A Decade of Disparities in Diabetes Technology Use and HbA_{1c} in Pediatric Type 1 Diabetes: A Transatlantic Comparison

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OBJECTIVE

As diabetes technology use in youth increases worldwide, inequalities in access may exacerbate disparities in hemoglobin A_{1c} (HbA_{1c}). We hypothesized that an increasing gap in diabetes technology use by socioeconomic status (SES) would be associated with increased HbA_{1c} disparities.

RESEARCH DESIGN AND METHODS

Participants aged <18 years with diabetes duration ≥1 year in the Type 1 Diabetes Exchange (T1DX, U.S., $n = 16,457$) and Diabetes Prospective Follow-up (DPV, Germany, $n = 39,836$) registries were categorized into lowest (Q1) to highest (Q5) SES quintiles. Multiple regression analyses compared the relationship of SES quintiles with diabetes technology use and HbA_{1c} from 2010–2012 to 2016–2018.

RESULTS

HbA_{1c} was higher in participants with lower SES (in 2010–2012 and 2016–2018, respectively: 8.0% and 7.8% in Q1 and 7.6% and 7.5% in Q5 for DPV; 9.0% and 9.3% in Q1 and 7.8% and 8.0% in Q5 for T1DX). For DPV, the association between SES and HbA_{1c} did not change between the two time periods, whereas for T1DX, disparities in HbA_{1c} by SES increased significantly ($P < 0.001$). After adjusting for technology use, results for DPV did not change, whereas the increase in T1DX was no longer significant.

CONCLUSIONS

Although causal conclusions cannot be drawn, diabetes technology use is lowest and HbA_{1c} is highest in those of the lowest SES quintile in the T1DX, and this difference for HbA_{1c} broadened in the past decade. Associations of SES with technology use and HbA_{1c} were weaker in the DPV registry.

Over the past decade, utilization of diabetes technology, such as insulin pumps and continuous glucose monitors (CGMs), for the management of pediatric type 1 diabetes has increased worldwide (1–3). Diabetes technology in the management of pediatric type 1 diabetes is associated with improved hemoglobin A_{1c} (HbA_{1c}) and quality of life and decreased rates of both diabetic ketoacidosis and severe hypoglycemia (2,4–7). Although the Type 1 Diabetes Exchange (T1DX) and Diabetes Prospective Follow-up (Diabetes-Patienten-Verlaufsdokumentation [DPV]) registries have demonstrated increasing adoption of diabetes technology in the past decade (1,2,8), there is a concern of inequities in device use by socioeconomic status (SES) (9–11).

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See accompanying article, p. 14.

Area deprivation indices, such as the German Index of Multiple Deprivation (GIMD) 2010, have been used as proxy measures when individual SES variables were not available in registries (12,13). Data from Scotland, evaluating all age-groups, and the DPV, evaluating those age <20 years, demonstrated that lower area-level SES was associated with lower rates of insulin pump therapy as well as higher HbA_{1c} and higher rates of diabetic ketoacidosis (14–16). Additionally, the T1DX registry reported both a lower use of diabetes technology and a higher HbA_{1c} for pediatric patients with lower SES and for those of minority status (1,2,17). These data raise the concern that inequitable access to diabetes technology may widen disparities in diabetes outcomes in pediatric patients with type 1 diabetes, especially as data accumulate on improved outcomes with closed-loop and hybrid closed-loop systems (18–20).

In this study, we compare the use of diabetes technology and HbA_{1c} for youth in the T1DX and DPV registries by SES between two time periods: 2010–2012 and 2016–2018. We hypothesized that youth of lower SES, compared with those of higher SES, would have lower rates of diabetes technology use and higher HbA_{1c}. In addition, we hypothesized that disparities of technology use and HbA_{1c} by SES increased over the past decade.

