Impatto dei sistemi Smart MDI sulla qualità di vita e sull'aderenza alla terapia

Michela Petrizzo
U.O.C. Endocrinologia e Malattie del Metabolismo
Direttore: Prof. Katherine Esposito
A.O.U. Università degli Studi della Campania Luigi Vanvitelli

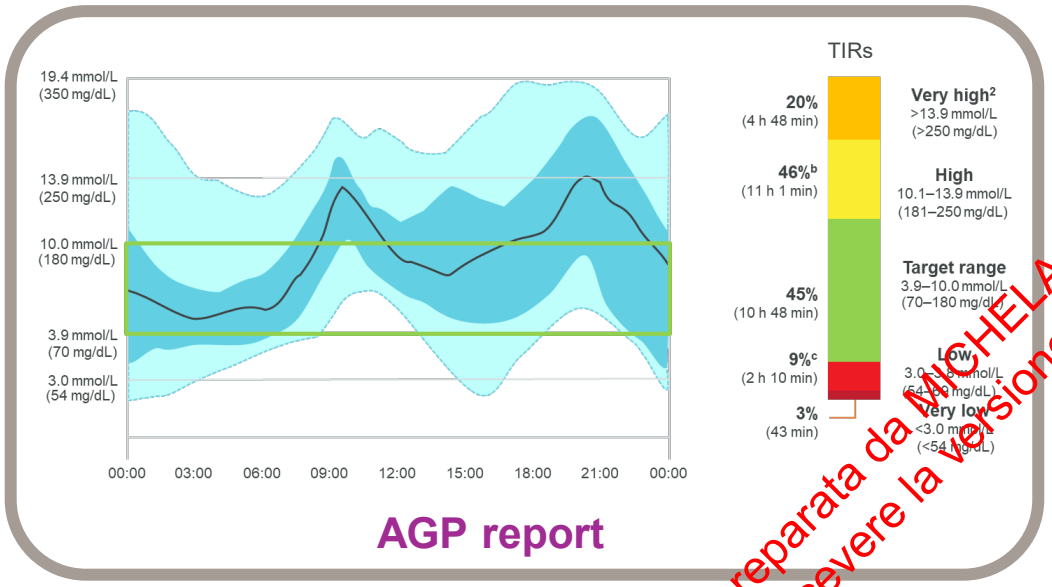
La sottoscritta dichiara di aver ricevuto negli ultimi due anni compensi o finanziamenti dalle seguenti Aziende Farmaceutiche e/o Diagnostiche:

- Farmaitalia

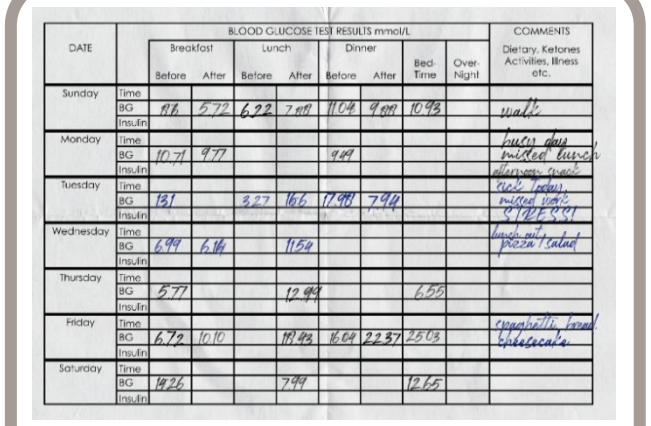
Dichiara altresì il proprio impegno ad astenersi, nell'ambito dell'evento, dal nominare, in qualsivoglia modo o forma, aziende farmaceutiche e/o denominazione commerciale e di non fare pubblicità di qualsiasi tipo relativamente a specifici prodotti di interesse sanitario (farmaci, strumenti, dispositivi medico-chirurgici, ecc.).

