# Impact of SHE Frequency and IAH Status on Sleep Quality in **Adult Continuous Glucose Monitor Users With Type 1 Diabetes: Results from a Cross-Sectional Survey Study**

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### INTRODUCTION

- Type 1 diabetes (T1D) is a lifelong chronic metabolic condition characterized by endogenous insulin deficiency leading to abnormal glucose regulation.<sup>1</sup> People with T1D (pwT1D) require lifelong exogenous insulin therapy and should aim to keep their hemoglobin A1c (HbA1c) levels <7%, according to the American Diabetes Association guidelines<sup>2-3</sup>
- Despite using advanced diabetes technologies such as continuous glucose monitors (CGM) and automated insulin delivery systems, many pwT1D are not meeting these guideline targets and experience severe hypoglycemic events (SHEs)<sup>3-4</sup>

#### **Statistical Analysis**

- Descriptive analyses (mean, standard deviation [SD], counts, percentages) of participant demographics and clinical characteristics are reported for the Problematic SHEs and No-SHE cohorts
- Participant responses to the mSQS were summarized descriptively, reported for Problematic SHEs and No-SHE cohorts and further stratified by insulin delivery method: Hybrid closed-loop system/ do-it-yourself (HCLS/DIY), Predictive low glucose suspend (PLGS), Pump without automated insulin-delivery (pump no-AID), and multiple daily injections (MDI)
- Participants with Problematic SHEs reported numerically lower mean sleep quality (lower mean mSQS score) compared to participants in the No-SHEs cohort, except from Pump no-AID users, where mSQS scores were similar between cohorts (**Figure 2**)

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Between Problematic SHEs and No-SHE cohorts, largest numerical difference in mean mSQS scores was observed in PLGS (4.8 [SD=2.8] vs. 6.2 [SD=2.1]), followed by MDI (5.4 [SD=2.4] vs. 6.4 [SD=2.1]), HCLS/DIY (5.7 [SD=2.3] vs. 6.4 [SD=2.0]) and Pump no-AID (6.1 [SD=2.3] vs. 6.0 [SD=2.0]) (Figure 2)

#### Figure 2. Numerical Comparison of Mean

- SHEs are characterized by altered mental and/or physical status, requiring the assistance of a third party for recovery. Repeated episodes of hypoglycemia can result in impaired awareness of hypoglycemia (IAH), further increasing the risk of SHEs. SHEs are associated with acute and chronic complications such as seizures, comas, and even death<sup>4</sup>
- While many pwT1D report overnight fear of SHEs, data describing the impact of SHEs and IAH on sleep quality in many pwT1D is limited

### OBJECTIVE

To describe the impact of SHEs and IAH on sleep quality in adult CGM users with T1D

### **METHODS**

#### **Study Design**

• An online cross-sectional survey was administered to people with T1D from the T1D Exchange Registry

#### **Key Inclusion Criteria**

- Self-reported clinical diagnosis of T1D  $\geq$ 5 years
- Current CGM user
- Aged  $\geq$ 18 years old

### RESULTS

- Results are summarized by the Problematic SHEs (N=375) and No-SHE (N=1033) cohorts (Table 2). Relative to the No-SHEs cohort, participants in the Problematic SHEs cohort were slightly older (mean age = 49.0 [SD = 14.6] vs. 45.6 [SD=15.7] years) (Table 2)
- More participants in the No-SHE cohort used HCLS/DIY (69.0%) relative to the Problematic SHEs cohort (55.7%). Endocrinologist use between the Problematic SHEs and No-SHE cohorts were similar (77.3% vs. 77.7%) (**Table 2**)
- Participants with Problematic SHEs self-reported numerically higher rates of sleep disorder relative to the No-SHE cohort (28.8% vs. 16.6%) (**Table 2**)