RESEARCH DESIGN AND METHODS

Registries

The T1DX was established in September 2010 and includes 73 U.S.-based pediatric and adult endocrinology clinics that had contributed 18,001 records to the registry as of January 2018. Each participating clinic received approval from its respective institutional review board, and for minors, parent/guardian consent was obtained as well as assent from the minor. Data were collected for inclusion in the registry from the participants' electronic medical records and comprehensive questionnaires completed by participants and/or their parent/guardian, as previously published (1,2,17). Demographic and clinical data collected at each center is anonymized and shared with the Jaeb Center for Health Research for quality assurance and data storage.

As of September 2018, the DPV registry included 538,531 records from 480 diabetes care centers predominantly located in Germany. Each center participating in DPV received approval from its respective institutional review boards. Demographic and clinical data were prospectively collected at each participating center, anonymized, and shared with the University of Ulm for analysis and quality assurance (21), with approval from the Medical Faculty Ethics Committee of the University of Ulm (16). Clinical sites for the DPV and T1DX registries are listed in the Supplementary Material.

Study Population

Participants in the T1DX and DPV registries aged <18 years with type 1 diabetes duration ≥1 year who had data registered in the 2010–2012 period, the 2016–2018 period, or both periods were included in this study for analysis. For DPV, only patients with German residence were included. Participants without information on minority status in the electronic medical record were excluded in T1DX ($n = 45$). In DPV, participants with information on migration background missing were assumed to have no history of migration. Individuals without information on address or district of residence in the DPV registry ($n = 261$) and those who did not have sufficient SES documentation in the T1DX registry ($n = 1,486$) were excluded from the analysis because these variables were required for our analytical models and for categorizing participants into SES quintiles. The final study population comprised 16,457 individuals for T1DX and 39,836 individuals for DPV.

Variables

Clinical Data

For both registries, demographic data, CGM use (defined as all systems that measure interstitial glucose values, e.g., real-time or intermittent CGM), and insulin modality (injections or insulin pump) were captured. Type 1 diabetes diagnosis was established clinically by physicians and by documentation of insulin use as well as age at onset ≥6 months. Adjusting for age and sex, BMI *z* score was computed according to Cole's least mean squares method using World Health Organization reference tables (22). For DPV and T1DX, HbA_{1c} was standardized to the reference range of the Diabetes Control and Complications Trial (DCCT) (4.05–6.05% [20.7–42.6 mmol/mol]) using the multiple of the mean method to adjust for differences between laboratories (23,24).

SES Quintiles

Insurance type, education level, annual income for T1DX, and the GIMD 2010 for DPV (16) were incorporated to categorize participants (or their districts of residence) into SES quintile–based groups from Q1 (lowest SES) to Q5 (highest SES). Because of data protection concern, a valid measure of individual-level SES was not available for Germany. In DPV, education level is incompletely documented, and household income is not available (16). Information on health insurance is missing in the DPV registry; however, in Germany, all children are covered by health insurance, and the differences between insurances for diabetes technology reimbursement are minimal or absent (16). The GIMD is a validated measure of area deprivation for Germany (16) that is based on the methodology of Noble et al. (25). This methodology is based on the >40 years of experience of indices to measure deprivation at a local level in the U.K. (25). The GIMD methodology has been previously described (16,26). The German index for the reference year 2010 (GIMD 2010) includes aggregated data for the 412 districts of Germany in seven deprivation domains, each weighted differently: income (25%), employment (25%), education (15%), municipal/district revenue (15%), social capital (10%), environment (5%), and security (5%) (16,26). The districts were categorized into deprivation quintiles according to the GIMD 2010. For the DPV registry, patients were assigned to districts using the five-digit postal code of their residence. For the 132 records that had missing postal codes, we used the postal code of the diabetes clinic where patients receive treatment.

