Glycemic control and socioeconomic status in Canadian children with type 1 diabetes using continuous glucose monitoring: A retrospective cohort study

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Abstract

Background: Type 1 diabetes (T1D) is one of the most common chronic childhood disorders and is associated with significant morbidity. Insulin pumps and continuous glucose monitoring (CGM) are part of routine care for T1D and can improve glycemic control and quality of life. However, access to these technologies is not equitable. In Canada, socioeconomic status (SES) disparities in pump use have been found, but disparities in CGM use have not been studied.

Objectives: Our first aim was to determine if SES disparities exist in CGM use in children with T1D. Our second aim was to determine if SES disparities exist in glycemic control, as measured by hemoglobin A1c (HbA1c), among those started on CGM.

Methods: Using a deidentified clinical database, we conducted a retrospective cohort study of children with T1D aged <18 years followed at a single center in Ontario from April 2009 to September 2021. For our first aim, the outcome was CGM use (yes: first recorded date of use in January 2017 or later; no: never user). Primary exposure was SES, defined by validated neighborhood-level dimensions (residential instability, economic dependency, ethnocultural composition, and situational vulnerability), each divided into quintiles. Covariables included age, sex, pump use, mean HbA1c in the prior 12 months, and diagnosis era, all defined at the first recorded date of use or the last recorded visit for non-users. We used multivariable logistic regression to examine the association between SES and CGM use. For our second aim, we analyzed the sub-cohort of CGM users with HbA1c data in both the 12 months prior to and after starting. The outcome was change in mean HbA1c between post- and pre-CGM start. Primary exposure was SES. We used multivariable linear regression to analyze the expected difference in

mean HbA1c by SES, adjusted for age, sex, diabetes duration, pump use, mean pre-use HbA1c, and CGM type, all defined at the first recorded date of use.

Results: For our first aim, we identified 481 CGM users (80.8%) and 114 non-users (19.2%). CGM users were 49.7% male with a mean age ± standard deviation of 11.1±3.8 years and mean HbA1c of 8.2±1.4%. Non-users were 63.2% male with a mean age of 12.4±3.7 years and mean HbA1c of 9.0±1.8%. The distribution of SES quintiles was similar for residential instability and economic dependency in both groups, but a larger proportion of non-users were in the most diverse ethnocultural composition quintiles and most situationally vulnerable (least educated) quintiles. In logistic regression, older age, male sex, and higher mean HbA1c were significantly associated with lower odds of CGM use (e.g., for each percent increase in mean HbA1c, adjusted odds ratio (aOR) 0.78, 95% confidence interval (CI) 0.68, 0.90). SES was not associated with CGM use, although situational vulnerability showed a tendency towards lower odds of use in the most deprived quintiles compared to the least (aOR 0.56, 95% CI 0.29, 1.08). For our second aim, we identified 290 CGM users, 53.8% without improvement in HbA1c after starting. In linear regression, age and mean pre-use HbA1c were significant predictors of expected difference in mean HbA1c (e.g., for each percent increase in mean pre-use HbA1c, expected change -0.14%, 95% CI -0.23%, -0.04%). SES was not significantly associated, although there was a tendency towards lower HbA1c in the most diverse ethnocultural composition quintiles compared to the least (-0.23%, 95% CI -0.52%, 0.06%).

Conclusion: In this cohort, the vast majority of children with T1D used CGM, and more than half did not have improvement in HbA1c in the 12 months after starting CGM. SES was not

significantly associated with CGM use and was not a significant predictor of change in HbA1c after starting. Although this center's practices may provide a model for exceptional access to CGM, further efforts such as education curriculums are needed to achieve glycemic benefit with CGM for all children with T1D irrespective of SES.

Résumé

Contexte : Le diabète de type 1 (DT1) est une des maladies chroniques infantiles les plus courantes et est associé à une morbidité importante. Les pompes à insuline et la surveillance du glucose en continu (SGC) sont la norme dans le traitement du DT1 et peuvent améliorer le contrôle glycémique et la qualité de vie. Cependant, l'accès à ces technologies n'est pas équitable. Au Canada, on a constaté des disparités de statut socioéconomique (SSE) chez les utilisateurs de pompe à insuline. Les disparités chez les utilisateurs de SGC n'ont pas été étudiées.

Objectifs : Notre premier objectif était de déterminer s'il y a des disparités de SSE chez les enfants diabétiques qui utilisent la SGC. Notre deuxième objectif était de déterminer s'il y a des disparités de SSE dans le contrôle glycémique, mesuré par l'hémoglobine A1c, chez les enfants utilisant la SGC.

Méthodes : En utilisant une base de données cliniques dépersonnalisées, nous avons mené, d'avril 2009 à septembre 2021, une étude de cohorte rétrospective auprès d'enfants atteints de DT1 de moins de 18 ans suivis à un seul centre en Ontario. Pour notre premier objectif, le résultat était l'utilisation de la SGC (oui : la première date d'utilisation enregistrée en janvier 2017 ou plus tard; non : la non-utilisation). L'exposition primaire était le SSE, défini par des dimensions au niveau des quartiers validés (instabilité résidentielle, dépendance économique, composition ethnoculturelle, vulnérabilité situationnelle), chacun divisé en quintiles. Les covariables comprenaient l'âge, le sexe, l'utilisation d'une pompe à insuline, l'A1c moyenne les 12 mois précédents et la période de diagnostic, définies à la première date d'utilisation enregistrée ou la dernière visite enregistrée pour les non-utilisateurs. Nous avons utilisé la logistique de

régression à variables multiples pour examiner le lien entre le SSE et l'utilisation de la SGC. Pour notre deuxième objectif, nous avons analysé la sous-cohorte d'utilisateurs de SGC avec des données d'A1c des 12 mois avant et après le début d'utilisation de la SGC. Le résultat a été un changement dans l'A1c moyenne avant et après le début d'utilisation. L'exposition primaire était le SSE. Nous avons utilisé la régression linéaire à variables multiples pour analyser le changement d'A1c moyenne attendu par SSE, ajusté pour l'âge, le sexe, la durée du diabète, l'utilisation d'une pompe à insuline, l'A1c moyenne préutilisation et le type de SGC, définies à la première date d'utilisation enregistrée.

Résultats : Pour notre premier objectif, nous avons identifié 481 utilisateurs de SGC (80,8%) et 114 non-utilisateurs (19,2%). En tout, 49,7 % des utilisateurs étaient de sexe masculin, leur moyenne d'âge ± l'écart type était de 11,1±3,8 ans et leur A1c moyenne de 8,2±1,4 %. Pour les non-utilisateurs, 63,2 % étaient de sexe masculin, leur moyenne d'âge de 12,4±3,7 ans et leur A1c moyenne de 9,0±1,8 %. La distribution des quintiles de SSE était semblable dans les deux groupes pour l'instabilité résidentielle et la dépendance économique, mais plus de non-utilisateurs étaient dans les quintiles de composition ethnoculturelle les plus diversifiés et les quintiles les plus vulnérables au plan situationnel (moins éduqués). Dans la régression logistique, les participants de sexe masculin plus âgés avec une A1c moyenne plus élevée étaient moins susceptibles d'utiliser la SGC (pour chaque pourcentage d'augmentation de l'A1c moyenne, un rapport de cote (RC) ajusté de 0,78 avec un intervalle de confiance (IC) à 95 % : 0,68, 0,90). Le SSE n'était pas lié à l'utilisation de la SGC, mais la vulnérabilité situationnelle a montré que les quintiles les plus défavorisés étaient moins susceptibles d'utiliser la SGC que les moins défavorisés (RC ajusté 0,56 IC 95 % : 0,29, 1,08). Pour notre deuxième objectif, nous avons identifié 290 utilisateurs de SGC,

dont 53,8 % sans amélioration de l'A1c après le début d'utilisation. Dans la régression linéaire, l'âge et l'A1c moyenne pré-utilisation prédisaient un changement de l'A1c (pour chaque pourcentage d'augmentation de l'A1c moyenne pré-utilisation, le changement attendu était -0,14 % IC 95 % : -0,23 %, -0,04 %). Les quintiles du SSE n'étaient pas étroitement liés malgré une A1c moins élevée chez les quintiles les plus diversifiés sur le plan de la composition ethnoculturelle que chez les moins diversifiés (-0,23 % IC 95 % : -0,52 %, 0,06 %).

Conclusion : Dans cette cohorte, la grande majorité des participants utilisaient la SGC et plus de la moitié n'ont pas vu leur A1c s'améliorer dans les 12 mois suivant l'utilisation de la SGC. Le SSE n'était pas étroitement lié à l'utilisation de la SGC et ne prédisait pas de changement dans l'A1c après le début d'utilisation. Même si les pratiques de ce centre peuvent offrir un modèle d'accès exceptionnel à la SGC, des efforts supplémentaires comme des programmes d'enseignement sont requis pour voir des bénéfices glycémiques avec l'utilisation de SGC chez tous les enfants diabétiques, peu importe leur SSE.

Preface

This thesis is divided into five main chapters:

- Chapter 1 is a broad introduction to the landscape and thesis objectives.
- Chapter 2 includes background on the clinical burden and care of type 1 diabetes as well as the effects of technology (namely pumps and continuous glucose monitoring) on glycemic control and quality of life. Inequities in use of these technologies and in disease outcomes are also explored. Of note, there is a wealth of literature on these topics, and this chapter is by no means an exhaustive systematic review but does highlight the well-known and clinically important previous research.
- Chapter 3 provides methodological details on our analyses undertaken for this thesis.
- Chapter 4 highlights the main results of our analyses.
- Chapter 5 interprets the important findings of our study, addresses study limitations, and highlights future directions for continued research.

Contribution of Authors

Dr. Jennifer M Ladd formulated the study question, helped to conceptualize the study design, and obtained Institutional Review Board approval for data transfer and this research. Under the guidance of thesis supervisors, Dr. Ladd conducted all primary and secondary statistical analyses and interpreted the data. Dr. Ladd drafted chapters of this thesis and subsequently completed all revisions after feedback from thesis supervisors and committee members. Dr. Ladd gave approval of the thesis for submission.

Dr. Elham Rahme helped to conceptualize the study design and provided oversight and guidance for statistical analysis and interpretation. Dr. Rahme provided feedback on earlier versions of this thesis and gave approval of the thesis for submission.

Dr. Caroline Zuijdwijk helped to obtain Institutional Review Board approval for data transfer and this research study and provided the data for analysis. Dr. Zuijdwijk provided feedback on earlier versions of this thesis and gave approval of the thesis for submission.

Dr. Ellen Goldbloom helped to obtain Institutional Review Board approval for data transfer and this research study and provided the data for analysis. Dr. Goldbloom provided feedback on earlier versions of this thesis and gave approval of the thesis for submission.

Dr. Rayzel Shulman provided feedback on earlier versions of this thesis and gave approval of the thesis for submission.

Dr. Daniele Pacaud provided feedback on earlier versions of this thesis and gave approval of the thesis for submission.

Dr. Julia von Oettingen helped to conceptualize the study design and interpret findings from statistical analyses. Dr. von Oettingen provided feedback on earlier versions of this thesis and gave approval of the thesis for submission.

Dr. Meranda Nakhla helped to conceptualize the study design, obtain Institutional Review Board approval, and provided guidance for statistical analysis and interpretation. Dr. Nakhla provided feedback on earlier versions of this thesis and gave approval of the thesis for submission.

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List of Abbreviations

%: Percentage

aHR: adjusted Hazard Ratio

aOR: adjusted Odds Ratio

CGM: Continuous Glucose Monitoring
rtCGM: real-time CGM
isCGM: intermittently scanned CGM

CI: Confidence Interval

CIMD: Canadian Index of Multiple Deprivation

DAs: Dissemination Areas

DCCT/EDIC: Diabetes Control and Complications Trial/Epidemiology of Diabetes Investigations and Complications

DKA: Diabetic Ketoacidosis

DPV: Diabetes Patienten Verlaufsdokumentation

HbA1c: Hemoglobin A1c

JDRF: Juvenile Diabetes Research Foundation

IQR: Interquartile Range

MDI: Multiple Daily Injections

N: Number

PCCF+: Postal Code Conversion File Plus

PROs: Patient Reported Outcomes

Q: Quintile

QOL: Quality of Life

RCT: Randomized Controlled Trial

SES: Socioeconomic Status

SD: Standard Deviation

T1D: Type 1 Diabetes Mellitus

U.K.: United Kingdom

U.S.: United States

Chapter 1: Introduction and Study Objectives

Type 1 diabetes mellitus (T1D) is among the most common chronic childhood disorders and is associated with significant morbidity and mortality.[1] T1D is an autoimmune disease resulting in profound hyperglycemia from a permanent deficit in insulin production. Life-threatening acute complications of T1D include diabetic ketoacidosis (DKA) and severe hypoglycemia (i.e., low blood glucose) while chronic complications include micro- and macrovascular damage.[1,2] Landmark studies, such as the Diabetes Control and Complications Trial/Epidemiology of Diabetes Investigations and Complications (DCCT/EDIC) starting in the 1980s, demonstrated that improved glycemic control delays development of these chronic complications.[3] Improved glycemic control has been facilitated by the advent of injectable insulins with more physiologic pharmacokinetics as well as new technologies including insulin pumps and continuous glucose monitoring (CGM).[4] These new technologies are not a cure and still require significant self-management, but also have benefits beyond improved glycemic control including enhanced quality of life.[5-9]

As may be expected, these technologies represent a substantial financial burden. At the present time, the cost of an insulin pump itself is approximately $7,000 CAD, with an additional $4,000 CAD per year required for associated supplies such as infusion sets.[10] CGM is similarly costly at approximately $2,500 – 4,000 CAD per year.[10]

All provinces in Canada have implemented universal pediatric insulin pump funding programs providing varying amounts of financial assistance, but few provinces have provided any coverage for CGM since Health Canada approval of newer devices in late 2016 and early 2017.[11,12]

During the study period of this thesis, Ontario covered the full cost of one type of CGM for selected pediatric patients as of September 2019.[13]

Even under these provincial programs, access to these expensive technologies is not universal among children with T1D, thus creating an inequitable care environment in Canada. Systematic evaluation of the pump programs in Ontario, Québec, and Manitoba have found socioeconomic status (SES) disparities in pump uptake, with those most deprived less likely to start or use pump therapy than those least deprived.[14,15] Additionally, studies in Ontario have shown SES disparities in glycemic control even after adjustment for pump use as well as SES disparities in acute and chronic complications, with those most deprived more likely to have worse glycemic control and increased rates of complications than those least deprived.[16-18] However, most of these studies did not adjust for any measure of ethnicity, and all of these studies were either conducted prior to Health Canada approval of newer CGMs or did not take CGM use into account.

