

Impact of Type 1 Diabetes and Severe Hypoglycemia on Productivity and Out-of-Pocket Costs of Adult Continuous Glucose Monitor Users: Results from a Cross-Sectional Survey in the United States

Adriana Boateng-Kuffour,¹ Patrick Callahan,¹ Keval Chandarana,¹ Dianne Barry,¹ Liang Chen,¹ Caitlin S. Kelly,² Huyen Nguyen,² Katherine Chapman,² Emilee Cornelius,² Wendy A. Wolf,² William H. Polonsky³

¹Vertex Pharmaceuticals Incorporated, Boston, MA, USA; ²T1D Exchange, Boston, MA, USA; ³Behavioral Diabetes Institute, San Diego, CA, USA

BACKGROUND

- Type 1 diabetes (T1D) is an autoimmune disease characterized by endogenous insulin deficiency leading to abnormal glucose regulation.^{1,2} Treatment of T1D requires exogenous insulin therapy within a therapeutic range, measured as HbA1c levels <7%.³ Recent guidelines also recommend Continuous Glucose Monitor (CGM) as part of the first-line approach in the management of T1D⁴
- Despite the use of advanced diabetes technologies, including CGM and hybrid closed loop systems (HCLS), many individuals with T1D are unable to reach glycemic targets⁵ and experience severe hypoglycemic events (SHEs) leading to micro- and macrovascular complications^{3,6-9} and impaired quality of life (QoL).¹⁰⁻¹² healthcare costs¹³⁻¹⁴ and productivity impairments¹³
 - Exogenous insulin is essential for treatment of T1D but requires careful assessment of blood glucose due to its narrow therapeutic window, increasing the risk of hypoglycemia.³⁻⁴ If hypoglycemia exposure persists, individuals with T1D may experience SHEs⁵⁻⁶
 - SHEs are medical emergencies characterized by altered mental or physical state often requiring the assistance of another person to treat^{3,7} can lead to seizures, cardiac arrhythmias, loss of consciousness, coma, or even death⁷⁻¹¹
 - Repeated recurrent SHEs can result in impaired awareness of hypoglycemia (IAH),¹⁵⁻⁵ which reduces the individual's ability to recognize and treat future episodes of low blood glucose¹⁶⁻¹⁸, further increasing their risk of experiencing SHEs by 6-fold¹⁹
- Individuals with T1D report significantly higher healthcare costs,¹³⁻¹⁴ and productivity impairments¹³ compared to those without T1D
- There is limited data on the T1D-related impacts on work and life productivity impairments and out-of-pocket costs in adult CGM users with SHEs and IAH in the United States

OBJECTIVES

- To quantify T1D-related productivity impairments and out-of-pocket costs among adult T1D CGM users with SHEs and IAH in the United States

METHODS

Study Design

- An online cross-sectional survey was administered to individuals with T1D from the T1D Exchange Registry who had previously consented to be contacted for research purposes

Key Inclusion Criteria

- Current Continuous Glucose Monitor (CGM) user
- Aged ≥18 years old

Survey Design & Administration

- SHE frequency was collected through participant responses to the question, “How many times did you experience a severe hypoglycemic event in the past 12 months?”
 - Participants were first provided a standardized definition of a SHE.
- Impaired awareness of hypoglycemia (IAH) status was determined using established cutoffs from the modified Gold measure.¹⁹ The Gold measure is a 1-item questionnaire that asks individuals to report their experience in detecting hypoglycemic events with responses ranging from 1 (always aware) to 7 (never aware) in a Likert type scale
 - A score of ≤2 = normal awareness (IAH–); 3 = borderline (undetermined); ≥4 suggests impaired awareness of hypoglycemia (IAH+)
- Work and life productivity impairment were quantified using the Diabetes Productivity Measure (DPM)²⁰
 - Work Productivity: Assessed with 5 items (performing; emotions; productive; miss work; reschedule)
 - Life productivity: Assessed with 9 items (limiting daily activities, increased time for tasks, prevents accomplishing and concentrating, morning active challenges, hypoglycemia symptoms interfering with daily activities)
 - Two stand-alone “non-validated” items are included in the DPM and reported separately
 - Short-Term Goals: Assessed with 1 item; higher scores indicate fewer problems reaching short-term goals
 - Long-Term Goals: Assessed with 1 item; higher scores indicate fewer problems reaching long-term goals
- Out-of-pocket (OOP) expenses were quantified using bespoke questions

