# Patient perceptions of insulin therapy in diabetes self-management and preferences for insulin injection devices

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**Statements and Declarations**

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**ABSTRACT**

**Aims**: Several insulin delivery systems are available to control glycemia in patients with diabetes. Recently introduced devices feature connectivity enabling data transfer to smartphone applications to provide decision support and reduce errors in dosing and timing, while reducing the cognitive burden.

**Methods**: We conducted an online survey in Italian patients with a self-reported diagnosis of diabetes to assess patient perceptions of insulin therapy management, and their impressions of connection-enabled insulin pens compared to standard insulin pens. The Morisky Medication Adherence Scale-8 was used to assess adherence to insulin therapy.

**Results**: Among 223 respondents (108 with type 1 diabetes; 115 with type 2 diabetes), the most prominent unmet need was the necessity to overcome the cognitive burden of care associated with measuring, calculating, timing, and recording therapy. Only 25% of respondents had high adherence; 28% had low adherence.

**Conclusions**: When asked to compare the attributes of a non-connected insulin pen with those of a new connected device, 71% of patients rated the new proposal "very useful". The cognitive burden associated with self-management of diabetes therapy drives preferences for advanced insulin delivery systems.

**Keywords:**

Diabetes mellitus, Insulin, Patient preference, Injection device; Connected insulin pen

## INTRODUCTION

Worldwide, over half a billion people (10.5% of the population) have diabetes and projections indicate that the number is will increase dramatically, rising to 12.2% by 2045 [1]. Self-management plays a key role in treatment success. The complexity of treatment regimens may cause patients to feel overwhelmed by diabetes management [2–4], and non-adherence leading to poor glycemic control is a common problem [5–7].

Convenience and ease of use can influence patient preference [8, 9], and identifying treatment attributes that meet patient preferences has been shown to improve adherence and outcomes [10]. In general, patients tend to prefer simpler treatments [11, 12], and simple interfaces for treatment decision-making support that reduce the cognitive burden of diabetes self-management [13, 14] Many patients prefer the simplicity and convenience of an insulin pen, compared to insulin injection using vials and syringes, an insulin pens provide equivalent or somewhat improved results [15].

Advances in technology have allowed patients to better approximate normal glucose homeostasis through point-of-care or continuous blood glucose monitoring and informatics support for calculating doses and timing [15]. These improvements can optimize insulin delivery and help to overcome problems of sub-optimal management due to errors of mental math, and non-adherence due to missed or mistimed doses.

Connected insulin pens and blood glucose self-monitoring devices transfer data to dedicated smartphone applications that provide dose calculations, send reminders, record injected doses, and integrate information on blood glucose, time and dose of previous injection; some systems track meals, physical activity, and insulin treatment [13, 16–18]. Smart connected insulin pens and use of digital technology are associated with improved glycemic control [19–21]; but may also improve the quality of life of people with diabetes by reducing their treatment burden.

We have surveyed patients' perceptions of insulin therapy in diabetes self-management to understand their unmet needs, assessing the potential of connection-enabled insulin devices to facilitate diabetes self-care and possibly to improve adherence, as well as determining the relative importance they place on features of digitally enhanced insulin delivery devices.

## METHODS

The aim of this study was to understand diabetes patients' satisfaction levels and unmet needs regarding daily insulin treatment, to investigate the possibility of new insulin pen functions and methods that may improve compliance, and to explore the potential of connection-enabled insulin pens compared to standard insulin pens.

Survey

*Qualitative phase*

During the qualitative phase, 2 focus groups were conducted to inform development of the final quantitative survey. These explored the impact of insulin therapy on the quality of life of patients with diabetes, assessing their reactions to different profiles of technological devices for insulin therapy and collected insight regarding the recently introduced Tempo Pen (Eli Lilly Italia S.p.A.).

Each focus group involved 6 adult patients with diabetes, including 2 patients with type 1 diabetes (T1D) receiving multiple daily insulin injections (basal bolus regimen), 2 patients with type 2 diabetes (T2D) receiving basal insulin, and 2 patients with T2D receiving basal bolus insulin. These focus groups were conducted online using the FocusVision platform (InterVu; Forsta, Inc. https://www.forsta.com) and engaged two different macro regions of North and Central-South Italy. Recordings were analyzed by the qualitative researchers.