#### Table 2. Participant Demographics & **Clinical Characteristics**<sup>a</sup>

Age (years), mean (SD)     49.0 (14.6)     45.6 (15.7)       Gender, n (%)        Male     108 (28.8)     354 (34.3)       Female     266 (70.9)     666 (64.5)       Non-binary / genderqueer     1 (0.3)     11 (1.1)       Prefer not to answer     0 (0)     1 (0.1)       Prefer not to answer     0 (0)     1 (0.1)       Race, n (%)     50.5)     Asian     1 (0.3)     10 (1.0)       Black/African American     21 (5.6)     13 (1.3)       Native Hawalian or Other     1 (0.3)     1 (0.1)       Pacific Islander     1 (0.3)     7 (0.7)       Eastern     1 (0.3)     7 (0.7)       White/Caucasian     324 (86.4)     32 (3.1)       Other     6 (1.6)     7 (0.7)       Ethnicity – Hispanic or Latino, n (%)     23 (6.1)     55 (5.3)       Most recent HbA1c, mean (SD)     6.9 (1.1)     6.6 (0.9)       Medical emergency treatment for     713 (69.0)     713 (69.0)       T1D (excluding SHEs) in the past 12     52 (13.9)     119 (11.5)       MDI     81 (21.6)     146 (14.1) <th></th> <th>Problematic SHEs<sup>b</sup> (N=375, 20.3%)</th> <th>No-SHE<sup>b</sup> (N=1033, 55.9%)</th>		Problematic SHEs <sup>b</sup> (N=375, 20.3%)	No-SHE <sup>b</sup> (N=1033, 55.9%)
Gender, n (%)     Male     108 (28.8)     354 (34.3)       Female     266 (70.9)     666 (64.5)       Non-binary / genderqueer     1 (0.3)     11 (1.1)       Prefer to self-identify     0 (0)     1 (0.1)       Prefer not to answer     0 (0)     1 (0.1)       Race, n (%)     5 (0.5)       American Indian/Alaskan Native     3 (0.8)     5 (0.5)       Asian     1 (0.3)     10 (1.0)       Black/African American     21 (5.6)     13 (1.3)       Native Hawailan or Other     1 (0.3)     1 (0.1)       Pacific Islander     1 (0.3)     7 (0.7)       Eastern     324 (86.4)     958 (92.7)       Mixed Race     18 (4.8)     32 (3.1)       Other     6 (1.6)     7 (0.7)       Ethnicity – Hispanic or Latino, n (%)     23 (6.1)     55 (5.3)       Most recent HbA1c, mean (SD)     6.9 (1.1)     6.6 (0.9)       Medical emergency treatment for     T10 (excluding SHEs) in the past 12     52 (13.9)     119 (11.5)       Diabetes technology subtypes, n (%)     106 (2.8)     255 (5.3)       Pump no-AID	Age (years), mean (SD)	49.0 (14.6)	45.6 (15.7)
Male     108 (28.8)     354 (34.3)       Female     266 (70.9)     666 (64.5)       Non-binary / genderqueer     1 (0.3)     11 (1.1)       Prefer to self-identify     0 (0)     1 (0.1)       Prefer not to answer     0 (0)     1 (0.1)       American Indian/Alaskan Native     3 (0.8)     5 (0.5)       Asian     1 (0.3)     10 (1.0)       Black/African American     21 (5.6)     13 (1.3)       Native Hawailan or Other     1 (0.3)     7 (0.7)       Pacific Islander     1 (0.3)     7 (0.7)       Eastern     324 (86.4)     958 (92.7)       Mixed Race     18 (4.8)     32 (3.1)       Other     6 (1.6)     7 (0.7)       Ethnicity - Hispanic or Latino, n (%)     23 (6.1)     6.6 (0.9)       Medical emergency treatment for     T1D (excluding SHEs) in the past 12     52 (13.9)     60 (5.8)       months, n (%)     Diabetes technology subtypes, n (%)     HCLS/DIY     209 (55.7)     713 (69.0)       PLGS     33 (8.8)     55 (5.3)     Pump no-AID     52 (13.9)     119 (11.5)       MDI	Gender, n (%)		