Blood glucose data may come to you in various formats

Blood glucose data may not be available



AGP report



Written logbook[a]

Digital logbook

	06:00	08:00	10:00	12:00	14:00	16:00	18:00	20:00	22:00	00:00
Mon	3.4	10.6		8.7	5.8		9.4	15.3	12.2	
Tue		8.4		7.8			9.6		8.8	
Wed	6.7			8.3	2.5		13.1	13.8	14.5	
Thu	13.4	14.4		9.2			10.1			
Fri	4.5			6.4			11.3		6.7	
Sat	2.9	9.2		11.9	14.6			11.6	15.8	12.8

Very high
High
Target range
Low
Very low

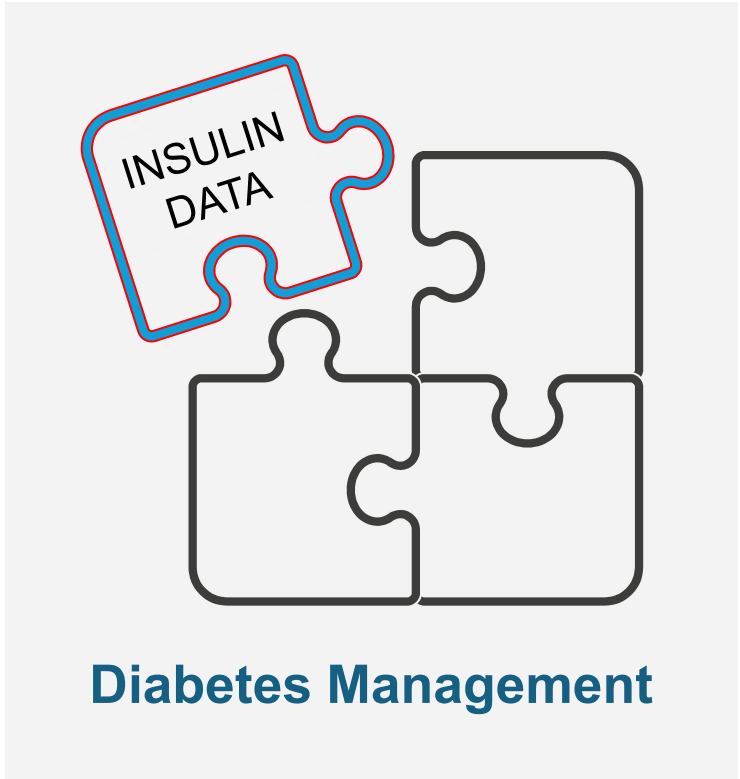
Data for a hypothetical patient.

[a]Written logbooks can be problematic for patients and their HCPs as they contain large volumes of complex information, errors and information gaps, and patients can forget to bring their logbook to visits.[1]
[b]Includes percentage of values >13.9 mmol/L (>250 mg/dL). [c]Includes percentage of values <3.0 mmol/L (<54 mg/dL).

AGP, ambulatory glucose profile; BG, blood glucose; HCPs, healthcare professionals; TIRs, time in ranges.

[1]Hinnen DA, et al. Journal of Diabetes Science and Technology. 2015;9(2): 293–301; [2]Battelino T, et al. Diabetes Care. 2019;42(8): 1593–1603.

Do we have all the relevant information?



Digital logbooks and AGP reports can provide data on glucose concentration.

But what if technology were available to also provide insulin-dosing information?

Using diabetes technology to monitor blood glucose and insulin injections can help improve life and health.[1]

1. American Diabetes Association. *Diabetes Care*. 2021;44(suppl 1):S85.

Adherence to Diabetes Medication

Adherence[1]

The extent to which a person's behavior in taking medication corresponds with agreed recommendations from an HCP regarding timing, doses, frequency, and periods

