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ORIGINAL ARTICLE

Development of a New Measure for Assessing Glucose Monitoring Device-Related Treatment Satisfaction and Quality of Life

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Abstract

Background: Many different devices are available to patients to measure glucose levels, but there is no validated method to assess treatment satisfaction with glucose monitoring devices and its impact on quality of life and other patient-reported outcomes. To address this problem, we developed the Glucose Monitoring System Satisfaction Survey (GMSS). We describe the construction and validation of the GMSS and examine how key patient factors are associated with glucose device satisfaction.

Materials and Methods: Items were developed from interviews with 15 adults with either type 1 diabetes (T1D) or type 2 diabetes (T2D) and 10 diabetes healthcare professionals, resulting in an initial pool of 42 items. Separate exploratory factor analyses (EFAs) were conducted with adults with T1D ($n = 254$) and with insulin-using T2D ($n = 206$). Construct validity was established with overall well-being (World Health Organization-5), diabetes distress (Diabetes Distress Scale), attitudes toward glucose monitoring (Self-Monitoring of Blood Glucose Obstacles scale), and the previously validated Blood Glucose Monitoring System Rating Questionnaire. Regression analyses examined associations between total scale satisfaction and demographics, diabetes status, and glucose monitor use.

Results: The two EFAs resulted in two 15-item scales, one for T1D and one for T2D, and yielded four coherent and meaningful factors in each sample: three factors with the same items in common for both samples (Emotional Burden, Behavioral Burden, and Openness) and a fourth factor unique to each sample (Trust for T1D, Worthwhileness for T2D). The final EFA accounted for 66.5% of the variance in the T1D sample and 67.0% in the T2D sample. Validity was established by significant correlations with criterion variables.

Conclusions: The GMSS is a reliable, valid measure of glucose device satisfaction in its T1D form and in its insulin-using T2D form. It provides a comprehensive profile of sources of device satisfaction for use in clinical care and research.

Introduction

As the number of new glucose monitoring devices continues to proliferate, many with novel and potentially game-changing features (e.g., innovative connectivity approaches, new ways of summarizing and presenting data, immediate decision support in response to observed glucose values and patterns, and real-time [RT] continuous glucose monitoring [CGM]), it is important to consider how these devices will be accepted or not accepted by patients. Which of these devices will patients perceive as valuable, which will positively affect quality of life (QOL) and/or patients' engagement with their own diabetes management, and which will continue to be used or not used over time? Although these are critical questions, there is currently no validated method to assess treatment satisfaction with glucose monitoring devices or the impact of such devices on QOL or other patient-reported outcomes.

Previous studies have examined broad attitudes toward blood glucose (BG) monitoring, highlighting how patients' confusion and frustration regarding BG data can influence adherence to monitoring recommendations,[1] but there has

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been little research directly examining patient views of the utility, usefulness, and satisfaction with their monitoring devices. For example, to evaluate a novel system integrating an insulin pump and RT continuous glucose monitor, Peyrot and Rubin[2] developed the BG Monitoring System Rating Questionnaire (BGMSRQ), which targeted eight key dimensions: convenience, interference, BG burden, BG control, overall satisfaction, desire to switch BG monitoring systems, willingness to recommend current BG monitoring system, and comparison of current and prior BG monitoring. Researchers for the JDRF CGM Study Group[3] developed the Glucose Monitoring Survey (GMS), a 22-item scale that examined both satisfaction with and the therapeutic impact of patients' current glucose monitoring systems (self-monitoring of BG [SMBG] alone or with CGM). Preliminary analyses revealed two key factors: glucose control (the perceived influence of BG monitoring on glycemic values) and social complications (how monitoring impacts on interpersonal relationships). Finally, Polonsky and Hessler[4] developed the 16-item RT-CGM QOL scale that assesses QOL-related benefits and losses associated with RT-CGM. Factor analysis pointed to three major factors evidencing acceptable internal reliability: perceived control over diabetes, hypoglycemic safety, and interpersonal consequences and support.

