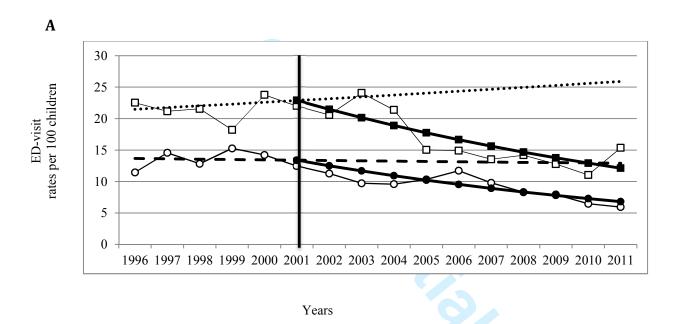
Figure 1: Rates of diabetes-related ED-visits and hospitalizations per 100 children aged 0-19 years in Ontario for 1996-2011. A: Rates of diabetes-related ED-visits. B: Rates of diabetes-related hospitalizations. Crude rate, white square; projected adjusted rates (without network implementation), dotted line; predicted adjusted rates (with network implementation), solid line.

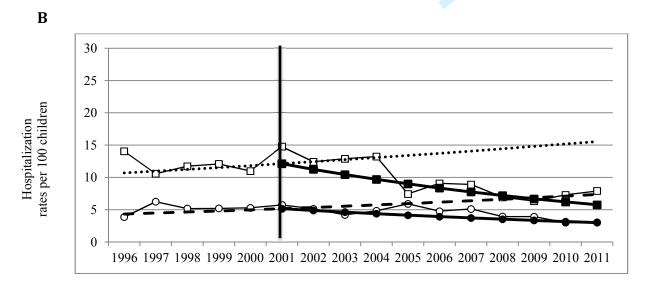




Years

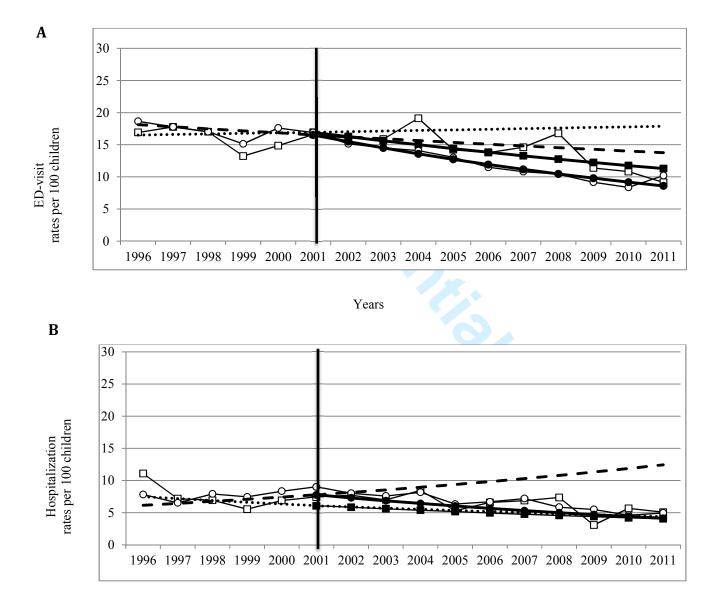
Figure 2: Rates of diabetes-related ED visits and hospitalizations per 100 children aged 0-19 years in Ontario for 1996-2011 by income quintile. A: Rates of diabetes-related ED-visits. B: Rates of diabetes-related hospitalizations. Crude rate Q1 (low SES), white squares; projected adjusted rates Q1 (low SES), dotted line; predicted adjusted rates Q1 (low SES), black squares; crude rate Q5 (high SES), white circles; projected adjusted rates Q5 (high SES), dashed line; predicted adjusted rates Q5 (high SES), black circles.





Years

Figure 3: Rates of diabetes-related ED visits and hospitalizations per 100 children aged 0-19 years in Ontario for 1996-2011 by rural-urban status. A: Rates of diabetes-related ED-visits. B: Rates of diabetes-related hospitalizations. Crude rate rural, white squares; projected adjusted rates rural, dotted line; predicted adjusted rural, black squares; crude rate urban, white circles; projected adjusted rates urban, dashed line; predicted adjusted rates urban, black circles.



The RECORD statement – checklist of items, extended from the STROBE statement, that should be reported in observational studies using routinely collected health data.

	Item No.	STROBE items	Location in manuscript where items are reported	RECORD items	Location in manuscript where items are reported
Title and abstract	t				
	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found		RECORD 1.1: The type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included. RECORD 1.2: If applicable, the geographic region and timeframe within which the study took place should be reported in the title or abstract.	Abstract Abstract
			1000	RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract.	Abstract
Introduction					
Background rationale	2	Explain the scientific background and rationale for the investigation being reported	Introduction, pages 4-5	9/	
Objectives	3	State specific objectives, including any prespecified hypotheses	Introduction, page 5, lines 25-32		
Methods					
Study Design	4	Present key elements of study design early in the paper	Methods, page 6, lines 8-13		
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Methods, pages 6-7		
Participants	6	(a) Cohort study - Give the eligibility criteria, and the		RECORD 6.1: The methods of study population selection (such as codes or	Methods, page 6, lines 22-53