For the T1DX registry, we calculated a composite SES score composed of three individual variables that were equally weighted: education level (highest of either parent), insurance type, and annual income. Education level was coded from 1 to 6 (professional/doctoral degree = 1; master's degree = 2; bachelor's degree = 3; associate's degree = 4; high school diploma = 5; less than high school diploma = 6). Insurance was coded as 1 (private), 3 (public), and 6 (no insurance). Annual income was coded from

1 to 6 (≥$100,000 = 1; <$100,000 to $75,000 = 2; <$75,000 to $50,000 = 3; <$50,000 to $35,000 = 4; <$35,000 to $25,000 = 5; <$25,000 = 6). If one of the three domains was not documented (n = 4,208), it was replaced by the mean of the domain; if two or more domains were missing, the records were excluded (n = 1,486 patients).

Minority Status

For the DPV registry, minority status is defined as youth with personal or any parental history of being born outside of Germany. For the T1DX registry, minority status was defined as any participant race/ethnicity other than non-Hispanic White. These definitions are consistent with prior joint publications (1,16,21).

Statistical Analysis

For each time period in DPV, we aggregated participant's data from the most recent year as median (BMI, HbA_{1c}) or maximum (age, diabetes duration). Pump and CGM use were defined as at least one pump use or CGM use documented in the last treatment year. In T1DX, we used participant data from the last visit in each time period. Age was categorized into three groups (1 to <6, 6 to <12, and 12 to <18 years) and diabetes duration into three groups (1 to <2, 2 to <5, and ≥5 years). All analyses were conducted for each registry separately because different methodologies were used to assess SES. We analyzed the effect of SES on the three outcomes (pump use, CGM use, and HbA_{1c}) within each time period and compared these effects between time periods.

We performed logistic (for pump and CGM use) and linear (for HbA_{1c}) multiple regression with SES, time period, and an interaction of SES and time period. First, we modeled SES as a categorical variable to obtain mean estimates (least mean squares) for each outcome by SES quintiles and time period. Next, we modeled SES as an ordinal variable to compare the slopes of the regression lines (effect of SES) for each outcome in each time period and to test whether associations between SES and outcomes within and between the two time periods were significantly different. All models were adjusted for sex, age-group, diabetes duration group, minority status, and interaction of minority status with SES. We repeated these analyses for HbA_{1c}, with an additional adjustment for pump and CGM use in the regression model. Considering the size of the study population, the level of significance of two-sided tests was set at $P < 0.01$. Statistical analysis was performed using SAS 9.4 software (SAS Institute, Cary, NC).

RESULTS

Study Population

Demographic data and clinical characteristics of participants are listed in Table 1 by registry in both 2010–2012 and 2016–2018. Diabetes technology use and HbA_{1c} by components of the SES and by minority status are presented for DPV (area-level income and education) (Supplementary Table 1*A*) and T1DX (income, education, and insurance) (Supplementary Table 1*B*).

Primary Outcomes

Insulin Pump Use

Insulin pump use increased in the DPV and T1DX registries from 2010–2012 to 2016–2018. When examined by SES quintiles in the DPV registry, insulin pump use in 2010–2012 increased from 53.8% in Q1 and 53.0% in Q2 to 57.0% in Q4 and then decreased to 49.1% in Q5 (slope −0.028, $P = 0.02$). The pattern was similar in 2016–2018, with an increase from 65.5% in Q1 to 71.5% in Q4 and a decrease to 63.2% in Q5 (slope −0.009, $P = 0.41$) (Fig. 1*A*). In the T1DX registry, insulin pump use in 2010–2012 was 28.6% for Q1 and 70.3% for Q5 (slope 0.462, $P < 0.001$), whereas in 2016–2018, it was 36.5% for Q1 and 75.8% for Q5 (slope 0.446, $P < 0.001$) (Fig. 1*B*).

CGM Use

CGM use increased in the DPV and T1DX registries from 2010–2012 to 2016–2018. When examined by SES quintiles in the DPV registry, CGM use in 2010–2012 was 5.7% for Q1 and 3.8% for Q5 (slope −0.053, $P = 0.04$), whereas in 2016–2018, it was 48.5% for Q1 and 57.1% for Q5 (slope 0.068, $P < 0.001$) (Fig. 1*C*). In the T1DX population, CGM use in 2010–2012 was 2.9% for Q1 and 11.0% for Q5 (slope 0.381, $P < 0.001$), whereas in 2016–2018, it was 15.0% for Q1 and 52.3% for Q5 (slope 0.460, $P < 0.001$) (Fig. 1*D*).