Unfortunately, it is unknown whether any of these three scales is applicable across the broad range of glucose monitoring devices or across different diabetes types. It is noteworthy, for example, that each of the three measures focuses exclusively on patients with type 1 diabetes (T1D).

Without the availability of a validated, comprehensive instrument, it is difficult to examine the differential psychological impact and perceived satisfaction across a range of glucose devices and to determine the acceptability of such devices and their features on patients and their self-care. To address these needs, we developed and validated the Glucose Monitoring System Satisfaction Survey (GMSS), which builds on the strengths of previously developed instruments and addresses many of their limitations. This report describes the construction, evaluation, and validation of the GMSS and examines how key patient factors are associated with glucose device satisfaction.

Research Design and Methods

Structured interviews, with content guided by the current literature, were conducted with 15 adults with either T1D or type 2 diabetes (T2D) and with 10 diabetes healthcare professionals (HCPs). Respondents' verbal descriptions of their wide-ranging personal experiences with glucose monitors and the different features of each instrument were documented, focusing on the positive and negative attributes of the devices, how the devices had affected their feelings about diabetes and their ability to manage diabetes, and the impact of the device on their overall health and QOL. Responses were reviewed for duplication and were converted into an initial set of 42 survey items. Patients and HCPs then reviewed the items for completeness and clarity. The draft scale was formatted such that respondents could rate each item on a 5-point scale: 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, and 5 = strongly agree. The 42 items were part of a larger, online assessment battery that included previously validated instruments to be used for documenting the construct validity of the new scale.

Separate samples of T1D adults and insulin-using T2D adults were recruited from the Taking Control of Your Diabetes (TCOYD) Research Registry. This Registry is a Health Insurance Portability and Accountability Act (HIPAA)–protected online platform that includes adults with diabetes, recruited primarily from TCOYD's 1-day diabetes education events conducted in multiple cities across the United States. By joining the Registry, patients agree to be contacted about participating in online survey research. For the current study, participants were required to be ≥ 19 years old, be diagnosed with T1D or T2D and using insulin for ≥ 1 year, and own and use a primary glucose monitor regularly for >3 months (minimum testing at least once weekly). After receiving the initial study announcement via e-mail and successfully completing a brief online eligibility questionnaire, participants completed informed consent and the survey battery online. Participants received a $10 electronic gift card for participation. Questionnaire data were entered into a central database using a HIPAA-protected server. The research protocol was approved by Ethical and Independent Review Services, a community-based, institutional review board.

Measures

In addition to the initial 42-item GMSS, three groups of measures were included to describe the sample and examine correlates of device satisfaction. First, demographic measures included age, gender, ethnicity (white vs. non-white), education (years), type of diabetes, number of years since diagnosis, number of years using insulin, and body mass index (BMI) (calculated from self-reported weight and height). In addition, the Subjective Numeracy Scale[5] was used to assess ability and preference for the presentation of numerical information (eight items) ($\alpha = 0.81$). Second, measures of diabetes status included self-reported glycated hemoglobin (A1C), insulin regimen (continuous subcutaneous insulin infusion vs. injections), use of RT-CGM, number of low blood glucose measurements (<70) in the past week, and number of diabetes complications (from a list of 14). Third, assessments of monitor use focused on frequency of SMBG, how regularly glucose results were reviewed with a clinician (ranging from 1 = never to 5 = at all of our visits), and—in response to high and/or low glucose results—how regularly the patient made dietary, activity, or medication changes or did nothing in response (all four items ranging from 1 = never to 4 = I do this regularly).[6]

The following scales were included to assess the construct validity of the GMSS. The World Health Organization-5 (WHO-5) is a five-item scale that assesses QOL[7] ($\alpha = 0.86$). The Diabetes Distress Scale (DDS) assesses worries and concerns specifically related to diabetes and its management; it has been shown to be a good marker of diabetes-related QOL[8] ($\alpha = 0.93$). T2D participants completed the original, 17-item DDS, whereas T1D subjects completed the new DDS version for T1D, the 28-item DDS-T1[9] ($\alpha = 0.91$). The SMBG Obstacles scale assesses two negative attitudes regarding SMBG: pointlessness ($\alpha = 0.70$) and avoidance ($\alpha = 0.83$).[1] Participants also completed the satisfaction subscale of the previously validated BGMSRQ.[2]

