Health care for children with diabetes mellitus in low-income families: a population-based cohort study of health systems in Ontario and California Sunitha V. Kaiser, MD MSc, a Vandana Sundaram, MPH, b Eyal Cohen, MD MSc, c,d Rayzel Shulman, MD PhD, de Jun Guan MSc, Lee Sanders, MD MPH, *b,f Astrid Guttmann, MDCM MSc* c,d **Affiliations**: ^aDepartment of Paediatrics, University of California San Francisco, 550 16th Street, Box 0110, San Francisco, CA 94158 ^bCentre for Policy, Outcomes and Prevention, Stanford University, 300 Pasteur Drive, Room H310, Palo Alto, CA 94305 ^cDivision of Paediatric Medicine, Department of Paediatrics, Hospital for Sick Children and the University of Toronto, 555 University Avenue, Toronto, ON M5G 1X8, Canada ^dInstitute for Clinical Evaluative Sciences, 2075 Bayview Ave., G-Wing, Toronto, Ontario M4N 3M5, Canada ^e Division of Endocrinology, Department of Paediatrics, Hospital for Sick Children and the University of Toronto, 555 University Avenue, Toronto, ON M5G 1X8, Canada ^fDivision of General Pediatrics, Stanford University, 300 Pasteur Drive, Room H310, Palo Alto, CA 94305 *equal contribution as senior authors **Corresponding Author:** Dr. Astrid Guttmann (astrid.guttmann@ices.on.ca)

Abstract

- 2 Background: Children with diabetes mellitus in low-income families have poor outcomes, but
- 3 little is known about how this relates to healthcare system structure. Our objective was to gain
- 4 insight into how best to structure health systems to serve these children by describing their
- 5 healthcare utilization in two varying health system models: 1) Canadian model with an organized
- 6 diabetes care network including generalists, 2) US model with targeted support services for
- 7 children from low-income families.
- *Methods:* Population-based retrospective cohort study of children 1-17 years with type 1
- 9 diabetes mellitus between 2009-2012 in the California Children's Services program and Ontario
- using administrative data. Ontario Drug Benefit Program enrolment used to identify children
- from low-income families. Proportions of children receiving ≥2 diabetes routine visits/year
- compared using Chi-square tests and diabetes-complication hospitalization rates compared using
- 13 direct standardization.
- **Results:** More California children from low-income families(n=4922) received diabetes routine
- care from paediatric endocrinologists (63.9% versus 26.9%,p<0.001) and used insulin pumps
- 16 (22.8% versus 16.4%,p<0.001) compared to Ontario children(n=2050). California children from
- low-income families were less likely to receive ≥ 2 diabetes routine visits/year compared to
- Ontario children (64.7% versus 75.7%,p<0.001), but had clinically comparable diabetes-
- complication hospitalization rates (Absolute Differences 0.02[95% Confidence Interval 0.02-
- 20 0.02] for males and 0.03[0.03-0.03] hospitalizations/patient-year for females).
- *Interpretation:* Ontario children from low-income families received more diabetes routine care
- compared to California children from low-income families and had clinically comparable rates of

- diabetes-complication hospitalizations. Diabetes care networks that integrate generalists may
- 2 play a role in improving access and outcomes for the growing population of children with
- 3 diabetes.

Background:

The prevalence of type 1 diabetes mellitus in children has been rapidly growing; between 2001-2009, it rose 22% in the United States (from 1.5 to 1.9 per 1000)(1) and 34% in Canada (from 2.0 to 3.0 per 1000) among children age ≤19 years.(2) Children with diabetes mellitus suffer severe morbidity and three-fold increased mortality,(3) primarily due to acute, potentially preventable complications(4) (e.g. diabetic ketoacidosis). Children from low-income families are at highest risk-- they have poorer disease control, higher rates of life-threatening complications, and worse outcomes.(5-7) It is unknown how different health system models affect health care delivery and outcomes for children with diabetes mellitus.

In Ontario, Canada, legal residents have universal access to health care and children with diabetes mellitus receive care from a network of specialized centres that integrate generalists. Since health insurance is universal, few programs specifically target support to children from low-income families. In contrast, in the United States, care for children with diabetes mellitus is covered by a variety of health-insurance payers (e.g., public, commercial, managed-care), as well as a variety of care-system structures (e.g., independent medical providers, health-management organizations). Federal funds (from Title V of the Social Security Act) enable programs such as California Children's Services to target supports for children from low-income families who suffer from chronic diseases, including diabetes mellitus.(8) The primary aim of this study was to gain insight into how best to structure health care systems to meet the needs of children with diabetes mellitus in low-income families by describing their demographics and health care utilization patterns in these two varying health system models. The secondary aim of this study was to examine outcomes across socioeconomic status within Ontario to better contextualize our findings.

Methods:

Data Source and Study Design:

We performed a retrospective cohort analysis using well-validated population-based administrative health databases from California Children's Services(9) and Ontario(10, 11). California Children's Services database contains demographics and information on all paid hospital, emergency department, and outpatient visits for enrolees. This database has not been not formally validated, but has been used in previous studies of children with diabetes. (9, 12) We used the 2006 Canadian Census to assign neighbourhood income quintile. Ontario databases are linked via unique encoded individual identifiers. These included: - Ontario Diabetes Database, a validated population-based database of all Ontario residents with diabetes mellitus(13, 14) - Registered Persons Database (demographics) - Ontario Health Insurance Plan Database (physician billing claims), from which diabetes diagnoses codes have been used in validation studies(13, 14) - Ontario Drug Benefit Program Database - Hospital Discharge Abstract Database, for which a diabetes diagnosis was found to be accurate in 94.5% of charts included in a large re-abstraction study(15) - National Ambulatory Care Registry (emergency department information) with 84% overall inter-rater reliability of diagnosis information(16) - Physician Database

- Assistive Devices Program database, which although not formally validated, has prevalence of insulin pump use in children that matches prospectively collected data on this population(17)

Ontario databases are linked via unique encoded individual identifiers; these included 1)

Ontario Diabetes Database, a validated population based database of all Ontario residents with diabetes mellitus,(12, 13)—2) Registered Persons Database (demographics), 3) Ontario Health Insurance Plan Database (physician billing claims), 4) Ontario Drug Benefit Program Database, 5) Hospital Discharge Abstract Database, 6) National Ambulatory Care Registry (emergency department information), 7) Physician Database, and 8) Assistive Devices Program database.

We used the 2006 Canadian Census to assign neighbourhood income quintile.

Study Population/Setting:

We included all children ages 1-17 years with diabetes mellitus from 2009-2012 enrolled in the California Children's Services program or residing in Ontario. We identified children in the California Children's Services program with diabetes mellitus by identifying children with the International Classification of Diseases, Ninth Revision, Clinical Modification code 250 (diabetes mellitus) listed as the eligible diagnosis code and with at least one insulin claim [Appendix 1].(12) In Ontario, we used the Ontario Diabetes Database (13) and divided children into two cohorts: 1) those with Ontario Drug Benefit Program claims (children from low-income families) and 2) all other children. We restricted all cohorts to children enrolled in healthcare for ≥365 consecutive days. For the main two cohorts, California Children's Services and Ontario Drug Benefit Program, we restricted to those with type 1 diabetes mellitus by excluding all children using oral hypoglycaemics (used primarily in type 2 diabetes mellitus) using drug

identification numbers (children in Ontario Drug Benefit Program) and national drug codes
 (children in California Children's Services) [Appendix 1].

California and Ontario are the most populous state and province in the United States and Canada, respectively.(18, 19) In 2010, children <18 years represented 25% of the California population, and children <20 years represented 23% of the Ontario population.(20, 21) California Children's Services supports care for children from low-income families with certain chronic diseases, including diabetes mellitus.(8) The program sets resource and care standards(22, 23) for the multidisciplinary care of children with diabetes mellitus at California Children's Services approved clinics, and can provide supplemental funding for clinics to meet these standards. California Children's Services also provides supplemental coverage for medical devices (e.g. glucometers, lancets) and case-management support (public health insurance enrolment, accessing care through California Children's Services approved centres, securing transportation, monitoring adherence).

In Ontario, every legal resident has access to universal government insurance that covers all medically necessary healthcare services except prescription drugs. Drug costs are handled out of pocket, with private extended health benefits, or through the Ontario Drug Benefit Program (covers those >65 years and those who receive social assistance). Medical care for children with diabetes mellitus in Ontario is provided by the Ontario Paediatric Diabetes Network, which consists of specialized paediatric diabetes centres (thirty secondary-level and five tertiary-level). These centres have multidisciplinary core teams consisting of nurses, dieticians, and social workers that work closely with paediatricians, and/or paediatric endocrinologists, and/or family physicians to provide comprehensive care.(24)

Patient Characteristics:

Socioeconomic status for children in Ontario was described using Ontario Drug Benefit Program enrolment and neighbourhood income quintile at the level of the dissemination area (representing a population of ≈400-700 individuals) adjusted for household and community size.(25) Children were eligible for Ontario Drug Benefit Program if expected prescription costs were >4% of household income, or if their families were receiving social assistance. Children were eligible for California Children's Services if medical expenses were >20% of household income(8) or if household income was <250% of the federal poverty line (annual household income <\$22,050 in 2009)(26). For children in California Children's Services, race and primary insurance were used to describe SES. During the study period, children in California qualified for Medicaid if household income was <100-133% of federal poverty level.(27)

We identified insulin pump utilization using the Assistive Devices Program database (Ontario), and billing claims for insulin pumps or pump batteries (California Children's Services) [Appendix 1]. We determined specialty of diabetes care provider by identifying the physician providing the majority of outpatient diabetes care (diagnosis code 250.xx), then using the physician database (Ontario) and the National Provider Identifier (California Children's Services). Distance from nearest diabetes centre was determined using home postal code.(28) We defined urban location in California using the United States Department of Agriculture definition (county population of ≥250,000)(29) and in Ontario using the Statistics Canada definition (≥400 persons per square kilometre).(19) Any missing data were described.

Outcome Measures:

We determined diabetes mellitus complication hospitalization rates using the Agency for Healthcare Research and Quality specifications (primary diagnoses: diabetic ketoacidosis, diabetes with hyperosmolarity, diabetes with coma, or uncontrolled diabetes).(30) ICD-9-CM codes were translated to ICD-10 for Ontario [Appendix 1]. We excluded hospitalizations for therapy initiation, defined as those within 30 days of diabetes mellitus diagnosis (Ontario) or California Children's Services enrolment (California). We determined the proportion of children receiving \geq 2/ outpatient diabetes routine visits per year [Appendix 1](31-33), rates of diabetes mellitus complication emergency department visits not resulting in hospitalizations (using the same codes as for diabetes mellitus complication hospitalizations), and rates of all other hospitalizations (to explore whether there may be different admission thresholds across jurisdictions).

Analysis:

We did separate but parallel analyses on both cohorts, as privacy legislation does not allow data from the two jurisdictions to be merged. We compared characteristics of children in our low-income cohorts (California Children's Services and Ontario Drug Benefit Program) using χ^2 tests for categorical variables and Student's t-tests for continuous variables. In order to compare diabetes mellitus complication hospitalization rates per person-year, we used direct standardisation to control for differences in age distribution and stratified by sex (standardised to 2010 California age distribution(18)). We then calculated absolute differences of rates with 95% confidence intervals. We compared proportions of children receiving ≥ 2 diabetes mellitus routine visits/year using χ^2 tests. We also compared characteristics and health care utilization within Ontario, comparing children from low-income families to all other Ontario children. We also

- performed a sensitivity analyses including only children using insulin pumps (to explore if rates
 differed by pump use).
- This study was approved by the Hospital for Sick Children (Toronto, Canada),
- 4 Sunnybrook Health Science Centre (Toronto, Canada), and Stanford University (Palo Alto,
- 5 United States) research ethics boards. SAS 9.2 (SAS Institute, Cary, NC) was used for analyses.

Results:

Characteristics of children with diabetes mellitus from low-income families in California (California Children's Services) and Ontario (Ontario Drug Benefit Program) are described in **Table 1**. There were 4,922 children from low-income families in California (11,836 patient-years, mean=2.4 years) and 2,050 children from low-income families in Ontario (5,300 patient-years, mean=2.6 years). There was a smaller proportion of male children from low-income families in California (p<0.001). A higher proportion children from low-income families in California were on insulin pumps compared to Ontario (22.8% versus 16.4%, p<0.001). Over twice as many children from low-income families in California had diabetes mellitus care by paediatric endocrinologists compared to Ontario (63.9% versus 26.9%, p<0.001).

