

# Diabetes Management Experience and the State of Hypoglycemia: National Data Sample from an Online Survey

Karim Zahed, Farzan Sasangohar, Ranjana Mehta, Madhav Erraguntla, Khalid Qaraqe

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## Abstract

**Background:** Hypoglycemia or low blood sugar for people with diabetes can be a serious life-threatening condition and serious outcomes can be avoided if low levels are proactively detected. While technologies exist to detect the onset of hypoglycemia, they are invasive, costly, or suffer from high false alarms. Tremors are a commonly reported symptom of hypoglycemia and may be used to detect hypoglycemic events, yet their onset is not well researched or understood.

**Objective:** This study seeks to understand diabetic patients' perceptions of hypoglycemic tremors as well as their user experiences with technology to manage diabetes, and expectations from a self-management tool, ultimately to inform the design of a non-invasive and cost-effective technology that detects tremors associated with hypoglycemia

**Methods:** A cross-sectional, internet panel survey was administered to adult type 1 diabetes patients using the Qualtrics platform in May 2019. Questions focused on three main constructs: (1) perceived hypoglycemia experiences, (2) experiences and expectations about a diabetes management device and mobile application, and (3) beliefs and attitudes regarding intention to use a diabetes management device. The analysis in this manuscript focuses on the first two constructs. Non-parametric tests were used to analyze Likert scale data, with Mann-Whitney U test, Kruskal-Wallis test, and Games-Howell post hoc test as applicable, for subgroup comparisons to highlight differences in perceived frequency, severity, and noticeability of hypoglycemic tremors across age, gender, years living with diabetes, and physical activity.

**Results:** Data from 212 respondents (60.9% female) revealed statistically significant differences in perceived noticeability of tremors by gender; whereby males noticed their tremors more; and age with the older population reporting lower noticeability than the young and middle age groups. Differences in noticeability were marginally significant, while severity was significant for with those living with diabetes ?1 year reporting higher than other groups. Severity of tremors were higher in those physically active, leading a marginally significant difference compared to those who were insufficiently active. Other subgroup comparisons in perceived frequency, severity, and noticeability were not found to be statistically significant. The majority (n=150) have used diabetes monitoring devices; descriptive results for technology use and feature preferences are also reported.

**Conclusions:** Our findings suggest that men notice their tremors significantly more than women and older adults confirmed that they notice their tremors less compared to younger patients, due to the inhibition of symptoms over time. While hypoglycemic tremors were perceived to occur frequently, such tremors were not found to be as severe compared to other symptoms reported in the literature, such as sweating. Using a combination of tremor and perspiration sensors may show promise in detecting the onset of hypoglycemic events.

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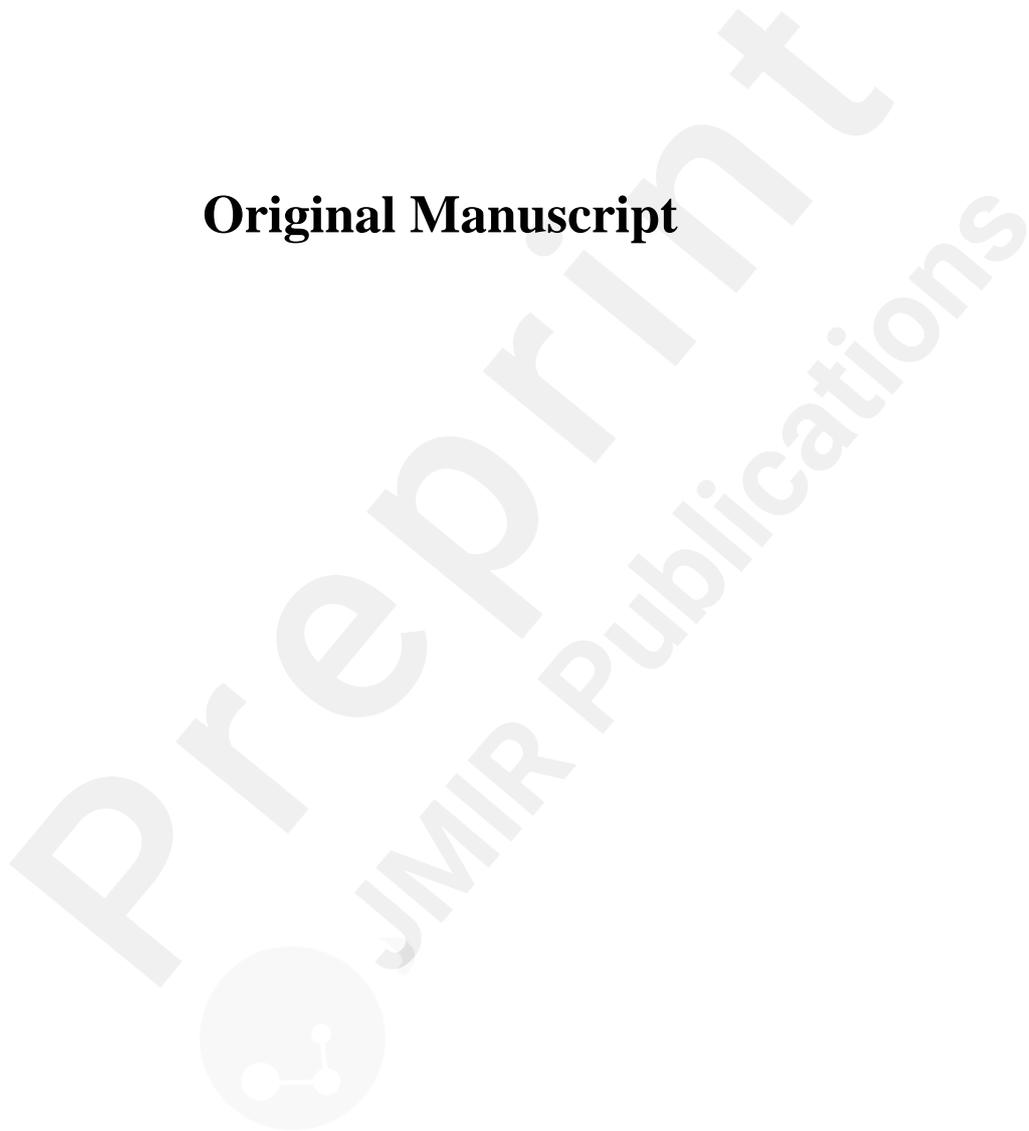
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## Original Manuscript



## Original Paper

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# Diabetes Management Experience and the State of Hypoglycemia: National Data Sample from an Online Survey

## Abstract

**Background:** Hypoglycemia or low blood sugar for people with diabetes can be a serious life-threatening condition and serious outcomes can be avoided if low levels are proactively detected. While technologies exist to detect the onset of hypoglycemia, they are invasive, costly, or suffer from high false alarms. Tremors are a commonly reported symptom of hypoglycemia and may be used to detect hypoglycemic events, yet their onset is not well researched or understood.

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**Results:** Data from 212 respondents (60.9% female) revealed statistically significant differences in perceived noticeability of tremors by gender; whereby males noticed their tremors more ( $P < .001$ ); and age, with the older population reporting lower noticeability than the young and middle age groups ( $P < .001$ ). Individuals living longer with diabetes noticed their tremors significantly less compared to those having diabetes for  $\leq 1$  but not in terms of frequency or severity. Additionally, the majority of our participants (150/212) reported experience with diabetes monitoring devices.

**Conclusions:** Our findings support the need for cost-efficient and non-invasive continuous monitoring technologies. While hypoglycemic tremors were perceived to occur frequently, such tremors were not found to be as severe compared to other symptoms, such as sweating, which was the highest rated symptom in our study. Using a combination of tremor and galvanic skin response sensors may show promise in detecting the onset of hypoglycemic events.

**Keywords:** Tremor; Hypoglycemia; Diabetes Mellitus; Remote Sensing Technology; Survey Methods

## Introduction

Diabetes is a chronic disease affecting more than 9.4% of the world population [1], with an estimated \$327 billion in economic costs each year [2]. The majority (about 90%) of the population living with diabetes has Type 2 Diabetes Mellitus (T2DM), while about 10% suffer from Type 1 Diabetes Mellitus (T1DM). Collectively, both types are responsible for around 12% of the annual deaths in the United States alone [3]. Management of diabetes is burdensome and requires regular monitoring of blood sugar, and careful attention to nutrition.