Statistical analysis

Descriptive statistics were computed to review item and scale distributions for each sample. The χ^2 and t tests, as

appropriate, were conducted to test for differences in patient characteristics and outcome variables across the two samples. Separate exploratory factor analyses (EFAs) were conducted with Promax rotation for each sample to determine whether the device satisfaction items could be reduced and grouped into meaningful subscales. Separate EFAs also were conducted to explore whether differences in response patterns might point to the construction of separate instruments for each sample with different subscales. Based on factor analytic results, subscales were created by averaging across items. Internal consistency of the subscales and the total scales was determined by Cronbach's α statistic. Construct validity was examined by Pearson correlations between subscale and total scale scores with QOL, diabetes distress, and glucose monitoring attitudes. Multiple regression analyses examined associations of total device satisfaction with the three groups of variables: demographics, diabetes status, and glucose monitor use.

Results

Of the 471 individuals who completed informed consent and started the survey, 460 (97%) completed the entire survey. A description of the T1D ($n=254$) and T2D ($n=206$) samples is presented in Table 1. As expected, the T1D group was significantly younger, with a lower BMI and with a longer duration of diabetes than the T2D group. The T1D sample included significantly more males, non-Hispanic whites, and insulin pump users than the T2D sample. In addition, T1D subjects reported a significantly lower A1C, higher QOL, and lower levels of SMBG obstacles than T2D subjects.

Table 1. Sample Description by Type of Diabetes

	Type 1 diabetes (n = *254*)	*Type 2 diabetes* (n = *206*)	P *value*
Age (years)	47.4 (14.5)	59.6 (11.0)	<0.001
Gender (female)	132 (52%)	126 (61%)	0.05
Education level	15.1 (3.9)	14.9 (3.6)	0.66
Ethnicity			0.004
Non-Hispanic white	219 (86.2%)	149 (72.3%)	
African American	7 (2.8%)	10 (4.9%)	
Hispanic	7 (2.8%)	13 (6.3%)	
Asian or Pacific Islander	8 (3.2%)	15 (7.3%)	
Native American	3 (1.2%)	1 (0.5%)	
Mixed race	3 (1.2%)	9 (4.4%)	
Other	7 (2.8%)	9 (4.4%)	
Years since diagnosis	26.7 (14.8)	15.7 (9.2)	<0.001
Number of complications	2.5 (2.3)	4.3 (2.3)	<0.001
Subjective Numeracy Scale	4.4 (0.9)	4.2 (0.9)	0.02
Years using insulin	26.1 (14.9)	7.6 (7.3)	<0.001
Insulin delivery system			<0.001
Multiple daily injections	61 (24.1%)	179 (87.3%)	
Pump	192 (75.9%)	26 (12.7%)	
CGM	160 (77.7%)	37 (18.0%)	<0.001
Number of hypoglycemic episodes in the past week	4.3 (2.8)	1.0 (1.5)	<0.001
Monitor use frequency			<0.001
A few times a week	1 (0.4%)	15 (7.3%)	
Once daily	3 (1.2%)	24 (11.7%)	
Twice daily	7 (2.8%)	37 (18.0%)	
More than twice daily	243 (95.7%)	130 (63.1%)	
Review monitor results with a clinician	4.2 (1.3)	3.8 (1.5)	0.008
Use monitor results to alter what you eat	3.3 (0.8)	3.2 (0.8)	0.25
Do nothing with monitor results	1.4 (0.7)	1.7 (0.9)	<0.001
BMI (kg/m^2)	27.1 (5.8)	34.9 (8.4)	<0.001
HbA1c (%)	7.2 (1.2)	7.8 (1.5)	<0.001
Quality of life (WHO-5)			
Mean	2.9 (1.0)	2.6 (1.1)	0.002
Total sum score	14.6 (5.1)	13.1 (5.6)	0.002
Diabetes Distress			
DDS-T1	2.2 (0.8)	—	
DDS	—	2.5 (1.1)	
SMBG Avoidance	2.5 (1.1)	2.9 (1.2)	<0.001
SMBG Pointlessness	1.6 (0.8)	2.0 (1.0)	<0.001
BGMSRQ	3.0 (0.7)	3.0 (0.7)	0.56

Mean and SD values are presented for continuous variables.