Age-standardized diabetes mellitus complication hospitalization rates are presented in **Figure 1**. Children from low-income families in Ontario had clinically comparable rates to children in California (0.06 versus 0.08 hospitalizations/patient-year for males and 0.08 versus 0.11 hospitalizations/patient-year for females, Absolute Differences 0.02 [95% Confidence Interval (CI): 0.02-0.02]) for males and 0.03 [95% CI 0.03-0.03] for females.

Table 2 shows a higher proportion of children from low-income families in Ontario received ≥2 diabetes routine visits per year compared to children in California (75.7% versus 64.7%, p<0.001). Children from low-income families in Ontario had an equal rate of diabetes mellitus complication emergency department visit rates to children in California (0.03 visits/patient-year, p=1). We found no differences in rates of other hospitalizations.

Ontario Children from Low-Income Families Compared to All Other Ontario Children with

Diabetes Mellitus

A lower proportion of Ontario children from low-income families (Ontario Drug Benefit Program) were on insulin pumps compared to other Ontario children (16.4% versus 23.5%, p<0.001) [**Table 3**]. Children from low-income families in Ontario had higher diabetes mellitus complication hospitalization rates compared to all other Ontario children with diabetes mellitus (0.06 versus 0.02 hospitalizations/patient-year for males and 0.08 versus 0.03 hospitalizations/patient-year for females, Absolute Differences 0.04 [0.04-0.04] and 0.05 [0.05-0.05]). However, a slightly higher proportion of children from low-income families in Ontario received \geq 2 diabetes routine visits per year (75.7% versus 71.0%, p<0.001).

Comparisons in Insulin Pump Users

Among children from low-income families in California, age-sex standardized diabetes mellitus complication hospitalization rates were lower for children on versus off insulin pumps (0.07 [0.06-0.08] versus 0.09 [0.09-0.10] hospitalizations/patient-year, Absolute Difference 0.02

- 1 [95% CI 0.0.2-0.02]). In children from low-income families in Ontario, there were no
- 2 differences by pump status. There were no differences in standardized diabetes mellitus
- 3 complication hospitalization rates between children from low-income families in California and
- 4 Ontario on pumps.

Interpretation:

In this large, population-based cross-national study, we found significant differences in health care delivery for children with type 1 diabetes mellitus from low-income families. Care for most children from low-income families in California was provided by paediatric endocrinologists, while in Ontario it was provided by general paediatricians. Ontario children from low-income families were more likely to receive diabetes mellitus routine care compared to California children from low-income families, but had clinically comparable rates of diabetes mellitus complication hospitalizations.

Major structural differences exist in how care is provided in California and Ontario, and these differences may contribute to some of our findings. In Ontario, the Ontario Paediatric Diabetes Network aids generalists in providing diabetes care by linking them to paediatric endocrinologists and multi-disciplinary teams at tertiary centres.(8) In contrast, most physician care in California Children's Services is provided directly by paediatric endocrinologists. Given the higher rates of routine visits and clinically comparable diabetes mellitus complication rates in Ontario, our findings suggest that models of care with generalists practicing within multidisciplinary diabetes settings may be effective. Previous studies comparing care models of subspecialist versus shared-care (generalists and paediatric endocrinologists) for children with diabetes mellitus found no differences in adherence to guideline recommendations or glycaemic

diabetes mellitus.(34)

- control.(5, 31) Shared-care models may help overcome geographic barriers to accessing care,
 which is important in the context of our findings that children in California Children's Services
 lived further from the nearest diabetes mellitus centres.(31) Given the rising prevalence of
 diabetes mellitus, shared-care models may become essential for meeting health care needs of this
 growing population. A 2008 US study found significant geographic disparities in supply of
 paediatric endocrinologists. Authors concluded that shared-care models and increased capacity
 of primary care physicians as medical homes were essential to address the needs of children with
 - We found lower complication rates for children from low-income families in California on compared to those not on insulin pumps. Previous Canadian work investigating the relationship between social determinants of health and glycaemic control in children with diabetes mellitus demonstrated that children who were most deprived had poorer glycaemic control and lower rates of pump use; however, pump use had a moderating effect on socioeconomic gradients in glycaemic control.(7) This is in line with our findings in children from low-income families in California. Pump use is higher among children from low-income families in California compared to Ontario, and a significant socioeconomic gradient exists within Ontario. Ontario has eligibility criteria for pump funding, but there are no such guidelines in California. Greater insulin pump use among children from low-income families in California may also be due to greater clinic support (care coordinators), comfort with pump use in high-risk populations, professional detailing by pump manufacturers, or commercial pressures due to a fee-for-service payment system. Ontario covers 100% of pump cost, but only 75% of pump supply costs, which may create a barrier for low-income families. Further research is needed to establish whether pumps can moderate socioeconomic gradients in health outcomes for children

with diabetes, and, if so, how best to support access to pumps for children from low-income
 families.

In order to gain insight into how best to structure health care systems to meet the needs of children with diabetes mellitus in low-income families, we focused our study to two settings in which we could clearly describe details of how the health systems are structured for readers to understand and contrast. California and Ontario were selected for our analysis to increase the generalizability of our study--they are the most populous state and province in the United States and Canada, respectively, and share highly diverse populations with similar proportions of immigrants.(19, 35-37) However, some of the differences we observed in care and outcomes may be due to population differences. The administrative data from both jurisdictions were limited by lack of important information such as direct measures of socio-economic status and glycaemic control. Low household income has been shown to be a strong determinant of health outcomes in children with diabetes mellitus (5-7) and our findings of higher diabetes mellitus complication hospitalization rates in Ontario children from low-income families compared to all other Ontario children are likely a reflection of the powerful effects of socio-economic factors. California Children's Services eligibility required an annual household income of <\$22,050 in 2009 (or medical expenses >20% of income), and the majority of children in Ontario Drug Benefit Program were in the lowest income quintiles (annual household income ≈\$20,000 for quintile 1 in 2009)(38) indicating comparability to children in California Children's Services. However, neighbourhood income quintile is a proxy measure of household income. Previous studies have demonstrated good correlation between these data and individual household income in another Canadian province, and this method is widely used in Canadian health services research, (39, 40) but the precision of this ecologic methodology may be more limited in rural

- 1 areas and by practices such as renting suites in homes. Secondly, for our comparisons of
- 2 children within Ontario with diabetes mellitus (those from low-income families versus all other
- 3 children), we were unable to exclude children in "all other" group who were on oral
- 4 hypoglycaemics, as drug utilization data were only available for children in Ontario Drug Benefit
- 5 Program. A higher proportion of children with type 2 diabetes mellitus in the "all other" group
- 6 may contribute to the lower rates of complications compared to children from low-income
- families (although rates of type 2 diabetes mellitus are very low in Canadian children(17, 41)).
- 8 Thirdly, we utilized differing strategies for identifying children with diabetes mellitus in
- 9 California Children's Services and Ontario. Our strategies have been used in prior analyses(12,
- 10 13); however, that used in California Children's Services has not been formally validated, and
- thus may contribute to differences between the study cohorts. Lastly, we were unable to
- 12 contextualize our findings in California by comparing outcomes with children from higher
- income families, as there are no population-based California data for these children. In order to
- ensure quality and validity of our analysis, we used comparable data sources from each country,
- created consistent definitions across jurisdictions, compared similar populations during the same
- time interval, and carefully considered differences across systems that might explain the
- variation we observed. Nevertheless, this study highlights the challenges of such cross-
- 18 jurisdictional analysis, as it is impossible to make causal assumptions of the health-system level
- determinants of the outcomes measured.

Conclusions and Implications:

- 22 Ontario children with diabetes mellitus in low-income families more commonly received
- 23 diabetes routine care from generalists supported by a diabetes care network. These children were

- 1 more likely to receive routine care and had clinically comparable diabetes complication
- 2 hospitalization rates to children for low-income families in California. Developing diabetes
- 3 networks that integrate generalists may play a role in increasing utilization of routine diabetes
- 4 care and reducing complications for children. The significant disparities in diabetes mellitus
- 5 outcomes within the universal access system in Ontario suggest an important research and policy
- 6 focus to improve observed socioeconomic gradients in health outcomes for this growing
- 7 population of children.

9 List of Abbreviations: CI- Confidence Interval

Competing Interests:

12 The authors declare that they have no competing interests

Author's Contributions:

- All authors were involved in the conceptualization and design of the study. VS conducted the
- 16 California Children's Services analysis, JG the Ontario data analysis. SK interpreted both the
- Ontario and California analyses and drafted the manuscript. All authors critically revised the
- manuscript. All authors read and approved the final manuscript and agree to act as guarantors of
- 19 this work.

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5	Figure 1. Age-Standardized Diabetes Mellitus Complication Hospitalization Rates by Sex,
6	Children from Low-Income Families in California (California Children's Services) and
7	Ontario (Ontario Drug Benefit Program)
8	Figure 1. Diabetes Mellitus Complication Hospitalization Rates were clinically comparable for
9	children from low-income families in Ontario compared to California (Absolute Differences
10	0.02[95% Confidence Interval: 0.02-0.02]/patient-year for males and 0.03[95% Confidence
11	Interval: 0.03-0.03]/patient-year for females), CCS: California Children's Services, ODBP:
12	Ontario Drug Benefit Program
13	Ontario Drug Benefit Program
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Table 1. Characteristics of Children with Diabetes Mellitus from Low-income Families in Ontario (Ontario Drug Benefit Program) and California (California Children's Services)

Characteristic	California CCS ^a (N=4,922)	Ontario ODBP ^b (N=2,050)	p-value ^c (CCS vs ODBP)
Male, n (%)	2,265 (46.0)	1,077 (52.5)	<0.001
Age			
mean (SD), years	10.8 (3.9)	10.5 (4.1)	0.004
median (IQR), years	11 (8-14)	11 (8-14)	
Income Quintile, n (%) ^d			
5 (high)		273 (13.3)	
4		339 (16.5)	
3		360 (17.6)	
2		431 (21.0)	
1 (low)		637 (31.1)	
Missing		10 (0.5)	
Type of Insurance, n (%) ^e			
Medicaid	2,511 (51.1)		
Healthy Families	350 (7.1)		
CCS-only	88 (1.8)		
Mixed ^f	1,973 (40.1)		
Race, n (%) ^e			
White	1,396 (28.4)		
Black	444 (9.0)		
Hispanic	2,288 (46.5)		
Native American	20 (0.4)		
Asian/Pacific Islander	190 (3.9)		
Other	471 (9.5)		
Unknown	113 (2.3)		
Insulin Pump, n (%)	1,124 (22.8)	336 (16.4)	<0.001
DM ^g Care Provider Type, n (%)	, ,		
Pediatric Endocrinologist	3,144 (63.9)	551 (26.9)	Reference
Pediatrician	676 (13.7)	971 (47.4)	< 0.001
Adult Endocrinologist	32 (0.7)	81 (4.0)	< 0.001
Family Physician	74 (1.5)	172 (8.4)	< 0.001
Internal Medicine	8 (0.2)	24 (1.2)	< 0.001
Unknown	627 (12.7)	200 (9.8)	-
Other	341 (6.9)	51 (2.5)	-
Distance to Nearest DM ^g Center,	, ,		
mean (SD), km	46.2 (53.6)	16.5 (23.8)	< 0.001
median (IQR), km	25.6 (12.2-59.9)	8 (4-20)	

Location, n (%)			
Rural	155 (3.2)	273 (13.3)	<0.001
Urban	4767 (96.9)	1,775 (86.6)	

^a California Children's Services, ^b Ontario Drug Benefit Program, ^c Determined using Chi-square test for categorical variables and Student's t-test for continuous variables, ^d Only calculated for Ontario children, ^e Only calculated for California CCS children, ^f Children who switched insurance status during the time period, ^g Diabetes Mellitus

Table 2. Comparison of Other Healthcare Utilization of Children with Diabetes Mellitus from low-income families in California (California Children's Services) and Ontario (Ontario Drug Benefit Program)

	Jurisdiction		
Type of Visit	California CCS ^a (N=4,922)	Ontario ODBP ^b (N=2,050)	p-value ^c (CCS vs ODBP)
DM ^d -Routine Visits	(·)-)	(')===/	
Proportion with ≥2 visits per person-year, n (%)	3,185 (64.7)	1552 (75.7)	< 0.001
Visits per Patient-Year, mean (95% CI)	2.85 (2.80-2.90)	3.40 (3.35-3.45)	< 0.001
Other Hospitalizations			
Hospitalizations per Patient-Year, mean (95% CI)	0.11 (0.11-0.09)	0.12 (0.11-0.13)	0.052
DM ^d -Complication Emergency Department			
Visit Rate ^e			
Visits per Patient-Year, mean (95% CI)	0.03 (0.02-0.03)	0.03 (0.03-0.04)	1.0