Therefore, our overall objective of this thesis was two-fold: first, to determine if SES disparities exist in CGM use in children with T1D in Ontario, Canada; and second, to determine if SES disparities exist in glycemic control, as measured by hemoglobin A1c (HbA1c), among those started on CGM. Based on existing literature from other countries, we hypothesized that SES disparities in CGM use would exist, with those in the most deprived quintiles less likely to use CGM than those in least deprived quintiles. We further hypothesized that SES disparities in glycemic control would exist amongst CGM users, with those in the most deprived quintiles having worse glycemic control than those in the least deprived quintiles.

Chapter 2: Background and Literature Review

Pathophysiology of T1D

Approximately 90 – 95% of children with diabetes have T1D,[19,20] an autoimmune disease that targets pancreatic beta cells resulting in a permanent decrease in insulin production and subsequent hyperglycemia.[2] Other forms of diabetes include type 2 diabetes (a condition resulting from severe insulin resistance which is more common in those who are overweight or obese), monogenic diabetes, and cystic fibrosis related diabetes. In T1D, hyperglycemia leads to the classic presenting symptoms of polyuria, polydipsia, polyphagia, and weight loss and can cause life-threatening complications. Acute complications of hyperglycemia include DKA (a preventable critical illness characterized by vomiting, rapid breathing, and altered mental status), and chronic complications include retinopathy leading to blindness, neuropathy, cardiovascular disease, and chronic kidney disease.[1,2] Life-long administration of subcutaneous insulin and blood glucose monitoring are mainstays of treatment for T1D.

The overarching goal of T1D treatment is to achieve near-normal glucose levels to prevent acute and chronic complications. The seminal research of DCCT/EDIC proved that intensive insulin therapy, through multiple daily injections (MDI) or pump therapy, improved glycemic control and delayed the development of long-term complications in T1D.[3] HbA1c is the most often used measure of glycemic control, reflecting the average glucose levels over the preceding three months. Consensus guidelines from Diabetes Canada, the American Diabetes Association, and the International Society for Pediatric and Adolescent Diabetes all cite a HbA1c of < 7.0% as the target for most children and adolescents with T1D, although these guidelines do acknowledge that a target HbA1c of < 7.5% may be more appropriate for select patients (such as those with

hypoglycemic unawareness, or inability to recognize low blood glucoses).[1,21,22] However, the less stringent target is not achieved by the majority of children and adolescents with T1D.[23,24] For instance, in the T1D Exchange Registry in 2016 – 2018, only 17% of 22,697 youth aged < 18 years from across the United States (U.S.) had a mean HbA1c of < 7.5%.[23]

Epidemiology and Public Health Burden of T1D

The onset of T1D can occur at any age, but has a bimodal distribution with peak incidences in the early school-age years (5 – 9 years) and pubertal years (10 – 14 years).[25] Rates of pediatric T1D vary by country. Data from the 1990s published in 2006 showed that the age-adjusted incidence of T1D in children ≤ 14 years was as low as 0.1 new cases per 100,000/year in Venezuela and as high as 40.9 new cases per 100,000/year in Finland.[26] Canada ranked sixth highest, with an incidence of approximately 20 new cases per 100,000 children/year and an annual increase in incidence of 5.1%.[26] A more recent study reports an overall incidence of 32/100,000 in Canada,[19] and the Public Health Agency of Canada in 2009 reported a prevalence rate of 0.3% of diabetes in Canadian children aged 1 to 19 years.[27]

The public health burden and costs of T1D are substantial. In 2019, the World Health Organization (WHO) estimated that diabetes was the ninth leading cause of death worldwide as well as the eighth leading cause of disability adjusted life-years[28] (a population health measure quantifying years of life lost to morbidity and mortality of specific diseases; commonly referred to as DALYs[29]). However, these WHO estimates combined T1D with other forms of diabetes, namely type 2 diabetes. Another study using data from several sources including the Global Health Data Exchange found a trend towards lower age-standardized mortality and DALYs of T1D in 2017 compared to 1990 in all countries, with more pronounced differences in more affluent

nations.[30] Yet this study also notes that overall life expectancy for those with T1D in many countries, including affluent nations, is still reduced by more than a decade compared with the general population.[30]

Clinical Management of T1D

T1D management focuses on stringent glycemic control to reduce complications related to hyperglycemia, while simultaneously avoiding hypoglycemia, which can occur related to excessive insulin administration, exercise, or vomiting, and can result in neuroglycopenic symptoms, seizures, coma or even death. This goal requires daily unrelenting attention to blood glucose levels and insulin treatment. Upon diagnosis with T1D, children and their families receive rigorous teaching from clinicians and allied health professionals over several weeks to months. Management of T1D involves subcutaneous insulin administration (to cover both background or basal needs and increased needs with food) paired with blood glucose monitoring.[1,22] Traditional T1D treatment includes MDI via insulin pen and capillary blood glucose monitoring via finger pricks and glucometer. Both insulin injections and glucose monitoring are ideally performed prior to each meal and snack and before bedtime, with additional glucose monitoring performed with any hypoglycemia or hyperglycemia symptoms. Thus, insulin injections and blood glucose checks can be required seven times or more per day for optimal management.

The advent of pumps and CGM has significantly decreased the number of daily insulin injections and finger pricks required, while potentially providing the ability for more refined control. Pumps are wearable devices that deliver a very precise, continuous basal infusion of insulin through an indwelling subcutaneous catheter in addition to separate user-administered boluses of insulin for carbohydrate coverage and correction of hyperglycemia.[31] Needle use is

required only every two to three days to change the indwelling catheter. Pumps can now function in manual or semi-automatic modes (hybrid closed-loop systems as described below), but both require an understanding of, and ability to use, complex technology. Prior to starting pump therapy, pediatric diabetes centers often require patients and families to attend several educational and training sessions as well as demonstrate advanced knowledge of carbohydrate counting.[31]

CGMs are separate wearable sensor devices which monitor interstitial glucose through a small subcutaneous catheter.[32] In addition to reducing the number of finger pricks (sensor changes are only needed every 10 to 14 days), a more comprehensive picture of glucose trends is possible than with static snapshots from finger pricks, with glucose readings captured every five minutes. This comprehensive picture may be transmitted continuously to a remote receiver or smartphone (real-time CGM, or rtCGM) or may require a direct scan of the sensor with a reader or smartphone (intermittently scanned CGM, or isCGM).[33] On certain CGM, alarms can also be set to signal hypoglycemia or hyperglycemia. In contrast to pump therapy, many pediatric diabetes centers do not require extensive training programs for patients and families prior to initiation of CGM.

Toward the goal of an artificial pancreas, several hybrid closed-loop systems, or sensor-augmented pump therapies, have recently been developed. In these systems, the CGM directly communicates with the pump to automatically adjust basal insulin rates to provide more optimal glycemic control and increased safety (e.g., through predictive algorithms suspending basal insulin delivery to prevent hypoglycemia). However, at this time, manual user input is still required to calculate insulin doses for carbohydrate coverage and in other specific situations such as exercise.

Technology use for T1D management has now become part of routine care. Technology is also constantly advancing with newer versions of pumps and CGMs continually available. Clinical practice guidelines state that pumps are safe for children of all ages and recommend that CGM be

considered for all patients, especially for those with hypoglycemic unawareness who have an increased risk of adverse events such as seizures, coma and death.[1,22] In Canada, studies using population-based health administrative data have found that almost 40% of children and adolescents with T1D use pumps in Ontario (as of 2012) and in Québec (as of 2017) whereas just under 20% are on pump therapy in Manitoba (as of 2017).[15,34] Newer studies are needed to assess the current prevalence of pump use. Additionally, none of these Canadian studies assessed the prevalence of CGM use in pediatric patients given data were analyzed from prior to Health Canada approval of newer CGMs and wider spread use.[11,12] In the U.S., data from the T1D Exchange registry including almost 10,000 youth aged < 18 years found that 64.9% were on pump and 30.1% used CGM in 2016 – 2018.[24] In Germany, 56.6% were on pump and 48.7% used CGM among the almost 27,000 youth aged < 18 years included in the Diabetes Patienten Verlaufsdokumentation (DPV) population-based registry in 2016 – 2018.[24]

Effect of Pumps on Glycemic Control and Quality of Life

The literature is mixed on the effect of pumps compared to MDI on glycemic control in children. In 2009, the SEARCH for Diabetes in Youth cross-sectional study found a lower adjusted HbA1c in those using pumps compared to those on any other insulin injection regimen.[5] This study included 2,743 youth aged < 20 years with T1D at six geographically diverse centers in the U.S., 22% of whom were on pump. Mean HbA1c was statistically significantly lower in those on pump compared to those using other insulin regimens (e.g., pump: mean ± standard deviation (SD) 9.0 ± 0.1%; MDI: 9.5 ± 0.1%), after adjustment for various factors including sex, ethnicity, center, number of glucose checks per day, and self-reported income.[5] However, it is worth noting that glycemic control in this cohort overall was poor and was measured only at a single visit, rather

than longitudinally. Subgroup analysis in a systematic Cochrane review from 2010 also found a slight improvement in HbA1c in children aged < 18 years using pumps compared to those on MDI (estimated mean difference of HbA1c in pump users compared to MDI users -0.2%, 95% confidence interval (CI) -0.4%, -0.03%), but only three of the seven pediatric studies included in this subgroup analysis had a duration of more than six months.[6] Moreover, a pooled multi-registry retrospective cohort study (including over 50,000 children aged < 18 years from the American T1D Exchange, the German/Austrian DPV registry, and the English/Welsh National Paediatric Diabetes Audit from 2011 – 2012) similarly found that pump use was associated with a significantly lower mean HbA1c than injection therapy (pump: 8.0 ± 1.2%; injection: 8.5 ± 1.7%), although no adjustment was performed for potential confounders including age and duration of diabetes.[35] A 2012 pediatric-specific analysis of results from an American/Canadian randomized controlled trial (RCT) of sensor-augmented pump therapy (STAR3) also found lower HbA1c in those on pumps compared to MDI.[36] Eighty-two children (aged 7 – 12 years) and 74 adolescents (aged 13 – 18 years) were randomized to sensor-augmented pump therapy or MDI and followed for one year. In both children and adolescents, baseline HbA1c was similar in pump users compared to MDI (e.g., in children, pump: 8.21 ± 0.56%; MDI: 8.19 ± 0.51%), and HbA1c was significantly lower at all subsequent time points (three, six, nine and twelve months) for those on sensor-augmented pump compared to those on MDI.[36] In each age cohort, participants randomized to pumps were slightly younger and had a slightly shorter diabetes duration than did those randomized to MDI, which could favor lower HbA1c regardless of insulin therapy given more parental involvement and given that glucoses are often easier to control in the initial months to years following T1D diagnosis due to residual pancreatic insulin production (known colloquially as the "honeymoon period").[37] Additionally, as CGM was integrally paired with pump use in this

study intervention, it is not clear whether the benefits seen in this trial are related to pump therapy, CGM, or the combination of the two.