Female     266 (70.9)     666 (64.5)       Non-binary / genderqueer     1 (0.3)     11 (1.1)       Prefer to self-identify     0 (0)     1 (0.1)       Prefer not to answer     0 (0)     1 (0.1)       Prefer not to answer     0 (0)     1 (0.1)       American Indian/Alaskan Native     3 (0.8)     5 (0.5)       Asian     1 (0.3)     10 (1.0)       Black/African American     21 (5.6)     13 (1.3)       Native Hawaiian or Other     1 (0.3)     1 (0.1)       Pacific Islander     1 (0.3)     7 (0.7)       Eastern     324 (86.4)     958 (92.7)       Mixed Race     18 (4.8)     32 (3.1)       Other     6 (1.6)     7 (0.7)       Ethnicity – Hispanic or Latino, n (%)     23 (6.1)     55 (5.3)       Most recent HbA1c, mean (SD)     6.9 (1.1)     6.6 (0.9)       Medical emergency treatment for     T1D (excluding SHEs) in the past 12     52 (13.9)     119 (11.5)       MDI     53 (21.3)     119 (11.5)     MDI     52 (13.9)     119 (11.5)       MDI     52 (13.9)     118 (14.1)	Male	108 (28.8)	354 (34.3)
Non-binary / genderqueer     1 (0.3)     11 (1.1)       Prefer to self-identify     0 (0)     1 (0.1)       Prefer not to answer     0 (0)     1 (0.1)       Race, n (%)     American Indian/Alaskan Native     3 (0.8)     5 (0.5)       Asian     1 (0.3)     10 (1.0)       Black/African American     21 (5.6)     13 (1.3)       Native Hawaiian or Other     1 (0.3)     1 (0.1)       Pacific Islander     1 (0.3)     7 (0.7)       Eastern     1 (0.3)     7 (0.7)       White/Caucasian     324 (86.4)     958 (92.7)       Mixed Race     18 (4.8)     32 (3.1)       Other     6 (1.5)     7 (0.7)       Ethnicity - Hispanic or Latino, n (%)     23 (6.1)     55 (5.3)       Most recent HbA1c, mean (SD)     6.9 (1.1)     6.6 (0.9)       Medical emergency treatment for     7 113 (69.0)       PLGS     33 (8.8)     55 (5.3)       Pump no-AID     52 (13.9)     119 (11.5)       MDI     81 (21.6)     146 (14.1)       Selected Complications, n (%)     222 (24.5)     108 (10.5) <t< td=""><td>Female</td><td>266 (70.9)</td><td>666 (64.5)</td></t<>	Female	266 (70.9)	666 (64.5)
Prefer to self-identify     0 (0)     1 (0.1)       Prefer not to answer     0 (0)     1 (0.1)       Race, n (%)	Non-binary / genderqueer	1 (0.3)	11 (1.1)
Prefer not to answer     0 (0)     1 (0.1)       Race, n (%)	Prefer to self-identify	0 (0)	1 (0.1)
Race, n (%)       American Indian/Alaskan Native     3 (0.8)     5 (0.5)       Asian     1 (0.3)     10 (1.0)       Black/African American     21 (5.6)     13 (1.3)       Native Hawaiian or Other     1 (0.3)     1 (0.1)       Pacific Islander     1 (0.3)     1 (0.1)       North African/Middle     1 (0.3)     7 (0.7)       Eastern     1 8 (4.8)     32 (3.1)       Other     6 (1.6)     7 (0.7)       White/Caucasian     324 (86.4)     958 (92.7)       Mixed Race     18 (4.8)     32 (3.1)       Other     6 (1.6)     7 (0.7)       Ethnicity - Hispanic or Latino, n (%)     23 (6.1)     55 (5.3)       Most recent HbA1c, mean (SD)     6.9 (1.1)     6.6 (0.9)       Medical emergency treatment for     T17     T13 (69.0)       PLGS     33 (8.8)     55 (5.3)       Pump no-AID     52 (13.9)     119 (11.5)       MDI     81 (21.6)     146 (14.1)       Selected Complications, n (%)     222 (21.5)     108 (10.5)       Retinopathy     92 (24.5)     108 (10.5) <td>Prefer not to answer</td> <td>0 (0)</td> <td>1 (0.1)</td>	Prefer not to answer	0 (0)	1 (0.1)
American Indian/Alaskan Native     3 (0.8)     5 (0.5)       Asian     1 (0.3)     10 (1.0)       Black/African American     21 (5.6)     13 (1.3)       Native Hawaiian or Other     1 (0.3)     1 (0.1)       Pacific Islander     1 (0.3)     1 (0.1)       North African/Middle     1 (0.3)     7 (0.7)       Eastern     1 8 (4.8)     32 (3.1)       Other     6 (1.6)     7 (0.7)       Ethnicity – Hispanic or Latino, n (%)     23 (6.1)     55 (5.3)       Most recent HbA1c, mean (SD)     6.9 (1.1)     6.6 (0.9)       Medical emergency treatment for     T1D (excluding SHEs) in the past 12     52 (13.9)     60 (5.8)       months, n (%)     Diabetes technology subtypes, n (%)     HCLS/DIY     209 (55.7)     713 (69.0)       PLGS     33 (8.8)     55 (5.3)     Pump no-AID     52 (13.9)     119 (11.5)       MDI     81 (21.6)     146 (14.1)     S1 (21.6)     146 (14.1)       Selected Complications, n (%)     Easterd (14.2)     222 (21.5)     Motrovascular       Meirovascular disease     8 (2.1)     24 (2.3)     224 (2.5)	Race, n (%)		