^a California Children's Services, ^b Ontario Drug Benefit Program, ^c Determined using Chi-square test for proportion with >2 DM-routine visits, Student's t-test for visit/hospitalization rates per patient-year, ^d Diabetes Mellitus, ^e Excludes visits that end in hospital admission

4 Table 3. Comparison of Children with Diabetes Mellitus from Low-income Families

5 (Ontario Drug Benefit Program) to All Other Children within Ontario

	Ontario ODBP ^a (N=2,050)	Other Ontario (N=6,120)	p-value ^b
Patient Ch	aracteristics		·
Male, n (%)	1,077 (52.5)	3,200 (52.3)	0.84
Age			
mean (SD), years	10.5 (4.1)	11.1 (4.0)	< 0.001
median (IQR), years	11 (8-14)	12 (9-14)	
Income Quintile, n (%)			
5 (high)	273 (13.3)	1,498 (24.5)	Reference
4	339 (16.5)	1,400 (22.9)	0.002
3	360 (17.6)	1,262 (20.6)	< 0.001
2	431 (21.0)	1,058 (17.3)	< 0.001
1 (low)	637 (31.1)	830 (13.6)	< 0.001
Missing	10 (0.5)	72 (1.2)	-
Insulin Pump, n (%)	336 (16.4)	1,441 (23.5)	<0.001
DM ^c Care Provider Type, n (%)			
Pediatric Endocrinologist	551 (26.9)	1,473 (24.1)	Reference
Pediatrician	971 (47.4)	2,685 (43.9)	0.58
Adult Endocrinologist	81 (4.0)	243 (4.0)	0.40
Family Physician	172 (8.4)	526 (8.6)	0.18
Internal Medicine	24 (1.2)	105 (1.7)	0.03
Unknown	200 (9.8)	1,013 (16.6)	-
Distance to Nearest DM ^c Center,			
mean (SD), km	16.5 (23.8)	24.4 (102.8)	< 0.001
median (IQR), km	8 (4-20)	9 (5-20)	
Location, n (%)			
Rural	273 (13.3)	818 (13.4)	0.89
Urban	1,775 (86.6)	5,263 (86.0)	
Health Car	re Utilization		
	Ontario ODBP ^a (N=2,192)	Other Ontario (N=6,120)	p-value ^d
Age-Standardized DM ^c -Complication Hospitalizations			
Males, Hospitalizations per Patient-Year, mean (CI)	0.06 (0.05-0.07)	0.02 (0.02-0.03)	<0.001
Females, Hospitalizations per Patient-Year, mean (CI)	0.08 (0.07-0.09)	0.03 (0.03-0.04)	<0.001
Other Hospitalizations	, i		
Hospitalizations per Patient-Year, mean (CI)	0.12 (0.11-0.13)	0.05 (0.05-0.05)	<0.001
DM ^c -Routine Visits	,	, , ,	
Proportion with ≥ 2 visits per person-year, n (%)	1,552 (75.7)	4,345 (71.0)	<0.001
Visits per Patient-Year, mean (CI)	3.40 (3.35-3.45)	3.18 (3.15-3.21)	<0.001
DM ^c -Complication Emergency Department Visit Rate	(2.22 2)	(2.12 (2.12)	0.001
Visits per Patient-Year, mean (CI)	0.03 (0.03-0.04)	0.02 (0.02-0.02)	<0.001

a Ontario Drug Benefit Program, b Determined using Chi-square test for categorical variables and Student's t-test for continuous variables, b Diabetes Mellitus, d Determined using Chi-square test for proportion with >2 DM-routine visits, Student's t-test for visit/hospitalization rates per patient-year



Health care for children with diabetes mellitus in low-income families: a population-based cohort study of health systems in Ontario and California Sunitha V. Kaiser, MD MSc, a Vandana Sundaram, MPH, b Eyal Cohen, MD MSc, c,d Rayzel Shulman, MD PhD, de Jun Guan MSc, Lee Sanders, MD MPH, *b,f Astrid Guttmann, MDCM MSc* c,d **Affiliations**: ^aDepartment of Paediatrics, University of California San Francisco, 550 16th Street, Box 0110, San Francisco, CA 94158 ^bCentre for Policy, Outcomes and Prevention, Stanford University, 300 Pasteur Drive, Room H310, Palo Alto, CA 94305 ^cDivision of Paediatric Medicine, Department of Paediatrics, Hospital for Sick Children and the University of Toronto, 555 University Avenue, Toronto, ON M5G 1X8, Canada ^dInstitute for Clinical Evaluative Sciences, 2075 Bayview Ave., G-Wing, Toronto, Ontario M4N 3M5, Canada ^e Division of Endocrinology, Department of Paediatrics, Hospital for Sick Children and the University of Toronto, 555 University Avenue, Toronto, ON M5G 1X8, Canada ^fDivision of General Pediatrics, Stanford University, 300 Pasteur Drive, Room H310, Palo Alto, CA 94305 *equal contribution as senior authors **Corresponding Author:** Dr. Astrid Guttmann (astrid.guttmann@ices.on.ca)

Abstract

- 2 Background: Children with diabetes mellitus in low-income families have poor outcomes, but
- 3 little is known about how this relates to healthcare system structure. Our objective was to gain
- 4 insight into how best to structure health systems to serve these children by describing their
- 5 healthcare utilization in two varying health system models: 1) Canadian model with an organized
- 6 diabetes care network including generalists, 2) US model with targeted support services for
- 7 children from low-income families.
- *Methods:* Population-based retrospective cohort study of children 1-17 years with type 1
- 9 diabetes mellitus between 2009-2012 in the California Children's Services program and Ontario
- using administrative data. Ontario Drug Benefit Program enrolment used to identify children
- from low-income families. Proportions of children receiving ≥2 diabetes routine visits/year
- compared using Chi-square tests and diabetes-complication hospitalization rates compared using
- 13 direct standardization.
- **Results:** More California children from low-income families(n=4922) received diabetes routine
- care from paediatric endocrinologists (63.9% versus 26.9%,p<0.001) and used insulin pumps
- 16 (22.8% versus 16.4%,p<0.001) compared to Ontario children(n=2050). California children from
- low-income families were less likely to receive ≥ 2 diabetes routine visits/year compared to
- Ontario children (64.7% versus 75.7%,p<0.001), but had clinically comparable diabetes-
- complication hospitalization rates (Absolute Differences 0.02[95% Confidence Interval 0.02-
- 20 0.02] for males and 0.03[0.03-0.03] hospitalizations/patient-year for females).
- *Interpretation:* Ontario children from low-income families received more diabetes routine care
- compared to California children from low-income families and had clinically comparable rates of

- diabetes-complication hospitalizations. Diabetes care networks that integrate generalists may
- 2 play a role in improving access and outcomes for the growing population of children with
- 3 diabetes.

Background:

The prevalence of type 1 diabetes mellitus in children has been rapidly growing; between 2001-2009, it rose 22% in the United States (from 1.5 to 1.9 per 1000)(1) and 34% in Canada (from 2.0 to 3.0 per 1000) among children age ≤19 years.(2) Children with diabetes mellitus suffer severe morbidity and three-fold increased mortality,(3) primarily due to acute, potentially preventable complications(4) (e.g. diabetic ketoacidosis). Children from low-income families are at highest risk-- they have poorer disease control, higher rates of life-threatening complications, and worse outcomes.(5-7) It is unknown how different health system models affect health care delivery and outcomes for children with diabetes mellitus.

In Ontario, Canada, legal residents have universal access to health care and children with diabetes mellitus receive care from a network of specialized centres that integrate generalists. Since health insurance is universal, few programs specifically target support to children from low-income families. In contrast, in the United States, care for children with diabetes mellitus is covered by a variety of health-insurance payers (e.g., public, commercial, managed-care), as well as a variety of care-system structures (e.g., independent medical providers, health-management organizations). Federal funds (from Title V of the Social Security Act) enable programs such as California Children's Services to target supports for children from low-income families who suffer from chronic diseases, including diabetes mellitus.(8) The primary aim of this study was to gain insight into how best to structure health care systems to meet the needs of children with diabetes mellitus in low-income families by describing their demographics and health care utilization patterns in these two varying health system models. The secondary aim of this study was to examine outcomes across socioeconomic status within Ontario to better contextualize our findings.

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Data Source and Study Design:

- We performed a retrospective cohort analysis using well-validated population-based administrative health databases from California Children's Services(9) and Ontario(10, 11). California Children's Services database contains demographics and information on all paid hospital, emergency department, and outpatient visits for enrolees. This database has not been not formally validated, but has been used in previous studies of children with diabetes.(9, 12) We used the 2006 Canadian Census to assign neighbourhood income quintile. Ontario databases are linked via unique encoded individual identifiers. These included:
 - Ontario Diabetes Database, a validated population-based database of all Ontario residents with diabetes mellitus(13, 14)
 - Registered Persons Database (demographics)
 - Ontario Health Insurance Plan Database (physician billing claims), from which diabetes diagnoses codes have been used in validation studies(13, 14)
 - Ontario Drug Benefit Program Database
 - Hospital Discharge Abstract Database, for which a diabetes diagnosis was found to be accurate in 94.5% of charts included in a large re-abstraction study(15)
 - National Ambulatory Care Registry (emergency department information) with 84% overall inter-rater reliability of diagnosis information(16)
 - Physician Database

- Assistive Devices Program database, which although not formally validated, has prevalence of insulin pump use in children that matches prospectively collected data on this population(17)

Study Population/Setting:

We included all children ages 1-17 years with diabetes mellitus from 2009-2012 enrolled in the California Children's Services program or residing in Ontario. We identified children in the California Children's Services program with diabetes mellitus by identifying children with the International Classification of Diseases, Ninth Revision, Clinical Modification code 250 (diabetes mellitus) listed as the eligible diagnosis code and with at least one insulin claim [Appendix 1].(12) In Ontario, we used the Ontario Diabetes Database (13) and divided children into two cohorts: 1) those with Ontario Drug Benefit Program claims (children from low-income families) and 2) all other children. We restricted all cohorts to children enrolled in healthcare for >365 consecutive days. For the main two cohorts, California Children's Services and Ontario Drug Benefit Program, we restricted to those with type 1 diabetes mellitus by excluding all children using oral hypoglycaemics (used primarily in type 2 diabetes mellitus) using drug identification numbers (children in Ontario Drug Benefit Program) and national drug codes (children in California Children's Services) [Appendix 1]. California and Ontario are the most populous state and province in the United States and Canada, respectively.(18, 19) In 2010, children <18 years represented 25% of the California

California Children's Services supports care for children from low-income families with certain

population, and children <20 years represented 23% of the Ontario population. (20, 21)

chronic diseases, including diabetes mellitus. (8) The program sets resource and care

standards(22, 23) for the multidisciplinary care of children with diabetes mellitus at California
Children's Services approved clinics, and can provide supplemental funding for clinics to meet
these standards. California Children's Services also provides supplemental coverage for medical
devices (e.g. glucometers, lancets) and case-management support (public health insurance

enrolment, accessing care through California Children's Services approved centres, securing transportation, monitoring adherence).

In Ontario, every legal resident has access to universal government insurance that covers all medically necessary healthcare services except prescription drugs. Drug costs are handled out of pocket, with private extended health benefits, or through the Ontario Drug Benefit Program (covers those >65 years and those who receive social assistance). Medical care for children with diabetes mellitus in Ontario is provided by the Ontario Paediatric Diabetes Network, which consists of specialized paediatric diabetes centres (thirty secondary-level and five tertiary-level). These centres have multidisciplinary core teams consisting of nurses, dieticians, and social workers that work closely with paediatricians, and/or paediatric endocrinologists, and/or family physicians to provide comprehensive care.(24)

Patient Characteristics:

Socioeconomic status for children in Ontario was described using Ontario Drug Benefit Program enrolment and neighbourhood income quintile at the level of the dissemination area (representing a population of ≈400-700 individuals) adjusted for household and community size.(25) Children were eligible for Ontario Drug Benefit Program if expected prescription costs were >4% of household income, or if their families were receiving social assistance. Children were eligible for California Children's Services if medical expenses were >20% of household

- 1 income(8) or if household income was <250% of the federal poverty line (annual household
- 2 income <\$22,050 in 2009)(26). For children in California Children's Services, race and primary
- 3 insurance were used to describe SES. During the study period, children in California qualified
- 4 for Medicaid if household income was <100-133% of federal poverty level.(27)
- We identified insulin pump utilization using the Assistive Devices Program database
- 6 (Ontario), and billing claims for insulin pumps or pump batteries (California Children's Services)
- 7 [Appendix 1]. We determined specialty of diabetes care provider by identifying the physician
- 8 providing the majority of outpatient diabetes care (diagnosis code 250.xx), then using the
- 9 physician database (Ontario) and the National Provider Identifier (California Children's
- Services). Distance from nearest diabetes centre was determined using home postal code. (28)
- We defined urban location in California using the United States Department of Agriculture
- definition (county population of \geq 250,000)(29) and in Ontario using the Statistics Canada
- definition (≥400 persons per square kilometre).(19) Any missing data were described.