Other studies have found more modest effects of pumps on glycemic control. In 2013, a retrospective multicenter cohort study of youth aged 5 – 20 years in Canada, Italy, and Spain reported that the total cohort HbA1c significantly improved from baseline at both one year after pump start and throughout the seven years of follow-up.[38] However, the total cohort size was small (115) compared to other observational studies, and the overall effect size was small (mean HbA1c difference of -0.04% from baseline to last visit after pump start), which while statistically significant is unlikely to be clinically significant. Additionally, a retrospective analysis of 2,529 youth (660 of whom were on pump) from 2012 – 2017 from the German/Austrian DPV registry found lack of persistent improvement in glycemic control over time with pump use.[39] Mean HbA1c was significantly lower in those on pump compared to those on MDI at one year of follow-up (pump: 7.5 ± 0.03%; MDI: 7.7 ± 0.02%; 0.3% between-group difference); results remained significant after adjustment for baseline HbA1c, age, sex, and diabetes duration. However, there was no significant between-group difference at two and three years of follow-up (mean HbA1c in both pump and MDI groups 8.0% at three years).[39]

Even assuming a small to negligible improvement in HbA1c with older versions of pumps used in these studies, pump therapy appears to have durability and psychological benefits for pediatric patients. An observational cohort study of 161 children and adolescents with T1D at an U.S. academic center from 1998 – 2005 found that only 18% discontinued pump therapy (over a mean 3.8 years of follow-up), for reasons such as DKA, "diabetes burnout," and infusion site concerns.[40] A large population-based study of youth with T1D in Ontario in 2012 showed an even lower rate of pump discontinuation (0.42 per 100 person-year).[14] A multicenter open RCT in

Germany from 2011 – 2014 aimed to assess patient reported outcomes (PROs) in terms of quality of life (QOL) for families of children on pumps compared to MDI.[41] Two hundred and eleven children aged 6 – 16 years were randomized to transition to pump therapy immediately or to a six-month waiting period prior to pump initiation in which they continued on MDI. Standardized questionnaires were used to assess diabetes-specific health-related QOL of children and caregiver burden. Diabetes-specific health-related QOL was significantly higher in children aged 8 – 11 years on pump compared to those still on MDI (difference of median score 9.5, 95% CI 3.6, 16.7, where higher score is better), but no significant difference was found for adolescents aged 12 – 16 years (difference of median score 2.7, 95% CI -3.2, 9.5). Caregiver burden was reported as significantly reduced in those whose children or adolescents were on pumps compared to MDI, but the 95% CI for difference in scores included the null of 0.[41]

Beyond quantitative work, qualitative studies highlight the real-life benefits of pumps.[42] In-depth interviews with 21 parents of children with T1D on pump therapy in the U.S. in 2004 found that despite concerns of technological complexity and visibility of the device, parents reported much more flexibility in daily life and perceived improvements in glycemic control compared to MDI.[7] Interviews of 19 parents conducted in the United Kingdom (U.K.) in 2012 – 2013 showed similar results, with parents reporting benefits of decreased injections, increased flexibility with meal times, and improved glycemic control (although this control was facilitated by increased attention and management).[43] However, both of these studies included homogenous samples of white and educated parents.[7,43] In a larger 2015 – 2016 U.S. survey of 96 ethnically and professionally diverse parents of young children with T1D not on pump therapy, 71% expressed concerns that the pump would be uncomfortable for their child to wear and 59% feared it would affect the ability to participate in sports.[44] Nevertheless, interviews of 20 children, parents,

and emerging adults (up to age 25 years) from varying financial backgrounds in Nova Scotia, Canada in 2018 found that pumps alleviated some fear of hypoglycemia and improved social experiences by increasing spontaneity with food and physical activities.[45]

Effect of CGM on Glycemic Control and Quality of Life

The literature has overall been more unified in suggesting a modest improvement in glycemic control with CGM use than with pump use, although there are some studies that do not support such an assertion. A cross-sectional study from the T1D Exchange registry of over 20,000 adults and children in two time periods (2010 – 2012 and 2016 – 2018) found that CGM use increased, especially in children, from the first to second period (7% to 30% overall) and that HbA1c was significantly lower in CGM users across all ages in 2016 – 2018 after adjustment for confounders including diabetes duration and ethnicity (e.g. for children aged < 13 years, mean HbA1c for no technology 9.0%, for CGM only 8.0%).[23] A follow-up analysis of the T1D Exchange 2016 – 2018 registry data showed graphically that HbA1c was lower in CGM users than non-users across the lifespan regardless of insulin regimen (pump or MDI) and that this difference persisted after stratification by income or insurance status.[46] These studies did not include information on real-time compared to intermittently scanned CGM or on sensor adherence. In a study from the international benchmarking network Better Control in Pediatric and Adolescent Diabetes: Working to Create Centers of Reference (SWEET), approximately 63% of 25,654 children aged < 18 years with T1D in 2017 – 2019 were using technology (pump alone 17.2%, CGM alone 15.0%, or both 30.4%).[47] In an adjusted linear regression analysis (including confounders such as sex, age, diabetes duration, and region), use of any technological component was associated with a significantly lower mean HbA1c than use of injections and finger pricks (no technology reference

group). The largest reduction in HbA1c was seen in those using both pump and CGM (reference group HbA1c: 8.72%, 95% CI 8.68%, 8.75%; pump and CGM HbA1c 7.81%, 95% CI 7.77%, 7.84%), but significant reduction in HbA1c was also seen for those using CGM alone (HbA1c 8.30%, 95% CI 8.25%, 8.35%).[47] However, the SWEET cohort does not standardize measures of HbA1c results across centers, thus decreasing the precision of HbA1c comparisons, and lacks information on SES, ethnicity, type of CGM, and percent time of sensor use.

In addition to these observational studies, a RCT from 2018 – 2019 found improvement in HbA1c with CGM use.[8] One hundred and fifty-three ethnically diverse adolescents and emerging adults (aged 14 – 24 years) with T1D in the U.S. were randomized to rtCGM use or standard finger pricks and followed for 26 weeks. In those randomized to rtCGM, mean HbA1c decreased from 8.9% to 8.5% over the study period (even despite only 68% of wearing CGM at least five days per week by the end of follow-up) whereas in those randomized to standard monitoring, mean HbA1c remained stable at 8.9%. After adjustment for clinical center, the between-group difference was significant (-0.37%, 95% CI -0.66%, -0.08%). Additionally, mean HbA1c decreased by at least 0.5% from baseline for 44% of participants in the rtCGM group compared to 23% of those in the standard monitoring group (adjusted between-group difference 23%, 95% CI 7%, 37%).[8] However, pump use and ethnicity were not evenly distributed between the two groups, and results were not adjusted for these potential confounders of glycemic control. For example, there was a higher percentage of those using pumps in the standard monitoring group compared to the intervention group (e.g. pumps: 49% in rtCGM vs. 59% in control). Additionally, while almost half of participants in the rtCGM group had a large decrease in HbA1c of 0.5%, whether this change can be sustained beyond six months and outside of the clinical trial setting is unknown.

Nonetheless, earlier RCTs including younger children found conflicting results. One RCT funded by the JDRF (formerly known as the Juvenile Diabetes Research Foundation) randomized children and adults with T1D in the U.S. in 2007 to rtCGM or standard finger pricks (control) and followed them for 26 weeks.[48] In the youngest age group included in the study (114 children aged 8 – 14 years), there was no significant mean difference in change in HbA1c between the two groups (-0.13, 95% CI -0.38, 0.11). However, there was a significantly higher percentage in the rtCGM group who reached the very stringent target HbA1c < 7.0% at 26 weeks (rtCGM: 27%; control: 12%), although as with many RCTs, the results may not be generalizable as highly educated, well-off participants and families were predominantly included who may have been more motivated to reach this target.[48] Another similarly designed RCT included even younger children.[49] One hundred and forty-six children (aged 4 – 9 years) with T1D in the U.S. in 2009 – 2010 were randomized to CGM use or standard finger pricks and followed for 26 weeks. Mean change in HbA1c from baseline was not significantly different between the two groups (-0.1 ± 0.6% in each group), and the proportion of participants with a decrease in HbA1c of at least 0.5% without severe hypoglycemias was not significantly different between the two groups although appeared lower in CGM group (CGM: 19%, control: 28%).[49] Separate subgroup analyses including based on age and insulin regimen (pump vs. MDI) showed no differences as well. Additionally, although only 41% of the group randomized to CGM were still wearing the device at least six days per week by the end of follow-up, no association was found between change in HbA1c and overall CGM use during the entire study period (Spearman r_s = -0.09).[49] However, overall glycemic control was close to target in both groups at recruitment (mean HbA1c 7.9 ± 0.8%), which may have left limited room for improvement especially given the priority of hypoglycemia avoidance in young children. It is

worth noting that these RCTs involving younger children were conducted with older CGM models, and comfort and accuracy of these devices have rapidly improved in recent years.

Beyond glycemic control, CGM has the potential to improve QOL, although studies have shown mixed results in different aspects of QOL. All of the aforementioned RCTs have incorporated PROs into their secondary outcomes using validated questionnaires (such as the pediatric version of the Problem Areas In Diabetes Survey (PAID) for assessing diabetes burden).[50] For adolescents and young adults aged 14 – 24 years at the end of the previously mentioned 2018 – 2019 RCT, there was a significant improvement in glucose monitoring system satisfaction for those in the rtCGM group compared to the control (adjusted between-group difference 0.27, 95% CI 0.06, 0.54, where higher score is better), but no difference in burden related to T1D management on the PAID survey (adjusted between-group difference 0.1, 95% CI -3.0, 4.0, where lower score is better).[8] For parents and pediatric participants aged < 18 years enrolled in the JDRF RCT, there were no significant differences in diabetes-specific QOL or hypoglycemia fear for either children or parents between the rtCGM and control groups (e.g., at 26 weeks for children, diabetes specific QOL score was 81.7 ± 12.9 for the rtCGM group and 82.6 ± 13.2 for the control group, where a score closer to 100 is better). However, ability to detect differences between groups or improvements may have been limited by high baseline QOL in this study.[51] For parents of young children aged 4 – 9 years enrolled in the 2009 – 2010 RCT and randomized to the CGM group, general satisfaction with CGM was high, but there was no between-group difference in PAID scores of diabetes burden or in fear of hypoglycemia.[49]

As these studies were not powered to find differences in PROs, qualitative studies can be used to supplement the findings and provide more rich data. In 2016 – 2017, interviews were conducted with 24 parents, adults, and adolescents in the initial training phase in a rtCGM trial;

five of these interview participants were between ages 13 and 20 years. Participants expressed that CGM was motivating and empowering for glycemic self-management, although did wish for additional training in using CGM.[52] However, these families may be more motivated than others to engage in self-management of diabetes given their concurrent participation in a clinical trial. In 2018 – 2019, interviews were conducted with twelve parents of varied educational backgrounds whose adolescent and young adult offspring aged 14 – 20 years with T1D were enrolled in an isCGM trial in New Zealand. Participants reported reduced worry about their children's health and reduced diabetes-related conflicts between children and their parents.[53] Moreover, interviews of 20 parents of young children aged 2 – 12 years with T1D and of different educational backgrounds recently enrolled in a rtCGM trial in Australia found that remote monitoring with CGM created peace of mind, improved sleep, and more freedom for children, although also it led to occasional conflicts between caregivers.[54]

Inequities in Use of Pumps and CGM

Overall, considering the aforementioned literature and limitations, pumps and CGM may have a modest benefit on glycemic control in aggregate and in clinical trials, CGM more so than pumps, and both improve some aspects of QOL especially based on qualitative studies. It is worth noting that both pump and CGM technology is rapidly advancing, such that the devices used in these studies are already outdated. Current models could potentially have a larger positive impact on glycemic control and QOL, although this needs to be studied further. Given this and given that technology use is now part of routine care for T1D management, access to, and use of, pumps and CGM should be equitable.

However, countries including the U.S., Germany, New Zealand, and Canada have demonstrated SES and ethnic disparities in uptake or use of these technologies, albeit with differing definitions of SES. In the U.S., in which there is no unified financial coverage for diabetes technology, the previously described 2009 SEARCH for Diabetes in Youth cross-sectional study found that insulin pump use was significantly higher in those self-reporting a higher household income, a higher parental education level, and identification as non-Hispanic white (e.g., 26.3% of non-Hispanic whites were on pump vs. 5.3% of Non-Hispanic black).[5] Also, in the previously described 2016 – 2018 T1D Exchange registry study, children identifying as non-Hispanic white were more likely to use pumps or CGM than black or Hispanic children in every self-reported income bracket (e.g. for those with an annual household income of < US$50,000, 26% of whites were using CGM compared to 8% of Non-Hispanic blacks and 14% of Hispanics).[23]

A multicenter study from 2013 – 2014 in Germany, which provides full financial coverage, demonstrated lower pump use in those of lower SES as measured by individually reported income, education, and employment.[55] In the logistic regression model including 1829 children with T1D aged < 18 years, the adjusted proportion using pump therapy was significantly lower in those of low SES compared to high SES (low SES: 44.3%, 95% CI 38.7%, 50.1%; high SES: 54.5%, 95% CI 49.9%, 59.0%), after controlling for age, sex, duration of T1D, and migration background (having one parent born out of country).[55] In another cohort study using the previously described population-based DPV registry with over 50,000 youth aged < 18 years, CGM use was significantly higher in those least deprived compared to those most deprived (57.1% vs. 48.5%), as defined by a validated, neighborhood-level index encompassing income, employment, education and social captial.[24] Ethnicity was not included in this study. Furthermore, disparities in pump use have also been seen in New Zealand, which publicly funds all pumps and supplies. In a

health administrative data study from 2012 – 2016 including 17,338 individuals with T1D, 19.6% of whom were aged < 20 years, those in the most deprived quintile had 40% lower odds of using an insulin pump than those in the least deprived quintile (adjusted odds ratio (aOR) 0.6, 95% CI 0.5, 0.7), controlling for age and sex.[56] Additionally, those of self-identified ethnic minorities had significantly lower odds of pump use than New Zealand Europeans (e.g. aOR for those identifying as Asian 0.2, 95% CI 0.1, 0.3).[56] It is worth noting that the overall proportion on pumps, 11.3% for adults and children, is lower than in the other countries previously described.

Canadian studies have shown similar disparities in technology access in different provinces, although to date, only uptake and use of pumps, not CGM, have been explored. The provincial pediatric pump program in Ontario covers the cost of the insulin pump itself, but only provides partial coverage of the associated supplies. In a population-based cohort study using health administrative data from youth aged < 19 years in Ontario from 2006 – 2013, children using pumps were significantly more likely to be in the least deprived quintile as compared to the most deprived quintile (29.6% vs. 19.1% respectively, as measured by a validated neighborhood level index for material deprivation).[14] Measures of ethnicity were not included. SES disparities are present in the provinces of Québec and Manitoba as well.[15] Québec's pediatric pump program is unique in Canada in that it covers 100% of all pump-related costs. Similarly to Ontario, Manitoba's program pays for only a portion of pump supplies, but with an income-based deductible before government coverage.[57] In parallel population-based cohort studies using health administrative data from youth aged < 18 years in both provinces from 2011 – 2017, increasing material deprivation (as measured by a validated neighborhood level index) was associated with decreased pump uptake in both Québec (adjusted hazard ratio (aHR) 0.89, 95% CI 0.85, 0.93) and Manitoba (aHR 0.70, 95% CI 0.60, 0.82). In a secondary analysis, ethnocultural disparities in pump uptake

(again as defined by a validated neighborhood level index) were seen in Québec (aHR 0.90, 95% CI 0.86, 0.95), but not in Manitoba, (aHR 0.98, 95% CI 0.71, 1.35).[15]

Disparities in T1D Outcomes

Not only are youth of lower SES and ethnic minorities less likely to use pumps and CGM, but studies have also shown disadvantaged youth have worse T1D outcomes, often assessed in terms of glycemic control. Studies have included different measures of SES and ethnicity, but regardless of the national healthcare system, significant disparities in T1D-related health outcomes have been found.