		sources and methods of selection		algorithms used to identify subjects)	
		of participants. Describe methods		should be listed in detail. If this is not	
		of follow-up		possible, an explanation should be	
		Case-control study - Give the		provided.	
		eligibility criteria, and the		r	
		sources and methods of case		RECORD 6.2: Any validation studies	
		ascertainment and control		of the codes or algorithms used to select	Methods, page 6
		selection. Give the rationale for		the population should be referenced. If	and reference #16
		the choice of cases and controls		validation was conducted for this study	
		Cross-sectional study - Give the		and not published elsewhere, detailed	
		eligibility criteria, and the		methods and results should be provided.	
		sources and methods of selection			
		of participants		RECORD 6.3: If the study involved	
		or passes passes		linkage of databases, consider use of a	Linkage and
		(b) Cohort study - For matched		flow diagram or other graphical display	databases used
		studies, give matching criteria		to demonstrate the data linkage process,	described in
		and number of exposed and) · · ·	including the number of individuals	Methods, page 6-7
		unexposed		with linked data at each stage.	, , , , , , , , , , , , , , , , , , ,
		Case-control study - For matched			
		studies, give matching criteria	40		
		and the number of controls per	CA		
		case		7 •	
Variables	7	Clearly define all outcomes,		RECORD 7.1: A complete list of codes	Methods, page 7
		exposures, predictors, potential		and algorithms used to classify	71 0
		confounders, and effect		exposures, outcomes, confounders, and	
		modifiers. Give diagnostic		effect modifiers should be provided. If	
		criteria, if applicable.		these cannot be reported, an explanation	
		, 11		should be provided.	
Data sources/	8	For each variable of interest, give	Methods, page 7,	•	
measurement		sources of data and details of	lines 6-48		
		methods of assessment			
		(measurement).			
		Describe comparability of			
		assessment methods if there is			
		more than one group			
Bias	9	Describe any efforts to address	Methods, page 7,		
		potential sources of bias	lines 29-48		
Study size		Explain how the study size was	Methods, Page 6,		

		arrived at	lines 22-34		
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	Methods, page 8, lines 22-50		
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) Cohort study - If applicable, explain how loss to follow-up was addressed Case-control study - If applicable, explain how matching of cases and controls was addressed Cross-sectional study - If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses	Methods, page 8, lines 34-51 and page 9, lines 9-25 Methods, page 6, lines 51-53		
Data access and cleaning methods				RECORD 12.1: Authors should describe the extent to which the investigators had access to the database population used to create the study population. RECORD 12.2: Authors should provide information on the data cleaning	Methods, page 6, lines 8-34 Methods, page 6, lines 22-53
Linkage				methods used in the study. RECORD 12.3: State whether the study included person-level, institutional-level, or other data linkage across two	Methods, page 6, lines 34-53

				or more databases. The methods of	
				linkage and methods of linkage quality	
				evaluation should be provided.	
Results					
Participants	13	(a) Report the numbers of individuals at each stage of the study (e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed) (b) Give reasons for non-participation at each stage. (c) Consider use of a flow diagram		RECORD 13.1: Describe in detail the selection of the persons included in the study (<i>i.e.</i> , study population selection) including filtering based on data quality, data availability and linkage. The selection of included persons can be described in the text and/or by means of the study flow diagram.	Methods, page 6, lines 22-53
Descriptive data	14	(a) Give characteristics of study participants (<i>e.g.</i> , demographic, clinical, social) and information on exposures and potential confounders (b) Indicate the number of participants with missing data for each variable of interest (c) <i>Cohort study</i> - summarise follow-up time (<i>e.g.</i> , average and total amount)	Results, page 9, line 36 Results, page 9, lines 37-39		
Outcome data	15	Cohort study - Report numbers of outcome events or summary measures over time Case-control study - Report numbers in each exposure category, or summary measures of exposure Cross-sectional study - Report numbers of outcome events or summary measures	Results, page 9, lines 46-53 and page 10, lines 46-53, Figures 1, 2 and 3		
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-	Results, page 9, lines 46-53 and page 10,		

		adjusted estimates and their	lines 46-53, Tables 1		
		precision (e.g., 95% confidence	and 2		
		interval). Make clear which			
		confounders were adjusted for			
		and why they were included			
		(b) Report category boundaries			
		when continuous variables were	Methods, page 7,		
		categorized	lines 34-47		
		(c) If relevant, consider			
		translating estimates of relative			
		risk into absolute risk for a	N/A		
		meaningful time period			
Other analyses	17	Report other analyses done—e.g.,	N/A		
J		analyses of subgroups and			
		interactions, and sensitivity			
		analyses			
Discussion					
Key results	18	Summarise key results with	Interpretation, pages		
		reference to study objectives	11-12		
Limitations	19	Discuss limitations of the study,	40	RECORD 19.1: Discuss the	Interpretation,
		taking into account sources of		implications of using data that were not	page 14, lines 11-
		potential bias or imprecision.		created or collected to answer the	51
		Discuss both direction and		specific research question(s). Include	
		magnitude of any potential bias		discussion of misclassification bias,	
				unmeasured confounding, missing data,	
				and changing eligibility over time, as	
				they pertain to the study being reported.	
Interpretation	20	Give a cautious overall	Interpretation, pages		
		interpretation of results	11-15		
		considering objectives,			
		limitations, multiplicity of			
		analyses, results from similar			
		studies, and other relevant			
G 11 1 111	0.1	evidence	T		
Generalisability	21	Discuss the generalisability	Interpretation, page		
		(external validity) of the study	15, lines 3-8		
		results			
Other Information	n				

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	Acknowledgements		
Accessibility of				RECORD 22.1: Authors should provide	Author contact
protocol, raw				information on how to access any	information
data, and				supplemental information such as the	
programming				study protocol, raw data, or	
code				programming code.	

^{*}Reference: Benchimol EI, Smeeth L, Guttmann A, Harron K, Moher D, Petersen I, Sørensen HT, von Elm E, Langan SM, the RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement. *PLoS Medicine* 2015; in press.

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