Article details: 2016-0075	
Title	Health care for children with diabetes mellitus in low-income families: a population-based cohort study of health systems in Ontario and California
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Reviewer 1	Dr. Shazhan Amed
Institution	Department of Pediatrics, University of British Columbia, Vancouver, BC
General comments (author response in bold)	How might the difference in case finding definition between the ODD and CCS affect the results? Suggest including this in the limitations section. **For CCS, we utilized the strategy of including children with DM listed as the diagnosis that made the child eligible for the CCS program. We also required a claim for insulin during the study interval. This approach has been utilized in previous published analyses, which we have now added additional references to in the manuscript. For Ontario, we used the Ontario Diabetes Database, and the case finding definition for this database (4 outpatient claims for DM) has been previously validated and used in several prior analyses (references provided). Given the CCS strategy requires less criteria, it is possible that the specificity is lower, leading to more children without DM being included in this cohort. However, a validation study would be required to establish this. We have added commentary in the limitations section to highlight to readers that differing case definitions were used across these jurisdictions: "we utilized differing strategies for identifying children with diabetes mellitus in California Children's Services and Ontario. Our strategies have been used in prior analyses(12, 14); however, that used in California Children's Services has not been formally validated, and thus may contribute to differences between the study cohorts" We have also now limited our primary analysis of the ODBP and CCS cohorts to those not on oral hypoglycaemics, so this should also improve the comparability of the cohorts. Page 14, Lines 11-14** How valid is using neighbourhood income quintile in Ontario? For example, in BC, there are many rental suites in homes which might skew the result. Comment on this in the limitations. **A previous study in Manitoba demonstrated good correlation between income quintile and household income, but this analysis has not been performed specifically in Ontario. Additional commentary on this has been added to the limitations section: "However, neighbourhood income quintile is a proxy measure of household income. Previous studies have demonstrated good correlation between these data and individual household income in another Canadian province, and this method is widely used in Canadian health services research,(36, 37) but the precision of this ecologic methodology may be more limited in rural areas and by practices such as renting suites in homes." Page 14, Lines 1-4** For distance from nearest DM-center - how frequently is the postal code updated in the registered persons database (to account for migration around the province). **The postal code in the Registered Persons Database is updated when health cards are renewed or when patients access hospital-based care (including clinics) and their address has changed. The vast majority of pediatric diabetes clinics are in hospitals, so these postal codes should be accurate.** Suggest to use a different term than "DM-complication hospitalization" rates given that the study only looks for hospitalizations for DKA (or its variants) but does not include severe hypoglycaemia, etc; or explicitly state that the complication being assessed is DKA as there are many complications related to diabetes and the term is misleading. **The metric we utilized, developed by the Agency for Healthcare Research and Quality (AHRQ), includes ICD-9-CM codes for diabetic ketoacidosis, hyperosmolar state, coma related to DM, and uncontrolled DM. Due to concern that it might mislead readers to label all these outcomes with the blanketed term "DKA," we have now added detail in the methods section to clearly describe the diagnoses included in this outcome: "We determined DM-complication hospitalization rates using the Agency for Healthcare Research and Quality specifications (primary diagnosis: diabetic ketoacidosis, diabetes with hyperosmolarity, diabetes with coma, or uncontrolled DM).(23)" If the reviewers still wish to simplify this wording to "DKA," we are happy to do so. Page 8, Lines 5-8** Please provide more detail on NACRS data - for example were diabetes related ED visits used or all ED visits (i.e. diabetes and non-diabetes related).