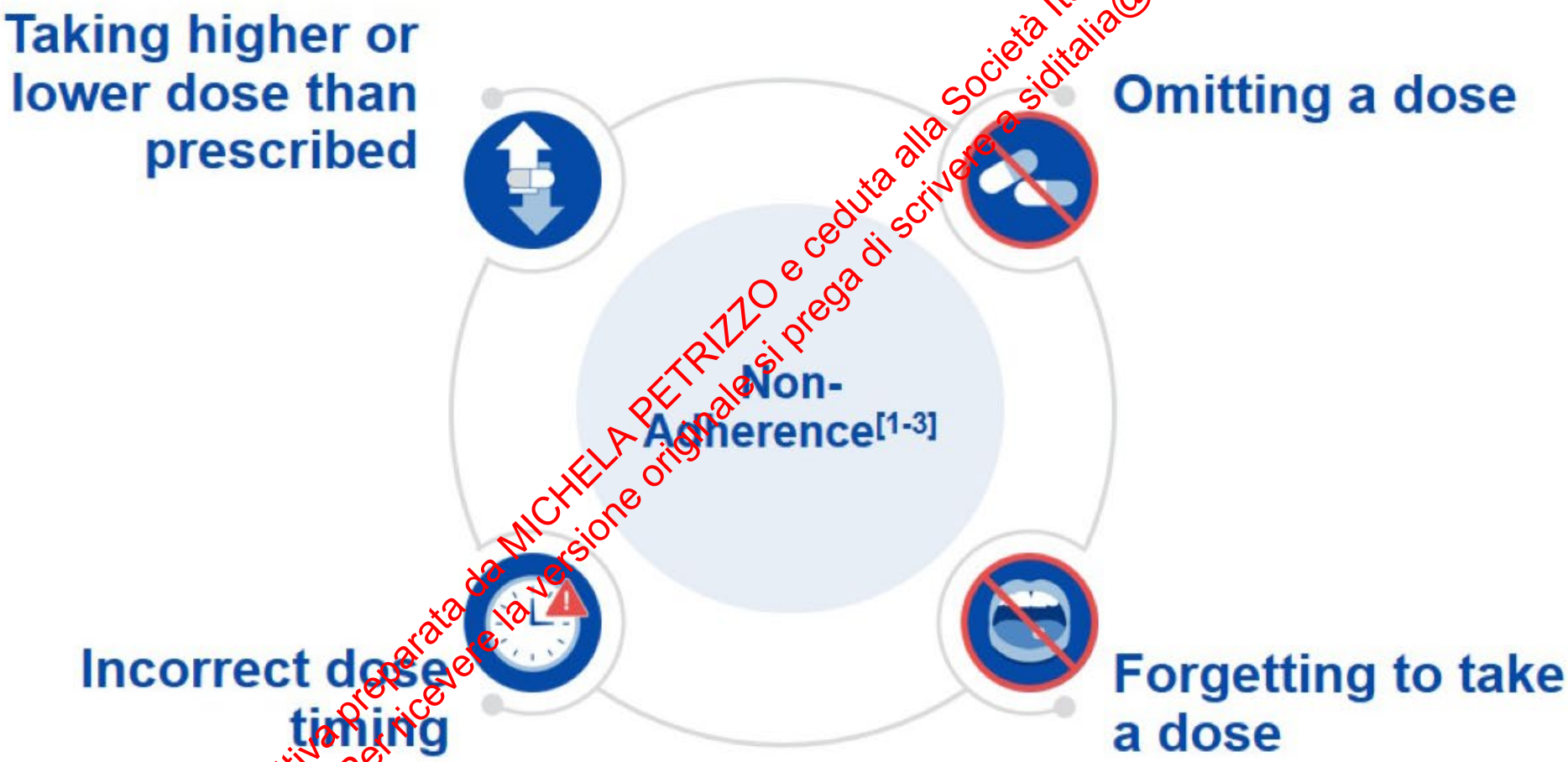
Concordance[2]

Encompasses the idea that the HCP and the patient are equals and that the person with diabetes makes informed decisions

HCP, healthcare professional.