*Quantitative phase*

Based on the qualitative findings, a survey was designed to investigate patients' perceptions of daily diabetes management and insulin therapy [**Supplemental Material 1**], including satisfaction, difficulties encountered, unmet needs, and the potential of new insulin treatment functions and methods to facilitate treatment management and promote compliance. We also assessed patients' impressions of connection-enabled insulin pens compared to standard insulin pens.

The survey population consisted of adult patients who had been diagnosed with T1D or T2D at least 6 months previously, and who had been receiving basal or basal-bolus insulin therapy for at least 6 months. Eligible respondents were recruited through either computer-assisted web interviewing or a patient panel. Results were interpreted in light of patient demographic and disease characteristics, as well as adherence to treatment assessed using the Morisky Medication Adherence Scale (MMAS)[1] [22–24], linguistically validated Italian version [25], to record patient-reported adherence to insulin treatment.

[1] The MMAS-8 Scale, content, name, and trademarks are protected by US copyright and trademark laws. Permission for use of the scale and its coding is required. A license agreement is available from MMAR, LLC., Donald E. Morisky, ScD, ScM, MSPH, 294 Lindura Ct., USA; donald.morisky@moriskyscale.com.

**RESULTS:**

Quantitative interviews were conducted in 223 patients, 108 with T1DM and 115 with T2DM, mean age 47 years. Patients with T1DM were all receiving basal-bolus therapy, while those with T2DM were receiving either basal-bolus (56%) or basal therapy (44%). Demographic and clinical characteristics of the population are presented in **Table 1**.

**Table 1.** Demographic and clinical characteristics of respondents to the quantitative survey (n = 223).

| Attribute | |
|---|---|
| Age, mean years | 47 |
| Women | 58% |
| T1DM, n | 108 |
| Disease duration, mean years | 13 |
| Treatment duration, mean years | 13 |
| Insulin treatment basal-bolus | 100% |
| Monotherapy | 98/108 (91%) |
| Combined with other hypoglycemic agents | 10/108 (9%) |
| T2DM, n | 115 |
| Disease duration, mean years | 7 |
| Treatment duration, mean years | 5 |
| Insulin treatment | |
| Basal-bolus | 64/115 (56%) |
| Monotherapy | 46/64 (72%) |
| Combined with other hypoglycemic agents | 18/64 (28%) |
| Basal | 51/115 (44%) |
| Monotherapy | 13/51 (25%) |
| Combined with other hypoglycemic agents | 38/51 (75%) |
| Employed full-time | 165/223 (74%) |
| Experience managing insulin with an app. | 96/223 (43%) |
| Geographic location in Italy | |
| North | 123/223 (55%) |
| South Central | 100/223 (45%) |
| No financial limitations for necessities | 176/223 (79%) |

Adherence to therapy (MMAS-8)

The results from the MMAS-8 scale identified three segments: more than a quarter of patients (28%) had low compliance with insulin therapy and only 25% had high adherence (**Figure 2**). Significantly more patients with high adherence were employed full-time, reported following recommendations for diet and physical activity, and having a stable, predictable lifestyle. Highly adherent patients were significantly more likely to record their treatment history using pen and paper, a smartphone, or a computer. Overall, patients reported forgetting the timing or dosage of their last injection 2.4 times per week, and the most frequent reasons given for this were difficulty in respecting instructions and having too much information to manage (**Figure 2**).