	The ED data presented for each cohort are ED visits related to DM-complications (diabetic ketoacidosis, hyperosmolar state, coma related to DM, and uncontrolled DM). This has been clarified in the methods section: "We determined DM-complication hospitalization rates using the Agency for Healthcare Research and Quality specifications (primary diagnosis: diabetic ketoacidosis, diabetes with hyperosmolarity, diabetes with coma, or uncontrolled diabetes).(23) We determined ..., rates of DM-complication emergency department visits not resulting in hospitalizations (using the same codes as for DM-complication hospitalizations)" Page 8, Lines 5-13 A big focus of the discussion/concluding section focuses on shared care models in the context of a network as the most likely explanation for the differences in receiving recommended care between OPDB and CCS. I would suggest providing a bit more detail on this 'network' in Ontario earlier on in the manuscript to help the reader better understand this conclusion. **A detailed description of the network as well as a reference from the network is now available in the first subsection of Methods, under Study Setting: "Medical care for children with diabetes mellitus in Ontario is provided by the Ontario Paediatric Diabetes Network, which consists of specialized paediatric diabetes centres (thirty secondary-level and five tertiary-level). These centres have multidisciplinary core teams consisting of nurses, dieticians, and social workers that work closely with paediatricians, and/or paediatric endocrinologists, and/or family physicians to provide comprehensive care.(21)" Page 6, Lines 21-23, Page 7, Lines 1-3** Please specify what income is required to be eligible for ODBP earlier in the manuscript (rather than in the discussion) **The eligibility criteria for ODBP has now been moved to the Methods section, under "Patient Characteristics." Page 7, Lines 9-12** Please label figure 1 appropriately **We apologize, but the Figure 1 legend was included in the main manuscript per the author instructions. We have now also added the labels directly to the figure.** Page 9, line 45 - 'all other Ontario children' could be misinterpreted as all children in Ontario. Suggest changing to 'all other Ontario children with diabetes' **This has been modified as suggested: "Ontario Children with Diabetes Mellitus from Low-Income Families Compared to All Other Ontario Children with Diabetes Mellitus" Page 10, Lines 9-10**
Reviewer 2	Dr. Celia Rodd
Institution	Department of Pediatrics and Child Health, Manitoba Institute of Child Health, Winnipeg, Man.
General comments (author response in bold)	The authors comment on the fact that their study covers 'diabetes mellitus' and not specifically Type 1 or 2. I appreciate that with administrative data, it is may be difficult to distinguish the two. However, I am deeply concerned that the authors did not present the data after excluding all individuals using oral hypoglycemic agents. The 2 populations in California vs. Ontario are different; there are nearly 20% of the children in California with presumed Type 2 diabetes (defined by use of oral medications) vs. 6.3% of the low income families in Ontario. While, some children with Type 2 dm may present with DKA, the risk of DKA is much lower compared to those with Type 1 dm. I appreciate that the authors did do sensitivity analyses to assess the impact of this limitation, but I feel that the main analyses should focus on children with a high likelihood of having Type 1 dm in both populations. Without trying to make the 2 populations comparable it is likely comparing 2 different mixtures (2 different risks of outcomes) and the interpretations and generalizability are limited. **We thank the reviewers very much for this valuable input, which we agree makes the manuscript stronger in terms of internal validity, generalizability, and clarity to readers. We have now redone our primary analysis excluding all children using oral hypoglycemic agents. The abstract, all sections of the manuscript, and all tables and figures have been modified accordingly.** I think that using the more restricted data should be the primary focus of the manuscript- if as ancillary analysis the authors wished to compare all children with DM in California to all in Ontario they could. However for the primary outcome(s), making the 2 groups more comparable is key. **More restricted data has been used for the primary analysis now as described in the response above. We did not have access to data on all children with DM in California to perform the ancillary analysis described.** Even when the authors compare the Ontario OBDP (drug benefits program)– vs. those