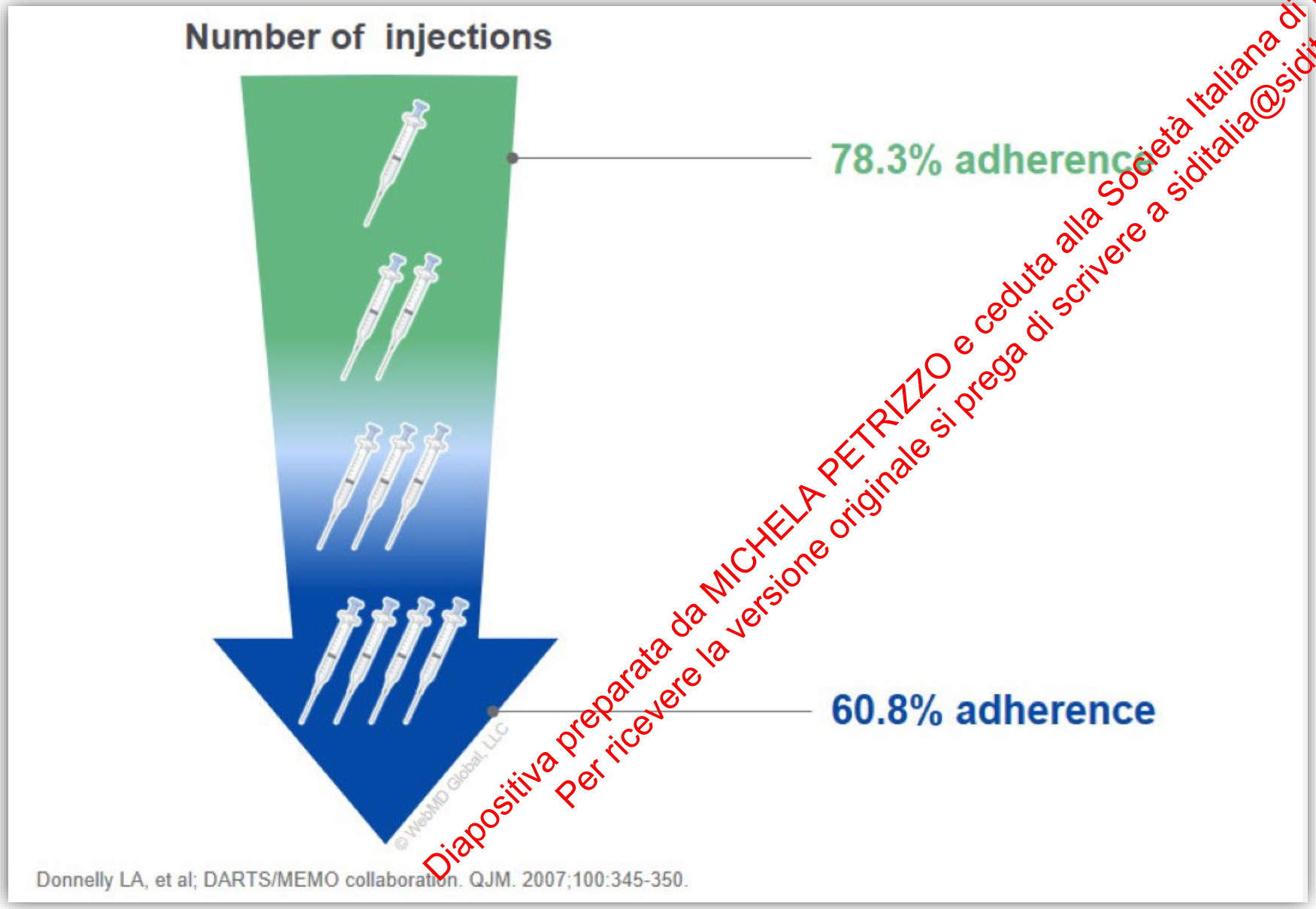
1. Osterberg L, et al. N Engl J Med. 2005;353:487-497; 2. Chakrabarti S. World J Psychiatry. 2014;4:30-36.

Example of Non-Adherence



1. WHO. 2003. World Health Organization Geneva. Accessed October July 9, 2024. https://www.paho.org/en/documents/who-adherence-long-term-therapies-evidence-action-2003; 2. Osterberg L et al. N Engl J Med. 2005;353:487-497; 3. Marcum ZA, et al. Clin Geriatr Med. 2012;28:287-300.

