

# Self-Management Behaviors in Adults on Insulin Pump Therapy: What Are Patients Really Doing?

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## Abstract

**Background:** Successful diabetes management requires behavioral changes. Little is known about self-management behaviors (SMB) in adults on insulin pump (IP) therapy.

**Objective:** Analyze and characterize observed common diabetes SMB in adult participants with type 1 diabetes (T1D) using IPs and to correlate behaviors with glycemic outcomes based on participant's individual glucose targets.

**Materials and Methods:** One month of IP data from adults with T1D were downloaded. Computer programs were written to automatically quantify the observed frequency of expected behaviors such as: insulin bolusing, checking blood glucose (BG), and recording carbohydrate intake, and other interactions with the IP.

**Results:** Nineteen participants were recruited and 4,249 IP interactions were analyzed to ascertain behaviors. Intersubject variability of adherence to minimally expected behaviors was observed: daily documentation of carbohydrates and BG checks in 76.6 (31.7)% and 60.0 (32.5)%, respectively, and bolusing without consulting the IPBC in 13.0 (16.9)% of delivered boluses, while daily insulin bolus delivery was consistent 96.8 (5.7)%. Higher frequency of adherence to daily behaviors correlated with a higher number of glucose readings at target.

**Conclusion:** Results indicate variability in SMB and do not always match recommendations. Case-scenarios based on observed real-life SMB could be incorporated into interviews/surveys to elucidate ways to improve SMB.

## Keywords

type 1 diabetes, self-management behaviors, insulin dosing, insulin pump, bolus calculator

Optimizing glucose control in patients with type 1 diabetes mellitus (T1D) is known to reduce microvascular and macrovascular complications.<sup>1</sup> The intensive insulin therapy needed to accomplish glycemic goals can be delivered either via multiple daily injections or continuous subcutaneous insulin infusion devices, also referred to as insulin pump (IP) therapy. However, intensive insulin therapy alone is not sufficient to achieve desired glycemic goals. Successful diabetes self-management requires behavioral changes to achieve glucose targets. The 2016 American Diabetes Association (ADA) Standards of Care Guidelines outline the behaviors required for daily self-management, including recommendations to monitor blood glucose (BG) 6-10 times per day, and dose prandial insulin 3-4 times per day as it relates to carbohydrate intake.<sup>2</sup>

As technology for diabetes has advanced, so have the informatics capabilities of IPs and BG monitors. Devices

store objectively measured data that can be downloaded and used to quantify behaviors and outcomes. IPs store data such as the bolus amount suggested by the insulin pump bolus calculator (IPBC), the bolus amount selected by the patient, carbohydrates entered into the IP by the patient, and BG levels from a connected BG monitor and/or a continuous glucose monitoring system (CGMS).

Adherence to self-management behaviors (SMB) such as carbohydrate intake, administering insulin boluses to cover

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meals, and monitoring of BG have been studied in children, youth and emerging adults (18-26 years old) with various criteria, methods and sources of data, including users of IPs.<sup>3-7</sup> Although IP therapy has been found to improve glyce-mic control, suboptimal adherence even with this technology can result in poor glyce-mic control.<sup>4,8</sup> There is a lack of stud-ies that describe SMB in adults with T1D. The objective of this study was to use IP data to analyze and characterize common behaviors related to insulin bolus dosing, BG moni-toring and carbohydrate intake observed in adults with T1D, and to correlate those behaviors with glyce-mic outcomes.

## Methods

### Study Recruitment

After Institutional Review Board approval, we recruited adults with T1D from an outpatient academic endocrinology practice. We identified potential participants at routine quar-terly visits and they were contacted to set up a recruiting appointment. After participant consent we remotely gathered data after 30 days of participation. Therefore, data were col-lected after the appointment with the provider and well before the next quarterly appointment.