	not on this drug plan, there are no children on oral hypoglycemic in the non- OBDP dataset, consistent with the greater prevalence of Type 2 dm with low SES. This is yet another compelling reason to make the CCS and OBDP groups comparable by focusing only on children with Type1 dm (or presumed T1DM). **Unfortunately, data on drug utilization (including oral hypoglycemics) is not available for those children not on the drug plan. Consequently, we do not know the prevalence of oral hypoglycemic use in "all other Ontario children" (not from low-income families) with DM. We have made our comparison of the CCS and OBDP groups now focus on children with type 1 DM as the review has suggested, and we have clarified this limitation in the drug data for "all other Ontario children" with DM in the limitation section of the manuscript: "Secondly, for our comparisons of children within Ontario with diabetes mellitus (those from low-income families versus all other children), we were unable to exclude children in "all other" group who were on oral hypoglycemics, as drug utilization data is only available for children in Ontario Drug Benefit Program." Page 14, Lines 4-8** The first paragraph of the Interpretation is incorrect; the authors have clearly stated that Ontario-DBDP patients have lower DM-complication hospitalizations with or without excluding those on oral hypoglycemic agents (see Figure 1 and Results). There was no difference in these rates when comparing ODBP and CCS patients on the pump. Unfortunately, what is written in the Interpretation first paragraph and also in the Abstract is incorrect in that the rates were comparable. I am fine if the authors dismiss the statistical significance because large n's may create statistical significance without real biological significance. If the authors wish to claim that the difference in dm-complication hospitalization rates are comparable then they should state this clearly in the Results to ensure clarity and consistency. Currently, readers might find these conflicting statements confusing. **We appreciate this valuable feedback regarding improving the clarity of our message for readers. We do think the DM-complication hospitalization rates are CLINCALLY comparable across jurisdictions and wish to dismiss the statistical significance, that is a result of large sample sizes (as the reviewer suggests). We have modified the abstract, as well as the results and interpretation sections of the manuscript to be more clear about our view of these findings: "Children in California Children's Services were less likely to receive >2 diabetes mellitus routine visits/year compared to Ontario children from low-income families (64.7% versus 75.7%, p<0.001) but had clinically comparable diabetes mellitus complication hospitalization rates (Absolute Differences 0.02 [95% Confidence Interval 0.02-0.02] hospitalizations/patient-year for males and 0.03 [0.03-0.03] hospitalizations/patient-year for females)." Page 1, Lines 18-21 Page 9, Lines 20-23** This premise then carries over into the Interpretation about how pediatricians as part of a multidisciplinary team may be as effective or perhaps more effective than pediatric endocrinologists. This is an important observation yet should be explored in more detail when comparing ODBP vs. non ODBP families in Ontario. There the context is more clearly defined and multivariable regression models could more likely affirm this supposition rather than comparing across 2 vastly different health care systems (single payer (On) vs. multi-payer, and generally for-profit (CA).) **We very much appreciate the reviewer's suggestion regarding this potential analysis. However, we were unable to undertake this additional analysis for several reasons. First, we are unable to apply parallel methods for excluding children with type 2 DM across these two cohorts. Drug data is only available for children in ODBP, so we would risk having differing proportions of children with type 2 DM across cohorts in this proposed analysis (which would act as a confounder). Second, given the powerful relationship between SES and DM outcomes, we think such an analysis would require the availability of several other detailed clinical variables (e.g. clinical comorbidities, measures of DM control) to be valid. Third, we recognize the limitations of our data sets and thus our primary and secondary study aims are exploratory in nature. We did not intend to analyze specific patient-level risk factors for DM-complication hospitalizations, and do not feel this is the ideal study to do so. In order to make the exploratory nature of our analysis more clear to readers, we have modified the language around this interpretation regarding care models (teams vs. specialists).** The authors do not mention why only 2 visits per year was considered a realistic outcome. In Canada, the recommendation from the CDA is that children should be seen quarterly; 3 or more visits per year is likely more reflective of compliance. The authors should consider assessing 3 or more visits and look at the differences in the 2 populations. **We described the frequency of preventive visits for the cohorts in two ways: 1) by describing and comparing the proportion of children in the cohort with at**