HbA_{1c}

HbA_{1c} was lower in the DPV registry at both time periods compared with the T1DX registry. The most deprived quintile had the highest HbA_{1c} in both registries and both time periods. For the DPV registry, mean HbA_{1c} in 2010–2012 was 8.0% for Q1 and 7.6% for Q5 (slope −0.093, $P < 0.001$). In 2016–2018, HbA_{1c} decreased to 7.8% in Q1 and 7.5% in Q5 (slope −0.078, $P < 0.001$) (Fig. 1*E*). In the T1DX registry, mean HbA_{1c} in 2010–2012 was 9.0% for Q1 and 7.8% for Q5 (slope −0.301, $P < 0.001$). In 2016–2018, HbA_{1c} was 9.3% for Q1 and 8.0% for Q5 (slope −0.354, $P < 0.001$) (Fig. 1*F*).

HbA_{1c} by SES was additionally adjusted for pump and CGM use in a regression model. In DPV, the adjusted mean HbA_{1c} in 2010–2012 was 7.9% for Q1 and 7.5% for Q5 (slope −0.094, $P < 0.001$). In 2016–2018, the adjusted mean HbA_{1c} was 7.8% for Q1 and 7.5% for Q5 (slope −0.074, $P < 0.001$) (Fig. 1*G*). In T1DX, adjusted mean HbA_{1c} in 2010–2012 was 8.7% for Q1 and 7.7% for Q5 (slope −0.255, $P < 0.001$). In 2016–2018, adjusted HbA_{1c} was 9.1% for Q1 and 8.1% for Q5 (slope −0.276, $P < 0.001$) (Fig. 1*H*).

Comparison of the Effect of SES on Device Use and HbA_{1c} Between 2010–2012 and 2016–2018

We compared the effect of SES between the two time periods for each outcome (Fig. 2). Changes in insulin pump use by SES between the two time periods were not statistically significant in either registry. The association between lower SES quintiles and lower CGM use was more pronounced in the 2016–2018 time period for DPV ($P < 0.001$), and change was not significant for T1DX ($P = 0.038$). Associations between HbA_{1c} and SES were not statistically different between the two time periods for DPV, and adjusting for pump and CGM use did not modify the results. For T1DX, although HbA_{1c} increased in all SES quintiles, the HbA_{1c} increased more in those of lower SES quintiles between the two time periods ($P = 0.0005$). When adjusting for pump use and CGM use, the increased effect was still observed but was no longer significant.

CONCLUSIONS

In this international comparison of 56,293 youth with type 1 diabetes, differences exist in diabetes technology use and HbA_{1c} between the U.S. and Germany by SES quintiles. As previously reported (2), HbA_{1c} in the youth <18 years of age in the T1DX increased from 2010–2012 to 2016–2018. Reasons for this are uncertain, likely multifactorial, and require additional