Cohort Definitions

Cohort	Definition
Recurrent SHEs with IAH	Individuals with 2+ SHEs and IAH+
Problematic SHEs	Individuals with 2+ SHEs and IAH– or 1+ SHE and IAH+
Single SHE/no-IAH	Individuals with 1 SHE and IAH–
No-SHE	Individuals with 0 SHE and IAH+; 0 SHE and IAH–

Statistical Analyses

- For the DPM, total subscale scores were calculated according to the scaling and scoring instructions of the DPM¹⁸. Individual subscale scores are between 0 -100. Higher scores indicate higher productivity
- Work Productivity was calculated for the subset of participants who reported full- or part-time employment using the DPM
- Descriptive analyses (mean [standard deviation (SD)]) of characteristics and OOP costs are reported for the overall participant population and SHE/IAH cohorts

RESULTS

Demographic Characteristics

- The analytic cohort comprised 1,510 participants, including recurrent SHEs with IAH (n=174), problematic SHEs (n=201), single SHE/no-IAH (n=102), and no-SHE (n=1,033) cohorts. Overall, participants' mean age was 46.4 years (SD =15.4), majority were female (66.3%), and most were employed either part- or full-time (67.8%) (**Table 1**)
- Across SHE/IAH cohorts, participants in the recurrent SHEs with IAH cohort reported lower levels of employment (55.1% compared to the sample overall [67.8%] and no-SHE cohort [71.2%]) (**Table 1**)

Table 1. Demographic Characteristics					
	Overall (N = 1510)	Recurrent SHEs with IAH (n = 174)	Problematic SHEs (n = 201)	Single SHE, no-IAH (n = 102)	No-SHE (n = 1033)
Age (years), mean (SD)					
Gender, n (%)					
Male	494 (32.7%)	44 (25.3%)	64 (31.8%)	32 (31.4%)	354 (34.3%)
Female	1001 (66.3%)	130 (74.7%)	136 (67.7%)	69 (67.6%)	666 (64.5%)
Non-binary/genderqueer	13 (0.9%)	0 (0%)	1 (0.5%)	1 (1.0%)	11 (1.1%)
Prefer to self-identify	1 (0.1%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Prefer not to answer	1 (0.1%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
Race, n (%)					
American Indian/Alaskan Native	8 (0.5%)	1 (0.6%)	2 (1.0%)	0 (0%)	5 (0.5%)
Asian	13 (0.9%)	0 (0%)	1 (0.5%)	2 (2.0%)	10 (1.0%)
Black/African-American	35 (2.3%)	8 (4.6%)	13 (6.5%)	1 (1.0%)	13 (1.3%)
Native Hawaiian or Other Pacific Islander	2 (0.1%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.1%)
North African/Middle-Eastern	8 (0.5%)	0 (0%)	1 (0.5%)	0 (0%)	7 (0.7%)
White	1374 (91.0%)	153 (87.9%)	171 (85.1%)	92 (90.2%)	958 (92.7%)
More than 1 race	55 (3.6%)	10 (5.7%)	8 (4.0%)	5 (4.9%)	32 (3.1%)
Other	15 (1.0%)	2 (1.1%)	4 (2.0%)	2 (2.0%)	7 (0.7%)
Ethnicity, n (%)					
Hispanic or Latino	90 (6.0%)	12 (6.9%)	11 (5.5%)	12 (11.8%)	55 (5.3%)
Employment status, n (%)					
Employed full-time (at least 32 hours per week)	867 (57.4%)	70 (40.2%)	102 (50.7%)	60 (58.8%)	635 (61.5%)
Employed part-time (less than 32 hours per week)	157 (10.4%)	26 (14.9%)	21 (10.4%)	10 (9.8%)	100 (9.7%)
Unemployed	75 (5.0%)	6 (5.1%)	6 (5.9%)	6 (5.9%)	45 (4.4%)
Student only	40 (2.6%)	4 (2.3%)	3 (1.5%)	2 (2.0%)	31 (3.0%)
Unpaid caregiver	35 (2.3%)	5 (2.9%)	4 (2.0%)	3 (2.9%)	23 (2.2%)
Retired	252 (16.7%)	30 (17.2%)	38 (18.9%)	13 (12.7%)	171 (16.6%)
Disabled, not able to work	84 (5.6%)	30 (17.2%)	18 (9.0%)	8 (7.8%)	28 (2.7%)