Asian     1 (0.3)     10 (1.0)       Black/African American     21 (5.6)     13 (1.3)       Native Hawaiian or Other     1 (0.3)     1 (0.1)       Pacific Islander     1 (0.3)     7 (0.7)       North African/Middle     1 (0.3)     7 (0.7)       Eastern     324 (86.4)     958 (92.7)       Mixed Race     18 (4.8)     32 (3.1)       Other     6 (1.6)     7 (0.7)       Ethnicity - Hispanic or Latino, n (%)     23 (6.1)     55 (5.3)       Most recent HbA1c, mean (SD)     6.9 (1.1)     6.6 (0.9)       Medical emergency treatment for     T1D (excluding SHEs) in the past 12     52 (13.9)       months, n (%)     Diabetes technology subtypes, n (%)        HCLS/DIY     209 (55.7)     713 (69.0)       PLGS     33 (8.8)     55 (5.3)       Pump no-AID     52 (13.9)     119 (11.5)       MDI     81 (21.6)     146 (14.1)       Selected Complications, n (%)         Microvascular         Cerebrovascular disease     8 (2.1)     24 (2.3)       Ca	American Indian/Alaskan Native	3 (0.8)	5 (0.5)
Black/African American     21 (5.6)     13 (1.3)       Native Hawaiian or Other     1 (0.3)     1 (0.1)       Pacific Islander     1 (0.3)     7 (0.7)       Eastern     1 (0.3)     7 (0.7)       Eastern     324 (86.4)     958 (92.7)       Mixed Race     18 (4.8)     32 (3.1)       Other     6 (1.6)     7 (0.7)       Ethnicity – Hispanic or Latino, n (%)     23 (6.1)     55 (5.3)       Most recent HbA1c, mean (SD)     6.9 (1.1)     6.6 (0.9)       Medical emergency treatment for     T1D (excluding SHEs) in the past 12     52 (13.9)     60 (5.8)       months, n (%)     Diabetes technology subtypes, n (%)     HCLS/DIY     209 (55.7)     713 (69.0)       PLGS     33 (8.8)     55 (5.3)     Pump no-AID     52 (13.9)     119 (11.5)       MDI     81 (21.6)     146 (14.1)     Selected Complications, n (%)     222 (21.5)       Microvascular     wephropathy     92 (24.5)     108 (10.5)     Retinopathy       Nephropathy     92 (24.5)     108 (10.5)     Sectiopatage     29 (7.7)     40 (3.9)       Macrovascular<	Asian	1 (0.3)	10 (1.0)
Native Hawaiian or Other Pacific Islander     1 (0.3)     1 (0.1)       North African/Middle Eastern     1 (0.3)     7 (0.7)       Eastern     324 (86.4)     958 (92.7)       White/Caucasian     324 (86.4)     958 (92.7)       Mixed Race     18 (4.8)     32 (3.1)       Other     6 (1.6)     7 (0.7)       Ethnicity – Hispanic or Latino, n (%)     23 (6.1)     55 (5.3)       Most recent HbA1c, mean (SD)     6.9 (1.1)     6.6 (0.9)       Medical emergency treatment for T1D (excluding SHEs) in the past 12     52 (13.9)     60 (5.8)       months, n (%)     209 (55.7)     713 (69.0)       PLGS     33 (8.8)     55 (5.3)       Pump no-AlD     52 (13.9)     119 (11.5)       MDI     81 (21.6)     146 (14.1)       Selected Complications, n (%)     146 (14.1)       Microvascular     222 (21.5)     108 (10.5)       Retinopathy     31 (8.3)     47 (4.5)       Neuropathy     92 (24.5)     108 (10.5)       Retinopathy     90 (24.0)     275 (26.6)       Mypertension     152 (40.5)     317 (30.7)	Black/African American	21 (5.6)	13 (1.3)