Table 1—Participant characteristics

	DPV			T1DX		
	2010–2012	2016–2018	*P* value	2010–2012	2016–2018	*P* value
Male sex	52.2	52.4	0.5654	51.2	51.6	0.5975
n	23,167	26,670		10,463	9,979	
Age (years)			<0.0001			<0.0001
Mean ± SD	12.9 ± 3.7	13.1 ± 3.7		11.8 ± 3.6	13.0 ± 3.5	
n	23,167	26,670		10,463	9,979	
Diabetes duration (years)			<0.0001			<0.0001
Mean ± SD	5.5 ± 3.6	6.7 ± 3.7		5.1 ± 3.5	7.3 ± 3.5	
n	23,167	26,670		10,463	9,979	
Minority status†	19.1	23.9	<0.0001	20.9	22.3	0.0194
n	23,167	26,670		10,463	9,979	
BMI *z* score			0.7498			0.0012
Mean ± SD	0.67 ± 0.9	0.67 ± 1.03		0.89 ± 1.04	0.93 ± 1.11	
n	22,917	26,543		10,315	9,838	
HbA_{1c}						
%			<0.0001			<0.0001
Mean ± SD	8.0 ± 1.4	7.9 ± 1.4		8.5 ± 1.5	8.9 ± 1.7	
n	22,872	26,400		10,409	9,601	
mmol/mol			<0.0001			<0.0001
Mean ± SD	63.9 ± 15.7	62.9 ± 15.3		69.3 ± 15.8	74.0 ± 19.0	
n	22,872	26,400		10,409	9,601	
HbA_{1c} <7.5%*	41.2	43.5	<0.0001	22.1	17.3	<0.0001
n	22,872	26,400		10,409	9,601	
Pump use	43.9	56.6	<0.0001	57.3	64.9	<0.0001
n	23,166	26,667		10,419	9,803	
CGM use	4.0	48.7	<0.0001	5.9	30.1	<0.0001
n	23,167	26,670		10,409	9,665	

Data are % unless otherwise indicated. †Defined as birthplace outside of Germany for the patient or for one or both parents in DPV and as not belonging to the non-Hispanic White group in T1DX. *Recommended HbA_{1c} target by the American Diabetes Association and International Society of Pediatric and Adolescent Diabetes during the study period.

investigation. In this analysis, we demonstrate a strong association between HbA_{1c} and SES, both cross-sectionally and across the two time periods: the increase in HbA_{1c} was greatest in those with lower SES. Both registries demonstrate higher HbA_{1c} in youth from the lowest SES quintiles, although the magnitude of difference is greater in T1DX. In the T1DX, we report lower rates of insulin pump and CGM use in those of the lowest SES quintiles. For the DPV registry, a linear association was not observed between pump use and SES quintiles; CGM use was modestly lower in those of lowest SES in the second time period. Although a disparity between the lowest and highest SES quintiles exists with regard to HbA_{1c} in both registries, the disparity in the T1DX is greater than in the DPV, and the disparity in HbA_{1c} has widened between the two time periods in the T1DX. For the DPV registry, the CGM use gap by SES increased between 2010–2012 and 2016–2018, but this increase was not observed in insulin pump use or HbA_{1c}.

Analysis of CGM use further highlights this SES disparity when comparing CGM use by SES in 2010–2012 to 2016–2018. For T1DX, Q5 saw an increase of 41 percentage points in use between these two time points, whereas Q1 only increased use by 12 percentage points. In contrast, in the DPV registry, both Q1 and Q5 had a comparable increase in use (43 and 53 percentage points, respectively). The increase in HbA_{1c} for T1DX was no longer significant after adjustment for technology use.

These data raise important considerations for the care being provided for youth with type 1 diabetes. Despite the numerous barriers that have been documented in the delivery of care to those of lower SES (27–30), the findings from the DPV registry demonstrate more comparable HbA_{1c} outcomes for youth with type 1 diabetes across the SES spectrum. Given that this is the first report comparing device use and HbA_{1c} by SES quintiles in these two registries, the causal factors for the differences among the SES quintiles in mean HbA_{1c} and device use rates between the two countries require further investigation. Data from T1DX demonstrate an association with CGM use and HbA_{1c}, irrespective of insulin delivery (insulin pump or multiple daily injection), and CGM may be a mediator in the relationship between SES and HbA_{1c} (11).