### Participant Selection

We adopted the following as inclusion criteria: patients who had been under the care of the endocrinology team for at least 1 year, 18-70 years of age, nonpregnant, English speak-ing, and using the same IP manufacturer, Medtronic. We used as exclusion criteria: fragile health, limited life expec-tancy, records of mental health problems, advanced vascular disease or micro-vascular complications, known history of severe hypoglycemia or advanced atherosclerosis. The inclu-sion/exclusion criteria and duration of the study was defined as part of a broader study that collected data to retrospec-tively compare insulin bolus algorithms.<sup>9,10</sup>

### Data Collection and Standardization

Participants' IP data were downloaded in its source format (ie, spreadsheet). IP data included carbohydrates recorded by the participant, BG levels from CGMS or capillary BG moni-tor or both, amount of insulin suggested and delivered by the pump, and personalized pump settings and BG targets which may have varied over the course of a 24-hour period. Computer programs were written to automate the process of quantifying the IP behaviors and glyce-mic outcomes.

We identified over 4000 interactions with the IP in this study. Using code, we removed duplicate BG readings that occurred in within 4 minutes of each other since CGMS sent readings every 5 minutes. We included in the analysis values that were entered manually, recorded from IP connected BG meters and CGMS. We did not identify any means to identify

BG readings that resulted from user-error, and as such, no BG values recorded with the IP were excluded after the data cleaning process.

### Minimally Expected Self-Management Behaviors

As in O'Connell et al<sup>4</sup> and Driscoll et al<sup>5</sup> the minimally expected daily SMB for glyce-mic control were defined as: counting carbohydrates 3 or more times per day (assuming at least 3 meals per day), delivering an insulin bolus 3 or more times per day to correspond to those meals, and checking BG 4 or more times per day (once for each meal and before bed-time). These behaviors were quantified on a daily basis for each participant and 2-sided, unequal t-tests were used between those using capillary glucose monitoring and CGMS. Fisher's exact test was used to compare adherent days to nonadherent days when considering BG readings that were within target. These parameters were assessed because they could be directly derived from IP/CGMS data.

The correlation of the above 3 diabetes SMB was ana-lyzed with BG outcomes. Glyce-mic control was addressed on a daily basis by categorizing BG as low, at target or high based on each participant's personalized BG targets. The number of BG readings within the target range for the par-ticipant over the course of a 24-hour day were compared to the total number of BG readings. BG readings were obtained from manual entry, synchronized glucose meter or CGMS. All data are reported as mean and standard deviation (SD) where applicable.

### Insulin Bolusing Behaviors

How often participants selected the same, smaller or larger insulin bolus that was suggested by IPBC was evaluated. In addition, the number of times the IPBC was accessed was counted and this value was used to calculate the percentage of IPBC overrides.

Finally, participants may have opted to deliver insulin boluses without consulting the IPBC. They may have changed the waveform (eg, normal to square), which is con-sidered an advanced IP feature. The delivered boluses for each participant were counted and used to calculate the per-centage of delivered boluses that were self-determined (ie, the participant did not access the IPBC for a suggestion before delivering an insulin bolus) and how often the bolus waveform was changed.

## Results

### Participant Characteristics

There were 19 participants recruited; 7 employed CGMS and the remainder utilized capillary glucose monitoring (Paradigm System), with 13 participants using 1 or more BG meters that communicated with the IP. Four IPs were

**Table 1.** Observed Frequency of Investigator-Defined Minimally Expected Daily Behaviors, Differentiating Between the Group of Participants Under Capillary Glucose Monitoring and the Group Using CGMS.