Pacific Islander     1 (0.3)     1 (0.1)       North African/Middle     1 (0.3)     7 (0.7)       Eastern     1 (0.3)     7 (0.7)       White/Caucasian     324 (86.4)     958 (92.7)       Mixed Race     18 (4.8)     32 (3.1)       Other     6 (1.6)     7 (0.7)       Ethnicity – Hispanic or Latino, n (%)     23 (6.1)     55 (5.3)       Most recent HbA1c, mean (SD)     6.9 (1.1)     6.6 (0.9)       Medical emergency treatment for     T1D (excluding SHEs) in the past 12     52 (13.9)     60 (5.8)       months, n (%)     Diabetes technology subtypes, n (%)          HCLS/DIY     209 (55.7)     713 (69.0)         PLGS     33 (8.8)     55 (5.3)         MDI     81 (21.6)     146 (14.1)         Selected Complications, n (%)           Microvascular            Nephropathy     31 (8.3)     47 (4.5)          Molrovascular </td <td>Native Hawaiian or Other</td> <td>1 (0.2)</td> <td>1 (0 1)</td>	Native Hawaiian or Other	1 (0.2)	1 (0 1)
North African/Middle Eastern     1 (0.3)     7 (0.7)       White/Caucasian     324 (86.4)     958 (92.7)       Mixed Race     18 (4.8)     32 (3.1)       Other     6 (1.6)     7 (0.7)       Ethnicity – Hispanic or Latino, n (%)     23 (6.1)     55 (5.3)       Most recent HbA1c, mean (SD)     6.9 (1.1)     6.6 (0.9)       Medical emergency treatment for     T1D (excluding SHEs) in the past 12     52 (13.9)     60 (5.8)       months, n (%)     209 (55.7)     713 (69.0)     PLGS     33 (8.8)     55 (5.3)       Pump no-AID     52 (13.9)     119 (11.5)     MDI     81 (21.6)     146 (14.1)       Selected Complications, n (%)     Microvascular      222 (21.5)     108 (10.5)       Metrovascular     S1 (8.3)     47 (4.5)     57 (5.5)     24 (2.3)       Cardiovascular disease     8 (2.1)     24 (2.3)     222 (21.5)       Macrovascular     156 (41.3)     371 (30.7)     39       Hypertension     152 (40.5)     317 (30.7)     39       Joint or bone issues     191 (50.9)     366 (35.4)     366 (35.4) <td>Pacific Islander</td> <td>T (0.3)</td> <td>Γ(0.1)</td>	Pacific Islander	T (0.3)	Γ(0.1)
Eastern     1 (0.0)     1 (0.1)       White/Caucasian     324 (86.4)     958 (92.7)       Mixed Race     18 (4.8)     32 (3.1)       Other     6 (1.6)     7 (0.7)       Ethnicity – Hispanic or Latino, n (%)     23 (6.1)     55 (5.3)       Most recent HbA1c, mean (SD)     6.9 (1.1)     6.6 (0.9)       Medical emergency treatment for     7110 (excluding SHEs) in the past 12     52 (13.9)     60 (5.8)       months, n (%)     209 (55.7)     713 (69.0)     PLGS     33 (8.8)     55 (5.3)       Pump no-AID     52 (13.9)     119 (11.5)     MDI     81 (21.6)     146 (14.1)       Selected Complications, n (%)     Microvascular       7 (4.5)       Neuropathy     92 (24.5)     108 (10.5)     Retinopathy     222 (21.5)       Macrovascular       24 (2.3)     27 (5.5)       Vascular disease     8 (2.1)     24 (2.3)     24 (2.3)       Cardiovascular disease     29 (7.7)     40 (3.9)     39       Hypertension     152 (40.5)     317 (30.7)     24 (2.3)       Diat	North African/Middle	1 (0.3)	7 (0 7)
White/Caucasian     324 (86.4)     958 (92.7)       Mixed Race     18 (4.8)     32 (3.1)       Other     6 (1.6)     7 (0.7)       Ethnicity – Hispanic or Latino, n (%)     23 (6.1)     55 (5.3)       Most recent HbA1c, mean (SD)     6.9 (1.1)     6.6 (0.9)       Medical emergency treatment for     52 (13.9)     60 (5.8)       T1D (excluding SHEs) in the past 12     52 (13.9)     60 (5.8)       months, n (%)     209 (55.7)     713 (69.0)       PLGS     33 (8.8)     55 (5.3)       Pump no-AID     52 (13.9)     119 (11.5)       MDI     81 (21.6)     146 (14.1)       Selected Complications, n (%)         Microvascular         Nephropathy     31 (8.3)     47 (4.5)       Neuropathy     92 (24.5)     108 (10.5)       Retinopathy     90 (24.0)     275 (26.6)       Hypothyroidism	Eastern	1 (0.0)	7 (0.7)