More Complex Insulin Regimens Lead to Lower Adherence

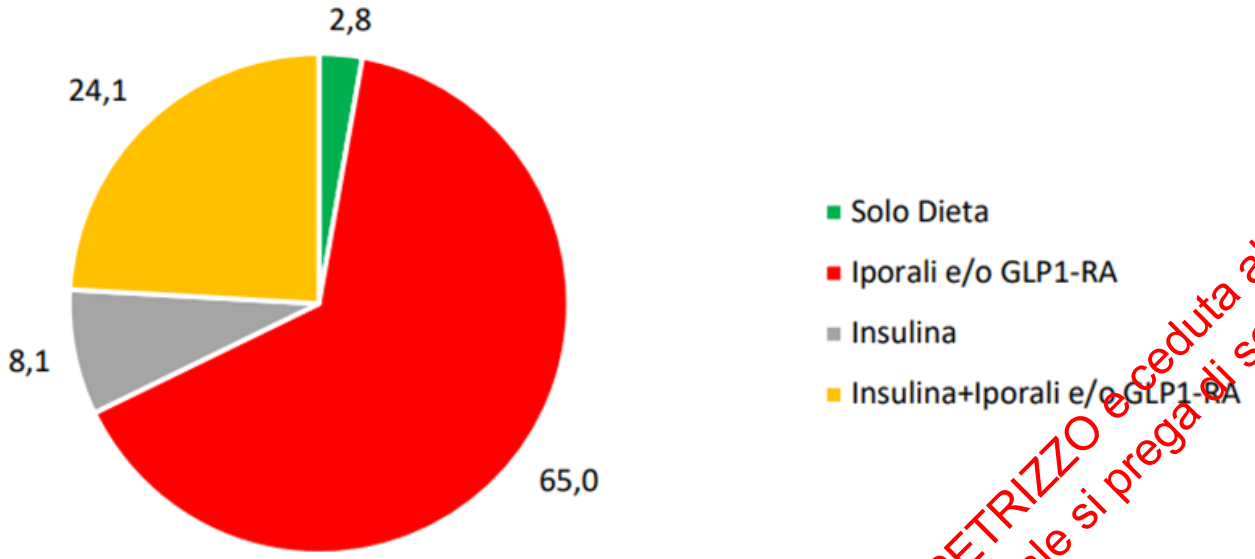


Donnelly LA, et al; DARTS/MEMO collaboration. QJM. 2007;100:345-350.

In patients with diabetes, there was an inverse relationship between adherence and the number of daily insulin injections (P<.0001)

Diabete tipo 2

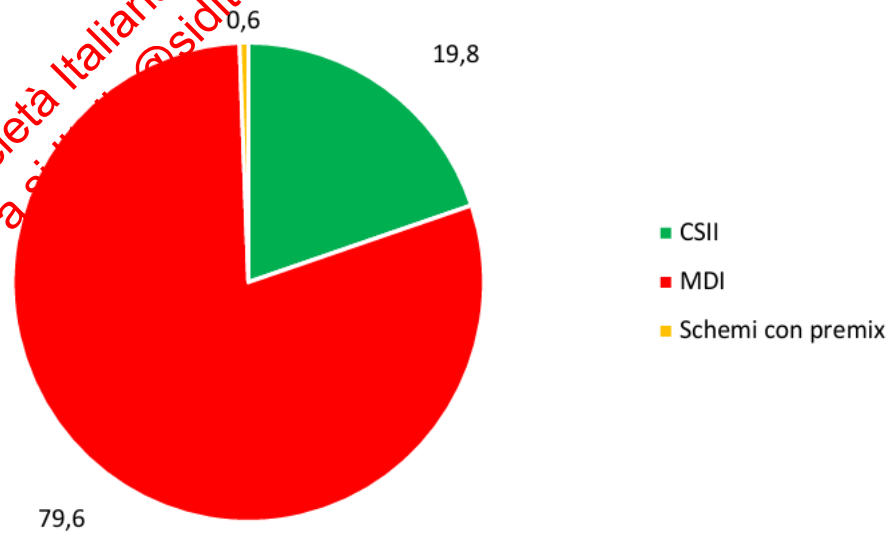
Distribuzione dei pazienti per intensità di trattamento anti-iperglicemizzante (%)



Il 2,8% dei pazienti visti non utilizza trattamenti farmacologici, il 65,0% dei pazienti utilizza solo anti-iperglicemizzanti orali/altri farmaci iniettabili diversi dall'insulina e il 32,2% utilizza insulina, da sola o in associazione ad altri farmaci anti-iperglicemici.

Diabete tipo 1

Distribuzione dei pazienti per schema di trattamento insulinico (%)



Il 19,8% dei pazienti è trattato con microinfusore, il 79.6% con schemi basal-bolus e meno dell'1% con schemi che includono l'insulina premiscelata.

Diabete tipo 1 in terapia MDI: HbA1c 7.7±1,3

Diabete tipo 2 in terapia MDI: HbA1c 7.7± 1.5

Errors in Insulin Dosing Are a Barrier to Informed Decision-Making

Low Adherence

- Approximately 1 in 4 meals are associated with late or missed insulin bolus[1]
- 1 in 3 people with diabetes report basal insulin dosing irregularity[2]

Medication Errors

- More medication errors with insulin than with any other type or class of drug[3]

Inadequate Initiation or Titration

- More than 1 in 2 PwD could not calculate an insulin dose based on a blood glucose reading or a specified carbohydrate intake[4]

1. Norlander LM, et al. Diabetes. 2018;67(Suppl 1):992-P; 2. Peyrot M, et al. Diabet Med. 2012;29:682-689; 3. Pa Patient Saf Advis. 2010;7:9-17; 4. Zaugg SD, et al. Clin Diabetes. 2014;32:152-157.