BG behavior	Capillary glucose monitoring	CGMS	P value	Group total
Documented carbohydrates 3 or more times/day, %	72.3 (33.3) 0.0-100	84.0 (29.7) 17.2-100	.44	76.6 (31.7) 0.0-100
Administered insulin bolus 3 or more times/day, %	97.4 (5.6) 80.6-100	95.6 (6.2) 82.8-100	.53	96.8 (5.7) 80.6-100
Documented BG 4 or more times/day, %	55.8 (36.1) 0.0-94.4	67.8 (26.4) 37.9-96.4	.45	60.0 (32.5) 0.0-96.4
All 3 behaviors/day, %	48.4 (35.5) 0.0-88.9	61.5 (32.9) 6.9-93.6	.43	53.2 (34.3) 0.0-93.6
Documented carbohydrates/day, #	3.8 (1.5) 1.1-6.0	4.2 (1.8) 1.4-6.7	.62	3.9 (1.6) 1.1-6.7
Administered insulin bolus/day, #	6.5 (2.3) 3.8-11.8	9.4 (4.8) 3.9-18.3	.17	7.5 (3.6) 3.8-18.3
Documented BG/day, #	4.2 (2.5) 1.2-11.1	4.5 (1.4) 3.2-7.2	.72	4.3 (2.1) 1.2-11.1

Values are reported as mean (SD), range.

used by the participants: 9 on MiniMed 530G-551, 1 on MiniMed 530G-751, 5 on ParadigmRevel-523, and 4 on ParadigmRevel-723. The average participant age was 48 (15) years and the self-reported duration of T1D and duration of IP therapy was 27 (13) and 11 (5) years, respectively. Mean HbA1c was 7.3 (1.0). There was a higher percentage of recruited women (63%) and most were white (95%). We analyzed an average of 32 (4.8) days of data from each participant and a total of 4,249 interactions with the IPBC.

### Daily Minimally Expected Self-Management Behaviors

Intersubject variability to the 3 minimally expected daily behaviors was observed (Table 1). Carbohydrates were entered into the IPBC 3 or more times per day an average of 76.6 (31.7)%. Levels of adherence were similar between those on CGMS and capillary glucose monitoring, 84.0 (29.7)%, and 72.3 (33.3)%, respectively. Five participants showed adherence to this behavior 100% of the time, while 1 participant showed a maximum of 2 carbohydrate entries per day. Carbohydrates were documented an average of 3.9 (1.6) times per day.

Participants delivered insulin boluses an expected 3 or more times per day an average 96.8 (5.7)%. There were 11 participants whose observed bolus adherence was 100%; all but 1 participant achieved 90% or better adherence. On average participants delivered an insulin bolus 7.5 (3.6) times per day. Although not statistically significant, participants on CGMS delivered an average of 9.4 (4.8) boluses per day while participants using capillary glucose monitoring averaged 6.5 (2.3) boluses per day.

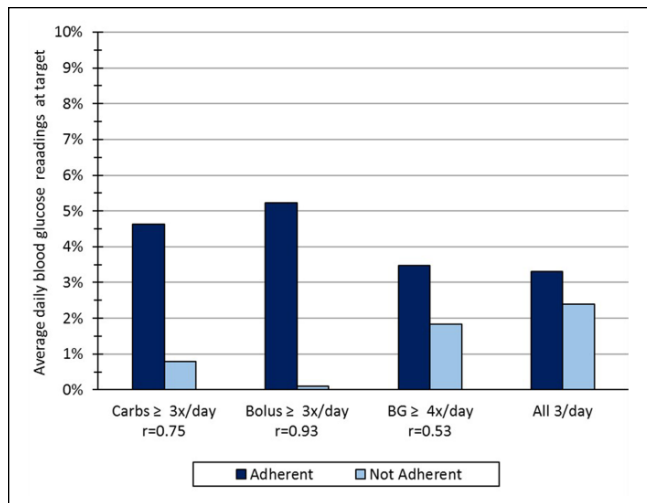
Adherence to glucose checks was similar for participants on CGMS when compared to those on capillary glucose

monitoring even though providers at the Mayo Clinic advise patients on CGMS to calibrate with a capillary glucose check a minimum of 2 times per day. On average, participants on CGMS checked BG 4.5 (1.4) times per day and those on capillary glucose monitoring checked 4.2 (2.5) times per day. None of the participants were perfectly adherent to checking or recording BG and only 3 achieved 90% or better adherence.