Fluctuating blood sugar levels outside the normal ranges tend to be common among T1DM [4]. Hypoglycemia or low Blood Glucose (BG) is a dangerous condition that affects diabetics when blood glucose level falls below 70mg/dL [5]. If the BG level continues falling below 54mg/dL, it may result in severe hypoglycemia [5]. Values below this level can cause severe cognitive impairment, seizure, loss of consciousness, and in some cases coma [6]. Severe hypoglycemia has also been associated with a higher rate of mortality. In one study for example, 10% of the children surveyed had passed away by the time of follow up [7]. Over time, recurrent hypoglycemia can inhibit the associated symptoms, leading the affected person to lose sensitivity to or become unaware of hypoglycemic symptoms [6]. With the body unable to secrete epinephrine that generates the hypoglycemic symptoms [8], the risk of death could increase by more than three fold [9]. This is particularly risky during sleep where nocturnal hypoglycemia leads to cases of “dead in bed” [10]. Despite evidence suggesting the existence of such self-unawareness and lost sensitivity to hypoglycemic symptoms, not much research exists to document the extent of such phenomenon among diabetics.

The most prevalent technology to monitor BG particularly for T2DM is blood glucose meters which require manual application of a test strip (typically by pricking a finger). The main limitation of traditional meters is that the measurement is periodic and manual. Continuous Glucose Monitors (CGMs) were commercialized at the beginning of this century [11], and have gained popularity especially among T1DM patients as they are capable of monitoring BG levels continuously and autonomously. CGMs can provide information about BG trends and can warn against the onset of hyper- and hypoglycemia. However, these tools are invasive, costly, and require regular maintenance and calibration [12]. In a large survey of T1DM patients, around a third of the sample used CGMs [13], and in another survey of 877 of CGM users, nearly half noted that they were not satisfied with the cost [14]. More recent studies also showed that CGMs in many cases are not cost-effective [15,16], which generally limits their utility particularly in medically-underserved areas where there is less access to health care [17], less health and technological literacy [18], and in many cases low socioeconomic status. Therefore, there is a critical need to have affordable non-invasive alternative methods and technologies for monitoring and self-management of diabetes and early detection of hypoglycemic onsets. However, availability of alternatives particularly for detection and monitoring of hypoglycemia has been very limited. A few non-invasive devices such as HypoMon®, GlucoWatch® G2, and Diabetes Sentry made it to market but suffered from high false alarms, and were sensitive to environmental conditions [19]. Those that could not be commercialized were prototypes that suffered from significant wearability issues [19]. One study even claimed that non-invasive options were incapable of competing with invasive methods in terms of accuracy [20]. Our overall research objective is to address this gap by designing a non-invasive and cost-effective technology that detects tremors associated with hypoglycemia.

In a past review, we reported that “tremors” and “trembling” have been found to be very common among diabetic patients [19]. In another study surveying elderly subjects, trembling was reported in 71% percent of the diabetics [21]. Tremors have been shown to be a significant symptom of

hypoglycemia in several other survey studies [22–25], as well as in lab studies [26,27]. In this paper, we document findings from a large survey of T1DM patients regarding their perception of hypoglycemic symptoms. In particular, we highlight the differences in how patients perceive the frequency of occurrence, severity, and noticeability of hypoglycemic tremors across age, gender, years living with diabetes, and physical activity to inform the design of future interventions. Additionally, we highlight patient experiences with technologies used to monitor their blood sugar, and their preferences for a CGM-alternative wearable device.

## Methods

### Study Design

A cross-sectional, internet panel survey of 212 United States adults with T1DM was conducted using the Qualtrics platform (Qualtrics, Provo, UT) in May 2019. The study was conducted in accordance with STrengthening the Reporting of OBServational studies in Epidemiology (STROBE) guidelines [28]. After the institutional review board at the authors' institution reviewed and approved the study protocol, participants were then recruited through a Qualtrics panel. Individuals who qualified for the survey based on self-reported demographic data (18+ years, diagnosed with T1DM) were invited via email to join the panel. The email included information such as the title of the survey, its duration, and a link to follow if they were interested to participate which would increase their points that can be redeemed later for a reward. To further evaluate this criteria and to assess the quality of responses, a pilot dataset consisting of the first 10% of responses (n=20) was shared with the research team. Additionally, automated logic was added to the instrument to automatically remove data that was deemed unreasonable or responses that were not relevant to the question. No identifiable information was recorded, but latitude and longitude were stored by Qualtrics for each respondent and used to confirm that all participants were located within the United States.

### Survey Design

The survey was designed to target three main constructs: (1) perceived hypoglycemia experiences, (2) experiences and expectations about a diabetes management device and mobile application, and (3) beliefs and attitudes regarding intention to use a diabetes management device. Questions targeting the first set of constructs attempted to understand the frequency and severity of hypoglycemic tremors when compared to other symptoms of hypoglycemia [29,30]. Additional questions were related to noticeability of hypoglycemic tremors. These questions were rated by the participants on a 10-point Likert scale. (e.g., 1= Not Frequent, 5= Neutral, 10= Very Frequent). Questions related to a second set of constructs attempted to document the variety and prevalence of type of technologies such as smartphone apps, continuous glucose monitors, insulin pumps, and the regular blood glucose meters used for diabetes self-management. Additionally, several questions were designed to elicit patients' preference for features and characteristics of an ideal diabetes management mobile application and issues related to wearability. Finally, participants were asked about their preference for the frequency of BG measurement and time of the day they preferred for such measurement. Beliefs and attitudes relating to intention to use a device will be reported elsewhere.

### Analysis

After the pilot data collection and consultation with the research team, a Qualtrics team evaluated the responses for consistency, completeness, and speed of completion. All analyses were performed on

JASP (v 0.10.2.). Non-parametric tests were used to analyze the Likert scale data [31]. To compare noticeability, frequency of occurrence, and severity of tremors across genders, a Mann-Whitney U test was performed. To compare them across age groups, years with diabetes, and physical activity, a Kruskal-Wallis test was performed. When a significant difference was found, the analysis was followed with a Games-Howell post hoc test to identify differing groups.

## Results

### Demographics

Participants' demographics and comparison with national averages are summarized in Table 1. All participants were located in the United States and represented 40 out of 50 states. Out of 212 participants, 129 (60.9%) were females. 117 participants were between the ages of 30 and 50 years contributing to more than half the sample size (55.2%). As expected, our data over-represents the middle age groups and underrepresents older adults who might not be inclined to take an online survey. Other demographic factors align with the national data available. 182 individuals in our sample (82%) were white non-Hispanic, and 92 participants (43.4%) had a household income greater than \$60,000.

Table 1 – Participant demographics

Online data sample		National data		
Characteristic	N (%)	Characteristic	%	References
<b>Gender</b>				
Female	129 (60.9%)	-	51.0%	[32]
Male	83 (39.1%)	-	49.0%	
<b>Age</b>				
18-29	34 (16.0%)	20-29	18.4%	[33]
30-39	64 (30.2%)	30-39	17.8%	
40-49	53 (25.0%)	40-49	16.6%	
50-59	33 (15.6%)	50-59	17.4%	
60+	28 (13.2%)	60+	29.8%	
<b>Race</b>				
White	182 (85.9)	-	76.5%	[35]
Native Hawaiian or Other Pacific Islander	2 (0.9%)	-	0.2%	
Black or African American	13 (6.1%)	-	13.4%	
Asian	6 (2.8%)	-	5.9%	
Two or more races	6 (2.8%)	-	2.7%	
Other	3 (1.4%)	-	-	
<i>White non-Hispanic</i>	<i>174 (82.1%)</i>	-	60.4%	
<i>Hispanic or Latino</i>	<i>17 (8.0%)</i>	-	18.3%	
<b>Smartphone</b>				
None	15 (7.1%)	-	19.0%	[34]
Yes	197 (92.9%)	-	81.0%	
<i>Android</i>	<i>103</i>	-	51.1%	

iOS	(52.2%) 93 (47.2%)	-	48.1%
Other	1 (0.5%)	-	0.8%
<b>Income Level</b>			
< \$20,000	24 (11.3%)	< \$25,000	19.1%
\$20,000 - \$29,999	20 (9.4%)	\$25,000 - \$35,000	8.8%
\$30,000 - \$39,999	23 (10.9%)	\$35,000 - \$50,000	12.0%
\$40,000 - \$49,999	17 (8.0%)	\$50,000-\$75,000	17.2% [35]
\$50,000 - \$59,999	29 (13.7%)	> \$75,000	42.9%
> \$60,000	92 (43.4%)	Did not Answer	-
Did not answer	7 (3.3%)		
<b>Educational Level</b>			
-	-	None	1.4%
Less than Highschool	2 (0.9%)	-	4.2%
Highschool	36 (17.0%)	-	34.9%
Some College, No Degree	43 (20.3%)	-	21.0% [36]
Bachelor's	61 (28.8%)	-	18.8%
Associate Degree or Trade School	20 (9.4%)	-	8.2%
Graduate or Professional	50 (23.6%)	-	11.5%
<b>Years living with Diabetes</b>			
≤1	69 (32.5%)		
>1 & ≤ 10	46 (21.7%)		Data not available
>10 & ≤ 25	39 (18.4%)		
>25	58 (27.4%)		
<b>Daily Blood Sugar Measurements</b>			
0	12 (5.9%)		
1-3	85 (41.7%)		Data not available
4-10	107 (52.5%)		

Android users constituted (103, 52.3%) of smartphone users, and iOS users constituted (93, 47.2%), while 15 participants (7.1%) indicated that they do not own a smartphone. Participants were also asked how many years they have lived with diabetes. More participants were recently affected (≤1 year; 69, 32.5%) or have lived with diabetes for more than 25 years (58, 27.4%), compared to >1 but ≤10 years (46, 21.7%), and >10 but ≤25 years (39, 18.4%). Participants were also asked to provide their overall level of physical activity as highly active, active, insufficiently active, or inactive per the guidelines specified by the Office of Disease Prevention and Health Promotion (ODPHP) [32]. The ODPHP definitions were provided as reference. 50 out of 212 participants reported to be inactive (23.58%), and 74 reported being insufficiently active (34.9%); 65 participants claimed to be active (30.66%), and only 23 (10.85%) claimed to be highly active. When participants were asked how often they measure their blood glucose level, they reported an average of 3.51 times per day (Range = 0-10; SD = 2.18) with around 97 participants (47.5%) performing the measurements less than the required minimum of 4 times a day [38].