SES-related health disparities have been found in many countries including the U.S., Germany, Denmark, and Canada. A study of 222 youth with T1D aged < 20 years enrolled in the U.S. SEARCH food insecurity sub-study from 2013 – 2015 found in a latent class analysis that those of lower SES profiles had significantly higher risk of having a "high-risk" HbA1c (defined as HbA1c > 9.0%).[58] This study used self-reported parental education and income, insurance status, and two measures of food insecurity to classify individuals into a lower or a higher SES class. Those of the lower SES class had significantly higher odds of having a high risk HbA1c compared to those of higher SES class (aOR 2.24, 95% CI 1.16, 4.33), controlling for age, sex, ethnicity, and duration of T1D.[58] Technology use was not included. A more recent study in the U.S. and Germany further described SES disparities in technology use through the T1D Exchange registry (U.S.) and the DPV registry (Germany).[24] As previously described, measures of SES such as income and education were self-reported in the T1D Exchange registry and were determined by a validated, neighborhood level index in the DPV registry. In both registries, those in the most deprived quintiles had higher HbA1c than those in the least deprived quintiles, with more

pronounced differences seen in the U.S. (e.g. in 2016–2018, in the U.S., HbA1c 9.3% in most deprived quintile vs. 8.0% in least deprived quintile; in Germany, 7.8% vs. 7.5%); these differences persisted even after adjustment for pump and CGM use. Moreover, in Denmark, where there is universal health care and full coverage for diabetes supplies, disparities in maternal education have been found in T1D outcomes.[59] Four thousand and seventy-nine children with T1D from 2000 – 2013 were identified in a nationwide registry, and maternal education level pre-birth was also obtained from this registry. In regression analysis, HbA1c was significantly lower in children whose mothers had higher education levels (e.g., in the crude model, HbA1c was -0.8%, 95% CI -0.94%, -0.67%, lower in those whose mothers had higher degrees compared to those with high school or less); this association persisted after adjustment for several possible confounders including age at onset of T1D, duration of T1D, maternal income, and pump use.[59] CGM use was not assessed.

In Canada, much of the research in SES disparities comes from Ontario. A cross-sectional study in Ontario assessed SES disparities in glycemic control for all 854 pediatric patients with T1D followed at a single tertiary care center in 2010 – 2011.[16] SES was reported as quintiles based on several neighborhood-level, validated measures to describe material deprivation, social deprivation, and ethnocultural composition. In the entire cohort, those in the most deprived quintiles for all measures had higher HbA1c than those in the least deprived quintiles (e.g., for material deprivation, mean HbA1c 9.2% for those most deprived and 8.3% for those least deprived, $p < 0.0001$; for ethnocultural composition, mean HbA1c 8.9% for those in the most diverse quintile and 8.4% for those in the least diverse quintile, $p < 0.03$), although this relationship did not hold when only pump users were assessed (no differences by SES quintiles). In regression analysis adjusted for age and sex, a higher mean HbA1c was significantly associated with more material

deprivation, but not with more ethnocultural diversity.[16] However, a population-based retrospective cohort study in Ontario of youth aged < 19 years in 2006 – 2013 found SES disparities in health outcomes and diabetes-related acute adverse events even amongst pump users.[17] SES was defined by a validated, neighborhood-level measure of material deprivation. In Cox proportional hazard models adjusted for variables including age, sex, duration of T1D and baseline HbA1c, being in the most deprived quintile as compared to the least was significantly associated with a 58% higher hazard of DKA hospital admission or death (aHR 1.58, 95% CI 1.05, 2.38) and a 60% higher rate of a diabetes-related hospitalization or emergency room visit (adjusted rate ratio 1.60, 95% CI 1.27, 2.00).[17] The effect of ethnicity was not assessed in this study. Another cross-sectional study at a single center in Ontario from 2013 – 2014 found SES disparities in glycemic control in 519 children with T1D based on a neighborhood-level composite deprivation index considering economic, social, and other forms of deprivation. In a linear regression model controlling for age, sex, duration of T1D and pump use, those living in the most-deprived neighborhoods had significantly higher expected HbA1c than those living in the least-deprived neighborhoods.[18] One additional Canadian study was a single center study from Québec of 1766 individuals diagnosed with insulin-dependent diabetes from 1980 – 2011.[60] In linear regression adjusted for variables including age at diagnosis, sex and ethnicity, there was a significant negative linear association in which HbA1c decreased by 0.1% for every $15,000 CAD increase in median annual household income based on a neighborhood-level measure.[60] This study did not adjust for pump use. In fact, all the aforementioned Canadian studies were performed before the widespread availability of CGM in Canada and thus did not take CGM use into account.

Beyond SES disparities, studies predominantly from the U.S. have looked at ethnic disparities in glycemic control. One of the previously described 2016 – 2018 T1D Exchange

registry studies showed that across the childhood years, for each pump users, CGM users, and non-technology users, average HbA1c was lowest for Non-Hispanic whites, followed by Hispanics, followed by Non-Hispanic blacks.[46] Another study from the U.S. found ethnic differences in long-term glycemic control even after controlling for SES.[61] In this longitudinal study of 1313 youth with T1D aged < 20 years included in the SEARCH 2002 – 2005 cohort, those self-identifying as non-Hispanic black had significantly higher odds of being in the worse long-term HbA1c trajectory group (moderate long-term increase) compared to the better group (mild long-term increase) than those self-identifying as non-Hispanic white (aOR for non-Hispanic blacks in worse vs. better group 4.54, 95% CI 2.08, 9.89). This association persisted after adjustment for possible confounders such as SES (self-reported parental education, household structure and insurance) and was modified by sex and age at diagnosis (association was more pronounced in males and those diagnosed before age 9 years).[61] This study did control for insulin regimen (pump use), but did not include CGM use. However, a follow-up reinforcement learning analysis by the same researchers of 978 youth with T1D from the same cohort estimated that disparities in mean HbA1c would still exist between those identifying as non-Hispanic white and non-white even if treatment regimen including pump and CGM use were equivalent.[62] The population mean HbA1c was 8.2% for non-Hispanic white and 9.2% for non-white in the cohort; mathematical modeling showed that if the non-white subgroup received the same treatment regimen as the non-Hispanic white subgroup, mean HbA1c was estimated to decrease by 0.33%, 95% CI -0.45, -0.21%.[62] Thus, technology use can likely account for some, but not all, of the ethnic disparities in glycemic control seen in youth with T1D.

Overall, pumps and CGM are associated with modest effects on glycemic control and improvements in QOL. Yet SES disparities exist in use of these technologies and in T1D-related

health outcomes. However, these SES disparities in CGM use, and including measures of ethnicity, have not been fully described in Canada. Thus, we had two objectives for this thesis work:

Objective 1: To determine if there are SES disparities in CGM use in children with T1D in Ontario, Canada

Objective 2: To determine if there are SES disparities in glycemic control, as measured by HbA1c, among those started on CGM.

Based on the existing literature from other countries, we hypothesized that there would be SES disparities in CGM use, with those in the most deprived quintiles less likely to use CGM than those in the least deprived quintiles. We further hypothesized that there would be SES disparities in glycemic control amongst CGM users, with those in the most deprived quintiles having worse glycemic control than those in the least deprived quintiles.

Chapter 3: Methods

Study Design and Data Source

We conducted a retrospective cohort study of children < 18 years with T1D followed at a single academic center in Ottawa, Ontario. We used a deidentified clinical database, which included all patients followed at this center's pediatric diabetes clinic from April 2009 to September 2021. The database included demographic information (i.e., date of birth, sex, and postal code) as well as discretely captured clinical, treatment, and laboratory information from each clinic visit every three to five months (i.e., HbA1c values, pump use, and CGM use) pulled directly from the electronic medical record. This research received Institutional Review Board approval from both the McGill University Health Centre and the Children's Hospital of Eastern Ontario. Individual informed consent or assent was not required by the ethics boards.

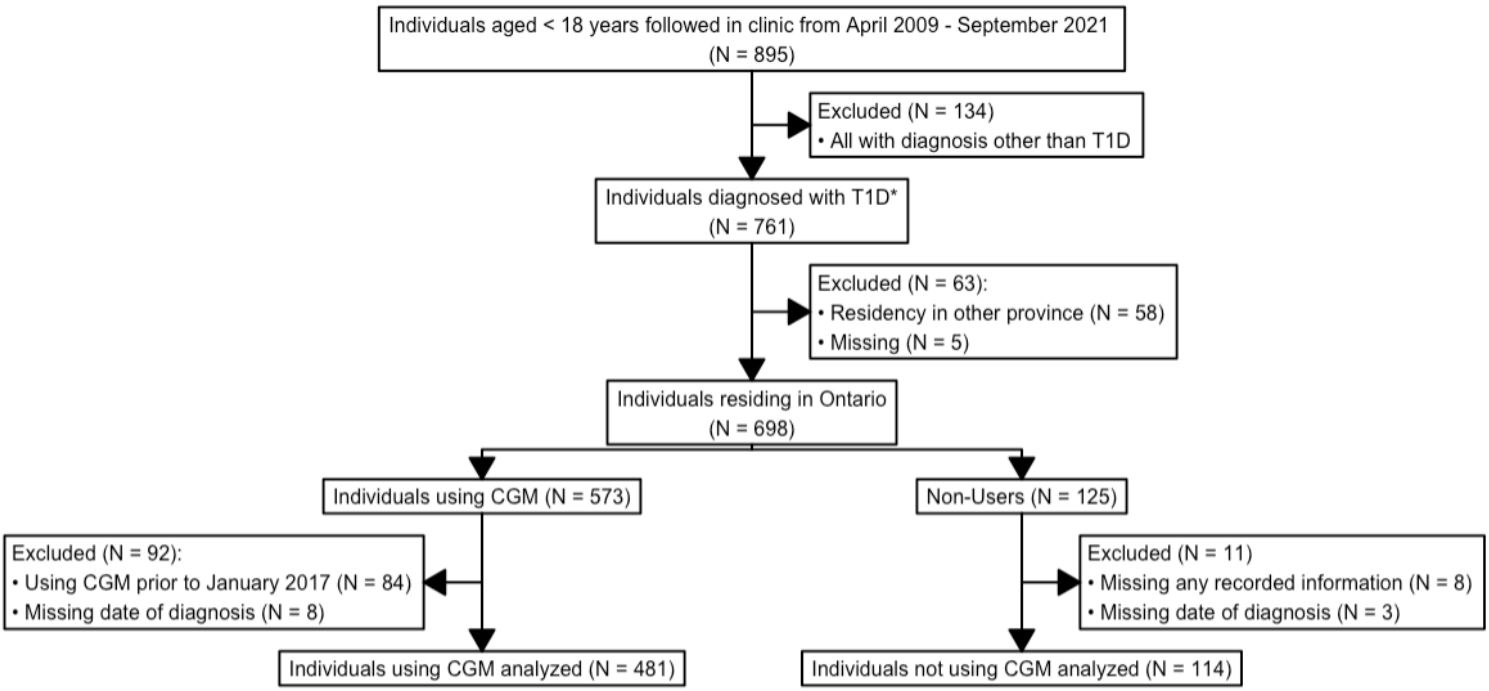
Cohort Identification

Objective 1: Within the single center's deidentified clinical database, we identified individuals aged < 18 years diagnosed with T1D residing in Ontario (Figure 1). T1D was diagnosed and recorded by each individual's treating physician based on clinical characteristics and autoantibody testing if there was diagnostic uncertainty. Individuals with other forms of diabetes, such as type 2 diabetes, were excluded. We limited the cohort to only those residing in Ontario given CGM coverage is under provincial jurisdiction and only Ontario had coverage for isCGM for those individuals aged < 25 years without private insurance as of September 2019.[13] Of the 698 individuals identified, 481 had a first recorded date of CGM use as of January 2017 or later, and 114 were classified as non-users (i.e., never users), for a total cohort size of 595. We

excluded those using CGM prior to January 2017 (84 individuals) given Health Canada approved the currently used brands of CGMs at that time (and thus current CGMs were more widely available).[11,12] We also excluded those missing dates of T1D diagnosis (11 individuals) and those without any recorded information on CGM use (8 individuals).

Objective 2: We limited the cohort of those identified as CGM users in the previous objective to only those with at least one HbA1c available in the 12 months prior to the first recorded date of CGM use and at least one HbA1c available in the 12 months after. We identified 290 individuals for this sub-cohort.

Figure 1: Cohort Identification



Note: N = number, T1D = type 1 diabetes, CGM = continuous glucose monitoring

Primary Outcome

Objective 1: The primary outcome was CGM use, defined as a first recorded date of CGM use in January 2017 or later, as detailed above. Non-use of CGM was defined as never use (i.e., use of CGM at all available visit dates recorded as "No" in the database). CGM use was considered to be a binary variable (yes/no) in the logistic regression model.

Objective 2: The primary outcome was the difference in mean HbA1c defined as the mean HbA1c post-CGM start minus the mean HbA1c pre-CGM start. Mean HbA1c pre-start was calculated for each individual by averaging all available HbA1c in the 12 months prior to, and including, the first recorded date of CGM use. All HbA1c within three months of diagnosis were excluded as they are not reflective of an individual's glycemic control (given treatment has not yet been, or is only newly, started). The HbA1c at the first recorded date of CGM use was included in the pre-CGM rather than post-CGM mean HbA1c because it reflects glycemic management in the time period prior to the CGM start. Mean HbA1c post-start was calculated for each participant by averaging all available HbA1c in the 12 months starting at the first clinic visit after the first recorded date of CGM use (i.e., three months after the first recorded date of CGM use). Each 12-month time frame included at least one, and up to five, HbA1c values for each individual. Difference in mean HbA1c was used as a continuous variable in the linear regression model.