Abbreviations: SHEs, Severe Hypoglycemic Events; IAH, Impaired Awareness of Hypoglycemia; SD, standard deviation

Clinical Characteristics

- Mean duration of T1D diagnosis in the overall sample was 29.4 years (SD = 5.2). Majority of participants used hybrid closed loop systems (HCLS)/do-it-yourself looping systems (DIY) (65.5%) and had used CGM for ≥5 years (55.5%) (**Table 2**)
- Overall, participants reported 1.9 mean SHEs (SD = 14.2) in the past 12 months and 41.1% had impaired awareness of hypoglycemia (IAH+, Gold score: ≥4). On average, 34.0% of participants were unable to achieve glycemic targets (HbA1c <7%) (**Table 2**)
- Across SHE/IAH cohorts, higher mean rates of SHE was observed in the recurrent SHEs with IAH (8.6, SD = 19.4) compared to the overall sample (1.92, SD = 14.2). On average, 43.7% of participants in the recurrent SHE with IAH cohort were unable to achieve glycemic targets (HbA1c <7%) compared to the overall sample (34.0%) and no-SHE (31.3%) cohorts (**Table 2**)

Table 2. Clinical Characteristics					
	Overall (N = 1510)	Recurrent SHEs with IAH (n = 174)	Problematic SHEs (n = 201)	Single SHE, no-IAH (n = 102)	No-SHE (n = 1033)
Duration of T1D (years), mean (SD)					
Number of SHEs in past 12 months					
Mean (SD)	1.9 (14.2)	8.6 (19.4)	6.5 (33.5)	1.0 (0.0)	0.0 (0.0)
Median (min, max)	0 (0, 360)	3 (2, 150)	1 (1, 360)	1 (1, 1)	0 (0, 0)
Impaired Awareness of Hypoglycemia, n (%)					
IAH–	889 (58.9%)	0 (0%)	98 (48.8%)	102 (100%)	689 (66.7%)
IAH+	621 (41.1%)	174 (100%)	103 (51.2%)	0 (0%)	344 (33.3%)
Diabetes technology subtypes, n (%)					
HCLS/DIY	986 (65.3%)	90 (51.7%)	119 (59.2%)	64 (62.7%)	713 (69.0%)
PLGS	97 (6.4%)	17 (8.5%)	17 (8.5%)	9 (8.8%)	55 (5.3%)
Pump no AID	182 (12.1%)	31 (17.8%)	21 (10.4%)	11 (10.8%)	119 (11.5%)
MDI	245 (16.2%)	37 (21.3%)	44 (21.9%)	18 (17.6%)	146 (14.1%)
Length of CGM use, n (%)					
Less than 3 months	17 (1.1%)	3 (1.7%)	1 (0.5%)	4 (3.9%)	9 (0.9%)
At least 3 months but less than 1 year	43 (2.8%)	13 (7.5%)	8 (4.0%)	6 (5.9%)	16 (1.5%)
At least 1 year but less than 3 years	249 (16.5%)	34 (19.5%)	42 (20.9%)	17 (16.7%)	156 (15.1%)
At least 3 years but less than 5 years	370 (24.5%)	44 (25.3%)	55 (27.4%)	28 (27.5%)	243 (23.5%)
5 or more years	831 (55.0%)	80 (46.0%)	95 (47.3%)	47 (46.1%)	609 (59.0%)
Most recent HbA1c, mean (SD)					
HbA1c <7%, n (%)					
6.69 (1.0)	6.69 (1.0)	6.94 (1.1)	6.84 (1.1)	6.59 (1.0)	6.63 (0.9)
514 (34.0%)	514 (34.0%)	76 (43.7%)	83 (41.3%)	32 (31.4%)	323 (31.3%)
No	514 (34.0%)	76 (43.7%)	83 (41.3%)	32 (31.4%)	323 (31.3%)
Yes	996 (66.0%)	98 (56.3%)	118 (58.7%)	70 (68.6%)	710 (68.7%)