## Perception of Hypoglycemic Symptoms

As shown in Table 2, none of the symptoms were rated very severe or very frequent on average. However, three symptoms were reported to be severe (i.e., had an average rating above 5). These were sweating, tingly feeling, and change in body temperature. Similarly, four symptoms were reported as frequent (sweating; tingly feeling; change in body temperature; and headaches). Severity and frequency were found to be positively correlated using the spearman correlation ( $\rho > 0.8$ ,  $P < .001$ ) for all symptoms listed.

Table 2 – Average reported rating of severity and frequency of occurrence for different hypoglycemic symptoms

Symptom	Frequency <sup>a</sup>	Severity <sup>b</sup>	Spearman correlation
---------	------------------------	-----------------------	----------------------

	Mean	SD	Median	Mean	SD	Median	$\rho$
Nausea	4.15	2.75	4	4.08	2.8	4	0.88
Change in saliva	4.46	2.88	5	4.29	2.88	4	0.90
Tremor	4.83	2.77	5	4.59	2.71	4	0.84
Headache	5.36	2.92	6	4.95	2.97	5	0.85
Change in body temperature	5.59	2.87	6	5.24	2.89	5	0.86
Tingly feeling in limbs	5.76	2.82	6	5.26	2.74	5	0.82
Sweating	5.95	2.78	6	5.75	2.81	6	0.84

<sup>a</sup> (1= extremely rare, 5= neither rare nor frequent, 10= extremely frequent)  
<sup>b</sup> (1= extremely mild, 5= neither mild nor severe, 10= extremely severe)

While tremors were generally reported to have medium severity and frequency, when participants were asked how often they encounter hypoglycemic tremors, 110 participants (51.9%) reported having hypoglycemic tremor at least once a week (Table 3).

Table 3 - Reported frequency of occurrence of tremors

Tremor occurrence	Count	Percentage
Never	11	5.2
Rarely	48	22.6
Once a month	43	20.3
Once a week	36	17
Once every few days	39	18.4
Once a day	24	11.3
More than once a day	11	5.2

To compare the effect of hypoglycemia awareness on perception of symptoms, the question on tremor noticeability was used to split participants into two groups. If tremors were rated as less noticeable ( $\leq 5$ ), participants were categorized as hypoglycemia impaired, otherwise they were categorized as hypoglycemia aware. A Mann-Whitney test showed that all symptoms were rated significantly higher in terms of frequency and severity for the aware group (Table 4).

Table 4 - Symptom Frequency and Severity Across Hypoglycemia Impaired / Aware Groups

Symptom	Symptom Frequency <sup>a</sup>			Symptom Severity <sup>b</sup>		
	Impaired M (SD)	Aware M (SD)	Significance <sup>c</sup>	Impaired M (SD)	Aware M (SD)	Significance <sup>c</sup>
Nausea	3.08 (2.09)	5.29 (2.93)	$P < 0.001$	2.87 (1.94)	5.38 (3.01)	$P < 0.001$
Tremor	3.19 (1.97)	6.59 (2.40)	$P < 0.001$	2.97 (1.84)	6.33 (2.4)	$P < 0.001$
Headache	4.49 (2.72)	6.30 (2.84)	$P < 0.001$	3.99 (2.67)	5.99 (2.93)	$P < 0.001$
Change in Saliva	3.12 (2.23)	5.9 (2.82)	$P < 0.001$	2.92 (2.24)	5.76 (2.76)	$P < 0.001$
Sweating	4.87 (2.67)	7.11 (2.41)	$P < 0.001$	4.46 (2.51)	7.14 (2.44)	$P < 0.001$
Change in Body Temp	4.3 (2.52)	7.0 (2.55)	$P < 0.001$	3.86 (2.43)	6.73 (2.59)	$P < 0.001$
Tingly Feeling in Limbs	4.61 (2.78)	7.01 (2.28)	$P < 0.001$	4.04 (2.46)	6.57 (2.41)	$P < 0.001$

<sup>b</sup> (1= extremely rare, 5= neither rare nor frequent, 10= extremely frequent)

<sup>b</sup> (1= extremely mild, 5= neither mild nor severe, 10= extremely severe)

<sup>c</sup> Mann-Whitney Test results

A separate analysis of variance for tremor noticeability, frequency, and severity was performed to compare differences across gender, age, years with diabetes, and physical activity. A Shapiro-Wilk test confirmed that the data did not adhere to the condition of normality ( $P < .001$ ) possibly because the responses were performed on a 10-point Likert scale.

### Effects of Gender:

First, the noticeability of tremors (DV) was assessed across the two genders. A Mann-Whitney test revealed a significant difference ( $U = 3887, P < .001$ ) whereby males reported noticing their tremors significantly more than females. In terms of frequency of occurrence, tremors were reported to be higher for males compared to females. Males tended to report more tremors “Once a Day” while females reported more “Once a Month” (Figure 1). However this difference was not statistically significant ( $U = 4661, P = .11$ ). As for the reported severity, it was in fact significantly different ( $U = 4428, P = .03$ ) between females and males (Table 5).

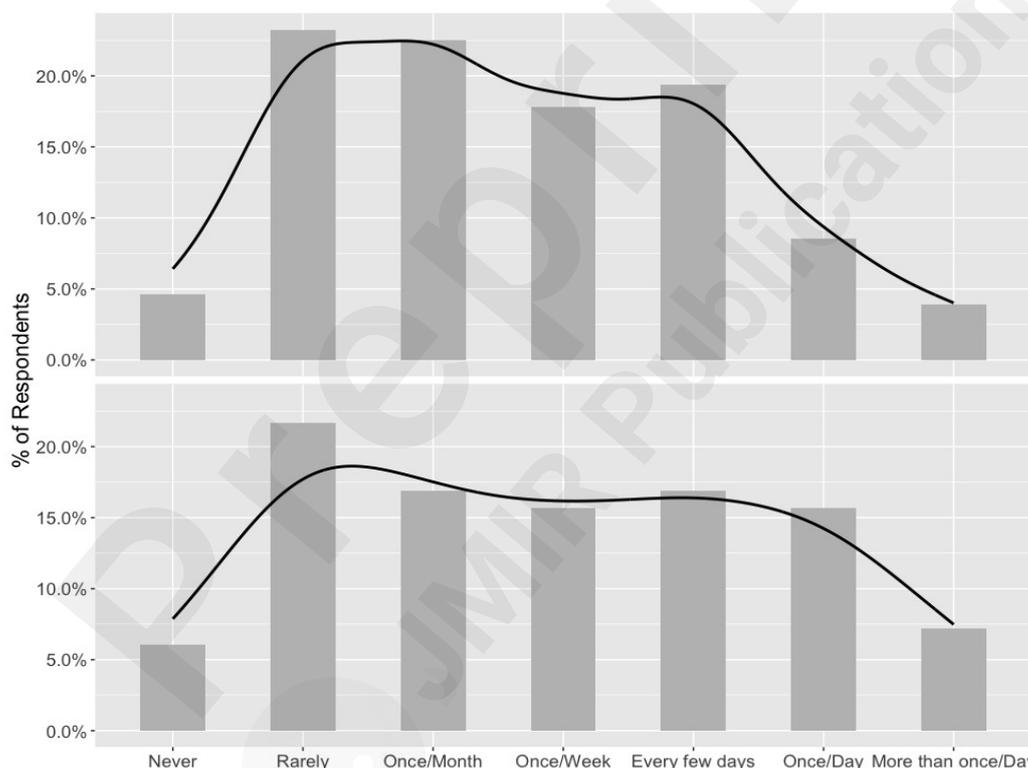


Figure 1- Frequency of Hypoglycemic Tremors across Gender (top: females, bottom: males)