Outcome Measures:

We determined diabetes mellitus complication hospitalization rates using the Agency for Healthcare Research and Quality specifications (primary diagnoses: diabetic ketoacidosis, diabetes with hyperosmolarity, diabetes with coma, or uncontrolled diabetes).(30) ICD-9-CM codes were translated to ICD-10 for Ontario [Appendix 1]. We excluded hospitalizations for therapy initiation, defined as those within 30 days of diabetes mellitus diagnosis (Ontario) or California Children's Services enrolment (California). We determined the proportion of children receiving \geq 2/ outpatient diabetes routine visits per year [Appendix 1](31-33), rates of diabetes mellitus complication emergency department visits not resulting in hospitalizations (using the

- same codes as for diabetes mellitus complication hospitalizations), and rates of all other
- 2 hospitalizations (to explore whether there may be different admission thresholds across
- 3 jurisdictions).

Analysis:

We did separate but parallel analyses on both cohorts, as privacy legislation does not allow data from the two jurisdictions to be merged. We compared characteristics of children in our low-income cohorts (California Children's Services and Ontario Drug Benefit Program) using χ^2 tests for categorical variables and Student's t-tests for continuous variables. In order to compare diabetes mellitus complication hospitalization rates per person-year, we used direct standardisation to control for differences in age distribution and stratified by sex (standardised to 2010 California age distribution(18)). We then calculated absolute differences of rates with 95% confidence intervals. We compared proportions of children receiving ≥ 2 diabetes mellitus routine visits/year using χ^2 tests. We also compared characteristics and health care utilization within Ontario, comparing children from low-income families to all other Ontario children. We also performed a sensitivity analyses including only children using insulin pumps (to explore if rates differed by pump use).

This study was approved by the Hospital for Sick Children (Toronto, Canada),
Sunnybrook Health Science Centre (Toronto, Canada), and Stanford University (Palo Alto,
United States) research ethics boards. SAS 9.2 (SAS Institute, Cary, NC) was used for analyses.

Results:

Characteristics of children with diabetes mellitus from low-income families in California (California Children's Services) and Ontario (Ontario Drug Benefit Program) are described in **Table 1**. There were 4,922 children from low-income families in California (11,836 patient-years, mean=2.4 years) and 2,050 children from low-income families in Ontario (5,300 patient-years, mean=2.6 years). There was a smaller proportion of male children from low-income families in California (p<0.001). A higher proportion children from low-income families in California were on insulin pumps compared to Ontario (22.8% versus 16.4%, p<0.001). Over twice as many children from low-income families in California had diabetes mellitus care by paediatric endocrinologists compared to Ontario (63.9% versus 26.9%, p<0.001).

Age-standardized diabetes mellitus complication hospitalization rates are presented in **Figure 1**. Children from low-income families in Ontario had clinically comparable rates to children in California (0.06 versus 0.08 hospitalizations/patient-year for males and 0.08 versus 0.11 hospitalizations/patient-year for females, Absolute Differences 0.02 [95% Confidence Interval (CI): 0.02-0.02]) for males and 0.03 [95% CI 0.03-0.03] for females.

Table 2 shows a higher proportion of children from low-income families in Ontario received ≥2 diabetes routine visits per year compared to children in California (75.7% versus 64.7%, p<0.001). Children from low-income families in Ontario had an equal rate of diabetes mellitus complication emergency department visit rates to children in California (0.03 visits/patient-year, p=1). We found no differences in rates of other hospitalizations.

- Ontario Children from Low-Income Families Compared to All Other Ontario Children with
- 22 Diabetes Mellitus

A lower proportion of Ontario children from low-income families (Ontario Drug Benefit Program) were on insulin pumps compared to other Ontario children (16.4% versus 23.5%, p<0.001) [**Table 3**]. Children from low-income families in Ontario had higher diabetes mellitus complication hospitalization rates compared to all other Ontario children with diabetes mellitus (0.06 versus 0.02 hospitalizations/patient-year for males and 0.08 versus 0.03 hospitalizations/patient-year for females, Absolute Differences 0.04 [0.04-0.04] and 0.05 [0.05-0.05]). However, a slightly higher proportion of children from low-income families in Ontario received \geq 2 diabetes routine visits per year (75.7% versus 71.0%, p<0.001).

Comparisons in Insulin Pump Users

Among children from low-income families in California, age-sex standardized diabetes mellitus complication hospitalization rates were lower for children on versus off insulin pumps (0.07 [0.06-0.08] versus 0.09 [0.09-0.10] hospitalizations/patient-year, Absolute Difference 0.02 [95% CI 0.0.2-0.02]). In children from low-income families in Ontario, there were no differences by pump status. There were no differences in standardized diabetes mellitus complication hospitalization rates between children from low-income families in California and Ontario on pumps.

19 Interpretation:

In this large, population-based cross-national study, we found significant differences in health care delivery for children with type 1 diabetes mellitus from low-income families. Care for most children from low-income families in California was provided by paediatric

- 1 endocrinologists, while in Ontario it was provided by general paediatricians. Ontario children
- 2 from low-income families were more likely to receive diabetes mellitus routine care compared to
- 3 California children from low-income families, but had clinically comparable rates of diabetes
- 4 mellitus complication hospitalizations.

Major structural differences exist in how care is provided in California and Ontario, and these differences may contribute to some of our findings. In Ontario, the Ontario Paediatric Diabetes Network aids generalists in providing diabetes care by linking them to paediatric endocrinologists and multi-disciplinary teams at tertiary centres. (8) In contrast, most physician care in California Children's Services is provided directly by paediatric endocrinologists. Given the higher rates of routine visits and clinically comparable diabetes mellitus complication rates in Ontario, our findings suggest that models of care with generalists practicing within multidisciplinary diabetes settings may be effective. Previous studies comparing care models of subspecialist versus shared-care (generalists and paediatric endocrinologists) for children with diabetes mellitus found no differences in adherence to guideline recommendations or glycaemic control.(5, 31) Shared-care models may help overcome geographic barriers to accessing care, which is important in the context of our findings that children in California Children's Services lived further from the nearest diabetes mellitus centres.(31) Given the rising prevalence of diabetes mellitus, shared-care models may become essential for meeting health care needs of this growing population. A 2008 US study found significant geographic disparities in supply of paediatric endocrinologists. Authors concluded that shared-care models and increased capacity of primary care physicians as medical homes were essential to address the needs of children with diabetes mellitus.(34)

We found lower complication rates for children from low-income families in California on compared to those not on insulin pumps. Previous Canadian work investigating the relationship between social determinants of health and glycaemic control in children with diabetes mellitus demonstrated that children who were most deprived had poorer glycaemic control and lower rates of pump use; however, pump use had a moderating effect on socioeconomic gradients in glycaemic control.(7) This is in line with our findings in children from low-income families in California. Pump use is higher among children from low-income families in California compared to Ontario, and a significant socioeconomic gradient exists within Ontario. Ontario has eligibility criteria for pump funding, but there are no such guidelines in California. Greater insulin pump use among children from low-income families in California may also be due to greater clinic support (care coordinators), comfort with pump use in high-risk populations, professional detailing by pump manufacturers, or commercial pressures due to a fee-for-service payment system. Ontario covers 100% of pump cost, but only 75% of pump supply costs, which may create a barrier for low-income families. Further research is needed to establish whether pumps can moderate socioeconomic gradients in health outcomes for children with diabetes, and, if so, how best to support access to pumps for children from low-income families.

In order to gain insight into how best to structure health care systems to meet the needs of children with diabetes mellitus in low-income families, we focused our study to two settings in which we could clearly describe details of how the health systems are structured for readers to understand and contrast. California and Ontario were selected for our analysis to increase the generalizability of our study--they are the most populous state and province in the United States and Canada, respectively, and share highly diverse populations with similar proportions of

may be due to population differences. The administrative data from both jurisdictions were limited by lack of important information such as direct measures of socio-economic status and glycaemic control. Low household income has been shown to be a strong determinant of health outcomes in children with diabetes mellitus (5-7) and our findings of higher diabetes mellitus complication hospitalization rates in Ontario children from low-income families compared to all other Ontario children are likely a reflection of the powerful effects of socio-economic factors. California Children's Services eligibility required an annual household income of <\$22,050 in 2009 (or medical expenses >20% of income), and the majority of children in Ontario Drug Benefit Program were in the lowest income quintiles (annual household income \approx\$\$\\$20.000\$ for quintile 1 in 2009)(38) indicating comparability to children in California Children's Services. However, neighbourhood income quintile is a proxy measure of household income. Previous studies have demonstrated good correlation between these data and individual household income in another Canadian province, and this method is widely used in Canadian health services research, (39, 40) but the precision of this ecologic methodology may be more limited in rural areas and by practices such as renting suites in homes. Secondly, for our comparisons of children within Ontario with diabetes mellitus (those from low-income families versus all other children), we were unable to exclude children in "all other" group who were on oral hypoglycaemics, as drug utilization data were only available for children in Ontario Drug Benefit Program. A higher proportion of children with type 2 diabetes mellitus in the "all other" group may contribute to the lower rates of complications compared to children from low-income families (although rates of type 2 diabetes mellitus are very low in Canadian children (17, 41)).

immigrants.(19, 35-37) However, some of the differences we observed in care and outcomes

Thirdly, we utilized differing strategies for identifying children with diabetes mellitus in

California Children's Services and Ontario. Our strategies have been used in prior analyses(12, 13); however, that used in California Children's Services has not been formally validated, and thus may contribute to differences between the study cohorts. Lastly, we were unable to contextualize our findings in California by comparing outcomes with children from higher income families, as there are no population-based California data for these children. In order to ensure quality and validity of our analysis, we used comparable data sources from each country, created consistent definitions across jurisdictions, compared similar populations during the same time interval, and carefully considered differences across systems that might explain the variation we observed. Nevertheless, this study highlights the challenges of such crossjurisdictional analysis, as it is impossible to make causal assumptions of the health-system level determinants of the outcomes measured.

Conclusions and Implications:

Ontario children with diabetes mellitus in low-income families more commonly received diabetes routine care from generalists supported by a diabetes care network. These children were more likely to receive routine care and had clinically comparable diabetes complication hospitalization rates to children for low-income families in California. Developing diabetes networks that integrate generalists may play a role in increasing utilization of routine diabetes care and reducing complications for children. The significant disparities in diabetes mellitus outcomes within the universal access system in Ontario suggest an important research and policy focus to improve observed socioeconomic gradients in health outcomes for this growing population of children.

1 <u>List of Abbreviations:</u> CI- Confidence Interval

3 Competing Interests:

4 The authors declare that they have no competing interests

Author's Contributions:

- 7 All authors were involved in the conceptualization and design of the study. VS conducted the
- 8 California Children's Services analysis, JG the Ontario data analysis. SK interpreted both the
- 9 Ontario and California analyses and drafted the manuscript. All authors critically revised the
- manuscript. All authors read and approved the final manuscript and agree to act as guarantors of
- 11 this work.