Primary Exposure

Objectives 1 and 2: The primary exposure variable for both objectives was SES, which was determined using a validated method developed by Statistics Canada known as the 2016 Canadian Index of Multiple Deprivation (CIMD), which is the most recently updated version of the 2006 Canadian Marginalization Index.[63,64] This measure has been used previously in numerous

diabetes studies.[14,16,17] CIMD includes both national-level and region-specific datasets which can be used for SES assignment. Given our plans to extend this work across Canada in future research, we have chosen to use the national-level CIMD for consistency. It is worth noting that other Canadian diabetes studies[15,65] have used a different neighborhood-level, validated index developed by the Institut national de santé publique du Québec.[66] However, this index encompasses only material and social deprivation and does not include any measures of ethnicity.

CIMD is divided into four dimensions of deprivation: residential instability, economic dependency, ethnocultural composition, and situational vulnerability (Figure 2).[63] Residential instability includes, among other indicators, the proportion of dwellings that are owned, the proportion of persons living alone, and the proportion of persons who moved within the last five years. Economic dependency includes, among other indicators, the ratio of employment to the population and the dependency ratio (population aged 0 – 14 years or 65 years and older divided by population aged 15 – 64 years). Ethnocultural composition includes the proportion who self-identify as a visible minority, are foreign-born, are recent immigrants, and who have no knowledge of either official national language (English or French). Situational vulnerability includes the proportion of the population aged 25 – 64 years without a high school diploma, the proportion who identify as Aboriginal, and the proportion of dwellings needing major repairs. All dimensions are uncorrelated, with quintile (Q) 1 representing those least deprived and Q5 those most deprived within a given dimension.

To assign CIMD deprivation quintiles to individuals in our study, we first linked six-digit postal codes to dissemination areas (DAs) using the Postal Code Conversion File Plus (PCCF+). Access to the PCCF+ was provided through the McGill University Library. Of note, a postal code may be divided into multiple DAs which in turn may be linked to different deprivation quintiles

(i.e. not all DAs within a given postal code may be assigned the same deprivation quintile). The PCCF+ assigns a single DA to each postal code based on population-weighting and random allocation and is generally considered to be a more accurate and representative assignment than simply assigning a DA to each postal code based solely on majority of dwellings (as is the case with use of the standard PCCF).[67] DA assignment was performed using SAS Version 9.4 (SAS Institute, Cary, NC). Once we assigned DAs, we then linked them to deprivation quintiles in R Studio Version 1.3.1073 (open-source software) using publicly available CIMD datasets.[68]

CIMD quintiles were used as categorical variables for each dimension, grouping the least deprived quintiles 1 and 2 together, the most deprived quintiles 4 and 5 together, and leaving quintile 3 on its own as this led to a better model fit based on Akaike information criteria. Given initial exploratory analysis showing the greatest differences in the dimension of situational vulnerability for Objective 1 and ethnocultural composition for Objective 2, these dimensions were each considered to be the main SES exposure in analysis respectively.

Figure 2: Canadian Index of Multiple Deprivation

CIMD Dimensions			
Residential Instability	**Economic Dependency**	**Ethnocultural Composition**	**Situational Vulnerability**
• Proportion of persons living alone • Proportion of persons who are married • Proportion of dwellings that are owned • Proportion of persons who moved within the last five years • Proportion of dwellings that are apartments	• Ratio of employment to the population • Proportion of persons in labor force • Proportion aged 65 years and older • Dependency ratio • Proportion of persons receiving government transfer payments	• Proportion who self-identify as a visible minority • Proportion who are foreign-born • Proportion who are recent immigrants • Proportion who have no knowledge of either official national language	• Proportion who identify as Aboriginal • Proportion of the population aged 25 – 64 years without a high school diploma • Proportion of dwellings needing major repairs
For each dimension, six-digit postal code is linked to dissemination area, which is in turn linked to deprivation quintile through pre-defined code (Q1 least deprived, Q5 most deprived)			

Note: CIMD = Canadian Index of Multiple Deprivation, Q = quintile

Covariables

Objective 1: Covariables included age, sex, pump use, mean HbA1c, and diagnosis era, all determined at either the first recorded date of CGM use for CGM users or the last recorded visit date for non-users. These dates were chosen to standardize the time at which baseline characteristics were determined for all participants. Mean HbA1c was determined by the averaging all available HbA1c in the 12 months prior to, and including, either the first recorded date of CGM use for CGM users or the last recorded visit date for non-users. Diagnosis era was based on the date of T1D diagnosis and was defined as pre-January 2017 (date of diagnosis September 2004 – December 2016; before Health Canada approval of newer CGM models), between January 2017 and September 2019 (when Ontario began to provide some coverage of isCGM for selected children), and September 2019 onwards (until March 2021). Diagnosis era, rather than duration of T1D alone, was included as it may influence the decision to start newer technology. Age and mean HbA1c were included as continuous variables in the logistic regression model; sex, pump use (yes/no) and diagnosis era were used as categorical variables.

Objective 2: Covariables included age, sex, duration of T1D, pump use, CGM type (rtCGM or isCGM), and mean pre-use HbA1c, all determined at the first recorded date of CGM use. Duration of T1D, rather than diagnosis era, was used for this objective given the sub-cohort was already limited to those on CGM, and duration of T1D is a more relevant confounder for glycemic control than are the dates of Health Canada approval and provincial coverage. Mean HbA1c was determined by the averaging all available HbA1c in the 12 months prior to, and including, the first recorded date of CGM use. Mean pre-use HbA1c was included as a covariable because HbA1c prior to CGM use may affect expected change in HbA1c (e.g., for higher HbA1c, there is more potential for decrease than at HbA1c closer to the target of 7.0%). Age, duration of

T1D, and mean pre-use HbA1c were included as continuous variables in the linear regression model; sex, pump use, and CGM type were used as categorical variables.

Power Calculation

Objective 1: For our given sample size of 595 individuals, and setting significance at 0.05, we had 80% power to detect 0.62 odds ratio of CGM use. This power calculation was performed using a z-test in G*Power Version 3.1.9.6 (open-source software).

Objective 2: For our given sample size of 290 individuals and all predictors, and setting significance at 0.05, we had 80% power to detect a 0.07% difference in HbA1c. This power calculation was performed using a f-test in R Studio Version 1.3.1073 (open-source software).

Statistical Analysis

Objective 1: For descriptive analyses, we calculated proportions for categorical variables and means and SD for continuous variables. Comparisons between CGM users and non-users were made between continuous variables using t-tests and amongst categorical variables using chi-square tests. We used multivariable logistic regression to examine the association between SES and CGM use, including all *a priori* covariables. Assuming data were missing at random, multiple imputation by Chained Equations was used to assign mean HbA1c for participants with missing data using predictive mean matching; five replicates were generated.[69] Routine diagnostics included variance inflation factors for assessing collinearity. We also conducted the following sensitivity analyses:

- Stratified by diagnostic era (pre-January 2017, between January 2017 and September 2019, and September 2019 onwards).

- Rerun with another iteration of DA assignments from the PCCF+ given that the PCCF+ uses both population-weighting and random allocation to assign DAs, which are then linked to CIMD dimension quintiles.[67]

Objective 2: For descriptive analyses, we calculated proportions for categorical variables and means and SD for continuous variables. Comparisons between rtCGM users and isCGM users were made between continuous variables using t-tests and amongst categorical variables using chi-square tests. We used multivariable linear regression to examine the association between SES and glycemic control (defined as difference in mean HbA1c), including all *a priori* covariables. Given that this sub-cohort was limited to those with glycemic data available, multiple imputation was not needed. Routine diagnostics included residuals vs. fitted, normal Q-Q, scale-location, and residuals vs. leverage plots. We also conducted the following sensitivity analyses:

- Stratified by CGM type (rtCGM or isCGM), given that Ontario covered isCGM, but not rtCGM, for pediatric patients without private insurance as of September 2019.[13]
- Stratified by mean pre-use HbA1c of 8.1% (i.e. two categories: HbA1c <= 8.1% and HbA1c > 8.1%). This cut-off point was chosen as 8.1% because it was the mean HbA1c in the full sub-cohort (Table 4).
- Limited to those with a duration of T1D of at least one year before the first recorded date of CGM use. This analysis excluded individuals potentially in the honeymoon period (i.e., those within their first year after diagnosis) as glycemic control is often better within this timeframe given residual pancreatic insulin production, and HbA1c is often lower.[37]

- Rerun with another iteration of DA assignments from the PCCF+ given that the PCCF+ uses both population-weighting and random allocation to assign DAs, which are then linked to CIMD dimension quintiles.[67]

All statistical analyses were performed using R Studio Version 1.3.1073 (open-source software). Significance was two-sided with $p < 0.05$.

Chapter 4: Results

Objective 1: Full Cohort Characteristics

Of the 595 individuals included in the database who met inclusion criteria, we identified 481 (80.8%) using CGM and 114 (19.2%) non-users. The entire cohort had a mean age ± SD of 11.3 ± 3.8 years, was 52.3% male, and had mean HbA1c of 8.4 ± 1.6% (Table 1). For each of the four CIMD dimensions, all five quintiles were represented, although there was a skew towards individuals being in the least deprived quintiles (Q1-2) for residential instability, economic dependency, and situational vulnerability (e.g., for situational vulnerability 60.2% were in Q1-2 with 19.5% in Q3 and 20.3% in Q4-5). In contrast, the highest proportion of individuals was in the most diverse ethnocultural quintiles (44.4% in Q4-5) compared to the least diverse (34.8% in Q1-2). Additional characteristics are detailed Table 1.

Among CGM users, the mean age was 11.1 ± 3.8 years and 49.7% were male. The mean pre-start HbA1c was 8.2% ± 1.4%. Forty-three percent were diagnosed prior to January 2017 with 21.4% diagnosed in September 2019 or later, and the remaining 35.6% diagnosed between those two dates. Thirty-one percent were using pump therapy at the time of first recorded use of CGM. Almost 60% were using rtCGM, with approximately 40% using isCGM. For each of the four CIMD dimensions, all five quintiles were represented, although there was a skew towards individuals being in the least deprived quintiles (Q1-2) for residential instability, economic dependency, and situational vulnerability (e.g., for situational vulnerability 62.2% were in Q1-2 with 19.3% in Q3 and 18.5% in Q4-5). In contrast, the highest proportion of individuals was in the most diverse ethnocultural quintiles (42.4% in Q4-5) compared to the least diverse (36.0% in Q1-2) (Table 1).

Among non-users, the mean age was 12.4 ± 3.7 years, statistically significantly older than CGM users ($p < 0.001$). Approximately 63% of non-users were male, statistically significantly more than CGM users ($p = 0.01$). The mean HbA1c was 9.0% ± 1.8%, statistically significantly higher than CGM users ($p < 0.001$). Approximately 52% were diagnosed prior to January 2017 with 25.4% diagnosed in September 2019 or later, and the remaining 22.8% diagnosed between those two dates. Approximately 21% percent were using pump therapy. For each of the four CIMD dimensions, all five quintiles were represented, although there was a skew towards individuals being in the least deprived quintiles (Q1-2) for residential instability, economic dependency, and situational vulnerability (e.g., for situational vulnerability 51.8% were in Q1-2 with 20.2% in Q3 and 28.1% in Q4-5). In contrast, the highest proportion of individuals was in the most diverse ethnocultural quintiles (52.6% in Q4-5) compared to the least diverse (29.8% in Q1-2). Overall, the distribution of SES quintiles was similar for residential instability and economic dependency in non-users compared to CGM users, but a larger proportion of non-users were in the most diverse ethnocultural composition quintiles and most situationally vulnerable (least educated) quintiles, although these differences were not significant (Table 1).