Table 5 - Effect of gender on tremor noticeability, frequency, and severity

	Gender	N	Median	Mean	SD	Significance
Noticeability <sup>a</sup>	F	129	5	4.94	2.55	P < .001
	M	83	7	6.23	2.69	
Frequency <sup>b</sup>	F	129	4	4.57	2.63	P = .11
	M	83	5	5.24	2.95	
Severity <sup>c</sup>	F	129	4	4.26	2.61	P = .033
	M	83	5	5.10	2.80	

<sup>a</sup>(1= extremely non-noticeable, 5= neither non-noticeable nor noticeable,10= extremely noticeable)

<sup>b</sup>(1= extremely rare, 5= neither rare nor frequent, 10= extremely frequent)

<sup>c</sup> (1= extremely mild, 5= neither mild nor severe, 10= extremely severe)

### Effects of Age:

The age groups listed in the demographics were split into three groups. Participants were defined as young if their age was between 18-30 years, of middle age if they responded as 31-60 years or elderly if they responded with 60+ years. The Kruskal-Wallis test showed a significant difference between the three groups ( $H(2) = 14.56, P < .001$ ). The older group reported significantly lower noticeability rating compared to both the younger group ( $MD = 1.82, SE = 0.617, P = .01$ ) and middle age group ( $MD = 2.166, SE = 0.57, P < .001$ ). No difference was found between the younger group and the middle age group ( $P = .66$ ).

Differences in the perceived frequency of hypoglycemic tremor were assessed across the three age groups. The Kruskal-Wallis test showed no significant difference ( $H(2) = 4.2, P = .12$ ) between the younger group, middle age group, and older group. However, the older group reported a lower perceived frequency compared to the other two groups as seen in Figure 2. In particular, the older group did not report any daily tremors, rather they had higher responses for “Once a Month” and “Never” compared to the other age groups. A similar analysis was performed for the perceived severity of tremors for the three age groups. No significant difference was found ( $H(2) = 5.371, p=.068$ ) between the younger group middle group, and the older group even though the older population tended to perceive the severity of their tremors to be low compared to medium for middle age and young respondents. See **Table 6** for a summary of these differences.

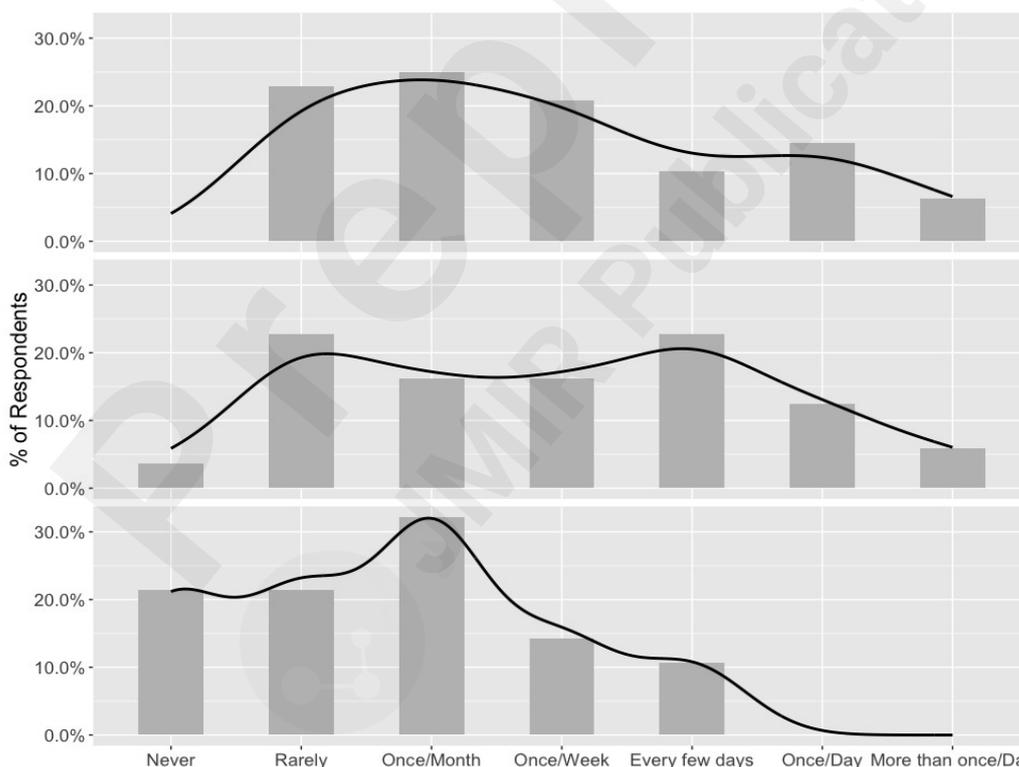


Figure 2- Frequency of Hypoglycemic Tremors across Age Groups (top: youngest group (18-30); middle: 30-60; bottom: oldest group (60+))

Table 6 - Effect of age on tremor on tremor noticeability, frequency, and severity

	Age Groups	N	Mean	Median	SD	Significance
Noticeability <sup>a</sup>	18-30	48	5.46	5	2.32	$P < .001$
	31-60	136	5.81	6	2.64	

	60+	28	3.64	2.5	2.74	
<b>Frequency<sup>b</sup></b>	18-30	48	4.58	4.5	2.583	<i>P</i> = .12
	31-60	136	5.09	5	2.82	
	60+	28	3.96	3	2.76	
<b>Severity<sup>c</sup></b>	18-30	48	4.56	4	2.74	<i>P</i> = .068
	31-60	136	4.82	5	2.71	
	60+	28	3.54	3	2.5	

<sup>a</sup>(1= extremely non-noticeable, 5= neither non-noticeable nor noticeable,10= extremely noticeable)

<sup>b</sup>(1= extremely rare, 5= neither rare nor frequent, 10= extremely frequent)

<sup>c</sup>(1= extremely mild, 5= neither mild nor severe, 10= extremely severe)

### Effects of Years with Diabetes:

A significant difference ( $H(3) = 6.322, P = .01$ ) between groups was found in regards to the noticeability of hypoglycemia tremors. Those who were more recently diagnosed with diabetes ( $\leq 1$  Yr), reported significantly more noticeable tremors ( $MD = 1.253, SE = 0.479, P = .049$ ) compared to those who have been living with diabetes for more than 25 years (Figure 3).

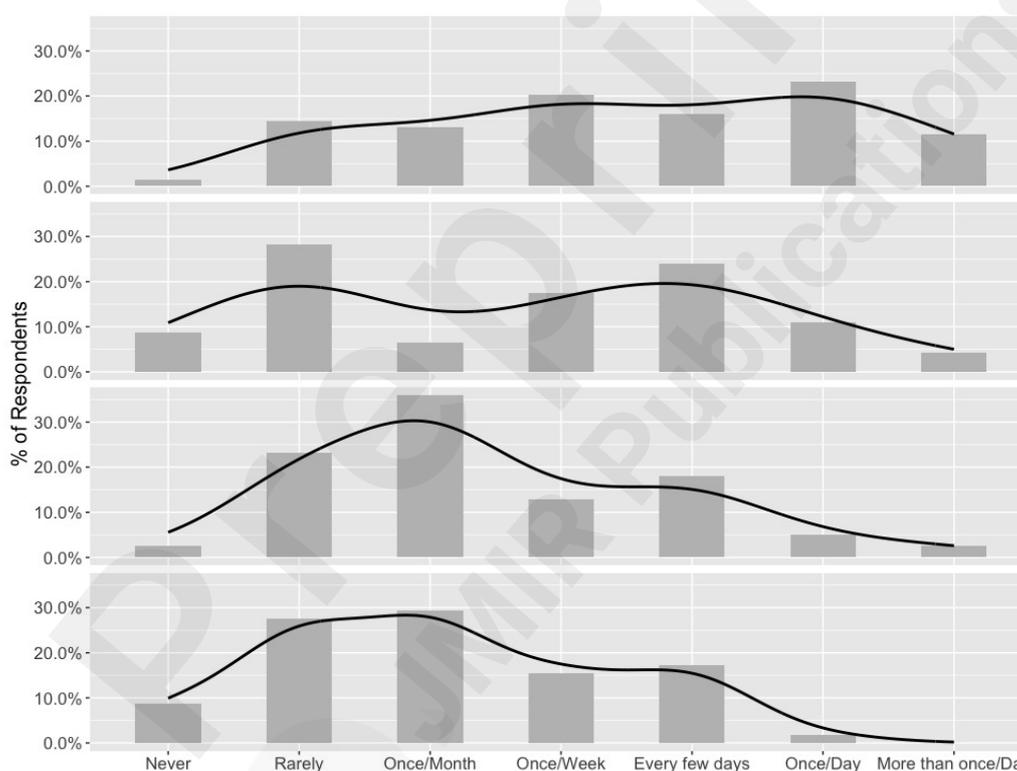


Figure 3- Frequency of Hypoglycemic Tremors across years with diabetes groups (top: most recently diagnosed, bottom: longest diagnosed)

The effect of years living with diabetes was also analyzed over the frequency of hypoglycemic events but no significant difference was found ( $H(3) = 5.85, P = .12$ ). Similarly, there was no significant difference with regard to the severity of these tremors ( $H(3) = 7.16, P = .07$ ) (Table 7).