Comparing patients diagnosed with type 1 versus type 2 diabetes (t test or χ^2 test).

BMI, body mass index; BGMSRQ, Blood Glucose Monitoring System Rating Questionnaire; CGM, continuous glucose monitoring; DDS, Diabetes Distress Scale; DDS-T1, Diabetes Distress Scale for type 1 diabetes; HbA1c, glycated hemoglobin; SMBG, self-monitoring of blood glucose; WHO-5, World Health Organization-5.

Table 2. Factor Analysis of Glucose Monitoring System Satisfaction Survey Items by Type of Diabetes

	Type 1 diabetes				*Type 2 diabetes*			
	Openness	*Emotional Burden*	*Behavioral Burden*	*Trust*	*Openness*	*Emotional Burden*	*Behavioral Burden*	*Worthwhileness*
Helps me feel more satisfied with how things are going with my diabetes.	**0.724**	0.038	−0.139	−0.045	**0.609**	0.028	0.023	0.361
Helps me feel less restricted by diabetes.	**0.815**	−0.077	0.106	0.088	**0.885**	0.001	−0.024	−0.117
Helps me be more spontaneous in my life.	**0.808**	−0.024	0.046	−0.009	**0.802**	−0.094	−0.013	−0.067
Helps me be more open to new experiences in life.	**0.863**	0.094	−0.017	−0.020	**0.734**	0.003	0.001	0.125
Makes me think about diabetes more than I want to.	0.041	**0.730**	−0.057	−0.082	−0.076	**0.837**	0.021	0.272
Makes me worry a lot.	0.015	**0.817**	0.088	−0.011	−0.008	**0.833**	−0.077	−0.084
Makes me feel more frustrated with my diabetes.	−0.045	**0.789**	−0.021	0.092	−0.035	**0.737**	0.119	−0.032
Makes me feel more down and depressed.	0.006	**0.832**	−0.011	0.033	0.044	**0.839**	−0.049	−0.152
Takes too much time to use.	−0.038	0.084	**0.711**	0.021	−0.158	−0.033	**0.770**	0.137
Is too much of a hassle to use.	−0.070	0.109	**0.739**	0.052	−0.024	0.071	**0.763**	−0.089
Causes too many skin irritations or bruises.	0.049	−0.155	**0.816**	0.095	0.017	−0.103	**0.906**	0.040
Is too painful to use.	0.046	0.010	**0.904**	−0.143	0.178	0.135	**0.626**	−0.188
Doesn't seem to be as accurate as I would like it to be. (R)	0.038	−0.024	0.018	**0.874**	—	—	—	—
Gives me numbers that I don't entirely trust. (R)	−0.033	−0.015	−0.052	**0.931**	—	—	—	—
Often gives me results that don't make sense. (R)	0.019	0.044	0.023	**0.728**	—	—	—	—
Helps me and my doctor to know how much of my diabetes medications to take.	—	—	—	—	0.029	0.033	0.065	**0.847**
Gives me information that I don't find very useful. (R)	—	—	—	—	0.024	0.115	0.065	**–0.802**
Helps me understand how food and activity affect me.	—	—	—	—	0.061	0.123	−0.011	**0.774**

(R) indicates the item is reverse-scored before averaging for subscale score. In addition, items that load onto the emotional burden and behavioral burden subscales are reverse-scored before averaging across all items to obtain the total scale score.

Bolded items are those that load most highly on the individual factor.