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- 4 Information or the Ontario Ministry of Health and Long-Term Care is intended or should be
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- 1 Figure 1. Age-Standardized Diabetes Mellitus Complication Hospitalization Rates by Sex,
- 2 Children from Low-Income Families in California (California Children's Services) and
- 3 Ontario (Ontario Drug Benefit Program)
- 4 Figure 1. Diabetes Mellitus Complication Hospitalization Rates were clinically comparable for
- 5 children from low-income families in Ontario compared to California (Absolute Differences
- 6 0.02[95% Confidence Interval: 0.02-0.02]/patient-year for males and 0.03[95% Confidence
- 7 Interval: 0.03-0.03]/patient-year for females), CCS: California Children's Services, ODBP:
- 8 Ontario Drug Benefit Program

Table 1. Characteristics of Children with Diabetes Mellitus from Low-income Families in Ontario (Ontario Drug Benefit Program) and California (California Children's Services)

Characteristic	California CCS ^a (N=4,922)	Ontario ODBP ^b (N=2,050)	p-value ^c (CCS vs ODBP)
Male, n (%)	2,265 (46.0)	1,077 (52.5)	<0.001
Age			
mean (SD), years	10.8 (3.9)	10.5 (4.1)	0.004
median (IQR), years	11 (8-14)	11 (8-14)	
Income Quintile, n (%) ^d			
5 (high)		273 (13.3)	
4		339 (16.5)	
3		360 (17.6)	
2		431 (21.0)	
1 (low)		637 (31.1)	
Missing		10 (0.5)	
Type of Insurance, n (%) ^e			
Medicaid	2,511 (51.1)		
Healthy Families	350 (7.1)		
CCS-only	88 (1.8)		
Mixed ^f	1,973 (40.1)		
Race, n (%) ^e	,,,,,		
White	1,396 (28.4)		
Black	444 (9.0)		
Hispanic	2,288 (46.5)		
Native American	20 (0.4)		
Asian/Pacific Islander	190 (3.9)		
Other	471 (9.5)		
Unknown	113 (2.3)		
Insulin Pump, n (%)	1,124 (22.8)	336 (16.4)	< 0.001
DM ^g Care Provider Type, n (%)	, (11)		
Pediatric Endocrinologist	3,144 (63.9)	551 (26.9)	Reference
Pediatrician	676 (13.7)	971 (47.4)	<0.001
Adult Endocrinologist	32 (0.7)	81 (4.0)	<0.001
Family Physician	74 (1.5)	172 (8.4)	<0.001
Internal Medicine	8 (0.2)	24 (1.2)	<0.001
Unknown	627 (12.7)	200 (9.8)	-
Other	341 (6.9)	51 (2.5)	_
Distance to Nearest DM ^g Center,	- ()	(3-7)	
mean (SD), km	46.2 (53.6)	16.5 (23.8)	< 0.001
median (IQR), km	25.6 (12.2-59.9)	8 (4-20)	
Location, n (%)	,	<u> </u>	
Rural	155 (3.2)	273 (13.3)	< 0.001
Urban	4767 (96.9)	1,775 (86.6)	

^a California Children's Services, ^b Ontario Drug Benefit Program, ^c Determined using Chi-square test for categorical variables and Student's t-test for continuous variables, ^d Only calculated for Ontario children, ^e Only calculated for California CCS children, ^f Children who switched insurance status during the time period, ^g Diabetes Mellitus

1 Table 2. Comparison of Other Healthcare Utilization of Children with Diabetes Mellitus from

low-income families in California (California Children's Services) and Ontario (Ontario Drug

3 Benefit Program)

	Jurisdiction		
Type of Visit	California CCS ^a (N=4,922)	Ontario ODBP ^b (N=2,050)	p-value ^c (CCS vs ODBP)
DM ^d -Routine Visits			
Proportion with ≥ 2 visits per person-year, n (%)	3,185 (64.7)	1552 (75.7)	< 0.001
Visits per Patient-Year, mean (95% CI)	2.85 (2.80-2.90)	3.40 (3.35-3.45)	< 0.001
Other Hospitalizations			
Hospitalizations per Patient-Year, mean (95% CI)	0.11 (0.11-0.09)	0.12 (0.11-0.13)	0.052
DM ^d -Complication Emergency Department			
Visit Rate			
Visits per Patient-Year, mean (95% CI)	0.03 (0.02-0.03)	0.03 (0.03-0.04)	1.0

^a California Children's Services, ^b Ontario Drug Benefit Program, ^c Determined using Chi-square test for proportion with >2 DM-routine visits, Student's t-test for visit/hospitalization rates per patient-year, ^d Diabetes Mellitus, ^e Excludes visits that end in hospital admission

1 Table 3. Comparison of Children with Diabetes Mellitus from Low-income Families

2 (Ontario Drug Benefit Program) to All Other Children within Ontario

	Ontario ODBP ^a (N=2,050)	Other Ontario (N=6,120)	p-value ^b
Patient Cl	naracteristics		I
Male, n (%)	1,077 (52.5)	3,200 (52.3)	0.84
Age			
mean (SD), years	10.5 (4.1)	11.1 (4.0)	<0.001
median (IQR), years	11 (8-14)	12 (9-14)	
Income Quintile, n (%)			
5 (high)	273 (13.3)	1,498 (24.5)	Reference
4	339 (16.5)	1,400 (22.9)	0.002
3	360 (17.6)	1,262 (20.6)	<0.001
2	431 (21.0)	1,058 (17.3)	<0.001
1 (low)	637 (31.1)	830 (13.6)	<0.001
Missing	10 (0.5)	72 (1.2)	-
Insulin Pump, n (%)	336 (16.4)	1,441 (23.5)	<0.001
DM ^c Care Provider Type, n (%)	, ,		
Pediatric Endocrinologist	551 (26.9)	1,473 (24.1)	Reference
Pediatrician	971 (47.4)	2,685 (43.9)	0.58
Adult Endocrinologist	81 (4.0)	243 (4.0)	0.40
Family Physician	172 (8.4)	526 (8.6)	0.18
Internal Medicine	24 (1.2)	105 (1.7)	0.03
Unknown	200 (9.8)	1,013 (16.6)	-
Distance to Nearest DM ^c Center,			
mean (SD), km	16.5 (23.8)	24.4 (102.8)	<0.001
median (IQR), km	8 (4-20)	9 (5-20)	
Location, n (%)			
Rural	273 (13.3)	818 (13.4)	0.89
Urban	1,775 (86.6)	5,263 (86.0)	
Health Ca	re Utilization		
	Ontario ODBP ^a (N=2,192)	Other Ontario (N=6,120)	p-value ^d
Age-Standardized DM ^c -Complication Hospitalizations	, ,		
Males, Hospitalizations per Patient-Year, mean (CI)	0.06 (0.05-0.07)	0.02 (0.02-0.03)	<0.001
Females, Hospitalizations per Patient-Year, mean (CI)	0.08 (0.07-0.09)	0.03 (0.03-0.04)	<0.001
Other Hospitalizations	, , ,	, ,	
Hospitalizations per Patient-Year, mean (CI)	0.12 (0.11-0.13)	0.05 (0.05-0.05)	<0.001
DM ^c -Routine Visits	(,		
Proportion with >2 visits per person-year, n (%)	1,552 (75.7)	4,345 (71.0)	<0.001
Visits per Patient-Year, mean (CI)	3.40 (3.35-3.45)	3.18 (3.15-3.21)	<0.001
DM ^c -Complication Emergency Department Visit Rate	3 (3.32 33)	3.10 (3.10 3.21)	3.001
Visits per Patient-Year, mean (CI)	0.03 (0.03-0.04)	0.02 (0.02-0.02)	<0.001
Visits per Patient-Year, mean (CI)		0.02 (0.02-0.02)	<0.001

³ a Ontario Drug Benefit Program, b Determined using Chi-square test for categorical variables and Student's t-test for continuous variables, C Diabetes Mellitus, Determined using Chi-square test for proportion with >2 DM-routine

⁵ visits, Student's t-test for visit/hospitalization rates per patient-year

Page Figure 1. Age-Standardized Diabetes Mellitus Complication Hospitalization Rates by Sex, Children from Low-Income Families in California (California Children's Services) and Ontario (Ontario Drug Benefit Program)

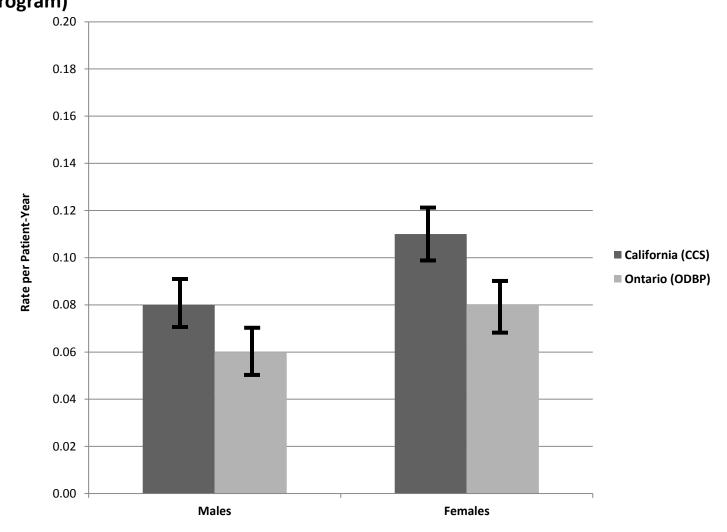


Figure 1. Diabetes Mellitus Complication Hospitalization Rates were clinically comparable for children from low-income families in Ontario compared to California (Absolute Differences 0.02[95% Confidence Interval: 0.02-0.02]/patient-year for males and 0.03[95% Confidence Interval: 0.03-0.03]/patient-year for females), CCS: California Children's Services, ODBP: Ontario Drug Benefit Program

Appendix 1: Codes Used for Analysis

Codes Used to Id	dentify Use of Insulin
NDC Number	Generic Name
00169330312	insulin aspart, recombinant
00169633910	insulin aspart, recombinant
00169750111	insulin aspart, recombinant
54868277700	insulin aspart, recombinant
54868605400	insulin aspart, recombinant
00169368213	insulin aspart/insulin aspart protamine
00169368512	insulin aspart/insulin aspart protamine
00169369619	insulin aspart/insulin aspart protamine
54868520100	insulin aspart/insulin aspart protamine
54868532700	insulin aspart/insulin aspart protamine
00169368712	insulin detemir
00169643910	insulin detemir
54868011200	insulin detemir
54868588300	insulin detemir
00088221905	insulin glargine, recombinant
00088222033	insulin glargine, recombinant
00088222052	insulin glargine, recombinant
00088222060	insulin glargine, recombinant
49999099410	insulin glargine, recombinant
54569560500	insulin glargine, recombinant
54868462600	insulin glargine, recombinant
54868576500	insulin glargine, recombinant
55045368501	insulin glargine, recombinant
68115083910	insulin glargine, recombinant
00088250033	insulin glulisine
00088250052	insulin glulisine
00088250205	insulin glulisine
00002831501	insulin human isophane (nph)
00002831517	insulin human isophane (nph)
00002831591	insulin human isophane (nph)
00002831759	insulin human isophane (nph)
00002873059	insulin human isophane (nph)
00003183410	insulin human isophane (nph)
00169004571	insulin human isophane (nph)
00169022201	insulin human isophane (nph)
00169033301	insulin human isophane (nph)
00169183411	insulin human isophane (nph)
00169183417	insulin human isophane (nph)
00169183418	insulin human isophane (nph)
00169231421	insulin human isophane (nph)
00169347418	insulin human isophane (nph)
00403296118	insulin human isophane (nph)
54569231800	insulin human isophane (nph)
54569231801	insulin human isophane (nph)

54560202500	
54569383500	insulin human isophane (nph)
54569383501	insulin human isophane (nph)
54569383502	insulin human isophane (nph)
54868142901	insulin human isophane (nph)
54868238001	insulin human isophane (nph)
58016478801	insulin human isophane (nph)
59060183402	insulin human isophane (nph)
59060231404	insulin human isophane (nph)
68115072905	insulin human isophane (nph)
68258898501	insulin human isophane (nph)
68258898601	insulin human isophane (nph)
00002871501	insulin human isophane (nph)/insulin human regular
00002871591	insulin human isophane (nph)/insulin human regular
00002871759	insulin human isophane (nph)/insulin human regular
00002877059	insulin human isophane (nph)/insulin human regular
00002951501	insulin human isophane (nph)/insulin human regular
00003183710	insulin human isophane (nph)/insulin human regular
00169001771	insulin human isophane (nph)/insulin human regular
00169183711	insulin human isophane (nph)/insulin human regular
00169183717	insulin human isophane (nph)/insulin human regular
00169183718	insulin human isophane (nph)/insulin human regular
00169231721	insulin human isophane (nph)/insulin human regular
00169347718	insulin human isophane (nph)/insulin human regular
49999099310	insulin human isophane (nph)/insulin human regular
54569291800	insulin human isophane (nph)/insulin human regular
54569291801	insulin human isophane (nph)/insulin human regular
54569291802	insulin human isophane (nph)/insulin human regular
54569346700	insulin human isophane (nph)/insulin human regular
54569346701	insulin human isophane (nph)/insulin human regular
54868274600	insulin human isophane (nph)/insulin human regular
54868347400	insulin human isophane (nph)/insulin human regular
54868582400	insulin human isophane (nph)/insulin human regular
55045350801	insulin human isophane (nph)/insulin human regular
55045362401	insulin human isophane (nph)/insulin human regular
59060183702	insulin human isophane (nph)/insulin human regular
59060231704	insulin human isophane (nph)/insulin human regular
00002821501	insulin human regular
00002821517	insulin human regular
00002821591	insulin human regular
00002821759	insulin human regular
00002850101	insulin human regular
00003183310	insulin human regular
00003183315	insulin human regular
00003183415	insulin human regular
00003183715	insulin human regular
00169004471	insulin human regular
00169183311	insulin human regular
00169183317	insulin human regular
00107100011	