Abbreviations: T1D, Type 1 Diabetes; SD, standard deviation; SHEs, Severe Hypoglycemic Events; IAH, Impaired Awareness of Hypoglycemia; HCLS, Hybrid Closed Loop System; DIY, Do-it-yourself looping system; PLGS, predictive low glucose suspend systems; AID, Automated Insulin Delivery; MDI, multiple daily injections of insulin; CGM, Continuous Glucose Monitor; HbA1c, Hemoglobin A1C

Self-reported out-of-pocket (OOP) costs

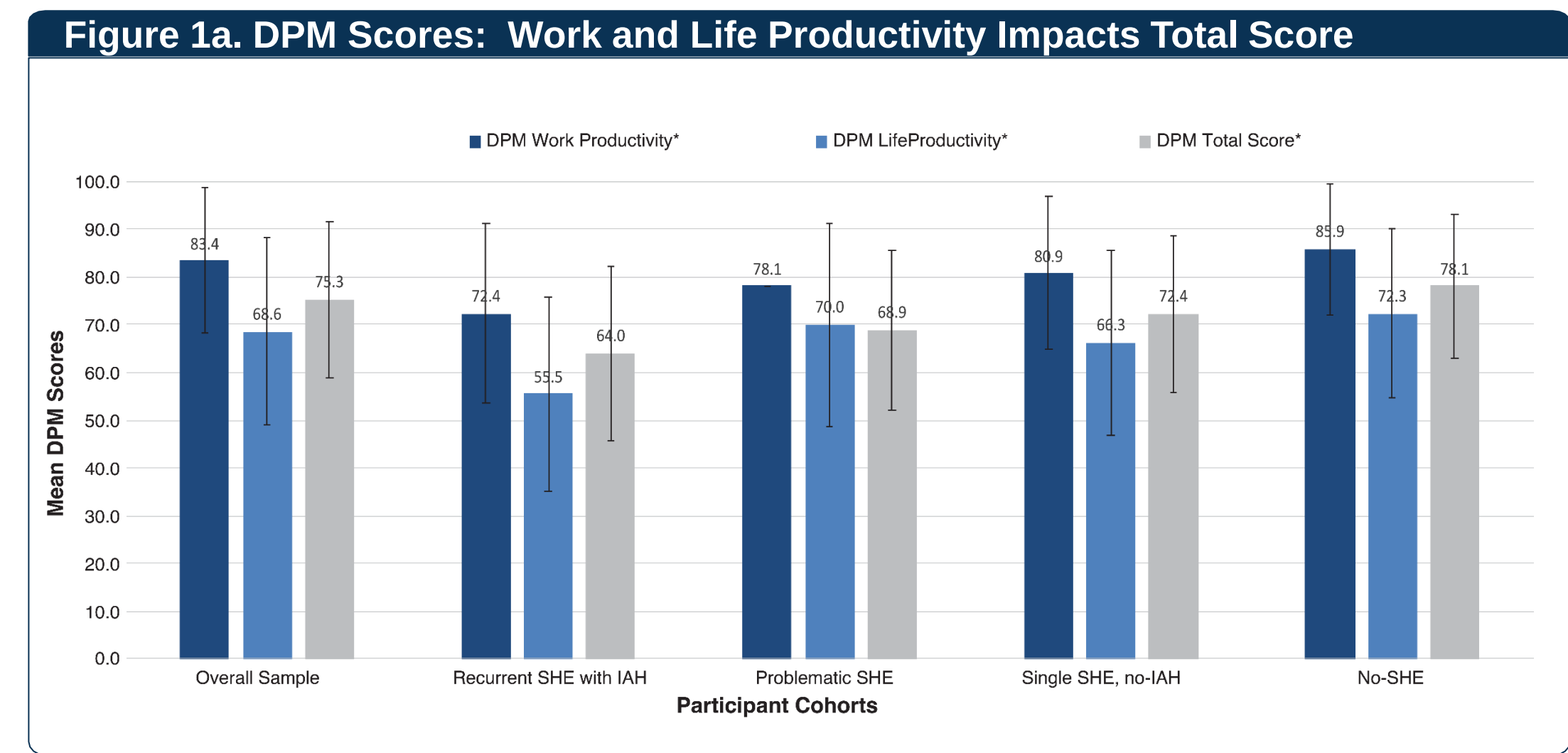
- Higher OOP spend was reported in the recurrent SHEs with IAH cohort (\$3,758) compared to the overall sample (\$2595) and to those with no-SHE (\$2416) (**Table 3**)