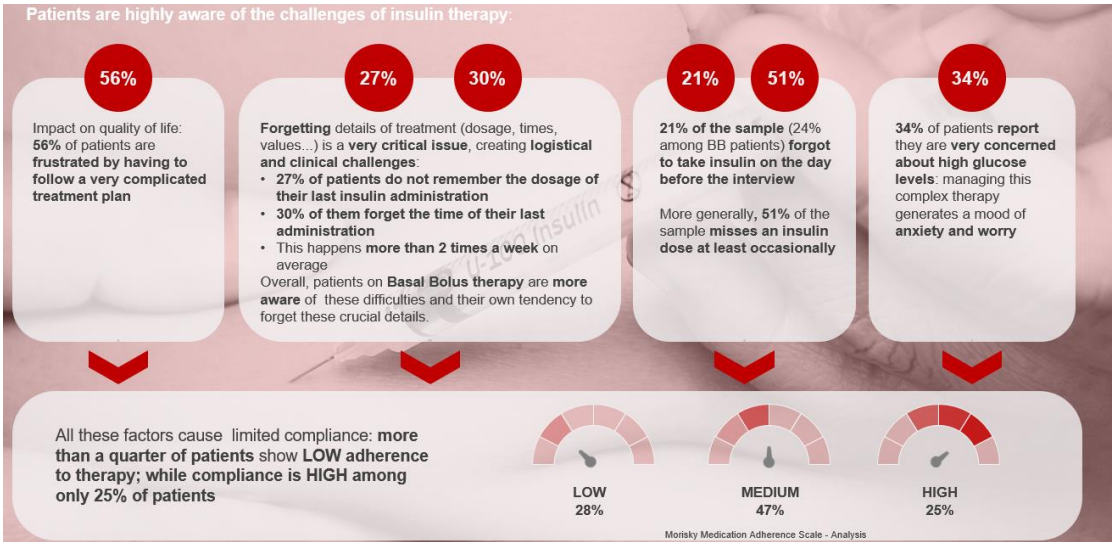


**Figure 2**. Summary of factors influencing adherence to insulin therapy.

Unmet needs that emerged from the survey

The most prominent unmet need highlighted by the survey was the necessity to overcome the cognitive burden of care associated with measuring, calculating, timing, and recording aspects of therapy. Issues mentioned by patients included the amount and complexity of data (82% of mentions), difficulty with following the rules,-and the high level of dosage accuracy required (60% of mentions). Patients report needing support specifically for administering the correct amount of insulin (58%), maintaining blood glucose in their target range (57%), monitoring blood glucose values (53%), and correctly timing insulin administrations (50%).

*New device testing*

Data on new device characteristics

When asked to compare the attributes of their current (non-connected) insulin pen with those of a connected device, 71% of patients rated the new proposal "very useful" (**Figure 3**).