Mixed Race     18 (4.8)     32 (3.1)       Other     6 (1.6)     7 (0.7)       Ethnicity – Hispanic or Latino, n (%)     23 (6.1)     55 (5.3)       Most recent HbA1c, mean (SD)     6.9 (1.1)     6.6 (0.9)       Medical emergency treatment for     T1D (excluding SHEs) in the past 12     52 (13.9)     60 (5.8)       months, n (%)     Diabetes technology subtypes, n (%)          HCLS/DIY     209 (55.7)     713 (69.0)         PLGS     33 (8.8)     55 (5.3)         Pump no-AID     52 (13.9)     119 (11.5)          MDI     81 (21.6)     146 (14.1)   <	White/Caucasian	324 (86.4)	958 (92.7)
Other     6 (1.6)     7 (0.7)       Ethnicity – Hispanic or Latino, n (%)     23 (6.1)     55 (5.3)       Most recent HbA1c, mean (SD)     6.9 (1.1)     6.6 (0.9)       Medical emergency treatment for     T1D (excluding SHEs) in the past 12     52 (13.9)     60 (5.8)       months, n (%)     Diabetes technology subtypes, n (%)          HCLS/DIY     209 (55.7)     713 (69.0)         PLGS     33 (8.8)     55 (5.3)         Pump no-AID     52 (13.9)     119 (11.5)         MDI     81 (21.6)     146 (14.1)          Selected Complications, n (%)            Microvascular              Nephropathy     31 (8.3)     47 (4.5)	Mixed Race	18 (4.8)	32 (3.1)
Ethnicity – Hispanic or Latino, n (%)     23 (6.1)     55 (5.3)       Most recent HbA1c, mean (SD)     6.9 (1.1)     6.6 (0.9)       Medical emergency treatment for     T1D (excluding SHEs) in the past 12     52 (13.9)     60 (5.8)       months, n (%)     Diabetes technology subtypes, n (%)     713 (69.0)     PLGS     33 (8.8)     55 (5.3)       Pump no-AID     52 (13.9)     119 (11.5)     MDI     81 (21.6)     146 (14.1)       Selected Complications, n (%)     Microvascular     146 (14.1)     Selected Complications, n (%)       Microvascular     202 (24.5)     108 (10.5)     Retinopathy     92 (24.5)     108 (10.5)       Retinopathy     92 (24.5)     108 (10.5)     S7 (5.5)     Vascular disease     47 (12.5)     57 (5.5)       Vascular disease     47 (12.5)     57 (5.5)     57 (5.5)     57 (5.5)     57 (5.5)       Vascular disease     29 (7.7)     40 (3.9)     40 (3.9)     41 (30.7)       Hypothyroidism     90 (24.0)     275 (26.6)     41     41 (3.5)     57 (5.5)       Vascular disease     90 (24.0)     275 (26.6)     41     59 (3.5,4) <td>Other</td> <td>6 (1.6)</td> <td>7 (0.7)</td>	Other	6 (1.6)	7 (0.7)
Most recent HbA1c, mean (SD)     6.9 (1.1)     6.6 (0.9)       Medical emergency treatment for T1D (excluding SHEs) in the past 12 months, n (%)     52 (13.9)     60 (5.8)       Diabetes technology subtypes, n (%)       713 (69.0)       HCLS/DIY     209 (55.7)     713 (69.0)        PLGS     33 (8.8)     55 (5.3)        Pump no-AlD     52 (13.9)     119 (11.5)        MDI     81 (21.6)     146 (14.1)        Selected Complications, n (%)       108 (10.5)       Meuropathy     31 (8.3)     47 (4.5)        Nephropathy     92 (24.5)     108 (10.5)        Retinopathy     106 (28.3)     222 (21.5)        Macrovascular           Cerebrovascular disease     8 (2.1)     24 (2.3)         Cardiovascular disease     29 (7.7)     40 (3.9)         Hypothyroidism     90 (24.0)     275 (26.6)         Hypertension     152 (40.5)     317 (30.7) <td< td=""><td>Ethnicity – Hispanic or Latino, n (%)</td><td>23 (6.1)</td><td>55 (5.3)</td></td<>	Ethnicity – Hispanic or Latino, n (%)	23 (6.1)	55 (5.3)
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<b>Anxiety</b> 175 (46.7) 341 (33.0)	Depression	184 (49.1)	325 (31.5)
	Anxiety	175 (46.7)	341 (33.0)