Table 7 - Effect of years living with diabetes on tremor on tremor noticeability, frequency, and severity

	Years with Diabetes	N	Mean	SD	Median	Significance
<b>Noticeability<sup>a</sup></b>	$\leq 1$	69	6.03	2.46	6	<i>P</i> = .01
	$>1 \ \& \ \leq 10$	46	5.44	2.61	6	
	$>10 \ \& \ \leq 25$	39	5.41	2.67	5	
	$> 25$	58	4.78	2.87	5	
<b>Frequency<sup>b</sup></b>	$\leq 1$	69	5.44	2.89	5	<i>P</i> = .12
	$>1 \ \& \ \leq 10$	46	4.67	2.65	5	

	>10 & ≤25	39	4.87	2.76	5	
	> 25	58	4.21	2.65	4	
<b>Severity<sup>c</sup></b>	≤1	69	5.20	2.79	5	<i>P</i> = .07
	>1 & ≤10	46	4.59	2.74	5	
	>10 & ≤25	39	4.51	2.50	4	
	> 25	58	3.91	2.62	3	

<sup>a</sup>(1= extremely non-noticeable, 5= neither non-noticeable nor noticeable,10= extremely noticeable)  
<sup>b</sup>1= extremely rare, 5= neither rare nor frequent, 10= extremely frequent)  
<sup>c</sup>(1= extremely mild, 5= neither mild nor severe, 10= extremely severe)

### Effects of Physical Activity:

The effect of physical activity levels was assessed in regard to noticeability, frequency, and severity of hypoglycemic tremors as summarized in Table 8. For noticeability of hypoglycemic tremors no significant difference was found between the groups ( $H(3) = 3.98$ ,  $P = .26$ ). Similarly, there was no significant effect of activity level on the perceived frequency of hypoglycemic tremors ( $H(3) = 4.88$ ,  $P = .18$ ) or their perceived severity ( $H(3) = 6.39$ ,  $P = .09$ ).

Table 8 - Effect of the level of physical activity on tremor noticeability, frequency, and severity

	Level of Physical Activity	N	Mean	SD	Media n	Significance
<b>Noticeability<sup>a</sup></b>	Highly Active	23	6.48	2.94	7	<i>P</i> = .26
	Active	65	5.17	2.52	5	
	Insufficiently Active	74	5.42	2.40	5.5	
	Inactive	50	5.36	3.06	5	
<b>Frequency<sup>b</sup></b>	Highly Active	23	5.78	3.06	6	<i>P</i> = .18
	Active	65	4.79	2.70	4	
	Insufficiently Active	74	4.34	2.50	5	
	Inactive	50	5.18	3.04	5	
<b>Severity<sup>c</sup></b>	Highly Active	23	5.65	3.01	5	<i>P</i> = .09
	Active	65	4.75	2.78	5	
	Insufficiently Active	74	4.00	2.40	4	
	Inactive	50	4.76	2.79	4.5	

<sup>a</sup>(1= extremely non-noticeable, 5= neither non-noticeable nor noticeable,10= extremely noticeable)

<sup>b</sup>1= extremely rare, 5= neither rare nor frequent, 10= extremely frequent)

<sup>c</sup>(1= extremely mild, 5= neither mild nor severe, 10= extremely severe)

### Technology Preferences:

When participants were asked if they have used any technology to manage their diabetes, the majority ( $N = 150$ , 70.75%) reported that they currently use or have used at least one in the past. Among them, 107 (71.33%) have used a blood glucose meter, 57 (38%) have used a smartphone app, 41 (27.33%) have used a CGM, and 49 (32.67%) have used an insulin pump to help them with diabetes self-management. Additionally, around 79 of technology users (52.7%) claimed that they use some combination of these technologies. When asked what device brands they used, the most frequent responses as listed in Table 9 were: *Medtronic*, *One Touch*, *Dexcom*, *Freestyle Libre*, *Accu-Check*, *Bayer Contour Omnipod*, and *Reli-On*.

Table 9 – Device brands reported

Brand	Count	%
<b>Medtronic</b>	25	16.6
<b>One Touch</b>	24	15.9
<b>Dexcom</b>	17	11.3
<b>Freestyle libre</b>	10	6.6

<b>Accu-Chek</b>	7	4.6
<b>Bayer Contour</b>	7	4.6
<b>OmniPod</b>	7	4.6
<b>Rel-ion</b>	4	2.6
<b>True Metrix</b>	3	2.0
<b>Other brands</b>	9	6.0
<b>Don't know/Unidentified</b>	31	20.5

Participants were also asked to rate the important features in an ideal smartphone application that would help them in managing hypoglycemia as commonly found in diabetes management apps [39]. While overall all features received favorable ratings, continuous glucose monitor, insulin log, and graphical display of data received the highest ratings (Table 10).

Table 10 - Rating of features for a smartphone app to manage diabetes

Smartphone app Features	Mean <sup>a</sup>	SD	Median
<b>Glucose monitor</b>	7.11	2.74	8
<b>Insulin log</b>	6.59	2.8	7
<b>Graphical display of diabetes data</b>	6.55	2.85	7
<b>Log for abnormal sugar levels</b>	6.54	2.9	7
<b>Food log</b>	6.34	2.98	7
<b>Medication log</b>	6.16	3.01	7
<b>Reminders</b>	6.14	3.06	7
<b>Educational content</b>	5.59	2.84	6

<sup>a</sup>(1= not important, 5= Neutral, 10= very important)

When asked about the characteristics of a diabetes management tool reported in the literature [40,41], high accuracy of readings, low cost, low maintenance, and 24-hour monitoring received very high ratings (Table 11). Other characteristics such as no effects on daily habits, high privacy and security, customizability, and non-invasiveness also received favorable ratings. When asked for their preferred time of the day to measure blood glucose, morning was most preferred, (187, 88.2%), followed by evening (125, 58.9%), night (118, 55.6%), afternoon (114, 53.8%), and around noon (98, 46.2%).

Table 11 -Rating of characteristics for a device to manage diabetes

Device Characteristics	Mean <sup>a</sup>	SD	Median
<b>High accuracy of reading</b>	8.49	1.88	9
<b>Low Cost</b>	8.21	2.27	9
<b>Low maintenance</b>	8.06	2.18	9
<b>24-hour monitoring</b>	8.02	2.28	9
<b>Doesn't affect daily habits</b>	7.97	2.16	8
<b>High privacy and security</b>	7.85	2.28	8
<b>Customizability</b>	7.59	2.36	8
<b>Not invasive</b>	7.54	2.57	8
<b>Sending health data to caregiver</b>	6.92	2.62	7

<sup>a</sup>(1= not important, 5= Neutral, 10= very important)

A modified Comfort Rating Scale (CRS) [42] was used to evaluate the characteristics of a wearable wrist-worn sensor for hypoglycemia management. While all constructs related to CRS were rated

highly, size, and minimized risk for harm received very high ratings followed by emotions felt by the user, social discreteness, and aesthetics (Table 12).

Table 12 - Rating of items from the comfort rating scale

<b>Wearability Characteristic</b>	<b>Mean<sup>a</sup></b>	<b>SD</b>	<b>Median</b>
<b>Aesthetics</b> (I care about how the device looks)	6.59	2.85	7
<b>Social Discreteness</b> (I don't want to feel that people look at my wrist and ask about my device)	6.65	3.01	7
<b>Emotions</b> (I don't want to feel anxious wearing it)	6.76	2.95	7.5
<b>Harm</b> (I don't want this device to cause harm to me)	7.71	2.67	9
<b>Size</b> (I want the device to not be bulky)	7.77	2.34	8

<sup>a</sup>(1= not important, 5= Neutral, 10= very important)

## Discussion and Conclusion

A nationwide survey of 212 Type 1 diabetes patients was conducted to investigate noticeability of hypoglycemic tremor as well as perceived frequency and severity of such tremors among patients. Our findings suggest that while tremors are perceived to be less noticeable, frequent, or severe compared to other hypoglycemia symptoms such as sweating, changes in body temperature, and headache, in line with the literature [19, 21], such hypoglycemic tremors do occur in moderate frequency and are being noticed by most patients. Indeed, our study shows that more than 50% of the respondents encountered hypoglycemic events at least once a week. This is in line with the established evidence suggesting the rate of 1-2 mild episodes/week among diabetics [43,44]. Given such prevalence, there is a timely need for detection and mitigation of mild hypoglycemia before becoming severe [45,46]. However, according to these results, if tremors are tested and found to be a viable predictor of hypoglycemic onset in future work, tremors should be assessed in conjunction with other symptoms (similar to [47]). In past research, relying solely on body temperature and skin conductance was shown to cause high false alarms which resulted in the devices to be withdrawn from the market [48,49].