When all 3 minimally expected behaviors were considered together participants were simultaneously adherent to all 3 investigator-defined guidelines on average 52.3 (34.3)% of days. None of the participants were found to be 100% adherent and 2 individuals never engaging in the 3 recommendations simultaneously. Adherence of all 3 behaviors between CGMS and capillary glucose monitoring was similar, 61.5 (32.9)% and 48.4 (35.5)%, respectively.

### Relationship Between Daily Minimally Expected Behaviors and Glucose Targets

As depicted in Figure 1, when participants entered carbohydrates 3 or more times per day they achieved their individualized target BG in 4.6 (4.1)% of the recorded BG values during the 24-hours. Days when that behavior was not observed the target BG was achieved 0.8 (1.7)%. When participants were observed bolusing 3 or more times per day it resulted in 5.2 (3.7)% BG readings at target, days when bolusing was less than 3 the target BG was recorded 0.1 (0.3)%. On days that participants checked BG 4 or more times per day they achieved target BG 3.5 (3.0)% versus 1.8 (3.3)% on days that expected behavior was not observed. When participants were adherent to all 3 minimally expected behaviors BG was at target 3.3 (3.0)%, and 2.4 (3.2)% on days they failed to meet all 3 behaviors. Although these findings were not significant (Fisher's exact test), there was a



**Figure 1.** Comparison of blood glucose control for observed adherent/nonadherent days based on investigator-defined optimal behaviors and percentage of blood glucose readings at target for the day.

high correlation between the observed frequency of behaviors and the percentage of BG readings that were at target. Increasing the number of daily insulin boluses had the largest impact on increasing the number of BG readings at target for the day,  $r = 0.93$ . Consuming carbohydrates and checking BG had correlation values of  $r = 0.75$  and  $r = 0.53$ , respectively.

### Daily Insulin Bolusing Behaviors

Table 2 provides results for additional behaviors that were observed and analyzed. Over the course of the month participants accessed the IPBC on average 198.7 (94.3) times and insulin boluses were delivered 220.7 (78.7) times during the same time period. Two-thirds, 66.6 (16.1)%, of the IPBC recommendations resulted from participants entering carbohydrates. Correction BG readings were provided by participants in 74.8 (24.4)% of the IPBC recommendations. Nine participants frequently entered BG corrections (>90%) while 4 participants entered BG corrections less than 50% of the time.

Participants chose to deliver the same bolus amount as suggested by the IPBC in 85.7 (12.7)% of delivered boluses (Table 2). There were 8 participants who very often (>90%) chose the same bolus as the IPBC, while 1 participant chose a different bolus in 51% of the delivered boluses. Participants were nearly even on their preference for choosing a larger or smaller bolus, 7.4 (6.1)% and 6.9 (9.3)%, respectively.

In 6.4 (10.8)% of the delivered boluses participants changed the waveform from normal to dual or square. A majority of the participants ( $n = 14$ ) never or rarely (<5.0%) changed the bolus waveform while 3 participants changed the waveform in over 25% of the boluses they delivered. Participants occasionally chose to deliver an insulin bolus

**Table 2.** Overview of the Insulin Pump Bolus Calculator (IPBC), Insulin Bolus Decisions, and Additional Information Regarding the Optimal Behaviors.

Access IPBC	Value
IPBC recommendation provided, #	198.7 (94.3), 62-449
BG control guidelines	
Carbohydrates entered to IPBC, %	66.6 (16.1), 38.8-100
Boluses delivered, #	220.7 (78.7), 109-380
BG entered to IPBC, %	74.8 (24.4), 35.8-100
Bolus recommendations from IPBC	
Select same bolus suggested by IPBC, %	85.7 (12.7), 49.1-100
Select larger bolus than suggested by IPBC, %	7.4 (6.1), 0.0-18.5
Select smaller bolus than suggested by IPBC, %	6.9 (9.3), 0.0-32.7
Other bolus decisions	
Select square or dual bolus waveform, %	6.4 (10.8), 0.0-30.4
Bolus without consulting IPBC, %	13.0 (16.9), 0.0-52.7

Values are reported as mean or % (SD), range.

without consulting the IPBC, which constituted 13.0(16.9)% of the delivered boluses. While 10 participants never or rarely (<5.0%) delivered an insulin bolus without consulting the IPBC, 2 participants delivered approximately 50% of their insulin boluses without accessing the IPBC.