mSQS Scores Between the Problematic SHEs and No-SHE Cohorts and Stratified by **Insulin Delivery Methods** 



Note: Stratification of SHE/IAH cohorts by insulin delivery methods resulted in unequal group sizes: HCLS/DIY (Problematic SHEs [n=205] vs. No-SHE [n=712]); PLGS (Problematic SHEs [n=33 vs. No-SHE [n=55]); Pump no-AID (Problematic SHEs [n=52] vs. No-SHE [n=119]); MDI (Problematic SHEs [n=81] vs. No-SHE [n=146]) <sup>a</sup>Error bars = SD

AID: automated insulin delivery; HCLS/DIY: hybrid close loop system/do-it-yourself; IAH: impaired awareness of hypoglycemia; MDI: multiple daily injection; PLGS: predictive low glucose suspend systems; SHE: severe hypoglycemic event; **mSQS:** modified Sleep Quality Score

#### Limitations

- Study participants were from the T1D Exchange Registry, 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 or Latino, identified as female, highly educated, were self-selected and needed access to the internet and email, which may all impact the generalizability of these results

#### **Survey Design & Administration**

- SHE frequency was collected through participant responses to the question:
  - "A severe hypoglycemic event (SHE) is a low blood sugar where you experience a change in your mental or physical status (like increased confusion or loss of consciousness) and where you need help from another person to recover. How many times did you experience a severe hypoglycemic event in the past 12 months?"
- IAH status was determined using established cutoffs from the modified Gold score.<sup>5</sup> The Gold score 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  $\leq 2$  = normal awareness (IAH–); 3 = borderline (undetermined);  $\geq$ 4 suggests impaired awareness of hypoglycemia (IAH+)
- Self-reported sleep disorder was measured with a bespoke question "Have you ever been diagnosed with or treated by a medical professional for any of the following conditions..."
- Sleep disorder was listed as one of the conditions
- Response options included Yes, No, and Unsure
- Sleep quality was assessed using a modified version of the single-item sleep quality scale (mSQS)<sup>6</sup>
- The following question refers to your overall sleep quality for the majority of nights in the past 7 days ONLY.
- Please think about the quality of your sleep overall such as how many hours of sleep you got, how easily you fell asleep, how often you woke up in the middle of the night (except to go to the bathroom), how often you woke up earlier than you had to in the morning, and how refreshing your sleep was.