In addition to these aggregate trends, our findings show gender- and age-specific differences. While evidence suggests similar occurrence rates of severe hypoglycemia among males and females [50], our findings suggest that, males perceive their hypoglycemic tremors more than females. These results are in line with previous findings which suggest that men were found to have a higher level of adrenaline [51] which is believed to trigger hypoglycemic tremors [52]. In addition, the younger population reported noticing their tremors significantly more than the older population. Similarly, those who have had diabetes for a year or less, reported noticing their tremors significantly more than those who have had diabetes for a longer period. This is in line with previous findings that suggests radical reduction in the incidence of hypoglycemic symptoms in elderly subjects compared to the younger population [53]. Such evidence posits that recurrent hypoglycemia delays the onset of symptoms to lower levels of blood sugar [54] and corroborate the previous evidence that patients with a longer history of diabetes may lose sensitivity to hypoglycemia symptoms or perceive such symptoms less [7,8]. These findings further highlight the importance of objective methods for continuous measurement and monitoring of hypoglycemic symptoms for the older population. Participants with higher levels of physical activity also noticed their tremor symptoms more, which may suggest being prone to declining blood sugar levels during and after exercise [55].

While diabetes self-management technologies are gaining popularity, findings from our nationwide survey shows that nearly one third of our sample have not used any technologies to monitor or manage their blood sugar, which suggests low adherence to the basic American Diabetes Association

guidelines for the self-management of diabetes [56]. For those who reported using technology, technology adoption was limited to either a Blood Glucose Monitor (BGM) or Continuous Glucose Monitor (CGM), suggesting the low prevalence of non-intrusive methods for measurement of BG.

As a preliminary step to design a non-intrusive hypoglycemic tremor monitoring tool, we used a patient-centered approach to elicit and document intended users' preferences and expectations for various features, characteristics, and context of use. It is well understood that incorporating such feedback into the design of patient-facing tools facilitates adoption and increases the odds of sustainable usage [57]. For example, while CGM technologies have proven to be reliable [58], these technologies are not affordable, are invasive, and require frequent maintenance [12,59]. These limitations may explain our survey results where more than 66% reported not using CGMs. Also, as evident from our results, for a sensor to be deemed as "wearable" by patients, it should be comfortable, streamlined in appearance, accurate, affordable, and low-maintenance. In addition, any smartphone application that connects to the device must provide a graphical display of the patient's BG data as well as a log for insulin. Finally, when participants were asked when they preferred to measure their BG, the most common answers were in the morning and evening, which may suggest expectations for minimal interruptions to professional work. Participants also claimed that they measure their blood sugar around 4 times per day, which is the minimum requirement for T1DM as per several guidelines [38,60]. While reported number of measurements ranged from 0 to 10, alarmingly, around half of the respondents claimed that they do not check their blood sugar as advised. This bolsters the argument in support of continuous monitoring technologies [61,62], since reliance on users' memory to sustain usage has proven to be challenging not just for diabetes but also other chronic diseases [63,64].

While the study shed light on the nature of perceived hypoglycemic tremor among Type 1 diabetics and provided information that may guide the design of future tremor-centric interventions, it had some limitations. First, the study only included patients with T1DM and results may not generalize to T2DM patients, especially since hypoglycemia is less common among those patients [65]. In addition, participants were self-identified as T1DM with no objective evidence confirming their condition. Second, the data collected in this study was self-reported. Future work is needed to validate the findings in controlled lab environments. Third, since our data was based on Likert-scale questions, the analysis was performed through non-parametric tests. However, we believe our large sample size adds to the robustness of the inference [31]. Finally, a convenience sample was provided utilizing Qualtrics panels. Ideally, a stratified nation-wide sample should be used to improve the generalizability of findings.

Regardless of differences observed in the population studied, this study establishes the potential efficacy of tremor for a subset of the population as a reliable yet non-intrusive metric for hypoglycemia monitoring technologies and confirms previously reported conclusions [27,47]. The evidence presented in this paper also supports the need for wearable continuous monitoring tools beyond CGMs that are affordable, non-intrusive, and are easy to use. Work is in progress to design and evaluate a hypoglycemia monitoring technology that utilizes sensors to detect hypoglycemic tremor and mobile health applications to enable self-management.

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## Conflicts of Interest

None declared.

## References

1. Diabetes.co.uk. How Many People Have Diabetes - Diabetes Prevalence Numbers [Internet]. 2015 [cited 2019 Oct 15]. Available from: <https://www.diabetes.co.uk/diabetes-prevalence.html>
2. American Diabetes Association, Arlington S 900, Va 22202 1-800-Diabetes. The Cost of Diabetes [Internet]. Am Diabetes Assoc. [cited 2019 Jul 21]. Available from: <http://www.diabetes.org/advocacy/news-events/cost-of-diabetes.html>
3. Stokes A, Preston SH. Deaths Attributable to Diabetes in the United States: Comparison of Data Sources and Estimation Approaches. PLOS ONE 2017;12(1):e0170219. [doi: 10.1371/journal.pone.0170219]
4. American Diabetes Association, Arlington S 900, Va 22202 1-800-Diabetes. Hypoglycemia (Low Blood Glucose) [Internet]. Am Diabetes Assoc. [cited 2019 Jul 25]. Available from: <http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/hypoglycemia-low-blood.html>
5. Heller SR. Glucose Concentrations of Less Than 3.0 mmol/L (54 mg/dL) Should Be Reported in Clinical Trials: A Joint Position Statement of the American Diabetes Association and the European Association for the Study of Diabetes | Diabetes Care [Internet]. 2017 [cited 2019 Oct 15]. Available from: <https://care.diabetesjournals.org/content/40/1/155>
6. Gold AE, Macleod KM, Frier BM. Frequency of Severe Hypoglycemia in Patients With Type I Diabetes With Impaired Awareness of Hypoglycemia. Diabetes Care 1994 Jul 1;17(7):697–703. PMID:7924780
7. Skriverhaug T, Bangstad H-J, Stene LC, Sandvik L, Hanssen KF, Joner G. Long-term mortality in a nationwide cohort of childhood-onset type 1 diabetic patients in Norway. Diabetologia 2006 Feb;49(2):298–305. PMID:16365724
8. Kendall DM, Rooney DP, Smets YFC, Bolding LS, Robertson RP. Pancreas Transplantation Restores Epinephrine Response and Symptom Recognition During Hypoglycemia in Patients With Long-Standing Type I Diabetes and Autonomic Neuropathy. Diabetes 1997;46(2):249–257. PMID:9000702
9. McCoy RG, Van Houten HK, Ziegenfuss JY, Shah ND, Wermers RA, Smith SA. Increased Mortality of Patients With Diabetes Reporting Severe Hypoglycemia. Diabetes Care 2012 Sep 1;35(9):1897–1901. [doi: 10.2337/dc11-2054]
10. Campbell I. Dead in Bed Syndrome: a New Manifestation of Nocturnal Hypoglycaemia? Diabet Med 1991;8(1):3–4. [doi: 10.1111/j.1464-5491.1991.tb01507.x]