Table 3. Self-reported out-of-pocket (OOP) costs in the past 12 months					
	Overall (N = 1510)	Recurrent SHEs with IAH* (n = 174)	Problematic SHEs (n = 201)	Single SHE, no-IAH (n = 102)	No-SHE (n = 1033)
OOP cost of T1D care (\$), mean (SD)					
OOP cost of T1D care categories, n (%)					
\$0	72 (4.8%)	14 (8.0%)	15 (7.5%)	5 (4.9%)	38 (3.7%)
\$1 - \$499	227 (15.0%)	30 (17.2%)	34 (16.9%)	12 (11.8%)	151 (14.6%)
\$500 - \$999	186 (12.3%)	18 (10.3%)	25 (12.4%)	14 (13.7%)	129 (12.5%)
\$1,000 - \$2,499	439 (29.1%)	47 (27.0%)	56 (27.9%)	28 (27.5%)	308 (29.8%)
\$2,500 - \$4,999	345 (22.8%)	31 (17.8%)	33 (16.4%)	24 (23.5%)	257 (24.9%)
\$5,000 - \$9,999	192 (12.7%)	23 (13.2%)	28 (13.9%)	16 (15.7%)	125 (12.1%)
≥10,000	46 (3.1%)	8 (4.5%)	10 (5.0%)	3 (2.9%)	25 (2.5%)
Missing	3 (0.2%)	3 (1.7%)	0 (0%)	0 (0%)	0 (0%)

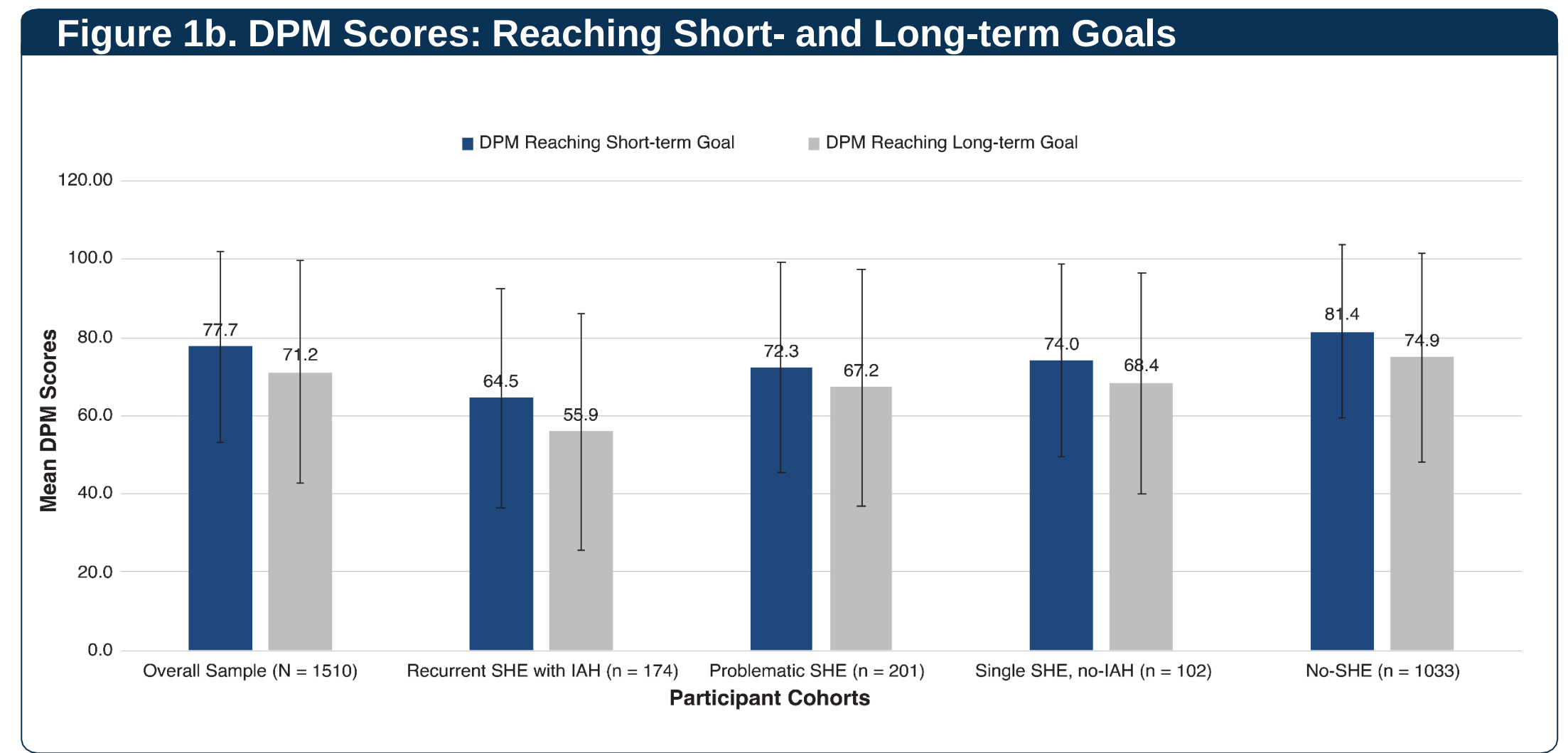
*Two individuals contributed to the high mean and SD in the Recurrent SHE with IAH cohort. However, upon excluding these values, the pattern of results across cohorts remained the same although the observed differences are smaller in magnitude. Abbreviations: T1D, Type 1 Diabetes; SHEs, Severe Hypoglycemic Events; IAH, Impaired Awareness of Hypoglycemia; OOP, Out-of-pocket; SD, standard deviation