00169183318	insulin human regular
00169231321	insulin human regular
00169347318	insulin human regular
00403344918	insulin human regular
23490668700	insulin human regular
54569231900	insulin human regular
54569231900	insulin human regular
54569383300	insulin human regular
54569383301	insulin human regular
54569383302	insulin human regular
54868359800	insulin human regular
54868361900	insulin human regular
55045350601	insulin human regular
59060183302	insulin human regular
68115070905	insulin human regular
68115072810	insulin human regular
00002821601	insulin human regular, buffered
00169007011	insulin human regular, buffered
00002751001	insulin lispro, recombinant
00002751017	insulin lispro, recombinant
00002751559	insulin lispro, recombinant
00002751659	insulin lispro, recombinant
00002872559	insulin lispro, recombinant
00002879959	insulin lispro, recombinant
35356010200	insulin lispro, recombinant
54868510800	insulin lispro, recombinant
54868583600	insulin lispro, recombinant
54868589900	insulin lispro, recombinant
66143751005	insulin lispro, recombinant
68115074610	insulin lispro, recombinant
00002751101	insulin lispro/insulin lispro protamine
00002751201	insulin lispro/insulin lispro protamine
00002879359	insulin lispro/insulin lispro protamine
00002879459	insulin lispro/insulin lispro protamine
00002879759	insulin lispro/insulin lispro protamine
00002879859	insulin lispro/insulin lispro protamine
54569532100	insulin lispro/insulin lispro protamine
54868438100	insulin lispro/insulin lispro protamine
00169011101	insulin, human regular buffered
00169750111	NOVOLOG 100/MLVIANOVN
08290328438	INSULIN SYRI31GX5/SYNBD D
08290328440	INSULIN SYRI31GX5/SYNBD D
HCPCS code	Description
X6366	INSULIN INJ/BEEF/PORK/PANCREAS
S8490	Insulin syringes (100 syringes, any size)
A4230	Infusion set for external insulin pump, non-needle cannula type
A4231	Infusion set for external insulin pump, needle type
A4232	Syringe with needle for external insulin pump, sterile, 3cc
11122	5,111150 with needle for external mount pamp, sterne, see

A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
E0784	External ambulatory infusion pump, insulin
J1815	Injection, insulin, per 5 units
J1817	Insulin for administration through DME (i.e., insulin pump) per 50 units
S5550	Insulin, rapid onset, 5 units
S5551	Insulin, most rapid onset (Lispro or Aspart); 5 units
S5552	Insulin, intermediate acting (NPH or LENTE); 5 units
S5553	Insulin, long acting; 5 units
S5560	Insulin delivery device, reusable pen; 1.5 ml size
S5561	Insulin delivery device, reusable pen; 3 ml size
S5565 S5566	Insulin cartridge for use in insulin delivery device other than pump; 150 units
S5500 S5570	Insulin cartridge for use in insulin delivery device other than pump; 300 units Insulin delivery device, disposable pen (including insulin); 1.5 ml size
S5571	Insulin delivery device, disposable pen (including insulin), 1.5 ml size Insulin delivery device, disposable pen (including insulin); 3 ml size
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)
	entify Use of an Insulin Pump
NDC Number	Trade name
61058602833	DELTEC COZMO CLEO INFUSION SET
	DELTEC COZMO CLEO INFUSION SET
61058602834	
61058602835	
61058602839	
61058602840	
61058602841	
65781439602	INSET 30 INFUSION SET
65781036102	INSET INFUSION SET
65781136102	
8521307010	INSULIN PUMP RESERVOIR
76300050001	MEDTRONIC REMOTE CONTROL
76300039010	MINIMED
76300039110	
76300039210	
76300039310	
76300039501	
76300039610	
76300039710	
76300039810	
76300039910	
76300010310	MINIMED RESERVOIR
76300010310	MINIMAD RESERVOIN
76300010324	MIO INFUSION SET
	MIO IM ODION DET
76300092310	
76300092510	
76300094110	
76300094310	
76300094510	

76300096510	
76300097510	
76300032610	PARADIGM
76300032620	
76300033210	
76300031221	PARADIGM INFUSION
76300031222	
76300012201	PARADIGM INSULIN PUMP PATHWAY
76300022201	
76300052201	
8290333200	PARADIGM LINK BLOOD GLUCOSE
8290333201	
8290333202	
8290333203	
76300001701	PARADIGM REAL-TIME
76300050301	PARADIGM REMOTE CONTROL
76300036810	PARADIGM SILHOUETTE
76300038110	
76300038210	
76300038310	
76300038410	
76300031512	QUICK RELEASE SOFT TEFLON
76300031612	
8189609000	QUICK-CHECK FILM
57565006090	
8189608000	QUICK-CHECK II
57565006080	
8189607000	QUICK-CHECK ONE
57565006070	
76300038610	QUICK-SET PARADIGM
76300038710	
76300039410	
76300036910	SILHOUETTE
76300037010	
76300037110	
76300037205	
76300037310	
76300037405	
76300037410	
76300037710	
76300037810	
76300037905	
76300037910	

76300038005	
76300038010	
76300038501	SIL-SERTER
763000030301	SOF-SENSOR
76300000211	BOT-BENDOR
7630003001	SOF-SERTER
76300011124	SOF-SET
76300011224	
76300031712	
76300031812	
76300032412	
76300032512	
76300032012	SOF-SET MICRO
76300032112	
50924058001	SOFT TOUCH
50924058510	
50924093720	
50924095120	
75537000580	
75537000585	
75537000937	
75537009512	
76300084010	SURE-T
76300087210	
76300086210	SURE-T PARADIGM
76300086410	
76300086610	
76300087410	
76300087610	
76300088610	
HCPCS Codes	Description
A4221	Supplies for maintenance of drug infusion catheter, per week (list drug separately)
A4222	Infusion supplies for external drug infusion pump, per cassette or bag (list drugs separately)
A4230	Infusion set for external insulin pump, non-needle cannula type
A4231	Infusion set for external insulin pump, needle type
A4232	Syringe with needle for external insulin pump, sterile, 3cc
A4601 A6257	Lithium ion battery for non-prosthetic use, replacement Transparent film, sterile, 16 sq. in. or less, each dressing
A6258	Transparent film, sterile, more than 16 sq. in. but less than or equal to 48 sq. in., each dressing
A6259	Transparent film, sterile, more than 48 sq. in., each dressing
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
E0784	External ambulatory infusion pump, insulin
J1817	Insulin for administration through DME (i.e., insulin pump) per 50 units
K0601	Replacement battery for external infusion pump
K0602	Replacement battery for external infusion pump

K0603	Replacement battery for external infusion pump
K0604	Replacement battery for external infusion pump
K0605	Replacement battery for external infusion pump
K0552	Supplies for external drug infusion pump, syringe type cartridge, sterile, each
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)
S9353	Home infusion therapy, continuous insulin infusion therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
Codes Used to 1	Identify Oral Hypoglycemic Use in Ontario
Drug Identification Code	Generic drug name
00009806	METFORMIN HCL
00012556	CHLORPROPAMIDE
00012564	CHLORPROPAMIDE
00012599	GLYBURIDE
00012602	TOLBUTAMIDE TOLBUTAMIDE
00012610	
00013730	CHLORPROPAMIDE
00013889	TOLBUTAMIDE
00015598	ACETOHEXAMIDE
00017167	TOLBUTAMIDE
00021350	CHLORPROPAMIDE
00021849	TOLBUTAMIDE
00024708	CHLORPROPAMIDE
00024716	CHLORPROPAMIDE
00093033	TOLBUTAMIDE
00156663	TOLBUTAMIDE
00156728	CHLORPROPAMIDE
00178543	TOLBUTAMIDE
00193662	GLYBURIDE
00209872	TOLBUTAMIDE
00209937	CHLORPROPAMIDE
00237000	TOLBUTAMIDE
00244449	GLYBURIDE
00247111	CHLORPROPAMIDE
00271330	CHLORPROPAMIDE
00309265	CHLORPROPAMIDE
00312711	CHLORPROPAMIDE
00312762	TOLBUTAMIDE
00314552	METFORMIN HCL
00314730	TOLBUTAMIDE
00324361	TOLBUTAMIDE
00377937	CHLORPROPAMIDE
00379948	CHLORPROPAMIDE
00399302	CHLORPROPAMIDE
00420336	GLYBURIDE
00430986	CHLORPROPAMIDE
00431168	TOLBUTAMIDE
00438111	GLYBURIDE

00454753	GLYBURIDE
00480290	GLYBURIDE
00480304	GLYBURIDE
00502391	TOLBUTAMIDE
00584932	CHLORPROPAMIDE
00586773	CHLORPROPAMIDE
00720933	GLYBURIDE
00720941	GLYBURIDE
00765966	GLICLAZIDE
00765996	GLICLAZIDE
00808733	GLYBURIDE
00808741	GLYBURIDE
00813176	GLICLAZIDE
00913662	GLYBURIDE
00913670	GLYBURIDE
00913689	GLYBURIDE
00990329	METFORMIN HCL
01900927	GLYBURIDE
01900935	GLYBURIDE
01913654	GLYBURIDE
01913662	GLYBURIDE
01913670	GLYBURIDE
01913689	GLYBURIDE
01959352	GLYBURIDE
01959360	GLYBURIDE
01987534	GLYBURIDE
01987542	TOLBUTAMIDE
01987828	TOLBUTAMIDE
01987836	GLYBURIDE
01990837	GLYBURIDE
01990845	GLYBURIDE
02020734	GLYBURIDE
02020742	GLYBURIDE
02045710	METFORMIN HCL
02084341	GLYBURIDE
02085887	GLYBURIDE
02099233	METFORMIN HCL
02147521	GLYBURIDE
02147548	GLYBURIDE
02148765	METFORMIN
02155850	GLICLAZIDE
02162822	METFORMIN HCL
02162849	METFORMIN HCL
02167786	METFORMIN HCL
02188902	METFORMIN HCL
02190885	ACARBOSE
02190893	ACARBOSE
02220628	METFORMIN HCL
02223562	METFORMIN HCL
02224550	GLYBURIDE

02224569	GLYBURIDE
02224771	TOLBUTAMIDE
02224798	TOLBUTAMIDE
02226804	GLYBURIDE
02226812	GLYBURIDE
02228920	GLYBURIDE
02228939	GLYBURIDE
02229516	METFORMIN HCL
02229517	METFORMIN HCL
02229519	GLICLAZIDE
02229595	GLYBURIDE
02229596	GLYBURIDE
02229656	METFORMIN
02229785	METFORMIN HCL
02229994	METFORMIN HCL
02230026	METFORMIN HCL
02230027	METFORMIN HCL
02230036	GLYBURIDE
02230037	GLYBURIDE
02230443	GLIPIZIDE
02230444	GLIPIZIDE
02230475	METFORMIN HCL
02230670	METFORMIN HCL
02230671	METFORMIN HCL
02231058	METFORMIN HCL
02231095	TROGLITAZONE
02231096	TROGLITAZONE
02231389	METFORMIN HCL
02233999	METFORMIN HCL
02234513	GLYBURIDE
02234514	GLYBURIDE
02236543	GLYBURIDE
02236548	GLYBURIDE
02236733	GLYBURIDE
02236734	GLYBURIDE
02236985	TROGLITAZONE
02236986	TROGLITAZONE
02237531	TROGLITAZONE
02238103	GLICLAZIDE
02238698	TROGLITAZONE
02238827	METFORMIN HCL
02239081	METFORMIN HCL
02239214	METFORMIN HCL
02239924	REPAGLINIDE
02239925	REPAGLINIDE
02239926	REPAGLINIDE
02241111	ROSIGLITAZONE MALEATE
02241112	ROSIGLITAZONE MALEATE
02241113	ROSIGLITAZONE MALEATE
02241114	ROSIGLITAZONE MALEATE