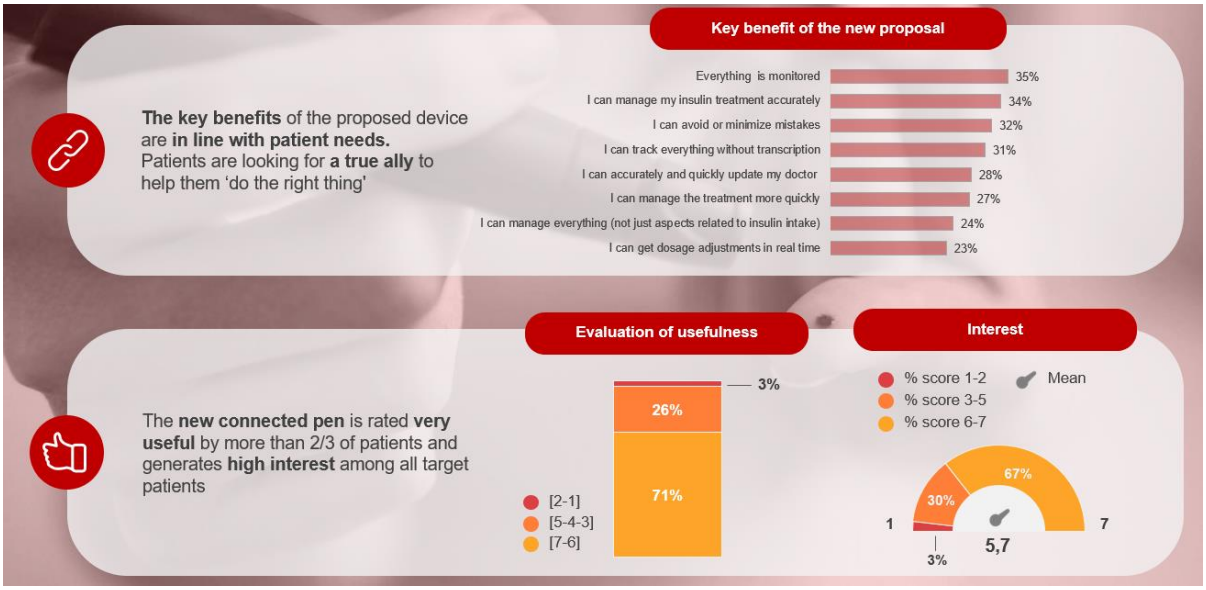


**Figure 3**. Comparison of current insulin pen with a new connected device.

## DISCUSSION

The American Diabetes Association and the European Association for the Study of Diabetes have identified patient preference as an important factor influencing medication choices [26]. We have surveyed patients' perceptions of insulin therapy in diabetes self-management to understand their unmet needs. Major patient concerns included the high cognitive burden associated with self-administration. We also assess their impression of the potential of connection-enabled insulin devices to facilitate their diabetes care. The concept of a connected insulin pen was assessed favorably, compared to non-connected pens. Findings suggest that connected insulin devices may improve patient experience with insulin therapy.

The device solution proposed in the quantitative survey was rated highest for the aspects of comprehensive monitoring of therapy (35%), favoring accurate administration of insulin treatment (34%), avoiding or minimizing mistakes (32%), and recording all data without requiring transcription (i.e., having connectivity) (31%).

We assessed adherence to treatment in this cohort of patients using non-connected insulin devices, and found that more than a quarter of respondents had low compliance with insulin therapy. This finding is consistent with the results of a patient preference survey of bolus insulin dose timing conducted in

patients with T2DM that also used the MMAS-8 scale and reported poor adherence in approximately 24% of respondents [27].

Our findings are consistent with those of a survey by Boye et al. [11], that assessed perceptions of injectable therapy among 504 patients with T2DM in the UK and US, finding that the most important characteristics of injectable medication were confidence in administering the correct dose (59.5%), ease of selecting the correct dose (53.2%), and overall ease of using the injection device (47.4%).

A discrete choice experiment conducted among 540 adult patients with T1DM or T2DM in the UK and US assessed patients' preferences for a connected insulin device over non-connected devices and the relative importance that patients place on attributes of connected insulin devices [28]. This study also revealed that patients assign a high relative importance to device attributes providing support for calculating doses and automatic transfer of blood glucose data (i.e., connectivity), and that advanced systems with either a connected smart pen or SmartButton were preferred over non-connected pens. A discrete choice experiment on injectable treatments for T2DM was conducted in Italian patients and also revealed a preference for simple treatment regimens [29].

Other recent developments that may contribute to simplifying diabetes treatment include ultra-long-acting basal insulin that allows once-weekly administration, and rapid-acting insulin that can simplify the timing of bolus dosing by eliminating the need for carefully timing bolus doses before meals.

*Study limitations:*

Some of the problems raised by our survey involve subjective issues with the level of inconvenience or complexity of the treatment regimen, rather than clinical outcomes; however, ease of use and convenience can have a strong impact on outcomes by improving adherence and by allowing more patients to administer insulin correctly. Moreover, we did not have access to data on the levels of glycated hemoglobin or other information about long-term blood glucose control that would have been useful to compare with the MMAS-8 adherence scores. Moreover, people with diabetes were recruited based on self-reported diagnosis without clinical confirmation and were identified through a convenience sample drawn from an opt-in panel of individuals who signed up to participate in healthcare research studies. The generalizability of the findings remains unknown.

**Conclusions**

This study on more than 200 patients provides numerous inputs for future research. The cognitive burden associated with self-management of diabetes therapy drives preferences for advanced insulin delivery

systems. When choosing between a standard pen and one with multiple advanced features, a connected smart pen or SmartButton was preferred.

## Statements and Declarations

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