DPM Results

- Higher mean impairments to productivity (i.e. lower scores) were observed in the recurrent SHEs with IAH compared to the overall sample and those without SHE (**Figure 1a**)
 - Participants in the recurrent SHEs with IAH cohort reported the highest mean impairments to their work productivity (72.4, SD = 18.8) compared to the overall sample (83.4, SD = 15.3) and those without SHE (85.9, SD = 13.8)
 - On average, participants in the recurrent SHEs with IAH cohort reported the highest impairment to life productivity (55.5, SD = 20.5) compared to the overall sample (68.6, SD = 19.6) and those without SHE (72.3, SD = 17.7)
- Overall, participants reported their T1D prevented them from reaching short-term goals (mean = 71.2, SD = 28.3) more than their long-term goals (mean = 77.7, SD = 24.4). A similar trend was observed across SHE/IAH cohorts although the mean short- and long-term goals impairment scores were higher in the recurrent SHEs with IAH cohort (**Figure 1b**)



*Work productivity and DPM Total Scores were calculated based on the sub-sample of participants who reported part- or full-time employment: Overall sample (n=1024), Recurrent SHEs with IAH (n = 96), Problematic SHEs (n = 123), Single SHE, no-IAH (n = 70), No-SHE (n = 735).
* Life productivity was calculated for all participants regardless of employment status: Overall sample (N = 1510), Recurrent SHEs with IAH (n = 174), Problematic SHEs (n = 201), Single SHE, no-IAH (n = 102), No-SHE (n = 1033).
Abbreviations: DPM, Diabetes Productivity Measure; SHEs, Severe Hypoglycemic Events; IAH, Impaired Awareness of Hypoglycemia.



Abbreviations: DPM, Diabetes Productivity Measure; SHEs, Severe Hypoglycemic Events; IAH, Impaired Awareness of Hypoglycemia.

LIMITATIONS

- Study participants were from the T1D Exchange online community, a cohort of individuals with T1D who tend to be highly engaged, have a high degree of diabetes technology use, and have historically been shown to be more likely to achieve glycemic targets
- Study participants were mostly White, non-Hispanic, identified as female, highly educated, were self-selected, and needed access to the Internet and email, which may impact the generalizability of these results
- All data were self-reported; eligibility and clinical data were not verified by a clinician

CONCLUSIONS

- Despite the high rates of advanced diabetes technology adoption among study participants, a substantial proportion of participants with recurrent SHEs with IAH (43.7%) reported not meeting their glycemic targets compared to other SHEs/IAH cohorts
- In general, a higher proportion of participants in the recurrent SHEs with IAH cohort experienced greater impairments to their work and life productivity, compared to the overall sample and those without SHE, as measured by the DPM
- Out-of-pocket costs were also higher among the recurrent SHEs with IAH cohort compared to the overall sample and those without SHE
- Collectively, these findings demonstrate the added economic burden among those living with T1D and severe hypoglycemia, highlighting the unmet need in this population

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AUTHOR DISCLOSURES

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