<sup>a</sup>Table 2 was previously presented elsewhere.

<sup>b</sup>The Overall sample also included Single SHE, no-IAH (n=102) and Undetermined IAH (n=337) cohorts. AID: automated insulin delivery; HbA1c: hemoglobin A1c; HCLS/DIY: hybrid closed loop system/ do-it-yourself; **IAH:** impaired awareness of hypoglycemia; **PLGS:** pump no automated insulin delivery; **MDI:** multiple daily injection; **SD:** standard deviation; **T1D:** type 1 diabetes

- All data were self-reported; eligibility and clinical data were not verified by a clinician
- Analysis conducted were descriptive; associations between sleep quality and SHE frequency/IAH status were not assessed

## CONCLUSIONS

- **Compared to the No-SHE cohort, participants with Problematic SHEs self-reported numerically higher** medical emergency treatments (excluding SHEs), potentially suggesting higher frequency or more severe comorbidities
- **Participants with Problematic SHEs reported** numerically lower sleep quality compared to those without SHE (No-SHE cohort)
- Numerically higher self-reported rates of sleep disorder (28.8% vs. 16.6%)
- Lower sleep quality (lower total mean mSQS) scores) across insulin delivery methods, except for pump-no-AID users, where total mean mSQS scores between the cohorts were similar
- **Collectively, these findings suggest a potential** link between SHE frequency and impaired sleep quality, which may affect QoL of pwT1D. Future research should evaluate the association between SHE frequency, IAH status and sleep quality across different insulin delivery methods

- During the past 7 days, how would you rate your sleep quality overall?
  - Rate your sleep quality on a scale of 0 ("Terrible") to 10 ("Excellent"). A higher score means better sleep quality

#### **Cohort Definitions**

Cohorts were defined<sup>7</sup> based on self-reported SHE frequency the past 12 months and IAH status (modified Gold score)

Table 1. Study Design		
Cohort	Definition	
<b>Problematic SHEs</b>	Individuals with SHE 1+/IAH+ or SHE 2+/IAH-	
Single SHE, no-IAH	Individuals with 1 SHE and IAH-	
Undetermined IAH	Individuals with SHE $\geq$ 0 and modified Gold score = 3	
No-SHE	Individuals with 0 SHE and IAH+ or 0 SHE and IAH-	
IAH: impaired awareness of hypog	lycemia; SHE: severe hypoglycemic event	

- Participants in the Problematic SHEs cohort reported numerically lower mean sleep quality (lower mSQS score) compared to the No-SHEs cohort (5.6 [SD=2.3] vs. 6.3 [SD=2.0]) (Figure 1)

### Figure 1. Mean mSQS Scores Between **Problematic SHEs and IAH Cohorts**



IAH: impaired awareness of hypoglycemia; SHE: severe hypoglycemic event; mSQS: modified Sleep Quality Scale <sup>a</sup>Error bars = SD

These findings also show how different insulin delivery methods may influence sleep quality in pwT1D and SHEs and highlight the need for innovative therapies beyond insulin delivery methods.

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#### **Author Disclosures**

CSK, HN, KSC, EMC, and WAW are employees of T1D Exchange. WHP has served as a consultant for Dexcom, Abbott Diabetes, Eli Lilly, Sanofi, Novo Nordisk, Vertex Pharmaceuticals, Embecta, Mannkind, Ascensia, and Sequel. WHP received research support from Dexcom and Abbott Diabetes. ABK, PC, KC, DB, and LC are employees of Vertex Pharmaceuticals and may hold stock or stock options in the company

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