Table 1: Full Cohort Characteristics

Characteristic		Total (N = 595)	CGM Users (N = 481)	Non-Users (N = 114)	*p*-value [e]
CGM use		481 (80.8)	481 (100)		
Type of CGM, N (%)	rtCGM	--	288 (59.9)		
	isCGM	--	193 (40.1)		
Age (years), mean ± SD [a]		11.3 ± 3.8	11.1 ± 3.8	12.4 ± 3.7	**< 0.001**
Sex, N (%)	Female	284 (47.7)	242 (50.3)	42 (36.8)	**0.01**
	Male	311 (52.3)	239 (49.7)	72 (63.2)	
Diagnosis Era	Pre Jan 2017	266 (44.7)	207 (43.0)	59 (51.8)	**0.03**
	Between	197 (33.1)	171 (35.6)	26 (22.8)	
	Sept 2019 Onwards	132 (22.2)	103 (21.4)	29 (25.4)	
Pump Use, N (%) [b]	No	422 (70.9)	332 (69.0)	90 (78.9)	0.05
	Yes	173 (29.1)	149 (31.0)	24 (21.1)	
Mean HbA1c, [c] mean ± SD median (IQR)		8.4% ± 1.6% 8.1% (7.3% – 9.1%)	8.2% ± 1.4% 8.0% (7.2% – 9.0%)	9.0% ± 1.8% 8.5% (7.8% – 9.9%)	**< 0.001**
Residential Instability, N (%) [d]	Q1-2	299 (50.3)	252 (52.4)	47 (41.2)	0.10
	Q3	130 (21.8)	101 (21.0)	29 (25.4)	
	Q4-5	166 (27.9)	128 (26.6)	38 (33.3)	
Economic Dependency, N (%) [d]	Q1-2	330 (55.5)	268 (55.7)	62 (54.4)	0.96
	Q3	100 (16.8)	80 (16.6)	20 (17.5)	
	Q4-5	165 (27.7)	133 (27.7)	32 (28.1)	
Ethnocultural Composition, N (%) [d]	Q1-2	207 (34.8)	173 (36.0)	34 (29.8)	0.14
	Q3	124 (20.8)	104 (21.6)	20 (17.5)	
	Q4-5	264 (44.4)	204 (42.4)	60 (52.6)	
Situational Vulnerability, N (%) [d]	Q1-2	358 (60.2)	299 (62.2)	59 (51.8)	0.05
	Q3	116 (19.5)	93 (19.3)	23 (20.2)	
	Q4-5	121 (20.3)	89 (18.5)	32 (28.1)	

Note: CGM = continuous glucose monitoring, rtCGM = real-time CGM; isCGM = intermittently scanned CGM, N = number, % = percentage, SD = standard deviation, HbA1c = hemoglobin A1c, IQR = interquartile range

[a] Age at first recorded date of CGM use for CGM users or last recorded visit date for non-users

[b] Recorded date of pump start on, or prior to, first recorded date of CGM use for CGM users or last recorded visit date for non-users

[c] Average HbA1c in the 12 months prior to first recorded date of CGM use for CGM users or last recorded visit date for non-users; multiple imputation used for missing data

[d] For given CIMD dimension, quintile (Q) 1 is least deprived and Q5 is most deprived

[e] Comparisons between CGM users and non-users, using t-tests for continuous variables and chi-square tests for categorical variables

Objective 1: SES Differences in CGM Use

In multivariable logistic regression of the full cohort controlling for age, sex, mean baseline HbA1c, pump use, and diagnosis era, SES was not significantly associated with use of CGM (Table 2). Specifically, CIMD dimension quintiles for residential instability, economic dependency, ethnocultural composition, and situational vulnerability were not significantly associated with use of CGM, with all confidence intervals crossing the null of 1. However, there was a tendency towards lower odds of use of CGM in the most situationally vulnerable (i.e. less educated) quintiles compared to the least vulnerable (aOR 0.56, 95% CI 0.29, 1.08) (Table 2). Significant associations between age, male sex, and mean baseline HbA1c and use of CGM were observed in these models. As age increased by one year, the odds of using CGM decreased by 8% (aOR 0.92, 95% CI 0.86, 0.98). Males had 39% lower odds of using CGM than females (aOR 0.61, 95% CI 0.39, 0.97). As mean HbA1c increased by one percent, the odds of using CGM decreased by 22% (aOR 0.78, 95% CI 0.68, 0.90). Pump use and diagnosis era did not have significant associations with CGM use (e.g., aOR for pump use 1.64, 95% CI 0.94, 2.90). Of note, variance inflation factors were checked and were all < 1.6, not indicative of significant collinearity.

In sensitivity analyses in which the cohort was stratified by diagnosis era, SES was overall not significantly associated with use of CGM in any era (Table 3). In the pre-January 2017 diagnosis era, age and pump use were significantly associated with CGM use (e.g. aOR 2.08, 95% CI 1.08, 4.03 for pump use), but these associations were not present in the other two diagnosis eras (Table 3).

In sensitivity analysis in which another iteration of the PCCF+ was run, assigned CIMD quintiles only changed for ten individuals, thus creating essentially the same distribution of individuals in each CIMD dimension as in the original descriptive analysis (Table 1). In rerunning the main logistic regression with multiple imputation, effect estimates and significance did not differ from the original analysis (Table 2) for any predictor other than for Q4-5 in situational vulnerability in which the estimate became significant (upper limit of 95% CI 0.98).

Table 2: Full Cohort Multivariable Logistic Regression with Outcome of CGM use

Variable		Adjusted OR (95% CI) [a]
Age		**0.92 (0.86, 0.98)**
Male		**0.61 (0.39, 0.97)**
Pump Use		1.64 (0.94, 2.90)
Mean HbA1c		**0.78 (0.68, 0.90)**
Diagnosis Era	Pre Jan 2017	Reference
	Between	1.52 (0.86, 2.67)
	Sept 2019 Onwards	0.94 (0.51, 1.73)
Residential Instability	Q1-2	Reference
	Q3	0.71 (0.40, 1.25)
	Q4-5	0.95 (0.52, 1.73)
Economic Dependency	Q1-2	Reference
	Q3	1.16 (0.61, 2.20)
	Q4-5	1.07 (0.60, 1.91)
Ethnocultural Composition	Q1-2	Reference
	Q3	0.86 (0.44, 1.68)
	Q4-5	0.73 (0.42, 1.27)
Situational Vulnerability	Q1-2	Reference
	Q3	0.81 (0.45, 1.47)
	Q4-5	0.56 (0.29, 1.08)

Note: OR = odds ratio, CI = confidence interval, HbA1c = hemoglobin A1c
[a] OR for CGM use. Multivariable logistic regression adjusted for age, sex, pump use, mean HbA1c, diagnosis era, and all CIMD dimensions

Table 3: Sensitivity Analysis, Stratification by Diagnosis Era

Variable		Pre-Jan 2017 Adjusted OR (95% CI) [a]	Between Adjusted OR (95% CI) [a]	Sept 2019 Onwards Adjusted OR (95% CI) [b]
Age		**0.87 (0.78, 0.98)**	0.91 (0.80, 1.03)	0.99 (0.83, 1.19)
Male		0.62 (0.32, 1.19)	0.51 (0.19, 1.38)	0.43 (0.12, 1.58)
Pump Use		**2.08 (1.08, 4.03)**	1.60 (0.46, 5.64)	-----
Mean HbA1c		0.96 (0.76, 1.20)	0.82 (0.62, 1.10)	0.44 (0.05, 4.13)
Residential Instability	Q1-2	Reference	Reference	Reference
	Q3	0.66 (0.29, 1.50)	0.42 (0.13, 1.34)	2.11 (0.41, 1.09)
	Q4-5	0.66 (0.28, 1.57)	0.89 (0.23, 3.38)	1.67 (0.38, 7.27)
Economic Dependency	Q1-2	Reference	Reference	Reference
	Q3	0.78 (0.32, 1.91)	4.58 (0.69, 30.34)	1.30 (0.27, 6.38)
	Q4-5	1.22 (0.53, 2.80)	1.42 (0.42, 4.80)	1.02 (0.23, 4.52)
Ethnocultural Composition	Q1-2	Reference	Reference	Reference
	Q3	0.66 (0.26, 1.67)	0.46 (0.11, 1.97)	2.26 (0.27, 1.91)
	Q4-5	1.03 (0.47, 2.30)	0.28 (0.08, 1.04)	0.96 (0.25, 3.68)
Situational Vulnerability	Q1-2	Reference	Reference	Reference
	Q3	1.09 (0.47, 2.53)	**0.26 (0.08, 0.86)**	1.03 (0.17, 6.41)
	Q4-5	0.61 (0.24, 1.54)	0.21 (0.04, 1.04)	1.97 (0.20, 2.00)

Note: OR = odds ratio, CI = confidence interval, HbA1c = hemoglobin A1c

[a] OR for CGM use. Multivariable logistic regression adjusted for age, sex, pump use, mean HbA1c, diagnosis era, and all CIMD dimensions

[b] OR for CGM use. Multivariable logistic regression adjusted for age, sex, mean HbA1c, diagnosis era, and all CIMD dimensions. Pump use was unable to be included as only a single individual was using a pump on, or prior to, first recorded date of CGM use

Objective 2: Sub-Cohort Characteristics

We identified 290 individuals using CGM for whom glycemic data were available in the 12 months both pre- and post-first recorded date of CGM use. The total sub-cohort had a mean age of 11.5 ± 3.4 years and was 49.3% male (Table 4). The mean duration of diabetes was 4.1 ± 3.5 years. The mean pre-CGM use HbA1c was 8.1 ± 1.3%, and the mean post-CGM use HbA1c was 8.3 ± 1.5%. Additional characteristics are detailed in Table 4.

Among rtCGM users, the mean age was 11.2 ± 3.3 years and 49.4% were male. The mean duration of diabetes was 3.8 ± 3.4 years. Approximately 53% were using pump therapy at the time of first recorded use of CGM. The mean pre-CGM use HbA1c was 7.9 ± 1.0%, and the mean post-CGM use HbA1c was 8.1 ± 1.3%. For each of the four CIMD dimensions, all five quintiles were represented, although there was a skew towards individuals being in the least deprived quintiles (Q1-2) for residential instability, economic dependency, and situational vulnerability (e.g., for situational vulnerability 67.6% were in Q1-2 with 18.2% in Q3 and 14.2% in Q4-5). In contrast, 39.2% of individuals were in the least diverse ethnocultural composition quintiles (Q1-2) and 38.1% were in the most diverse ethnocultural quintiles (Q4-5) (Table 4).

Among isCGM users, the mean age was statistically significantly older at 12.1 ± 3.3 years compared to rtCGM users ($p = 0.01$). Approximately 49% were male, and the mean duration of diabetes was 4.5 ± 3.6 years. Fewer individuals using isCGM were also using pumps at the time of first recorded use of CGM (25.4%) compared to rtCGM users ($p < 0.001$). The mean pre-CGM use HbA1c was 8.4 ± 1.6%, and the mean post-CGM use HbA1c was 8.6 ± 1.9%, both statistically significantly higher than in rtCGM users ($p = 0.02$ and $p = 0.01$, respectively). For each of the four CIMD dimensions, all five quintiles were represented, although there was a skew towards individuals being in the least deprived quintiles (Q1-2) for residential instability, economic

dependency, and situational vulnerability (e.g., for situational vulnerability 64.9% were in Q1-2 with 21.1% in Q3 and 14.0% in Q4-5). In contrast, the highest proportion of individuals was in the most diverse ethnocultural quintiles (50.9% in Q4-5) compared to the least diverse (27.2% in Q1-2) (Table 4).

In further exploratory analysis of these 290 individuals, 53.8% of all individuals regardless of SES had non-improvement in HbA1c in the 12 months after starting CGM. In this unadjusted descriptive analysis, non-improvement in HbA1c was defined as mean post-CGM use HbA1c either stable or higher than mean pre-CGM use HbA1c. There was no significant difference in the proportion of those with non-improvement by quintiles for any CIMD dimension of residential instability, economic dependency, or situational vulnerability. However, for ethnocultural composition, there was a significantly higher proportion of those with non-improvement in the least diverse quintiles compared to the most diverse (65.0% in Q1-2, 50.8% in Q3, and 46.4% in Q4-5, $p = 0.02$) (Table 5).

When limited to the 238 individuals with a duration of T1D of at least one year before the first recorded date of CGM use (i.e., those not in honeymoon), 53.4% of all individuals regardless of SES had non-improvement in HbA1c after starting CGM. There was no significant difference in the proportion of those with non-improvement by quintiles for any CIMD dimension of residential instability, economic dependency, ethnocultural composition, or situational vulnerability (Table 6).

Table 4: Sub-Cohort Characteristics of Those Using CGM with Glycemic Data Available Pre- and Post-Use

Characteristic		Total (N = 290)	rtCGM users (N = 176)	isCGM users (N = 114)	*p*-value [e]
Type of CGM, N (%)	rtCGM	176 (60.7)			
	isCGM	114 (39.3)			
Age (years), mean ± SD [a]		11.5 ± 3.4	11.2 ± 3.3	12.1 ± 3.3	**0.01**
Sex, N (%)	Female	147 (50.7)	89 (50.6)	58 (50.9)	1.0
	Male	143 (49.3)	87 (49.4)	56 (49.1)	
Duration of diabetes, mean ± SD [b]		4.1 ± 3.5	3.8 ± 3.4	4.5 ± 3.6	0.13
Pump Use, N (%) [c]	No	167 (57.6)	82 (46.6)	85 (74.6)	**< 0.001**
	Yes	123 (42.4)	94 (53.4)	29 (25.4)	
Mean pre-use HbA1c, mean ± SD median (IQR)		8.1% ± 1.3% 7.9% (7.3% – 8.9%)	7.9% ± 1.0% 7.9% (7.3% – 8.5%)	8.4% ± 1.6% 8.0% (7.3% – 9.2%)	**0.02**
Mean post-use HbA1c, mean ± SD median (IQR)		8.3% ± 1.5% 8.0% (7.4% – 8.9%)	8.1% ± 1.3% 7.9% (7.3% – 8.8%)	8.6% ± 1.9% 8.2% (7.6% – 9.2%)	**0.01**
Residential Instability, N (%) [d]	Q1-2	168 (57.9)	99 (56.2)	69 (60.5)	0.53
	Q3	56 (19.3)	33 (18.8)	23 (20.2)	
	Q4-5	66 (22.8)	44 (25.0)	22 (19.3)	
Economic Dependency, N (%) [d]	Q1-2	164 (56.6)	97 (55.1)	67 (58.8)	0.52
	Q3	39 (13.4)	22 (12.5)	17 (14.9)	
	Q4-5	87 (30.0)	57 (32.4)	30 (26.3)	
Ethnocultural Composition, N (%) [d]	Q1-2	100 (34.5)	69 (39.2)	31 (27.2)	0.06
	Q3	65 (22.4)	40 (22.7)	25 (21.9)	
	Q4-5	125 (43.1)	67 (38.1)	58 (50.9)	
Situational Vulnerability, N (%) [d]	Q1-2	193 (66.6)	119 (67.6)	74 (64.9)	0.83
	Q3	56 (19.3)	32 (18.2)	24 (21.1)	
	Q4-5	41 (14.1)	25 (14.2)	16 (14.0)	

Note: CGM = continuous glucose monitoring, rtCGM = real-time CGM; isCGM = intermittently scanned CGM, N = number, % = percentage, SD = standard deviation, HbA1c = hemoglobin A1c, IQR = interquartile range

[a] Age at first recorded date of CGM use

[b] Duration of diabetes at first recorded date of CGM use

[c] Recorded date of pump start on, or prior to, first recorded date of CGM use

[d] For given CIMD dimension, quintile (Q) 1 is least deprived and Q5 is most deprived