As previously hypothesized, differences in child-rearing practices (24), access to and cost of device use (24), individual type 1 diabetes management practices (31), education (31), expectations (32) specific to device use, maternal education level (33), and patient and provider factors (34) may also contribute to the observed difference between the two registries. Cost of insulin is higher in the U.S. than other countries, and this cost continues to increase (35,36). Additionally, out-of-pocket costs associated with some private insurance plans in the U.S. make diabetes technology access cost prohibitive, despite having insurance coverage, and the differential access to care among private payers warrants further studies. Difference in access to physicians, health care expenditure, and

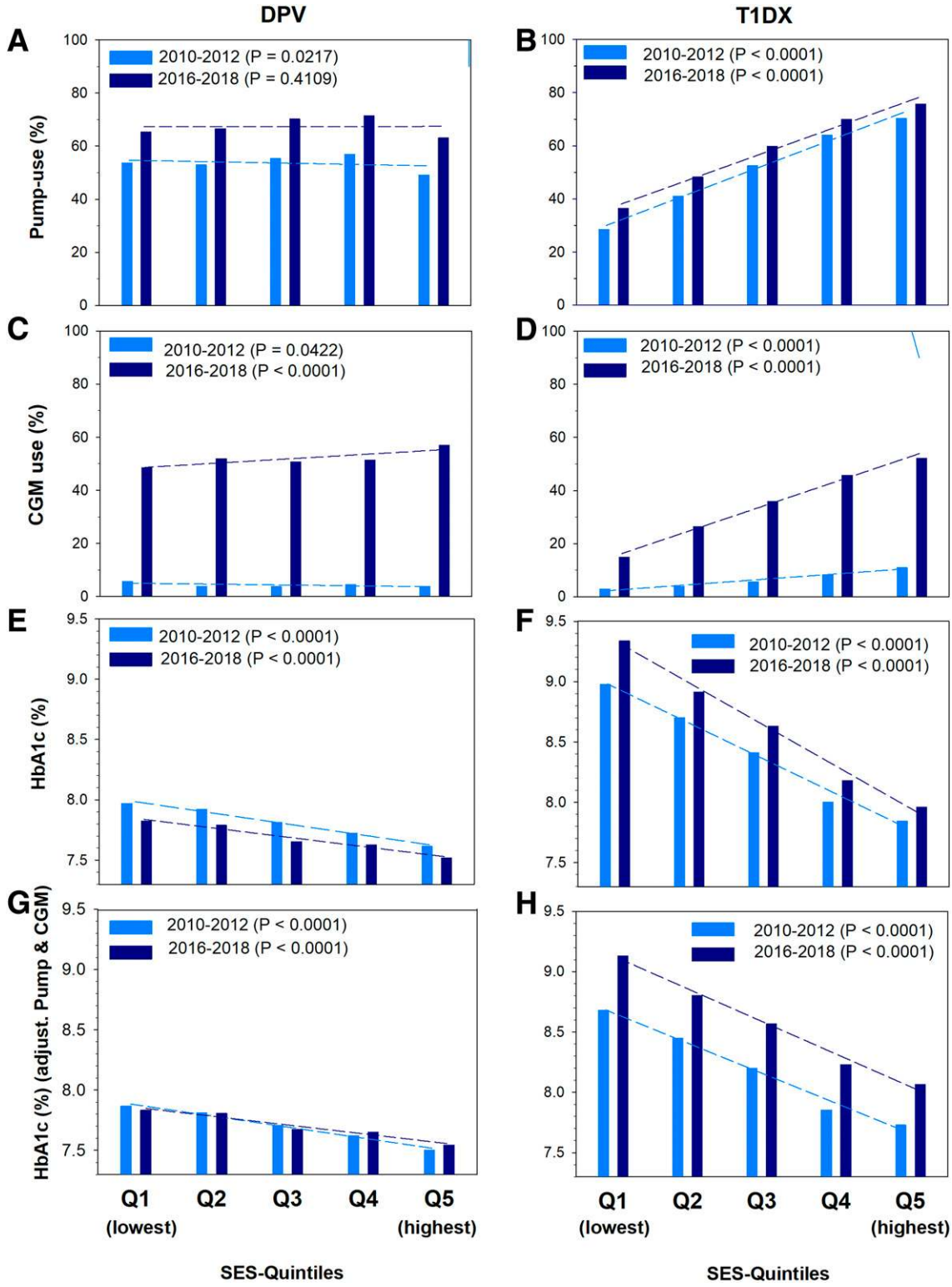

Figure 1—Pump use, CGM use, and HbA_{1c} by SES in the DPV and T1DX registries in 2010–2012 and 2016–2018. *A–F*: Mean estimates by SES quintiles and time period from logistic (pump use, CGM use) and linear (HbA_{1c}) regression models adjusted for sex, age, diabetes duration, SES, time period, minority status, SES-by–time period interaction, and SES-by–minority status interaction. *G* and *H*: Mean estimates with the regression model additionally adjusted for pump and CGM use. Dashed lines are connecting mean estimates for pump and CGM use or regression lines for HbA_{1c} from models including SES as an ordinal term. From these models, *P* values for trend are given for the association with SES within each time period. Q1 is the lowest and Q5 is the highest SES quintile.