11. Gross TM, Bode BW, Einhorn D, Kayne DM, Reed JH, White NH, Mastrototaro JJ. Performance evaluation of the MiniMed continuous glucose monitoring system during patient home use. *Diabetes Technol Ther* 2000;2(1):49–56. PMID:11467320
12. Facchinetti A. Continuous Glucose Monitoring Sensors: Past, Present and Future Algorithmic Challenges. *Sensors* 2016 Dec 9;16(12):2093. [doi: 10.3390/s16122093]
13. Weitzman ER, Kelemen S, Quinn M, Eggleston EM, Mandl KD. Participatory Surveillance of Hypoglycemia and Harms in an Online Social Network. *JAMA Intern Med* 2013;173(5):345. [doi: 10.1001/jamainternmed.2013.2512]
14. Polonsky WH, Hessler D. What Are the Quality of Life-Related Benefits and Losses Associated with Real-Time Continuous Glucose Monitoring? A Survey of Current Users. *Diabetes Technol Ther* 2013 Apr;15(4):295–301. [doi: 10.1089/dia.2012.0298]
15. García-Lorenzo B, Rivero-Santana A, Vallejo-Torres L, Castilla-Rodríguez I, García-Pérez S, García-Pérez L, Perestelo-Pérez L. Cost-effectiveness analysis of real-time continuous monitoring glucose compared to self-monitoring of blood glucose for diabetes mellitus in Spain. *J Eval Clin Pract* 2018;24(4):772–781. PMID:29971893
16. Wan W, Skandari MR, Minc A, Nathan AG, Winn A, Zarei P, O’Grady M, Huang ES. Cost-effectiveness of Continuous Glucose Monitoring for Adults With Type 1 Diabetes Compared With Self-Monitoring of Blood Glucose: The DIAMOND Randomized Trial. *Diabetes Care* 2018;41(6):1227–1234. PMID:29650803
17. Rural Health Information Hub. Chronic Disease in Rural America [Internet]. 2017 [cited 2019 Jun 10]. Available from: <https://www.ruralhealthinfo.org/topics/chronic-disease>
18. Douthit N, Kiv S, Dwolatzky T, Biswas S. Exposing some important barriers to health care access in the rural USA. *Public Health* 2015;129(6):611–620. PMID:26025176
19. Zahed K, Sasangohar F, Mehta R, Erraguntla M, Lawley M, Qaraq K. Investigating the Efficacy of Using Hand Tremors for Early Detection of Hypoglycemic Events: A Scoping Literature Review. *Proc Hum Factors Ergon Soc Annu Meet* 2018 Sep;62(1):1211–1215. [doi: 10.1177/1541931218621278]
20. Ferrante do Amaral CE, Wolf B. Current development in non-invasive glucose monitoring. *Med Eng Phys* 2008;30(5):541–549. [doi: 10.1016/j.medengphy.2007.06.003]
21. Jaap AJ, Jones GC, McCrimmon RJ, Deary IJ, Frier BM. Perceived symptoms of hypoglycaemia in elderly type 2 diabetic patients treated with insulin. *Diabet Med* 1998 May;15(5):398–401. PMID:9609362
22. Mühlhauser I, Heinemann L, Fritsche E, Lennep K von, Berger M. Hypoglycemic Symptoms and Frequency of Severe Hypoglycemia in Patients Treated With Human and Animal Insulin Preparations. *Diabetes Care* 1991 Aug 1;14(8):745–749. PMID:1954812
23. Berlin I, Sachon CI, Grimaldi A. Identification of factors associated with impaired hypoglycaemia awareness in patients with type 1 and type 2 diabetes mellitus. *Diabetes Metab* 2005 Jun;246–251. PMID:16142015

24. Chiarelli F, Verrotti A, di Ricco L, Altobelli E, Morgese G. Hypoglycaemic symptoms described by diabetic children and their parents. *Acta Diabetol* 1998;35(2):81–84. [doi: 10.1007/s005920050108]
25. Cox DJ, Gonder-Frederick L, Antoun B, Cryer PE, Clarke WL. Perceived Symptoms in the Recognition of Hypoglycemia. *Diabetes Care* 1993;16(2):519–527. PMID:8432227
26. Heller SR, Macdonald IA, Herbert M, Tattersall RB. Influence of sympathetic nervous system on hypoglycaemic warning symptoms. *Lancet Lond Engl* 1987 Aug 15;2(8555):359–363. PMID:2886822
27. George E, Harris N, Bedford C, Macdonald IA, Hardisty CA, Heller SR. Prolonged but partial impairment of the hypoglycaemic physiological response following short-term hypoglycaemia in normal subjects. *Diabetologia* 1995;38(10):1183–1190. [doi: 10.1007/bf00422367]
28. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Ann Intern Med* 2007 Oct 16;147(8):573–577. PMID:17938396
29. Cryer PE. Symptoms of Hypoglycemia, Thresholds for their Occurrence, and Hypoglycemia Unawareness. *Endocrinol Metab Clin North Am* 1999 Sep 1;28(3):495–500. [doi: 10.1016/S0889-8529(05)70084-0]
30. Mayo Clinic. Diabetic hypoglycemia - Symptoms and causes [Internet]. Mayo Clin. 2018 [cited 2019 Nov 13]. Available from: <https://www.mayoclinic.org/diseases-conditions/diabetic-hypoglycemia/symptoms-causes/syc-20371525>
31. Jamieson S. Likert scales: how to (ab)use them. *Med Educ* 2004;38(12):1217–1218. [doi: 10.1111/j.1365-2929.2004.02012.x]
32. Duffin E. US population: Proportion of woman and men [Internet]. Statista. 2017 [cited 2019 Nov 17]. Available from: <https://www.statista.com/statistics/737923/us-population-by-gender/>
33. US Census Bureau. American Community Survey 1-year estimates. Retrieved from Census Reporter Profile page for United States [Internet]. Census Report. 2018 [cited 2019 Nov 17]. Available from: <http://censusreporter.org/profiles/01000us-united-states/>
34. PEW Research Center, Suite 800 Washington, Inquiries D 20036USA202-419-4300 | M-857-8562 | F-419-4372 | M. Demographics of Mobile Device Ownership and Adoption in the United States [Internet]. Pew Res Cent Internet Sci Tech. [cited 2019 Nov 17]. Available from: <https://www.pewresearch.org/internet/fact-sheet/mobile/>
35. Holst A. Mobile OS market share in the U.S. 2019 [Internet]. Statista. 2019 [cited 2019 Nov 17]. Available from: <https://www.statista.com/statistics/266572/market-share-held-by-smartphone-platforms-in-the-united-states/>
36. Statistical Atlas. The Demographic Statistical Atlas of the United States [Internet]. 2018 [cited 2019 Nov 17]. Available from: <https://statisticalatlas.com/United-States/Educational-Attainment>
37. Office of Disease Prevention and Health Promotion. Chapter 4 - 2008 Physical Activity

- Guidelines - health.gov [Internet]. 2008 [cited 2019 Sep 5]. Available from: <https://health.gov/paguidelines/2008/chapter4.aspx>
38. Mayo Clinic. Blood sugar testing: Why, when and how - Mayo Clinic [Internet]. 2018 [cited 2019 Oct 20]. Available from: <https://www.mayoclinic.org/diseases-conditions/diabetes/in-depth/blood-sugar/art-20046628>
  39. Jimenez G, Lum E, Car J. Examining Diabetes Management Apps Recommended From a Google Search: Content Analysis. *JMIR MHealth UHealth* [Internet] 2019;7(1). PMID:30303485
  40. American Diabetes Association. Diabetes Technology: Standards of Medical Care in Diabetes —2019. *Diabetes Care* 2019 Jan 1;42:S71–S80. PMID:30559233
  41. Wahowiak L. Diabetes Devices: Favorite Features [Internet]. *Diabetes Forecast*. 2016 [cited 2019 Nov 15]. Available from: <http://www.diabetesforecast.org/2016/mar-apr/diabetes-devices-favorite-features.html>
  42. Knight JF, Baber C, Schwirtz A, Bristow HW. The comfort assessment of wearable computers. *Proc Sixth Int Symp Wearable Comput* [Internet] Seattle, WA, USA: IEEE; 2002 [cited 2019 Sep 6]. p. 65–72. [doi: 10.1109/ISWC.2002.1167220]
  43. Leese GP, Wang J, Broomhall J, Kelly P, Marsden A, Morrison W, Frier BM, Morris AD. Frequency of Severe Hypoglycemia Requiring Emergency Treatment in Type 1 and Type 2 Diabetes: A population-based study of health service resource use. *Diabetes Care* 2003;26(4):1176–1180. PMID:12663593
  44. Ovalle F, Fanelli CG, Paramore DS, Hershey T, Craft S, Cryer PE. Brief twice-weekly episodes of hypoglycemia reduce detection of clinical hypoglycemia in type 1 diabetes mellitus. *Diabetes* 1998;47(9):1472–1479. PMID:9726237
  45. Cryer PE. Severe Hypoglycemia Predicts Mortality in Diabetes. *Diabetes Care* 2012 Sep 1;35(9):1814–1816. PMID:22923682
  46. MacLeod KM, Hepburn DA, Frier BM. Frequency and morbidity of severe hypoglycaemia in insulin-treated diabetic patients. *Diabet Med J Br Diabet Assoc* 1993 Apr;10(3):238–245. PMID:8485955
  47. Schechter A, Eyal O, Zuckerman-Levin N, Amihai-Ben-Yaacov V, Weintrob N, Shehadeh N. A prototype of a new noninvasive device to detect nocturnal hypoglycemia in adolescents with type 1 diabetes--a pilot study. *Diabetes Technol Ther* 2012 Aug;14(8):683–689. PMID:22690891
  48. Skladnev VN, Ghevondian N, Tarnavskii S, Paramalingam N, Jones TW. Clinical Evaluation of a Noninvasive Alarm System for Nocturnal Hypoglycemia. *J Diabetes Sci Technol* 2010;4(1):67–74. PMID:20167169
  49. Therapeutic Goods Administration. HypoMon sleep-time hypoglycaemic monitor [Internet]. Ther Goods Adm TGA. 2013 [cited 2018 Jan 6]. Available from: <https://www.tga.gov.au/alert/hypomon-sleep-time-hypoglycaemic-monitor>