02242095	GLYBURIDE					
02242096	GLYBURIDE					
02242572	PIOGLITAZONE HCL					
02242573	PIOGLITAZONE HCL					
02242574	PIOGLITAZONE HCL					
02242589	METFORMIN HCL					
02242726	METFORMIN HCL					
02242783	METFORMIN HCL					
02242793	METFORMIN HCL					
02242794	METFORMIN HCL					
02242931	METFORMIN HCL					
02242974	METFORMIN HCL					
02242987	GLICLAZIDE					
02245247	GLICLAZIDE					
02245272	GLIMEPIRIDE					
02245273	GLIMEPIRIDE					
02245274	GLIMEPIRIDE					
02245438	NATEGLINIDE					
02245439	NATEGLINIDE					
02245440	NATEGLINIDE					
02246613	METFORMIN HCL					
02246614	METFORMIN HCL					
02246820	METFORMIN HCL					
02246821	METFORMIN HCL					
02246964	METFORMIN HCL					
02246965	METFORMIN HCL					
02247085	METFORMIN HCL & ROSIGLITAZONE MALEATE					
02247086	METFORMIN HCL & ROSIGLITAZONE MALEATE					
02247087	METFORMIN HCL & ROSIGLITAZONE MALEATE					
02248008	GLYBURIDE					
02248009	GLYBURIDE					
02248210	GLICLAZIDE					
02248440	METFORMIN HCL & ROSIGLITAZONE MALEATE					
02248441	METFORMIN HCL & ROSIGLITAZONE MALEATE					
02248453	GLICLAZIDE					
02252945	METFORMIN HCL					
02252953	METFORMIN HCL					
02254719	GLICLAZIDE					
02257726	METFORMIN HCL					
02257734	METFORMIN HCL					
02258781	GLIMEPIRIDE & ROSIGLITAZONE MALEATE					
02258803	GLIMEPIRIDE & ROSIGLITAZONE MALEATE					
02258811	GLIMEPIRIDE & ROSIGLITAZONE MALEATE					
02265575	METFORMIN HCL					
02265583	METFORMIN HCL					
02268493	METFORMIN HCL					
02268507	METFORMIN HCL					
02269031	METFORMIN HCL					
02269058	METFORMIN HCL					
02269589	GLIMEPIRIDE					

02269597	GLIMEPIRIDE
02269600	GLIMEPIRIDE
02269619	GLIMEPIRIDE
02273101	GLIMEPIRIDE
02273128	GLIMEPIRIDE
02273136	GLIMEPIRIDE
02273756	GLIMEPIRIDE
02273764	GLIMEPIRIDE
02273772	GLIMEPIRIDE
02274248	GLIMEPIRIDE
02274256	GLIMEPIRIDE
02274264	GLIMEPIRIDE
02274272	GLIMEPIRIDE
02274914	PIOGLITAZONE HCL
02274922	PIOGLITAZONE HCL
02274930	PIOGLITAZONE HCL
02279061	GLIMEPIRIDE
02279088	GLIMEPIRIDE
02279126	GLIMEPIRIDE
02284545	GLIMEPIRIDE
02284553	GLIMEPIRIDE
02284782	METFORMIN HCL
02284790	METFORMIN HCL
02286149	GLYBURIDE
02286157	GLYBURIDE
02287072	GLICLAZIDE
02293862	GLICLAZIDE
02294400	GLICLAZIDE
02295377	GLIMEPIRIDE
02295385	GLIMEPIRIDE
02295393	GLIMEPIRIDE
02297795	GLICLAZIDE
02297906	PIOGLITAZONE HCL
02297914	PIOGLITAZONE HCL
02297922	PIOGLITAZONE HCL
02298279	PIOGLITAZONE HCL
02298287	PIOGLITAZONE HCL
02298295	PIOGLITAZONE HCL
02300451	METFORMIN HCL
02301423	PIOGLITAZONE HCL
02301431	PIOGLITAZONE HCL
02301458	PIOGLITAZONE HCL
02302861	PIOGLITAZONE HCL
02302888	PIOGLITAZONE HCL
02302896	PIOGLITAZONE HCL
02302942	PIOGLITAZONE HCL
02302950	PIOGLITAZONE HCL
02302977	PIOGLITAZONE HCL
02303124	PIOGLITAZONE HCL
02303132	PIOGLITAZONE HCL

02303140	PIOGLITAZONE HCL
02303442	PIOGLITAZONE HCL
02303450	PIOGLITAZONE HCL
02303469	PIOGLITAZONE HCL
02303922	SITAGLIPTIN PHOSPHATE
02305062	METFORMIN HCL
02306166	ROSIGLITAZONE MALEATE
02306174	ROSIGLITAZONE MALEATE
02306182	ROSIGLITAZONE MALEATE
02307634	PIOGLITAZONE HCL
02307642	PIOGLITAZONE HCL
02307650	PIOGLITAZONE HCL
02307669	PIOGLITAZONE HCL
02307677	PIOGLITAZONE HCL
02307723	PIOGLITAZONE HCL
02312050	PIOGLITAZONE HCL
02312069	PIOGLITAZONE HCL
02312077	PIOGLITAZONE HCL
02313596	GLIMEPIRIDE
02314894	METFORMIN HCL
02314908	METFORMIN HCL
02316544	GLYBURIDE
02320754	PIOGLITAZONE HCL
02320762	PIOGLITAZONE HCL
02320770	PIOGLITAZONE HCL
02321475	REPAGLINIDE HCL
02321483	REPAGLINIDE HCL
02321491	REPAGLINIDE HCL
02326329	ROSIGLITAZONE MALEATE
02326337	ROSIGLITAZONE MALEATE
02326345	ROSIGLITAZONE MALEATE
02326477	PIOGLITAZONE HCL
02326485	PIOGLITAZONE HCL
02326493	PIOGLITAZONE HCL
02331519	METFORMIN HCL
02331527	METFORMIN HCL
02333554	SAXAGLIPTIN HCL
02333856	METFORMIN HCL & SITAGLIPTIN PHOSPHATE
02333864	METFORMIN HCL & SITAGLIPTIN PHOSPHATE
02333872	METFORMIN HCL & SITAGLIPTIN PHOSPHATE
02334437	METFORMIN HCL
02334445	METFORMIN HCL
02334674	PIOGLITAZONE HCL
02334682	PIOGLITAZONE HCL
02334690	PIOGLITAZONE HCL
02336316	GLICLAZIDE
02339110	METFORMIN HCL
02339129	METFORMIN HCL
02339587	PIOGLITAZONE HCL
02339595	PIOGLITAZONE HCL

02339676	PIOGLITAZONE HCL
02339684	PIOGLITAZONE HCL
02339692	PIOGLITAZONE HCL
02340763	GLYBURIDE
02340771	GLYBURIDE
02341522	METFORMIN HCL
02341603	METFORMIN HCL
02343606	METFORMIN HCL
02343614	METFORMIN HCL
02345366	PIOGLITAZONE HCL
02345374	PIOGLITAZONE HCL
02345382	PIOGLITAZONE HCL
02345854	GLYBURIDE
02345862	GLYBURIDE
02348578	GLICLAZIDE
02350289	METFORMIN HCL
02350300	METFORMIN HCL
02350459	GLYBURIDE
02350467	GLYBURIDE
02353377	METFORMIN HCL
02353385	METFORMIN HCL
02354144	ROSIGLITAZONE MALEATE
02354152	ROSIGLITAZONE MALEATE
02354160	ROSIGLITAZONE MALEATE
02354349	ROSIGLITAZONE MALEATE
02354357	ROSIGLITAZONE MALEATE
02354365	ROSIGLITAZONE MALEATE
02354926	REPAGLINIDE
02354934	REPAGLINIDE
02354942	REPAGLINIDE
02355663	REPAGLINIDE
02355671	REPAGLINIDE
02355698	REPAGLINIDE
02356422	GLICLAZIDE
02357453	REPAGLINIDE
02357461	REPAGLINIDE
02357488	REPAGLINIDE
02357887	ROSIGLITAZONE MALEATE & METFORMIN HCL
02357895	ROSIGLITAZONE MALEATE & METFORMIN HCL
02357909	ROSIGLITAZONE MALEATE & METFORMIN HCL
02357917	ROSIGLITAZONE MALEATE & METFORMIN HCL
02357925	ROSIGLITAZONE MALEATE & METFORMIN HCL
02361264	METFORMIN HCL
02361272	METFORMIN HCL
02363232	PIOGLITAZONE HCL
02363240	PIOGLITAZONE HCL
02363259	PIOGLITAZONE HCL
02363518	GLICLAZIDE
02363704	GLYBURIDE
02363712	GLYBURIDE

02364506	METFORMIN HCL
02364514	METFORMIN HCL
02365286	METFORMIN HCL
02365294	METFORMIN HCL
02365529	PIOGLITAZONE HCL
02365537	PIOGLITAZONE HCL
02366347	REPAGLINIDE
02366355	REPAGLINIDE
02366363	REPAGLINIDE
02373270	REPAGLINIDE
02373289	REPAGLINIDE
02373297	REPAGLINIDE
02374013	PIOGLITAZONE HCL
02374021	PIOGLITAZONE HCL
02374048	PIOGLITAZONE HCL
02374587	PIOGLITAZONE HCL
02374595	PIOGLITAZONE HCL
02375842	SAXAGLIPTIN HCL
02375850	PIOGLITAZONE HCL
02375869	PIOGLITAZONE HCL
02375877	PIOGLITAZONE HCL
02378043	METFORMIN HCL
02378051	METFORMIN HCL
02378116	METFORMIN HCL
02378124	METFORMIN HCL
02378620	METFORMIN HCL
02378639	METFORMIN HCL
02378841	METFORMIN HCL
02378868	METFORMIN HCL
02379767	METFORMIN HCL
02379775	METFORMIN HCL
02380196	METFORMIN HCL
02380218	METFORMIN HCL
02380722	METFORMIN HCL
02380730	METFORMIN HCL
02384906	PIOGLITAZONE HCL
02384914	PIOGLITAZONE HCL
02384922	PIOGLITAZONE HCL
02385341	METFORMIN HCL
02385368	METFORMIN HCL
02388766	METFORMIN HCL
02388774	METFORMIN HCL
02388839	SITAGLIPTIN PHOSPHATE
02388847	SITAGLIPTIN PHOSPHATE
02391600	PIOGLITAZONE HCL
02397307	PIOGLITAZONE HCL
02415968	REPAGLINIDE
02415976	REPAGLINIDE HCL
02415984	REPAGLINIDE HCL
02416794	METFORMIN HCL & SITAGLIPTIN PHOSPHATE

22022429	METFORMIN HCL
22297850	METFORMIN HCL
22399260	REPAGLINIDE
25022429	METFORMIN HCL
49012599	GLYBURIDE
81913662	GLYBURIDE
82148765	METFORMIN
82167786	METFORMIN HCL
99100755	METFORMIN HCL
	dentify Oral Hypoglycemic Use in CCS
NDC	Generic Drug Name
00093725401	GLIMEPIRIDE 1 MG TABTEVA
00093725501	GLIMEPIRIDE 2 MG TABTEVA
00093725601	GLIMEPIRIDE 4 MG TABTEVA
00781504601	GLIMEPIRIDE 2 MG TABSAND
16729000201	GLIMEPIRIDE 2 MG TABACCO
16729000301	GLIMEPIRIDE 4 MG TABACCO
45802077078	GLIMEPIRIDE 1 MG TABPERR
45802082278	GLIMEPIRIDE 2 MG TABPERR
45802094778	GLIMEPIRIDE 4 MG TABPERR
55111032001	GLIMEPIRIDE 1 MG TABDR.R
55111032101	GLIMEPIRIDE 2 MG TABDR.R
55111032105	GLIMEPIRIDE 2 MG TABDR.R
55111032201	GLIMEPIRIDE 4 MG TABDR.R
55111032205	GLIMEPIRIDE 4 MG TABDR.R
63304042501	GLIMEPIRIDE 1 MG TABRANB
66993016302	GLIMEPIRIDE 2 MG TABPRAS
66993016402	GLIMEPIRIDE 4 MG TABPRAS
60505014201	GLIPIZIDE 10 MG TABAPOT
00172365070	GLIPIZIDE 10 MG TABIVAX
00378111001	GLIPIZIDE 10 MG TABMYLA
00378111005	GLIPIZIDE 10 MG TABMYLA
00781145301	GLIPIZIDE 10 MG TABSAND
00781145310	GLIPIZIDE 10 MG TABSAND
00591046105	GLIPIZIDE 10 MG TABWATS
00591046110	GLIPIZIDE 10 MG TABWATS
59762503101	GLIPIZIDE 2.5 MGTABGRN1
00591090030	GLIPIZIDE 2.5 MGTABWATS
60505014102	GLIPIZIDE 5 MG TABAPOT
00172364960	GLIPIZIDE 5 MG TABIVAX
68645015054	GLIPIZIDE 5 MG TABLEGA
00378110501	GLIPIZIDE 5 MG TABMYLA
00378110505	GLIPIZIDE 5 MG TABMYLA
00781145201	GLIPIZIDE 5 MG TABSAND
00781145210	GLIPIZIDE 5 MG TABSAND
00591046001	GLIPIZIDE 5 MG TABWATS
00591046005	GLIPIZIDE 5 MG TABWATS
00591046010	GLIPIZIDE 5 MG TABWATS
00591084401	GLIPIZIDE 5 MG TABWATS
00228275211	GLYBMETFORHC2.5-50TABACTA