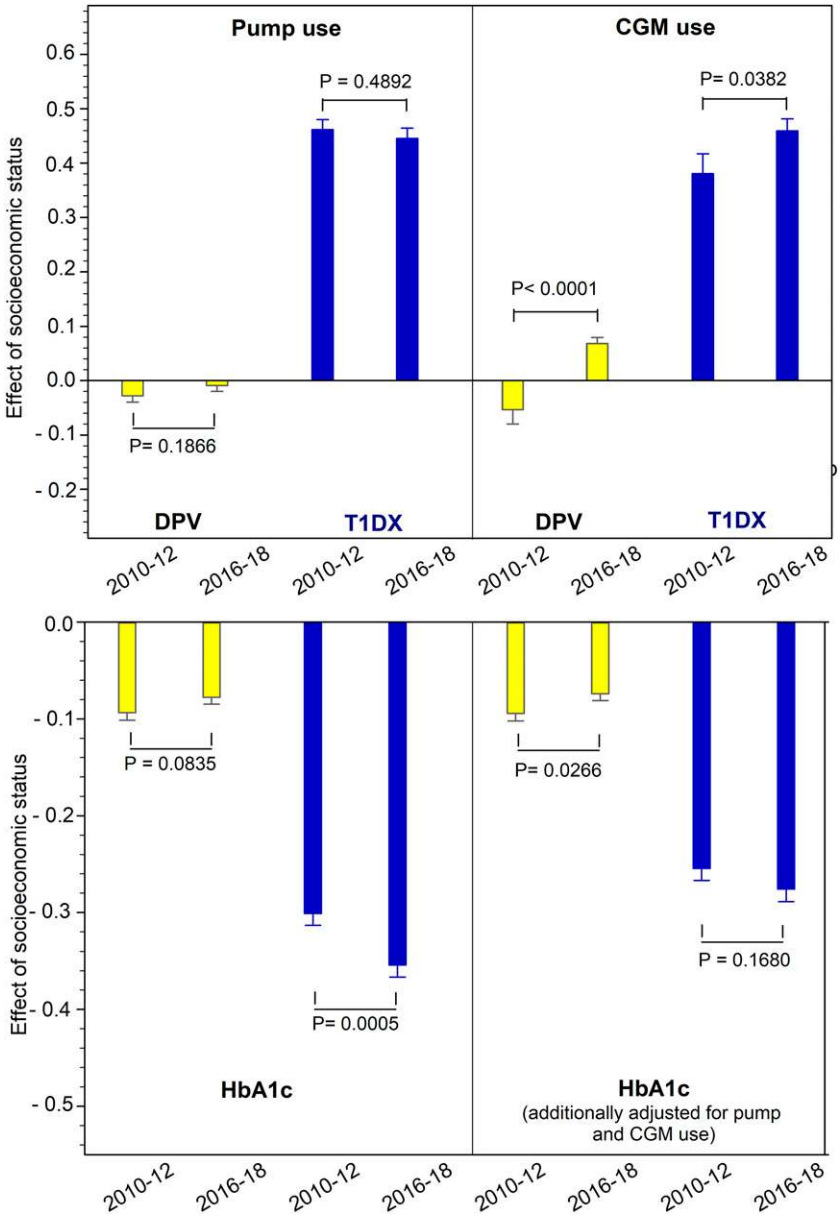

Figure 2—Effect of SES on insulin pump use, CGM use, and HbA_{1c}. Effects of SES are slopes with 95% CIs of the regression lines for the dependent variables derived from multiple regression models including sex, age, diabetes duration, SES, time period, minority status, SES-by–time period interaction, and SES-by–minority status interaction, with SES modeled as an ordinal term. A positive value in insulin pump use and CGM use indicates higher use in quintiles of higher SES. A negative value in HbA_{1c} indicates higher HbA_{1c} in quintiles of lower SES. *P* values are given for the difference in effects of SES between the two time periods.

payer structures may also contribute to the different outcomes in each country (37). Studies in the U.S. and Europe have demonstrated disparate care and poorer outcomes across medical conditions for people of lower SES or lower education level (27,30,38).

These data have strengths and limitations. The DPV registry is population based and inclusive of >85% youth living with type 1 diabetes in Germany (16), whereas the T1DX registry is not population representative but, rather, the largest registry sample of youth with type 1 diabetes in the U.S. (29). Because of constraints in data collection for each registry (and consistent with prior joint publications [1–3]), demographic variables were processed differently (aggregate of patient values in DPV vs. most recent visit in T1DX), and minority status was defined differently (not non-Hispanic White for T1DX vs. first- or second-generation migration for DPV) because of differences between minority and majority population on the respective continents. Furthermore, variables that may confound or affect the relationship between SES and outcomes, such as nutritional intake and approval for diabetes technology by payers, were not available, including differences between countries. Variables that are associated with both SES and diabetes outcomes warrant further studies. Additionally, SES quintiles for T1DX are calculated from individual-level variables, whereas the DPV registry used the GIMD, an area-based measure, as proxy for individual-level SES; therefore, analyses for DPV and T1DX were performed separately. However, area deprivation indices are frequently used as a surrogate for individual-level SES (12,13), a number of prior publications has demonstrated the validity of the GIMD (16,39), and