Factor analysis and construct validity of the GMSS

Inspection of individual item distributions led to the removal of one item, due to lack of variability within both samples. An EFA of the remaining 41 items, run separately for T1D and T2D patients, yielded seven-factor solutions (eigenvalues ≥ 1.00) for each sample that accounted for 59.2% of the common item variance for T1D and 63.3% for T2D. Inspection of the items in each factor and the scree plot of successive eigenvalues for each analysis indicated that four factors might provide a good description of the data in each analysis. Items that loaded <0.50 on all factors or were cross-loaded on multiple factors (i.e., ≥0.30) were dropped, and the remaining items were subjected to a second EFA for each patient group. This analysis included 15 items: 12 of which were common across the two samples and three items that were unique to each sample. This final EFA yielded four coherent and meaningful factors in each sample: three factors with the same items in common for both samples and a fourth factor unique to each sample. The final EFA accounted for 66.5% of the variance in the T1D sample and 67.0% in the T2D sample. Items and factor loadings are presented in Table 2.

Based on the item content, the three subscales common to both samples were labeled as follows: ''Openness'' centered on a sense of liberation and/or perceived reduction in feeling restricted due to monitor use (e.g., ''Helps me be more open to new experiences in life'') (four items; Cronbach's $\alpha = 0.81$ for T1D and 0.82 for T2D); ''Emotional Burden'' focused on the emotional stresses and strains of monitor use (e.g., ''Makes me feel more frustrated with my diabetes'') (four items; Cronbach's $\alpha = 0.82$ for T1D and 0.80 for T2D); and ''Behavioral Burden'' related to the day-to-day bother and annoyance associated with monitor use (e.g., ''Is too much of a hassle to use'') (four items; Cronbach's $\alpha = 0.80$ for T1D and 0.84 for T2D). Unique to the T1D sample, ''Trust'' focused on the perceived reliability of the monitor and the sense of confidence that the results were accurate (e.g., ''Gives me numbers that I don't entirely trust'') (three items; Cronbach's $\alpha = 0.80$). Unique to the T2D sample, ''Worthwhileness'' centered on the perceived personal value of monitor use (e.g., ''Helps me and my doctor to know how much of my diabetes medications to take'') (three items; Cronbach's $\alpha = 0.76$). The total GMSS score, which included all 15 items relevant for each sample, also demonstrated good internal consistency (Cronbach's $\alpha = 0.86$ and 0.90 for T1D and T2D, respectively). Thus, analysis of the initial GMSS items yielded coherent, internally consistent and reliable subscales that were both general and unique to each T1D and T2D sample.

Intercorrelations among subscales were low to moderate ($r = 0.17$ to $r = 0.53$ for T1D; $r = 0.44$ to $r = 0.54$ for T2D), suggesting related, but distinct, dimensions of glucose monitoring device satisfaction. Each scale score was calculated as the mean of the contributing items after reverse coding items (see Table 2), and the mean score per subscale was as follows: Openness, 3.40 (±0.84) for T1D and 3.14 (±0.80) for T2D; Emotional Burden, 1.73 (±0.75) for T1D and 1.95 (±0.77) for T2D; Behavioral Burden, 2.32 (±0.84) for T1D and 2.55 (±0.93) for T2D; Trust, 3.69 (±0.89) for T1D; and Worthwhileness, 3.89 (±0.73) for T2D. The average total GMSS satisfaction score (reverse coding negative subscales to be positive) was 3.76 (±0.60) for T1D and 3.61 (±0.64) for T2D. Of note is that mean T1D satisfaction scores were significantly higher than mean T2D satisfaction scores on each of the three commonly shared subscales (in all cases, $P < 0.005$).

The GMSS total scale and all four subscales were significantly related (all $P < 0.001$) to the criterion variables for both the T1D and T2D samples (Table 3). These findings support the validity of the subscales and total scale score for patients with T1D and T2D on insulin.

Predictors of BG monitor satisfaction

Three multiple regression equations were run for each sample to determine whether patient demographics, diabetes status, or device use predicted subsequent device satisfaction, as reflected by the total GMSS score (see Table 4 for standardized β values). Among the five demographic variables (age, gender, ethnicity, diabetes duration, and subjective numeracy), only subjective numeracy was associated with GMSS and only among T2D subjects ($P < 0.001$): higher subjective numeracy was associated with a higher total GMSS score.