	least 2 visits/year, and 2) by describing and comparing the mean visit rate per year with 95% CI. This was based on discussion with endocrinologists in both jurisdictions, review of guidelines from the time period of the analysis (2009-2012) in both jurisdictions, and review of the literature, including an analysis by Amed et. al. (citation below) that defines "optimal adherence" as 3 routine visits/year and "good adherence" as 2 routine visits/year. In response to this reviewer's feedback, we have changed the language in our manuscript from "recommended routine visits" to explicitly state >2 diabetes mellitus routine visits/year. (Citation: Amed S, Nuernberger K, McCrea P, Reimer K, Krueger H, Aydede SK, Ayers D, Collet JP. Adherence to clinical practice guidelines in the management of children, youth, and young adults with type 1 diabetes--a prospective population cohort study. J Pediatr. 2013 Aug;163(2):543-8.) Page 8, Lines 10-12 The background is generally clear. It is not clear in the first paragraph when the authors discuss prevalence what age groups they are referring to (1.48 per 1000 – children under 17y or under 19y? Additionally, was the prevalence really 2.0 and climbed to 3.0 per 1000 in Ontario. The California data is more precise out to 2 decimal points. Please be consistent in the precision. **We have now both clarified the age groups and made these statistics more parallel: "The prevalence of type 1 diabetes mellitus in children has been rapidly growing; between 2001-2009, it rose 22% in the United States (from 1.5 to 1.9 per 1000)(1) and 34% in Canada (from 2.0 to 3.0 per 1000) among children age <19 years.(2) Page 4, Lines 2-4** It would be helpful if the authors identified primary and secondary objectives/ outcomes; this would help later in the manuscript. **Primary and secondary objectives have now been specified at the end of the Background/Introduction section of the manuscript: "The primary aim of this study was to gain insight into how best to structure health care systems to meet the needs of children with diabetes mellitus in low-income families by describing their demographics and health care utilization patterns in these two varying health system models. The secondary aim of this study was to examine outcomes across socioeconomic status within Ontario to better contextualize our findings." Page 4, Line 18-23** I appreciate that the authors used the full Ontario dataset to contextualize the findings; I assume that they were unable to do so for the rest of California. This is a limitation in terms of their findings of the CCS data in California and should be mentioned later in the Discussion. **This limitation has been added to the discussion section of the manuscript: "Lastly, we were unable to contextualize our findings in California by comparing outcomes with children from higher income families as there are no population-based California data for these children." Page 14, Lines 14-16** Once the authors have decided which outcome is their primary, they could then undertake more nuanced analyses using multivariable regression models to take into consideration possible covariates (age, sex, income quintile, distance to nearest dm centre etc). There is no apparent restriction in the number of tables permitted in CMAJOpen. Addressing the question of care giver (generalist vs. specialist) could then be further explored in this manner. This could be applied to acute dm- hospitalization rates if this were deemed the primary objective. Additionally it could be applied to number of visits to dm team per year. **Please see the response above to reviewer comment #26. We were unable to undertake this analysis for several reasons, which are detailed above.** The authors describe California health insurance in Table 1 – Medicaid managed care vs. fee for service but do not discuss the bearing of this information to the readership. If it is not important, then please delete from the Table. If it has relevance, then discuss this in the manuscript. **We appreciate this feedback, as we want to make the manuscript as clear and simple for readers as possible. This information does not have bearing to the readership, and so these categories have been collapsed in Table 1.** The authors do not discuss in much detail that in Ontario ODBP vs. non ODBP patients differed in the number of visits. Not sure if this was explained by some covariates such as age of child. Or was it distance to centre that facilitate more ODBP visits. An important topic to explore. **We thank the reviewer very much for this feedback. When we incorporated reviewer 2's suggestion of re-running our primary analysis employing an exclusion of children with any claims for oral hypoglycemics, and all outcome data was recalculated by a new team statistician. This statistician had recently reviewed the feecodes being used for diabetes visits at ICES and discovered**

	that one of the outpatient visit codes utilized often occurred on the same date as another code, and thus likely represented double-counting of visits. She noticed we had included this code (as was done in prior analyses and papers by other ICES investigators), and looked at our data-- finding the same pattern. Thus our visit code list was modified and this code was removed. This modification adjusted all of our Ontario routine visit rates. We found that the rates comparing ODBP and "all other Ontario" were more comparable, and have updated all results in the manuscript and tables. There are several spelling or grammatical errors such as: a) data is plural and not singular- it requires 'are' and not 'is', in the tables, b) quartiles are listed in the first column however the data for income are actually quintiles (as per the Methods and the data in the Tables) **These errors have been corrected.** The Interpretation is well written and may change slightly with the revisions suggested. The references are comprehensive.