### Monthly Frequency of Expected Self-Management Behaviors

In addition to the daily analysis of participant's behavior (Tables 1 and 2), we analyzed for each participant the monthly frequency of 5 distinct behaviors: 1) disregarding BG readings and only accounting for carbohydrates when using the IPBC, 2) bolusing without consulting the IPBC, 3) changing the bolus waveform to dual/square, 4) choosing insulin boluses different from those suggested by the IPBC, and 5) frequent bolusing: 4 or more boluses in a 5-hour time period or delivering 10 or more boluses during a 24-hour period. As shown in Table 3, we categorized each participant as never (0 events), rarely (1-4 events), occasionally (5-14 events), regularly (15-90 events), or excessively (more than 90 events) showing a behavior over the course of 1 month.

We observed that 15 participants occasionally or regularly chose a different insulin bolus than the one recommended by the IPBC and that 4 participants rarely or never chose a different bolus. All the behaviors reported in Table 3 were automatically computed, except for the frequency of bolusing which was manually counted on a subset of the participants: 7 on CGMS and 2 on capillary glucose monitoring. Out of the subset of 9 participants, 3 occasionally or regularly bolused frequently while 6 rarely or never bolused frequently.

**Table 3.** Categories of Insulin Compensation Techniques Observed in Study Participants, Including (1) Disregarding BG Readings and Only Accounting for Carbohydrates When Using the IPBC, (2) Bolusing Without Consulting the Pump, (3) Changing the Insulin Bolus Delivery From Waveform to Square, (4) Choosing Insulin Boluses Different From Those Suggested by the IPBC, and (5) Bolusing 4 or More Times in a 5-Hour Period or Delivering 10 or More Boluses During a 24-Hour Period.

Behavior	Never (0 events)	Rarely (1-4 events)	Occasionally (5-14 events)	Regularly (15-90 events)	Excessively (90+ events)
Compute carbs only (n = 19)	7	2	1	5	4
Bolus without consulting pump (n = 19)	7	3	1	7	1
Change waveform to dual/square (n = 19)	10	3	0	5	1
Clinically different bolus selected (n = 19)	3	1	7	8	0
Frequent boluses (n = 9)	4	2	2	1	0

Using the IPBC to adjust for carbohydrate meal content while omitting a current BG reading was done regularly or excessively by 9 participants, while 9 rarely or never omitted a current BG reading and 1 occasionally did so. Bolusing without consulting the IPBC was done regularly or excessively by 8 participants and 10 rarely or never delivered a bolus without the IPBC and 1 occasionally bolused without the IPBC. There were 13 participants that never or rarely changed the bolus waveform and 6 who regularly or excessively changed the bolus waveform.

## Discussion

Diabetes behavior studies have mainly relied on self-reported data gathered from interviews, surveys and questionnaires.<sup>3,7,11</sup> These methods have been used to gather qualitative data, which contribute to the understanding of behavioral diabetes such as insights about the beliefs, motivations, perceptions and expectations of the patient which can be used to inform changes to therapy regimens that can improve adherence.<sup>12,13</sup> There are limitations to self-reported data such as recall bias (ie, inaccurately remember and report behaviors) and social desirability (ie, over-report favorable behavior and under-report poor behavior). White coat adherence may be a source of bias when measurement instruments are delivered during patient-provider encounters since patients may improve their SMB in the days or weeks leading up to the appointment.<sup>14,15</sup> In our case data were collected after the appointment with the provider and months before the next appointment.