Terapia MDI: sfide cliniche

Iniezioni di insulina dimenticate

Dimenticare due iniezioni di insulina alla settimana può causare un aumento dell'HbA1c di almeno lo 0.4%.[1]

Dosaggi non calcolati correttamente

Più del 60% delle persone necessita supporto nel calcolo dei propri dosaggi di insulina.[2-3]

Iniezioni effettuate in momenti non corretti

20-45% delle persone con diabete riferisce di aver effettuato delle iniezioni nel momento sbagliato.[5]

Sovrapposizione degli effetti delle iniezioni

Difficoltà nel calcolo dell'insulina attiva può portare alla sovrapposizione e quindi all'ipoglicemia. [4]

Mancanza di reportistiche accurate sulla terapia MDI

La mancanza di dati accurati sui dosaggi e le iniezioni effettuate è una barriera significative all'ottimizzazione del controllo glicemico.[3]

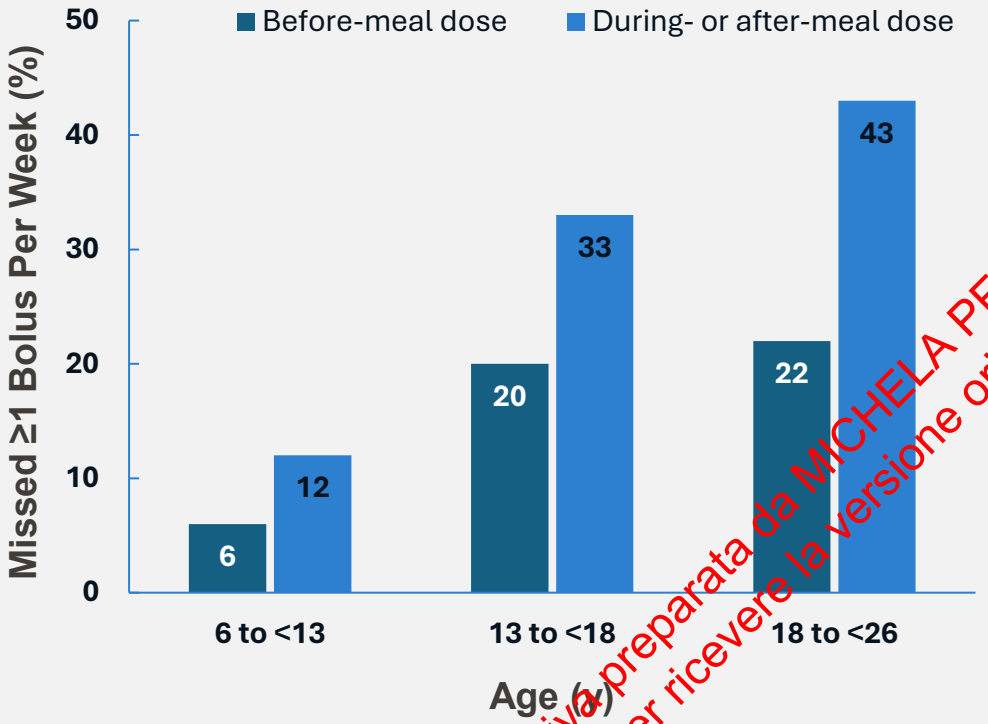
Limitate informazioni su come utilizzare i valori di glucosio forniti dal CGM

Quando si utilizza il CGM, il paziente necessita di essere educato e formato sul corretto utilizzo i dati del monitoraggio in continuo del glucosio per prendere le decisioni terapeutiche di tutti i giorni.