Among the five diabetes status variables (number of complications, A1C, insulin pump use, CGM use, and number of hypoglycemic events in the past week), A1C was significantly associated with GMSS scores for both samples (T1D, $P = 0.002$; T2D, $P < 0.006$): for both T1D and T2D groups, lower A1C was associated with higher GMSS scores. Furthermore, number of complications ($P = 0.003$) and insulin pump use ($P = 0.05$) were also significantly associated with GMSS scores, but only for the T2D sample: fewer complications and insulin pump use were independently associated with higher GMSS scores.

Finally, of the six device use variables (how frequently subjects checked their BG levels, reviewed results with their HCP, responded to out-of range BG results by altering their dietary intake, exercise level, or medications, or ''did nothing'' in response to out-of-range BG levels), only reviewed results with their HCP and ''did nothing'' emerged as independent predictors of GMSS and only for T2D subjects: those who typically did not take action in response to out-of-range BG levels had lower GMSS scores, whereas those who more regularly reviewed with their glucose results with their HCP had higher GMSS scores.

Of note is that device satisfaction was not associated with gender, age, ethnicity, years with diabetes, or frequency of monitor use for either the T1D or the T2D sample in any of the three equations. The regression equations were run again with adjustments for gender and ethnicity, and the results remained unchanged.

Discussion

Toward a more comprehensive understanding of patients' satisfaction with glucose monitoring devices, we developed the GMSS, a 15-item self-report scale with documented validity and reliability. The GMSS comprises four clinically meaningful subscales that capture key features contributing to device satisfaction. Three of the four subscales, representing 12 of the 15 items, are shared by both T1D and insulin-using T2D samples: Openness, which embodies the ways in which a glucose device may have a broad, favorable impact on diabetes-related quality of life; Emotional Burden, which captures the negative impact on diabetes-related QOL; and Behavioral Burden, which reflects the more narrow, day-to-day hassles associated with monitor use. The fourth subscale is different in

Table 3. Construct Validity Associations

	WHO-5	*Diabetes Distress*	*SMBG Avoidance*	*SMBG Pointless*	*BGMSRQ*
Type 1 diabetes GMSS					
Openness	0.281	−0.378	−0.387	−0.286	0.332
Emotional Burden	−0.208	0.389	0.428	0.387	−0.636
Behavioral Burden	−0.369	0.489	0.511	0.360	−0.489
Trust	0.236	−0.361	−0.316	−0.278	0.451
Total GMSS score	0.384	−0.563	−0.574	−0.454	0.654
Type 2 diabetes GMSS					
Openness	0.440	−0.392	−0.452	−0.325	0.435
Emotional Burden	−0.304	0.527	0.520	0.470	−0.621
Behavioral Burden	−0.407	0.632	0.654	0.586	−0.533
Worthwhileness	0.368	−0.405	−0.377	−0.494	0.448
Total GMSS score	0.486	−0.637	−0.657	−0.599	0.652

All correlations were significant at $P < 0.001$.

BGMSRQ, Blood Glucose Monitoring System Rating Questionnaire; GMSS, Glucose Monitoring System Satisfaction Survey; SMBG, self-monitoring of blood glucose.

the T1D and T2D samples. For T1D, the fourth subscale was Trust, which represents the subject's perception of how accurate or reliable the device may be. For T2D, the fourth subscale was Worthwhileness, which represents the perceived personal value of monitor use.

Several findings support the need for two GMSS scales: one for T1D patients and one for insulin-using T2D patients. First, the patterns of intercorrelations among subscales are strikingly different between the T1D and T2D samples. Second, the significantly different levels of reported device satisfaction in the two samples (T1D patients report markedly greater device satisfaction than T2D patients on the three shared GMSS subscales) suggest that studies including T1D and T2D samples should be careful not to combine subscale scores or total scores across samples. We suspect that these differences in device satisfaction between the two samples may reflect broader group differences in treatment burden. For example, the demands of day-to-day care are typically greater for T1D patients than for T2D patients (even insulin-using T2D patients), and T1D patients are likely to feel more dependent on glucose devices than T2D patients, perhaps because of the greater danger of severe hypoglycemic episodes.