50. Cryer PE. Are Gender Differences in the Responses to Hypoglycemia Relevant to Iatrogenic Hypoglycemia in Type 1 Diabetes? *J Clin Endocrinol Metab* 2000;85(6):2145–2147. [doi: 10.1210/jcem.85.6.6659]
51. Fanelli C, Pampanelli S, Epifano L, Rambotti AM, Ciofetta M, Modarelli F, Di Vincenzo A, Annibale B, Lepore M, Lalli C. Relative roles of insulin and hypoglycaemia on induction of neuroendocrine responses to, symptoms of, and deterioration of cognitive function in hypoglycaemia in male and female humans. *Diabetologia* 1994 Aug;37(8):797–807. PMID:7988782
52. Cryer PE. Mechanisms of hypoglycemia-associated autonomic failure and its component syndromes in diabetes. *Diabetes*. 2005 Dec 1;54(12):3592-601.
53. McAulay V, Deary IJ, Frier BM. Symptoms of hypoglycaemia in people with diabetes. *Diabet Med* 2001;18(9):690–705. [doi: 10.1046/j.1464-5491.2001.00620.x]
54. Frier BM. Morbidity of hypoglycemia in type 1 diabetes. *Diabetes Res Clin Pract* 2004;65:S47–S52. [doi: 10.1016/j.diabres.2004.07.008]
55. Younk LM, Mikeladze M, Tate D, Davis SN. Exercise-related hypoglycemia in diabetes mellitus. *Expert Rev Endocrinol Metab* 2011;6(1):93–108. PMID:21339838
56. Campbell A. Diabetes Blood Sugar Chart | Blood Glucose Chart [Internet]. *Diabetes Self Manag.* 2019 [cited 2019 Oct 20]. Available from: <https://www.diabetesselfmanagement.com/managing-diabetes/blood-glucose-management/blood-sugar-chart/>
57. Gåfväls C, Lithner F, Börjeson B. Living with Diabetes: Relationship to Gender, Duration and Complications. A Survey in Northern Sweden. *Diabet Med* 1993 Oct 1;10(8):768–773. [doi: 10.1111/j.1464-5491.1993.tb00162.x]
58. Mazze RS, Strock E, Borgman S, Wesley D, Stout P, Racchini J. Evaluating the Accuracy, Reliability, and Clinical Applicability of Continuous Glucose Monitoring (CGM): Is CGM Ready for Real Time? *Diabetes Technol Ther* 2009;11(1):11–18. [doi: 10.1089/dia.2008.0041]
59. Chua B, Desai SP, Tierney MJ, Tamada JA, Jina AN. Effect of microneedles shape on skin penetration and minimally invasive continuous glucose monitoring in vivo. *Sens Actuators Phys* 2013;203:373–381. [doi: 10.1016/j.sna.2013.09.026]
60. WebMD. Home Blood Sugar & Glucose Testing Methods for Diabetes [Internet]. [cited 2019 Oct 20]. Available from: <https://www.webmd.com/diabetes/home-blood-glucose-testing>
61. Juvenile Diabetes Research Foundation Continuous Glucose, Monitoring Study Group. Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes. *N Engl J Med* 2008 Oct 2;359(14):1464–1476. PMID:18779236
62. Klonoff DC. Continuous Glucose Monitoring: Roadmap for 21st century diabetes therapy. *Diabetes Care* 2005 May 1;28(5):1231–1239. PMID:15855600
63. Zogg JB, Woods SP, Saucedo JA, Wiebe JS, Simoni JM. The Role of Prospective Memory in Medication Adherence: A Review of an Emerging Literature. *J Behav Med* 2012 Feb;35(1):47–

62. PMID:21487722
64. Insel KC, Einstein GO, Morrow DG, Hepworth JT. A Multifaceted Prospective Memory Intervention to Improve Medication Adherence: Design of a Randomized Control Trial. *Contemp Clin Trials* 2013 Jan;34(1):45–52. PMID:23010608
65. American Diabetes Association. Insulin Basics | ADA [Internet]. [cited 2019 Oct 20]. Available from: <https://www.diabetes.org/diabetes/medication-management/insulin-other-injectables/insulin-basics>

## Abbreviations

BG — Blood Glucose

BGM — Blood Glucose Monitor

CRS — Comfort Rating Scale

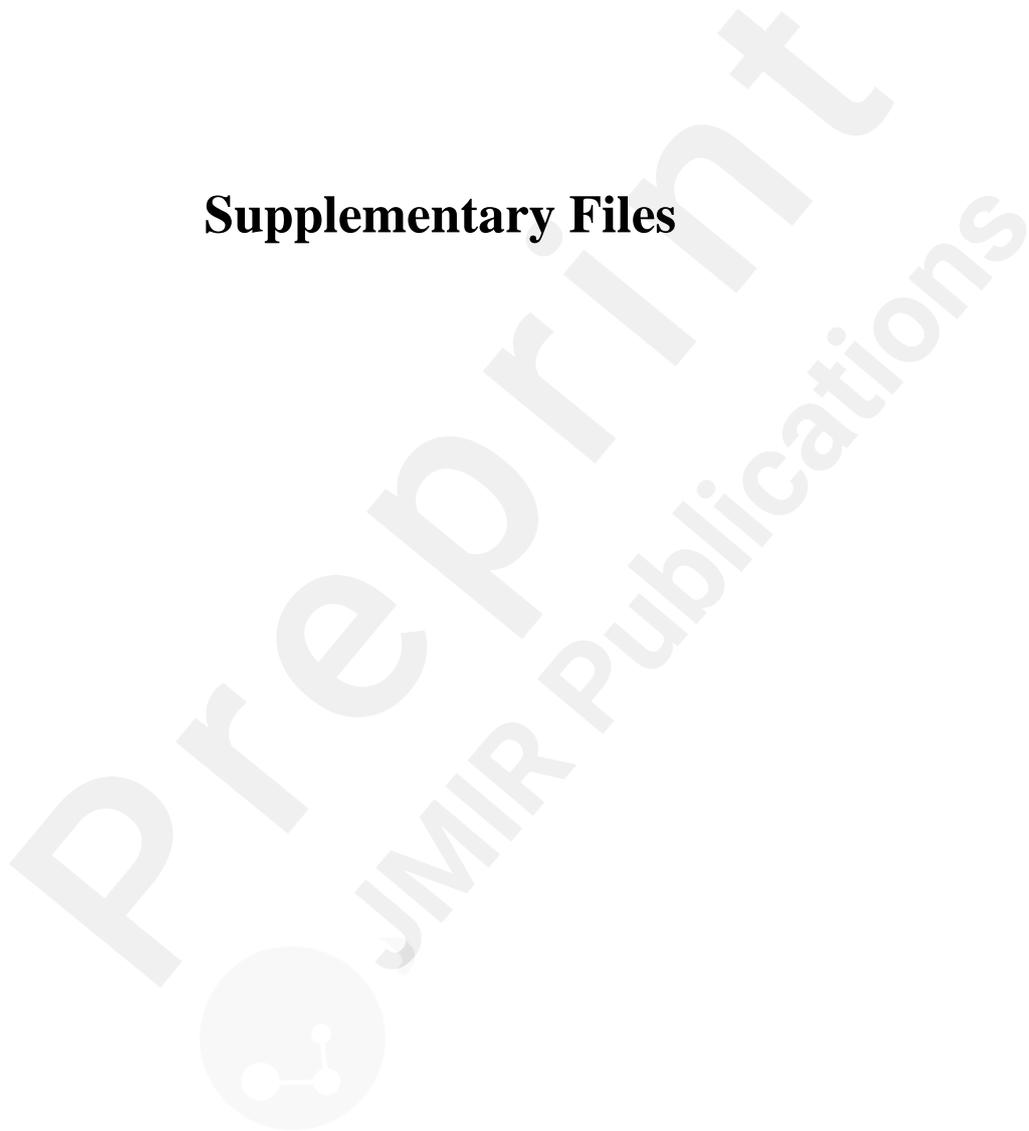
CGM — Continuous Glucose Monitor

DV — Dependent Variable

T1DM — Type 1 Diabetes Mellitus

T2DM — Type 2 Diabetes Mellitus

## Supplementary Files



## Other materials for editor/reviewers onlies

Revision with changes tracked.

URL: <https://asset.jmir.pub/assets/d857fcd641ed01ef2d8d57fac19a4908.docx>