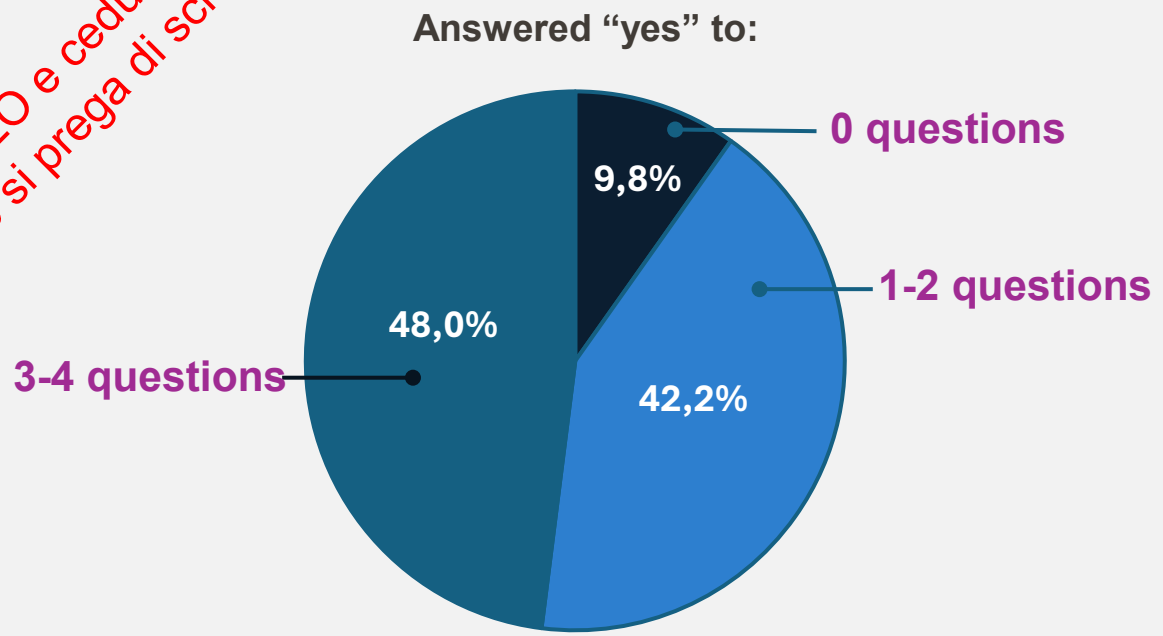
1. Randlov, J, Poulsen, JU. How Much Do Forgotten Insulin Injections Matter to Hemoglobin A1c in People with Diabetes, J Diabetes Sci Technol. 2008; 2(2):229-235.
2. Cavanaugh, K, et al. Association of numeracy and diabetes control. Annals of Internal Medicine 2008; 148(10):737-746.
3. Klonoff DC, Kerr D. Smart Pens Will Improve Insulin Therapy. J Dia Sci & Tech, 2018;12(3):551-553
4. Walsh J, et al. Confusion regarding duration of insulin action: a potential source for major insulin dose errors by bolus calculators. J Diabetes Sci Technol. 2014;8(1):170-178.
5. Robinson S et al. Missed and mistimed insulin doses in people with diabetes: a systematic literature review. Diab Technol Ther 2022: DOI: 10.1089/dia.2022.0164.

For many reasons, Non-Adherence Is Prevalent in People Living with T1D

Up to 43% of people with T1D (18 to <26 years of age) miss ≥1 mealtime insulin injection per week[1]



People with T1D were asked if in the last month they had 1) forgotten, 2) mistimed, 3) deliberately skipped, or 4) adjusted their dose without consulting their HCP[2]



T1D = type 1 diabetes.

1. Datye KA, et al. *J Diabetes Sci Technol*. 2018;12(2):349-355. 2. Gomes MB, Negrato CA. *Diabetes Res Clin Pract*. 2016;120:47-55.