Table 4. Predictors of Glucose Monitoring Device Satisfaction

	GMSS total satisfaction			
	T1D		*T2D*	
	β	P	β	P
Demographics				
Gender (female)	0.04	0.59	−0.06	0.40
Ethnicity (white)	0.01	0.91	0.12	0.08
Age	0.14	0.06	0.12	0.11
Years since diagnosis	0.06	0.43	0.01	0.99
Subjective numeracy	0.11	0.08	0.28	<0.001
Diabetes status				
Complications	−0.11	0.09	−0.21	0.002
HbA1c	−0.21	0.002	−0.20	0.005
Insulin pump	0.01	0.96	0.18	0.02
CGM	−0.12	0.08	0.01	0.84
Number of low blood sugar episodes in the last week	0.02	0.77	0.08	0.23
Monitor use				
Frequency of monitor use	−0.01	0.91	0.09	0.23
Review results with a clinician	0.05	0.41	0.14	0.04
Use the results to alter				
What you eat	0.09	0.23	0.04	0.62
Exercise	0.01	0.99	0.04	0.58
Medications	0.09	0.20	−0.01	0.98
Do nothing with the results	−0.03	0.68	−0.23	0.002

All analyses are controlling for gender and ethnicity.

CGM, continuous glucose monitoring; GMSS, Glucose Monitoring System Satisfaction Survey; HbA1c, glycated hemoglobin; T1D, type 1 diabetes; T2D, type 2 diabetes.

The GMSS provides several advantages over currently available instruments. First, although the GMSS examines satisfaction with both SMBG and CGM devices, the currently available RT-CGM QOL scale[4] is limited to use only with CGM devices. Furthermore, the RT-CGM QOL scale only examines the perceived impact of the device, not satisfaction per se. Second, the BGMSRQ[2] and GMS[3] have only been evaluated with T1D patients, preventing direct comparison of satisfaction between T1D and T2D patients, thus limiting their clinical utility. Third, both instruments are substantially longer than the GMSS (the BGMSRQ is 29 items; the GMS is 22 items). Fourth, the original standardization samples for both measures were markedly smaller than the GMSS sample (BGMSRQ study, $n = 28$; GMS study, $n = 120$ adults), and, unlike the GMSS, neither scale made use of factor analytic methods to document the statistical coherence of the subscales. Thus, our newly developed scale is far more psychometrically sound than previous measures.

As expected, greater device satisfaction, as assessed by the GMSS total and all subscales, is linked to greater well-being, lower levels of diabetes distress, and less negative attitudes toward BG monitoring, all lending support to the validity of the new measure. Although causality cannot be determined, these associations suggest that emotional distress (generic or diabetes-specific) may color a patient's perception of his or her monitoring device, rendering device satisfaction less likely. Alternatively, it is possible that greater device satisfaction may

help to alleviate distress. Regardless of the direction of influence, satisfaction with one's glucose monitoring device is a significant component of overall emotional distress.

Variations in device satisfaction based on participant characteristics raise important implications for how satisfaction might be enhanced. Among T2D subjects, greater device satisfaction is associated with a set of predictors that reflect a greater sense of willingness or ability to be personally engaged with their diabetes (more likely to take action in response to out-of range BG values, more frequently reviewing results with their HCP, insulin pump use, and higher level of subjective numeracy) as well as more favorable outcomes (fewer long-term complications and better glycemic control). This suggests that boosting device satisfaction may require support and training to help T2D patients understand and make better use of their own glucose data, leading to greater interest and engagement in self-management.[10,11] In contrast, greater device satisfaction among T1D subjects is linked only to better glycemic control but is not associated with any demographic or device use variable. Because T1D adults are more likely to be familiar and comfortable with glucose monitoring devices and how to interpret the resulting data, use their devices relatively more frequently, and feel more dependent on them, this last finding suggests that the various features of the monitoring device itself may be more important in determining satisfaction for T1D patients than any particular patient characteristic. As a practical matter, it is important to note that the ability to influence device satisfaction may be limited by common insurance company and/or governmental constraints, making careful selection of ''appropriate'' devices for each patient all the more important.