[e] Comparisons between rtCGM users and isCGM users, using t-tests for continuous variables and chi-square tests for categorical variables

Table 5: Proportion with Non-Improvement in HbA1c

CIMD Dimension [a]		Total, N	Individuals with non-improvement in HbA1c, [b] N (%)	*p*-value [c]
Residential Instability	Q1-2	168	94 (56.0%)	0.72
	Q3	56	27 (48.2%)	
	Q4-5	66	35 (53.0%)	
Economic Dependency	Q1-2	164	89 (54.3%)	0.35
	Q3	39	17 (43.6%)	
	Q4-5	87	50 (57.5%)	
Ethnocultural Composition	Q1-2	100	65 (65.0%)	**0.02**
	Q3	65	33 (50.8%)	
	Q4-5	125	58 (46.4%)	
Situational Vulnerability	Q1-2	193	100 (51.8%)	0.13
	Q3	56	28 (50.0%)	
	Q4-5	41	28 (68.3%)	

Note: N = number, % = percentage, HbA1c = hemoglobin A1c
[a] For given CIMD dimension, quintile (Q) 1 is least deprived and Q5 is most deprived
[b] Non-improvement in HbA1c defined as mean post-CGM use HbA1c either stable or higher than mean pre-CGM use HbA1c
[c] Comparisons using chi-square tests

Table 6: Proportion with Non-Improvement in HbA1c, Excluding Those in Honeymoon

CIMD Dimension [a]		Total, N	Individuals with non-improvement in HbA1c, [b] N (%)	*p*-value [c]
Residential Instability	Q1-2	136	79 (58.1%)	0.19
	Q3	46	20 (43.5%)	
	Q4-5	56	28 (50.0%)	
Economic Dependency	Q1-2	137	75 (54.7%)	0.39
	Q3	33	14 (42.4%)	
	Q4-5	68	38 (55.9%)	
Ethnocultural Composition	Q1-2	83	51 (61.4%)	0.16
	Q3	48	25 (52.1%)	
	Q4-5	107	51 (47.7%)	
Situational Vulnerability	Q1-2	157	82 (52.2%)	0.33
	Q3	47	23 (48.9%)	
	Q4-5	34	22 (64.7%)	

Note: N = number, % = percentage, HbA1c = hemoglobin A1c
[a] For given CIMD dimension, quintile (Q) 1 is least deprived and Q5 is most deprived
[b] Non-improvement in HbA1c defined as mean post-CGM use HbA1c either stable or higher than mean pre-CGM use HbA1c
[c] Comparisons via chi-square tests

Objective 2: Differences in HbA1c by SES for Those Using CGM

In multivariable linear regression of this sub-cohort of 290 individuals, controlling for age, sex, duration of T1D, pump use, CGM type and mean pre-use HbA1c, SES was not significantly associated with the outcome, expected difference in mean post- minus pre-CGM start HbA1c (Table 7). Specifically, CIMD dimension quintiles for residential instability, economic dependency, ethnocultural composition, and situational vulnerability were not significantly associated with expected difference in mean HbA1c, with all confidence intervals crossing the null of 0. However, there was a tendency towards a negative expected difference in HbA1c (i.e., lower HbA1c) for those in the most diverse ethnocultural quintiles compared to those in the least diverse (expected change -0.23%, 95% CI -0.52%, 0.06%) (Table 7). Only age and mean pre-use HbA1c were associated with the expected difference in mean HbA1c in this analysis. As age increased by one year, expected difference in HbA1c increased by 0.04% (95% CI 0.001%, 0.08%). As mean pre-use HbA1c increased by one percent, expected difference in HbA1c was -0.14% (95% CI -0.23%, -0.04%). Of note, routine model assumptions were checked, leading to exclusion of one outlier at > +4 SD on the residual vs. leverage plot. After this exclusion, the assumptions of linearity, normality of residuals, and homogeneity of variance were all met without influential outliers (Figure 3).

In the sensitivity analysis that stratified by CGM type (176 individuals using rtCGM and 114 individuals using isCGM), age and mean pre-use HbA1c were no longer significantly associated with expected difference in HbA1c, nor was any CIMD dimension significantly associated with expected difference in HbA1c (Table 8).

In the sensitivity analysis that stratified by mean pre-use HbA1c (using two categories divided at the mean sub-cohort pre-use HbA1c of 8.1%), age and duration of diabetes were

significantly associated with expected difference in HbA1c in only those with mean pre-use HbA1c of 8.1% or less, but not in those with a mean pre-use HbA1c of more than 8.1%. SES was again not significantly associated with expected difference in HbA1c in this analysis (Table 9).

In the sensitivity analysis limited to 238 individuals with a duration of T1D of at least one year before the first recorded date of CGM use (i.e. those not in honeymoon), SES was not significantly associated with expected difference in HbA1c (Table 10). There was a tendency towards a negative expected difference in HbA1c (i.e. lower HbA1c) for those with higher mean pre-use HbA1c (-0.09%, 95% CI -0.20%, 0.01%).

In sensitivity analysis in which another iteration of the PCCF+ was run, assigned CIMD quintiles did not change for these 290 individuals (Table 4). In rerunning the main linear regression, effect estimates and significance did not change for any predictor compared to the original analysis (Table 7).

Table 7: Sub-Cohort Multivariable Linear Regression with Outcome of Difference in HbA1c

Variable		Expected Difference in HbA1c, % change (95% CI) [a]
Age		**0.04 (0.001, 0.08)**
Male		0.09 (-0.15, 0.33)
Duration of diabetes		-0.02 (-0.06, 0.02)
Pump Use		-0.03 (-0.29, 0.23)
isCGM use		0.15 (-0.11, 0.40)
Mean pre-use HbA1c		**-0.14 (-0.23, -0.04)**
Residential Instability	Q1-2	Reference
	Q3	-0.18 (-0.49, 0.13)
	Q4-5	0.19 (-0.13, 0.51)
Economic Dependency	Q1-2	Reference
	Q3	-0.12 (-0.48, 0.24)
	Q4-5	0.01 (-0.27, 0.30)
Ethnocultural Composition	Q1-2	Reference
	Q3	-0.24 (-0.57, 0.09)
	Q4-5	-0.23 (-0.52, 0.06)
Situational Vulnerability	Q1-2	Reference
	Q3	0.07 (-0.23, 0.38)
	Q4-5	0.23 (-0.17, 0.62)

Note: HbA1c = hemoglobin A1c, CI = confidence interval, isCGM = intermittently scanned CGM

[a] Multivariable linear regression adjusted for age, sex, duration of diabetes, pump use, CGM type, mean pre-use HbA1c, and all CIMD dimensions

Figure 3: Linear Regression Diagnostic Plots

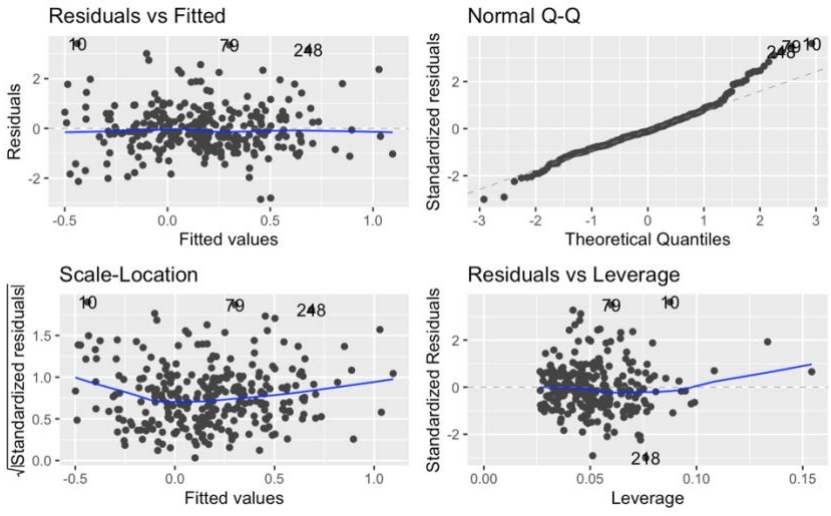


Table 8: Sensitivity Analysis, Stratification by CGM Type

Variable		rtCGM [a] Expected Difference in HbA1c, % change (95% CI) [b]	isCGM [a] Expected Difference in HbA1c, % change (95% CI) [b]
Age		0.04 (-0.003, 0.08)	0.02 (-0.06, 0.09)
Male		0.14 (-0.14, 0.41)	-0.04 (-0.52, 0.44)
Duration of diabetes		-0.01 (-0.06, 0.03)	-0.04 (-0.11, 0.03)
Pump Use		0.04 (-0.25, 0.34)	-0.15 (-0.67, 0.36)
Mean pre-use HbA1c		-0.14 (-0.28, 0.01)	-0.12 (-0.27, 0.02)
Residential Instability	Q1-2	Reference	Reference
	Q3	-0.18 (-0.55, 0.19)	-0.32 (-0.93, 0.29)
	Q4-5	0.21 (-0.14, 0.56)	0.12 (-0.59, 0.82)
Economic Dependency	Q1-2	Reference	Reference
	Q3	0.12 (-0.31, 0.55)	-0.52 (-1.21, 0.17)
	Q4-5	-0.01 (-0.33, 0.32)	0.01 (-0.58, 0.59)
Ethnocultural Composition	Q1-2	Reference	Reference
	Q3	-0.29 (-0.67, 0.09)	-0.05 (-0.71, 0.61)
	Q4-5	-0.38 (-0.73, -0.04)	0.07 (-0.52, 0.66)
Situational Vulnerability	Q1-2	Reference	Reference
	Q3	0.14 (-0.24, 0.51)	-0.01 (-0.58, 0.55)
	Q4-5	0.13 (-0.32, 0.57)	0.38 (-0.43, 1.18)

Note: CGM = continuous glucose monitoring, rtCGM = real-time CGM, isCGM = intermittently scanned CGM, HbA1c = hemoglobin A1c, CI = confidence interval

[a] rtCGM group includes 176 individuals; isCGM group includes 114 individuals

[b] Multivariable linear regression adjusted for age, sex, duration of diabetes, pump use, mean pre-use HbA1c, and all CIMD dimensions

Table 9: Sensitivity Analysis, Stratification by HbA1c

Variable		HbA1c <= 8.1% [a] Expected Difference in HbA1c, % change (95% CI) [b]	HbA1c > 8.1% [a] Expected Difference in HbA1c, % change (95% CI) [b]
Age		**0.07 (0.03, 0.11)**	0.01 (-0.07, 0.08)
Male		0.15 (-0.12, 0.41)	-0.03 (-0.49, 0.43)
Duration of diabetes		**-0.06 (-0.10, -0.02)**	0.03 (-0.04, 0.10)
Pump Use		-0.09 (-0.38, 0.21)	0.03 (-0.43, 0.49)
isCGM		0.18 (-0.10, 0.45)	0.05 (-0.41, 0.52)
Residential Instability	Q1-2	Reference	Reference
	Q3	-0.21 (-0.56, 0.14)	-0.09 (-0.68, 0.50)
	Q4-5	0.14 (-0.21, 0.48)	0.24 (-0.38, 0.86)
Economic Dependency	Q1-2	Reference	Reference
	Q3	-0.20 (-0.63, 0.23)	-0.02 (-0.67, 0.62)
	Q4-5	0.06 (-0.24, 0.36)	-0.07 (-0.62, 0.49)
Ethnocultural Composition	Q1-2	Reference	Reference
	Q3	-0.08 (-0.42, 0.26)	-0.42 (-1.06, 0.22)
	Q4-5	-0.14 (-0.47, 0.20)	-0.26 (-0.79, 0.27)
Situational Vulnerability	Q1-2	Reference	Reference
	Q3	-0.01 (-0.37, 0.35)	0.17 (-0.36, 0.70)
	Q4-5	0.25 (-0.16, 0.66)	0.27 (-0.52, 1.05)

Note: HbA1c = hemoglobin A1c, CI = confidence interval, isCGM = intermittently scanned CGM

[a] Stratification by mean pre-use HbA1c 8.1% was chosen as that was the mean value in the full sub-cohort (Table 4). 158 individuals had mean pre-use HbA1c <= 8.1%; 132 individuals had mean pre-use HbA1c > 8.1%.

[b] Multivariable linear regression adjusted for age, sex, duration of diabetes, pump use, CGM type, and all CIMD dimensions

Table 10: Sensitivity Analysis, Excluding Those in Honeymoon

Variable		Expected Difference in HbA1c, % change (95% CI) [a]
Age		0.03 (-0.02, 0.07)
Male		0.07 (-0.20, 0.34)
Duration of diabetes		-0.01 (-0.05, 0.03)
Pump Use		-0.01 (-0.30, 0.29)
isCGM use		0.09 (-0.22, 0.39)
Mean pre-use HbA1c		-0.09 (-0.20, 0.01)
Residential Instability	Q1-2	Reference
	Q3	-0.27 (-0.63, 0.09)
	Q4-5	0.06 (-0.30, 0.42)
Economic Dependency	Q1-2	Reference
	Q3	-0.10 (-0.51, 0.31)
	Q4-5	0.10 (-0.23, 0.44)
Ethnocultural Composition	Q1-2	Reference
	Q3	-0.19 (-0.57, 0.20)
	Q4-5	-0.09 (-0.43, 0.24)
Situational Vulnerability	Q1-2	Reference
	Q3	0.13 (-0.22, 0.48)
	Q4-5	0.29 (-0.15, 0.73)

Note: HbA1c = hemoglobin A1c, CI = confidence interval, isCGM = intermittently scanned CGM

[a] Includes 238 individuals with duration of T1D of at least one year before the first recorded date of CGM use (i.e. those not in honeymoon). Multivariable linear regression adjusted for age, sex, duration of diabetes, pump use, CGM type, mean pre-use HbA1c, and all CIMD dimensions

Chapter 5: Discussion

Summary and Interpretation of Results

In our retrospective cohort study, the vast majority of individuals were using CGM, but many did not achieve improvement in HbA1c after starting. In contrast to other studies, we did not find significant SES disparities in CGM use either in the full cohort or stratified by diagnosis era, but we did demonstrate a significant association of lower odds of CGM use with increasing age, male sex, and increasing mean HbA1c. Among a sub-cohort of CGM users, SES was not a significant predictor of expected difference in mean HbA1c after starting CGM in the full group, after stratification by CGM type or mean pre-use HbA1c, or after exclusion of those with duration of T1D of less than one year. Instead, increasing age and mean pre-use HbA1c were significantly associated with expected difference in mean HbA1c in the full sub-cohort, but not in stratified analyses.