Although we were able to assess the adherence to diabetes management recommendations and other SMB by using device recorded data, this study was limited by a small sample size which lacked the power to detect differences between groups. The demographics of this cohort may not be representative of the general T1D population based on race and HbA1c. Another limitation of this study is that participants may have used 1 or more glucose meters that did not communicate with the IP and

subsequently the use of those devices would not have been captured by the IP.

Consistent with other studies, we found that there was variability of observed behaviors across participants and that there was a direct correlation between daily adherence to expected SMB and better glycemic control.<sup>3-7</sup> Although this cohort had an average of 11 years' experience with IP therapy, advanced features, such as changing the bolus waveform to dual or square, were used infrequently.

The ADA guidelines suggest that treatment regimens may be intensified if patients are adherent to their current regimen, or in the case of poor adherence the routine should be simplified to improve adherence.<sup>2</sup> Clinicians relying only on self-reported assessments may overestimate patients' adherence since it has been shown that patients who struggle with adherence are less likely to honestly report their deficiencies in SMB.<sup>11,16</sup> While clinicians mainly rely on quantified data coming from diabetes technology, this type of data has limitations, too. Actual behaviors may be different from what was documented in the IP. For instance, a participant had a meal and delivered a bolus without entering carbohydrates and without requesting advice from the IPBC. This may partially explain why the behavior with the highest frequency was delivering insulin boluses.

In this study we found that increasing the frequency of insulin boluses, calculating carbohydrate consumption and checking BG had a positive impact on glycemic control with the delivery of insulin boluses having the greatest impact. Providing real-time monitoring via the IP, or other appropriate device (eg, smartphone app with wireless connection to IP) on these minimally expected behaviors could empower patients and improve daily diabetes self-management and glycemic control.

For providers, presenting information gathered by IPs in ways that are clinically relevant and actionable could be empowering, too. Availability of precise and complete BG data that are presented in a structured manner enables providers to more efficiently and accurately identify glucose patterns which can lead to more accurate therapeutic

decisions.<sup>17-19</sup> Take for instance Table 3, where we classified the frequency of 5 observed behaviors by monthly frequency (never, rarely, occasionally, regularly and excessively), instead of daily means and SDs (Table 2). This way to visualize the data could help the clinician to better identify patients that behaved in a certain way more often or less often than the average patient. For instance, if during the last month the patient never changed the bolus waveform, the clinician could spend time during the next clinical encounter reviewing how to change the bolus delivery in the IP and discussing potential meal types that could benefit from a square insulin delivery to improve glycemic control. For the example of the patient who frequently boluses (15-90 monthly events when the patient delivers 10 insulin boluses per day or more than 5 boluses within 4 hours), the clinician can review the patient's settings to identify if the basal rate needs to be changed to reduce frequency of insulin bolusing. It remains as an open question to understand which are the best ways to present patients' diabetes SMB to providers to facilitate their decision process.

## Conclusion

This study quantified observed SMB of adults on IP therapy by analyzing objectively recorded data from IPs. A limitation of our research is that we did not collect information on the reasons behind observed participants' behaviors. Nevertheless, the results from this quantitative study have guided on-going research that aims to survey patients on their knowledge on how carbohydrates, alcohol and exercise influence BG control and correlate those findings with observed SMB. Furthermore, we have future plans to use case-scenarios based on instances from real-life behaviors reported in this study to guide interviews with patients that will provide more information on beliefs and motives to exhibit identified SMB. Lessons learned from the described studies could help identify potentially undesirable patients' behaviors and gaps in patients' diabetes education that could be addressed through improved educational material and decision support systems.

## Abbreviations

ADA, American Diabetes Association; BG, blood glucose; CGMS, continuous glucose monitoring system; IP, insulin pump; IPBC, insulin pump bolus calculator; SD, standard deviation; SMB, self-management behaviors; T1D, type 1 diabetes.

## Authors' Note

DG and MAG equally contributed to this article.

## Declaration of Conflicting Interests

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