The strengths of this study are that relatively large samples of insulin-using patients—both T1D and T2D—were included, item content was developed directly from the T1D and T2D adults and providers, and results suggest excellent reliability and validity. Several cautions, however, should be noted. First, non–insulin-using T2D patients were not included in the current study, so the applicability and utility of the GMSS in that population have not been documented. Second, the study samples were primarily non-Hispanic whites and highly educated (see Table 1), factors that may limit generalizability. The scales should be reevaluated with a broader patient sample. Finally, glycemic control (A1C) was assessed via self-report rather than by a laboratory analysis, which may have introduced important bias. However, fewer than 3% of subjects were unable to report a value or reported an improbable value, and in our related work with T1D adults there was a high level of agreement between self-reported A1C and the laboratory result ($r = 0.84$; see Fisher et al.[9]).

The GMSS is a reliable, valid measure of device satisfaction, with versions available for adults with T1D and for adults with T2D. It provides a comprehensive profile of key contributors to device satisfaction, including both negative and positive influences.

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Author Disclosure Statement

W.H.P. has worked as a consultant for Sanofi Diabetes Care, Dexcom, Roche Diabetes Care, Abbott Diabetes Care, and Johnson & Johnson. L.F. has worked as a consultant for Roche Diabetes Care, Abbott Diabetes Care, and Sanofi Diabetes Care. D.H. reports no competing interest. S.V.E. has worked as a consultant for Sanofi Diabetes Care, Dexcom, Bayer Diabetes Care, Abbott Diabetes Care, and Johnson & Johnson.

W.H.P. and L.F. were responsible for study conception and protocol. D.H. was responsible for statistical analysis. All authors were responsible for manuscript development and read and approved the final manuscript.

References

1. Polonsky WH, Fisher L, Hessler D, Edelman SV: What is so tough about self-monitoring of blood glucose? Perceived obstacles among patients with Type 2 diabetes. Diabet Med 2014;31:40–46.
2. Peyrot M, Rubin RR: Patient-reported outcomes for an integrated real-time continuous glucose monitoring/insulin pump system. Diabetes Technol Ther 2009;11:57–62.
3. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Group: Validation of measures of satisfaction with and impact of continuous and conventional glucose monitoring. Diabetes Technol Ther 2010;12:679–684.
4. 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;15:295–301.
5. Fagerlin, A, Zikmund-Fisher BJ, Ubel PA, Jankovic A, Derry HA, Smith DM: Measuring numeracy without a math test: development of the Subjective Numeracy Scale (SNS). Med Decis Mak 2007;27:672–680.
6. Polonsky W, Fisher L, Hessler D, Edelman SV: A survey of blood glucose monitoring in patients with type 2 diabetes: are recommendations from health care professionals being followed? Curr Med Res Opin 2011;27(Suppl 3):31–37.
7. Hajos TR, Pouwer F, Skovlund SE, Den Oudsten BL, Geelhoed-Duijvestijn PH, Tack CJ, Snoek FJ: Psychometric and screening properties of the WHO-5 Well-being Index in adult outpatients with Type 1 or Type 2 diabetes mellitus. Diabet Med 2013;30:e63–e69.
8. Polonsky WH, Fisher L, Earles J, Dudl RJ, Lees J, Mullan J, Jackson RA: Assessing psychosocial distress in diabetes: development of the Diabetes Distress Scale. Diabetes Care 2005;28:626–631.
9. Fisher L, Polonsky WH, Hessler DM, Mashrani U, Blumer I, Peters AL, Strycker L, Bowyer V: Identifying the unique aspects of diabetes distress in adults with type 1 diabetes: development of a new self-report measure. J Diabetes Complications 2015;29:572–577.
10. Parkin CG, Hinnen D, Campbell RK, Geil P, Tetrick DL, Polonsky WH: Effective use of paired testing in type 2 diabetes: practical applications in clinical practice. Diabetes Educ 2009;35:915–927.
11. Polonsky WH, Fisher L: Right answer, but wrong question: self-monitoring of blood glucose can be clinically valuable for noninsulin users. Diabetes Care 2013;36:179–182.

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