The proportion of individuals using CGM in our cohort, 80.8%, was much higher than that in other studies. Unpublished data from other centers in Canada show approximately 35-45% of individuals using CGM in their clinics (personal communications), perhaps suggesting a difference in prescribing practices of healthcare providers in this clinic. Additionally, in the published literature, data from the T1D Exchange registry in the U.S. including almost 10,000 youth aged < 18 years found that 30.1% used CGM in 2016 – 2018.[24] In Germany, 48.7% used CGM among the almost 27,000 youth aged < 18 years included in the DPV population-based registry in 2016 – 2018.[24] Furthermore, the majority of our cohort was in the least deprived quintiles (Q1-2) for residential instability, economic dependency, and situational vulnerability, reflecting an overall well-off population. In fact, Ottawa is an affluent city, with a median total family income of $125,950 CAD in 2019.[70] By comparison in the same year, the median total family income in

Toronto was $97,640 CAD, in Montreal was $96,820 CAD, and for all of Canada was $98,690 CAD.[70] This high proportion of CGM users as well as the more affluent setting may explain why we did not find significant SES disparities in CGM use despite prior literature showing these disparities in other countries.[24]

Moreover, despite changing availability of CGM and provincial funding, we did not find significant associations with SES and odds of CGM use in the sensitivity analysis stratified by diagnostic era. However, this result is not surprising given that we did not find disparities in the full cohort and given that power to detect differences was likely limited by small sample sizes in each stratum of diagnosis era. Additionally, the federal government is a major employer in Ottawa[71] and offers generous health benefits, which could explain the limited effect of a change in provincial funding on the association of SES and CGM use. We did find that pump use was significantly associated with increased odds of CGM use only for those diagnosed before January 2017, before the time of Health Canada approval of more commonly used newer CGMs. This result suggests that once CGM was more widely available, it was not limited to only those who had been early adopters of other technology such as pumps.

We did find that increasing age and male sex were significantly associated with lower odds of CGM use. Age has been shown to be significantly associated with CGM use in other studies; in a U.S. single center study of 4003 individuals aged < 22 years with T1D, CGM users were statistically significantly younger than those using traditional blood glucose monitoring (e.g., mean age of MDI/CGM users 13.6 ± 4.7 years vs. mean age of MDI/traditional monitoring 15.4 ± 4.1 years, $p < 0.001$).[72] Sex has not previously been shown to be a significant predictor of CGM use in the pediatric literature. However, a U.S. survey of 4551 adults suggested that women were more likely to use wearable health care devices than men (aOR 1.26, 95% CI 0.96, 1.65), although this

study was not limited to those with diabetes and the 95% CI did cross the null of 1.[73] Further research into sex differences in children in use of diabetes technology may be needed.

Importantly, we also demonstrated that a higher mean HbA1c was associated with lower odds of CGM use and that while not statistically significant, there was a tendency towards lower odds of CGM use in the most situationally vulnerable (i.e., least educated) quintiles compared to the least situationally vulnerable (i.e., most educated) quintiles. The reasons for these findings could be related to patient and family preferences as well as health care provider biases. Patients and families may choose not to start CGM for a variety of reasons, including reluctance to wear visible devices[74,75] and parental concerns with complexity of the technology.[44] For example, in semi-structured interviews of 55 parents of children aged < 8 years with T1D, parents reported challenges with CGM use including painful insertion devices and overwhelming or inaccurate glycemic data.[75] Numeric literacy may also play a role in the decision to use CGM.[76] In a survey of 70 parents of children aged 3 – 9 years with T1D, parental diabetes-related numeracy was inversely correlated with their child's glycemic control ($r = -0.52$, $p < 0.01$),[77] and although not assessed in that study, we speculate that those with lower numeric literacy may be less inclined to use CGM given the large amount of numeric data generated. Additionally, providers may not offer CGM to families or patients they suspect are already struggling with diabetes management based on higher HbA1c or to already marginalized populations due to unconscious biases.[78-81] Given the benefits of CGM beyond glycemic control in terms of improvement of QOL,[52-54] future work should include qualitative studies to explore other patient or physician barriers to use of CGM, especially for those of lower numeric or digital literary.

In agreement with some prior studies[48,49] and in contrast to others[8], we found that over half of individuals did not achieve improvement in HbA1c after starting CGM. Of 290 individuals with

available glycemic data, 53.8% had a stable or higher HbA1c in the 12 months after starting CGM compared to the 12 months prior to starting. In descriptive analysis, including that limited to those not in the honeymoon period, there was no significant difference in the proportion of those with non-improvement by SES quintiles for any CIMD dimension other than ethnocultural composition (as discussed below). Additionally, it is worth noting that the mean pre-use HbA1c and mean post-use HbA1c in this sub-cohort, 8.1% and 8.3% respectively, are both higher than the target HbA1c of < 7.0% cited in pediatric guidelines.[1,21,22]

The lack of improvement in HbA1c in many individuals could be due to longer follow-up time than prior studies (12 months compared to six months)[8] or lack of adequate education on these devices. This center, as with many others in Canada, does not provide formal education for patients and families prior to starting CGM, in contrast to the standardized teaching programs that most Canadian centers have prior to starting pumps. However, centers in the U.S. have explored implementation of supplementary education for CGM. In focus groups with 22 adults with T1D within the first year of using CGM, most reported being self-taught or seeking out help on social media for how to use CGM, and most further desired formalized training on how to interpret CGM tracings and use the large amounts of data.[82] A 2018 pilot study evaluated the effects of a supplementary online educational intervention to improve self-efficacy and understanding of CGM.[83] Knowledge attainment varied, but only eight adolescents and young adults aged 15 – 24 years with T1D new to CGM use participated in the study, and all spent varying amounts of time interacting with the online modules. HbA1c was improved after module participation, but follow-up was only three months and the sample size was quite small.[83] A more robust intervention from 2018 – 2019 at a large academic pediatric center showed improved glycemic control.[84] Under this "4T Approach," CGM was initiated within the first month after T1D and paired with increased

CGM-specific education and increased data review by the healthcare team. Compared to historic controls, unadjusted HbA1c was 0.54% lower at six months after diagnosis in 65 youth with T1D treated with this approach.[84] Although more research is needed to see if this reduction in HbA1c is sustained, the literature does suggest a role and desire for increased patient and family education on CGM.

In our sub-cohort of CGM users, only age and mean pre-use HbA1c were significant predictors of expected difference in mean HbA1c after starting CGM. A higher mean pre-use HbA1c has also been shown to be associated with a greater reduction in HbA1c after pump use,[85] suggesting that those with worse glycemic control derive the most benefit from starting technology, as seen in our study. SES was not a significant predictor of difference in HbA1c in the full group or after stratification by CGM type or mean pre-use HbA1c, which is in contrast to previous studies[24,62] and perhaps related to the fact that this center is located in a more affluent city with an SES distribution skewed toward least deprived quintiles that is not likely representative of the remainder of the province.[70] However, similar to descriptive analysis of the full sub-cohort, there was a tendency towards a greater reduction in HbA1c following CGM use in the most diverse ethnocultural composition quintiles compared to the least diverse quintiles in regression analysis. The reasons for this are unclear as prior studies have shown worse glycemic outcomes in those of ethnic minority status.[23,61,62] Those studies have used individually reported ethnicity whereas our study used a validated neighborhood-level measure of diversity including visible minorities, immigrant status, and linguistic isolation.[63] As such, the findings in our study may be more a reflective of community support systems than individual measures on glycemic control.

In sum, although SES disparities were not found in CGM use, perhaps due to the exceptional access in this center, further efforts such as education curriculums are needed to achieve glycemic benefit with CGM for all children with T1D irrespective of SES.

Limitations

Although a large cohort study representative of an entire clinic, our research, as with all studies, does have limitations. The cohort does not include children living in Ottawa and the surrounding areas who were followed at another center, although that number is likely small given the consolidation of care in tertiary centers for children with T1D. Additionally, the dataset was pulled directly from the electronic medical record, and as such, available data was inherently determined by physician documentation. Although physician buy-in to flowsheet documentation is generally high in this center, prior studies have shown that documentation in the electronic medical record is a large source of stress for physicians[86] and that physician efficiency and proficiency with documentation varies.[87] For example, in focus groups conducted with 41 physicians working in several U.S. outpatient clinics, only 22% reported sufficient time for documentation, and 56% reported that much of that time was spent at home after work hours, with the amount of time spent documenting at home "moderately high or excessive."[86] Nevertheless, datasets pulled directly from the electronic medical record do have the benefit of providing individual diagnostic information and longitudinal laboratory values, which may be unavailable in other data sources such as health administrative data.[15]

Moreover, SES was defined at a neighborhood rather than individual level, which may result in exposure misclassification. For example, ethnicity was not self-reported but was instead measured by the CIMD ethnocultural composition dimension, which describes the neighborhood

proportion who self-identify as a visible minority, are foreign-born, are recent immigrants, and are linguistically isolated.[63] Although attributing individual ethnicity based on this ecologic construct is potentially more problematic than attributions based on other CIMD dimensions, the ethnocultural composition dimension used in this study has been used previously in numerous other diabetes studies for similar purposes.[14,16,17] Additionally, the incorporation of any measure of ethnicity is a strength of our study as several other Canadian diabetes studies using health administrative data did not assess the influence of ethnicity[17,65], and as detailed in the Introduction chapter, ethnicity has been shown to be an independent predictor of disparities in diabetes care.[23,56,61,62] Nonetheless, given our unanticipated findings using this neighborhood-level measure of ethnicity rather than individual identification, future studies should be conducted using self-reported measures of ethnicity and SES such as highest educational level attained, as well as of other social determinants of health such as food or childcare insecurity,[88] to provide a more comprehensive picture of factors affecting technology use and T1D outcomes in Canadian children.

Our database did not contain information on other T1D-related health outcomes such as DKA and severe hypoglycemia, although these have been shown to be associated with SES and technology use in other studies.[23,47,55,89] Our database also did not contain standardized measures of CGM adherence such as percent time use (i.e., wear time) which could be a confounder in the relationship between CGM use and glycemic control as measured by HbA1c. Other research has shown a decrease in HbA1c with continuous CGM use compared to only intermittent use. In a study of 264 U.S. youth with T1D, the difference in HbA1c after starting CGM was -0.29% (95% CI -0.61%, 0.02%) in those with continued use compared to 0.57% (95%CI 0.06%, 1.10%) in those with loss of CGM use prior to restarting.[90] We also did not have data on time in range

(percent of time blood glucose is within target, that is not hypo- or hyperglycemic), although this measure is only possible for CGM users. Time in range from CGM is arguably a more nuanced measure than HbA1c to assess overall glycemic control and variability, given that HbA1c only provides an average measure of glycemic control over the prior three months without providing information on day-to-day glycemic excursions.[91] These association of SES with time in range for those using CGM should be studied in future research.

Furthermore, although we used multiple imputation to handle missing data in our analysis for Objective 1 (determining if there were SES disparities in CGM use), we limited our cohort for Objective 2 (determining if glycemic control, as measured by HbA1c, changes by SES among those started on CGM) to those with at least one HbA1c measured in the 12 months pre- and the 12-months post- first recorded date of CGM use in order to ensure as accurate data as possible. However, this restriction considerably reduced our available sample size as many HbA1c measurements were missing starting in March 2020 due to the COVID-19 pandemic. Especially during the early months of the pandemic, clinical visits were mainly performed via remote methods and thus bloodwork such as HbA1c was not obtained. This reduction of sample size also limited power to detect associations in sensitivity analyses in which the cohort was stratified into even smaller groups.

Future Directions

Given the very high percentage of individuals using CGM in this cohort as well as the more affluent setting, findings may not be generalizable to other centers in Canada. Additionally, given the number of covariates that were clinically important to include, a larger sample size will help to improve power in the main analyses. We therefore plan to explore similar research questions

and objectives through a retrospective pooled cohort study using data from other Canadian centers in different provinces. More specifically, we will next be analyzing data from an academic center in Québec and an academic center in Alberta to further describe the Canadian landscape and to determine whether SES disparities exist in CGM use, and in glycemic control while on CGM, in other populations of children with T1D in Canada.

Additionally, since this study was performed, provincial governments other than Ontario have approved coverage of CGM for children with T1D. As of late May 2021 in Québec, rtCGM is fully covered for all children aged > 2years with T1D,[92] and the same is true in Alberta as of early February 2022.[93] Future research should compare SES disparities before and after these changes in provincial funding policies to evaluate the effect of these programs.

Conclusion

In this cohort, SES was not significantly associated with CGM use, although the vast majority of individuals were using CGM. SES was not a significant predictor of change in HbA1c after starting CGM, and over half of individuals did not have improvement in HbA1c after starting CGM. Although this center's practices may provide a model for exceptional access to this now standard-of-care technology regardless of SES, further efforts are needed to achieve glycemic benefit with CGM for all children with T1D. We hope that our findings will help to encourage the development of improved educational programs in Canada for optimal use of CGM in children with T1D.

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