individual-level data were not available in Germany because of data protection concerns. Data on diabetes technology use and HbA_{1c} by each individual component of the T1DX SES quintile score (annual income, parental education, and insurance type) were consistent with findings related to our calculated SES quintiles (Supplementary Table 1*B*). However, we cannot exclude that the differences observed in the effect of social disparity between the two countries are partly due to the different methodologies used to measure SES.

Overall, because of the observational, cross-sectional design of the study, a causal relationship between SES and HbA_{1c} or diabetes technology use cannot be established. Moreover, the association of SES with outcomes is much more complex than simply access to diabetes technology. Other contributors related to SES include barriers to high-quality health care, health beliefs, health behaviors (physical activity, nutrition, diabetes regimen adherence), and possible health care provider bias. In particular, we cannot exclude possible confounding with regard to who receives CGM: It is possible that providers offer CGM or pump therapy more often to youth of lower SES who have a lower HbA_{1c} than youth from lower SES who have a higher HbA_{1c}. Nevertheless, this is the largest study to date evaluating diabetes technology use and HbA_{1c} by SES and is the first to make international comparisons.

These data are real-world observations on the associations of diabetes technology use and HbA_{1c} by SES. Although causal conclusions cannot be drawn from these data, they indicate that the use of diabetes technology is lowest and HbA_{1c} is highest in those of the lowest SES quintile in the U.S., and this difference for HbA_{1c} has broadened in the past decade. Even though there is an association of HbA_{1c} and CGM with SES quintiles in the DPV registry, the widening gap of device use and HbA_{1c} seen in the T1DX is not as pronounced in the DPV. As advances are made in diabetes management, including the use of closed-loop and hybrid closed-loop systems (18–20), these data from the U.S. raise the concern that youth with type 1 diabetes from lower SES quintiles will be at a systematic disadvantage to achieve optimal diabetes outcomes. Further studies are needed to investigate the reasons for increasing HbA_{1c} despite increasing technology use in the U.S.

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