00228275250	GLYBMETFORHC2.5-50TABACTA
00228275350	GLYBMETFORHC5 MG-5TABACTA
00093571201	GLYBMETFORHC5 MG-5TABTEVA
00093571205	GLYBMETFORHC5 MG-5TABTEVA
64720012410	GLYBURIDE 2.5 MGTABCORE
00781114601	GLYBURIDE 2.5 MGTABSAND
00093834301	GLYBURIDE 2.5 MGTABTEVA
00093834310	GLYBURIDE 2.5 MGTABTEVA
00093943305	GLYBURIDE 2.5 MGTABTEVA
64720012510	GLYBURIDE 5 MG TABCORE
64720012511	GLYBURIDE 5 MG TABCORE
59762372707	GLYBURIDE 5 MG TABGRN1
68645021154	GLYBURIDE 5 MG TABLEGA
00781119101	GLYBURIDE 5 MG TABSAND
00781119110	GLYBURIDE 5 MG TABSAND
00093834401	GLYBURIDE 5 MG TABTEVA
00093834410	GLYBURIDE 5 MG TABTEVA
00093936401	GLYBURIDE 5 MG TABTEVA
00093936405	GLYBURIDE 5 MG TABTEVA
00093936410	GLYBURIDE 5 MG TABTEVA
64720012310	GLYBURIDE1.25 MG TABCORE
00093834201	GLYBURIDE1.25 MG TABTEVA
62584025901	METFORMIN 500 MGTABAHP
53746017801	METFORMIN 500 MGTABAMNE
53746017805	METFORMIN 500 MGTABAMNE
65162017510	METFORMIN 500 MGTABAMNE
65162017511	METFORMIN 500 MGTABAMNE
65162017550	METFORMIN 500 MGTABAMNE
60505019000	METFORMIN 500 MGTABAPOT
60505019001	METFORMIN 500 MGTABAPOT
60505019008	METFORMIN 500 MGTABAPOT
60505026001	METFORMIN 500 MGTABAPOT
65862000801	METFORMIN 500 MGTABAURO
65862000805	METFORMIN 500 MGTABAURO
57664039713	METFORMIN 500 MGTABCARA
57664039718	METFORMIN 500 MGTABCARA
57664039751	METFORMIN 500 MGTABCARA
57664039753	METFORMIN 500 MGTABCARA
57664039758	METFORMIN 500 MGTABCARA
57664039788	METFORMIN 500 MGTABCARA
00185441601	METFORMIN 500 MGTABEON
68462015905	METFORMIN 500 MGTABGLEN
68462015910	METFORMIN 500 MGTABGLEN
00172433160	METFORMIN 500 MGTABIVAX
00172433180	METFORMIN 500 MGTABIVAX
68645012059	METFORMIN 500 MGTABLEGA
00904563461	METFORMIN 500 MGTABMAJO
00904584980	METFORMIN 500 MGTABMAJO
53489046705	METFORMIN 500 MGTABMUTU
53489046710	METFORMIN 500 MGTABMUTU

00378023405	METFORMIN 500 MGTABMYLA
00378025403	METFORMIN 500 MGTABMYLA METFORMIN 500 MGTABMYLA
00378033203	METFORMIN 500 MGTABMYLA METFORMIN 500 MGTABMYLA
49884092101	METFORMIN 500 MGTABPAR
63304086001	METFORMIN 500 MGTABFANB METFORMIN 500 MGTABRANB
63304086005	METFORMIN 500 MGTABRANB
00781505001	METFORMIN 500 MGTABSAND
00781505005	METFORMIN 500 MGTABSAND
00781505010	METFORMIN 500 MGTABSAND
00781505061	METFORMIN 500 MGTABSAND
43547024810	METFORMIN 500 MGTABSOLC
43547024850	METFORMIN 500 MGTABSOLC
62756014201	METFORMIN 500 MGTABSUN
62756014202	METFORMIN 500 MGTABSUN
00093104801	METFORMIN 500 MGTABTEVA
00093104810	METFORMIN 500 MGTABTEVA
00093726701	METFORMIN 500 MGTABTEVA
00093726710	METFORMIN 500 MGTABTEVA
62037057101	METFORMIN 500 MGTABWATS
62037057110	METFORMIN 500 MGTABWATS
62037067401	METFORMIN 500 MGTABWATS
62037067410	METFORMIN 500 MGTABWATS
68382002801	METFORMIN 500 MGTABZYDU
68382002805	METFORMIN 500 MGTABZYDU
68382002810	METFORMIN 500 MGTABZYDU
53746017901	METFORMIN 750 MGTABAMNE
00555010702	METFORMIN 750 MGTABBAR2
62756014301	METFORMIN 750 MGTABSUN
00093721201	METFORMIN 750 MGTABTEVA
62037057701	METFORMIN 750 MGTABWATS
65162017450	METFORMIN 850 MGTABAMNE
65862000901	METFORMIN 850 MGTABAURO
65862000905	METFORMIN 850 MGTABAURO
57664043553	METFORMIN 850 MGTABCARA
57664043558	METFORMIN 850 MGTABCARA
00185021501	METFORMIN 850 MGTABEON
68462016005	METFORMIN 850 MGTABGLEN
00172433060	METFORMIN 850 MGTABIVAX
00172433080	METFORMIN 850 MGTABIVAX
00904585040	METFORMIN 850 MGTABMAJO
00904609161	METFORMIN 850 MGTABMAJO
53489046810	METFORMIN 850 MGTABMUTU
00378718605	METFORMIN 850 MGTABMYLA
00093104901	METFORMIN 850 MGTABTEVA
00093104910	METFORMIN 850 MGTABTEVA
68382002901	METFORMIN 850 MGTABZYDU
68382002905	METFORMIN 850 MGTABZYDU
68382002910	METFORMIN 850 MGTABZYDU
65162017710	METFORMIN1000 MG TABAMNE
65162017711	METFORMIN1000 MG TABAMNE

65162017750	METFORMIN1000 MG TABAMNE
60505019200	METFORMIN1000 MG TABAPOT
60505019201	METFORMIN1000 MG TABAPOT
65862001001	METFORMIN1000 MG TABAURO
65862001005	METFORMIN1000 MG TABAURO
57664047451	METFORMIN1000 MG TABCARA
57664047453	METFORMIN1000 MG TABCARA
57664047458	METFORMIN1000 MG TABCARA
57664047488	METFORMIN1000 MG TABCARA
00185022101	METFORMIN1000 MG TABEON
68462016105	METFORMIN1000 MG TABGLEN
68462016110	METFORMIN1000 MG TABGLEN
59762432200	METFORMIN1000 MG TABGRN1
00172443260	METFORMIN1000 MG TABIVAX
00172443280	METFORMIN1000 MG TABIVAX
00904585140	METFORMIN1000 MG TABMAJO
53489046905	METFORMIN1000 MG TABMUTU
53489046910	METFORMIN1000 MG TABMUTU
00378024401	METFORMIN1000 MG TABMYLA
00378718705	METFORMIN1000 MG TABMYLA
00781505201	METFORMIN1000 MG TABSAND
00781505205	METFORMIN1000 MG TABSAND
00781505261	METFORMIN1000 MG TABSAND
43547025010	METFORMIN1000 MG TABSOLC
43547025050	METFORMIN1000 MG TABSOLC
00093721401	METFORMIN1000 MG TABTEVA
00093721410	METFORMIN1000 MG TABTEVA
00591245501	METFORMIN1000 MG TABWATS
62037067601	METFORMIN1000 MG TABWATS
62037067610	METFORMIN1000 MG TABWATS
68382003001	METFORMIN1000 MG TABZYDU
68382003005	METFORMIN1000 MG TABZYDU
68382003010	METFORMIN1000 MG TABZYDU
00378313301	GLIPIZMETFOR5 MG-5TABMYLA
Codes Used to Io	dentify DM-Complication Hospitalizations and Emergency Visits
California	ICD-9-CM codes 250.10, 250.11, 250.12, 250.13, 250.20, 250.21, 250.22, 250.23, 250.30, 250.31, 250.32, 250.33
Ontario	ICD-10 codes E 10.0x, E 10.1x, E 10.64, E 11.0x, E 11.1x, E 11.64, E 13.0x, E 13.1x, E 13.64, E 14.0x, E 14.1x, E 14.64

DM-routine visits definition in Ontario

1) visit provided by an endocrinologist, or 2) billed with a DM-preventive visit fee code [K030, K029, Q040, K045, K046], or 3) billed as a general consultation with a diagnosis code of DM by a family physician, pediatrician, or internist [ICD-9-CM code 250.xx and billing codes A005, A905, A006, A003, A004, A265, A565, A266, A263, A264, A661, A261, A262, A135, A765, A435, A136, A133, A134, A131, or A138], or 4) or having a diagnosis code for DM (ICD-9 code 250.xx) and occurring within 2 weeks of a billing claim for measurement of serum Hemoglobin A1C [OHIP fee code L093]

DM-routine visits definition in CCS

1) visit provided by an endocrinologist, or 2) for DM care (ICD-9 code 250.xx)

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 abstra	ct				
	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		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.	Title
		summary of what was done and what was found	75.00	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
			10/0/	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	Background, page 4-5	9/	
Objectives	3	State specific objectives, including any prespecified hypotheses	Background, page 5, lines 106-110		
Methods					
Study Design	4	Present key elements of study design early in the paper	Methods, page 5, line 115		
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Methods, page 6, lines 127-132		
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 127-132 and

		sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> - Give the eligibility criteria, and the sources and methods of case		algorithms used to identify subjects) should be listed in detail. If this is not possible, an explanation should be provided. RECORD 6.2: Any validation studies	Appendix 1 Reference #16
		ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> - Give the eligibility criteria, and the sources and methods of selection		of the codes or algorithms used to select the population should be referenced. If validation was conducted for this study and not published elsewhere, detailed methods and results should be provided.	
		of participants (b) Cohort study - For matched studies, give matching criteria and number of exposed and unexposed Case-control study - For matched studies, give matching criteria and the number of controls per case		RECORD 6.3: If the study involved linkage of databases, consider use of a flow diagram or other graphical display to demonstrate the data linkage process, including the number of individuals with linked data at each stage.	Linkage and databases described and references provided (#14,15) in Methods, page 5-6, lines 115-124
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.		RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, an explanation should be provided.	Appendix 1
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	Methods, pages 5-7, lines 114-160		
Bias	9	Describe any efforts to address potential sources of bias	Methods, page 8, lines 173-176		
Study size	10	Explain how the study size was	Methods, page 6,		

		arrived at	lines 127-132		
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 165-172		
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 165-176 Methods, page 8, lines 173-176 Methods, page 7, line 149 Methods, page 8, lines 173-176		
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 7, lines 163-164 Methods, page 6-7, lines 135-149
Linkage				methods used in the study. RECORD 12.3: State whether the study included person-level, institutional-	Methods, page 5- 7, lines 114-149

				level, or other data linkage across two	
				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 127-132
Descriptive data	14	(a) Give characteristics of study participants (e.g., 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) Cohort study - summarise follow-up time (e.g., average and total amount)	Results, page 8-9, lines 182-188 and Table 1 Table 1 Results, page 8, lines 183-184		
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 189-201, Table 2, Table 3, and Figure 1		
Main results	16	(a) Give unadjusted estimates	Results, page 9, lines		

		and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative	189-201, Table 2, Table 3, and Figure 1 N/A		
		risk into absolute risk for a meaningful time period			
Other analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	Results, page 9, lines 189-201		
Discussion					
Key results	18	Summarise key results with reference to study objectives	Interpretation, page 10, lines 220-224		
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		RECORD 19.1: Discuss the implications of using data that were not created or collected to answer the specific research question(s). Include discussion of misclassification bias, unmeasured confounding, missing data, and changing eligibility over time, as they pertain to the study being reported.	Interpretation, pages 12-13, lines 256-277
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Interpretation, pages 10-13, lines 220-295		
Generalisability	21	Discuss the generalisability (external validity) of the study results	Interpretation, page 13, lines 288-295		

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	Acknowledgements				
Accessibility of protocol, raw data, and programming code				RECORD 22.1: Authors should provide information on how to access any supplemental information such as the study protocol, raw data, or programming code.	Appendix 1 and Author contact information		

^{*}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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