Mealtime insulin: mismatch between recommendations and reality

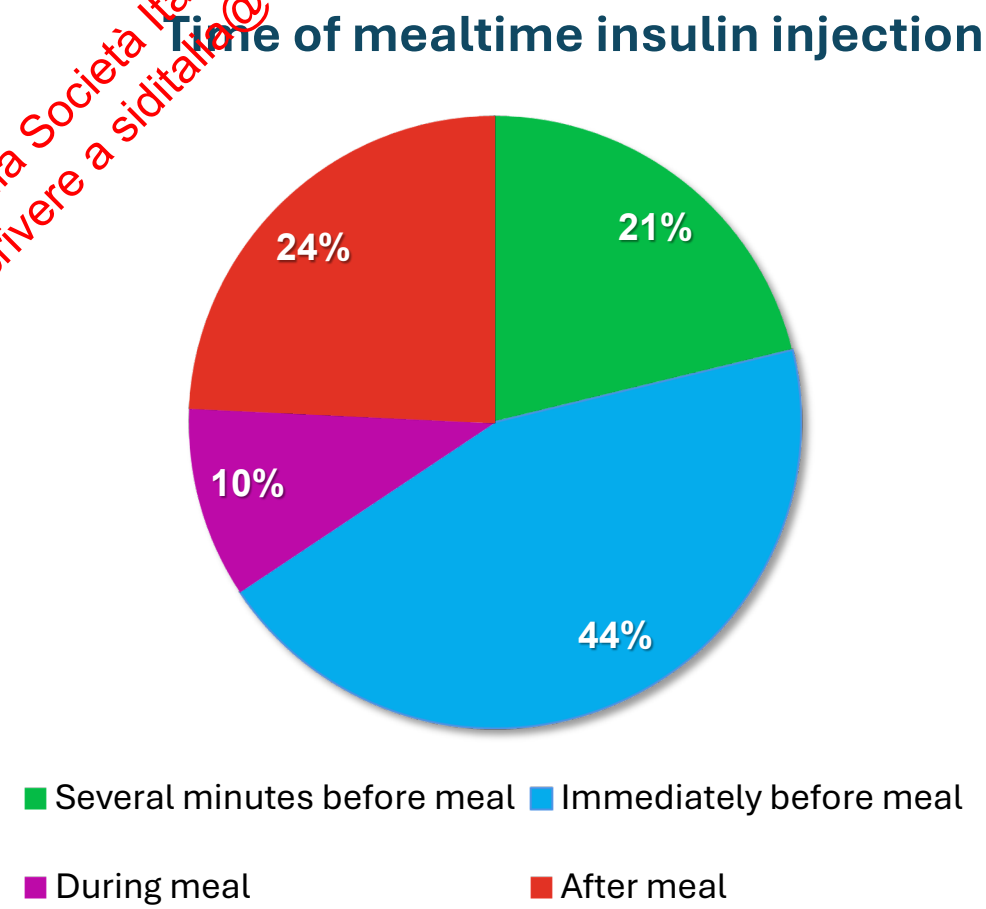
- Mismatch between insulin action and PPG elevations could result in elevated HbA1c

- Given that premeal insulin administration is associated with decreased self-report of missed meal insulin doses and lower HbA1c[1]

- Hypoglycaemia is less likely in those who dosed insulin before meals than those who dosed with or after[2]

- Currently available rapid-acting insulin analogues (e.g., insulin lispro, insulin aspart) are recommended to be injected 15–20 minutes before meal consumption to provide optimal PPG[3]

- Currently available *ultra* rapid-acting insulin analogues[a] (e.g., insulin lispro, insulin aspart) are recommended to be injected 0–2 minutes before meal consumption to provide optimal PPG[4]



[a]Ultra rapid-acting insulin analogues may not be available in all countries.

HbA1c, glycated haemoglobin; PPG, postprandial glucose.

[1]Datye KA, et al. Journal of Diabetes Science and Technology. 2018;12(2): 349–355; [2]Tamborlane WV, et al. Current Medical Research and Opinion. 2017;33(4): 639–645; [3]Slattery D, Amiel SA, Choudhary P. Diabetic Medicine. 2018;35(3): 306–316;

The time and effort required to track insulin doses can be challenging

21.6

bolus insulin doses missed

People with diabetes (PwD) in a 30-day period on average[a,1]

25%

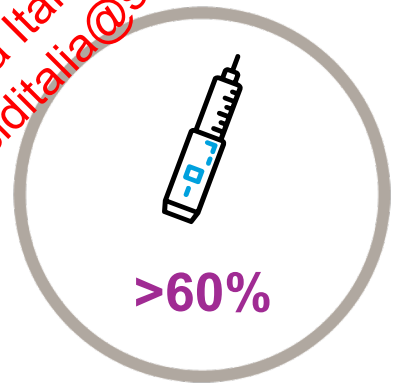
of all required mealtime insulin doses missed

PwD on mealtime insulin. Missed almost 1 dose a day on average[b,2]

1/3

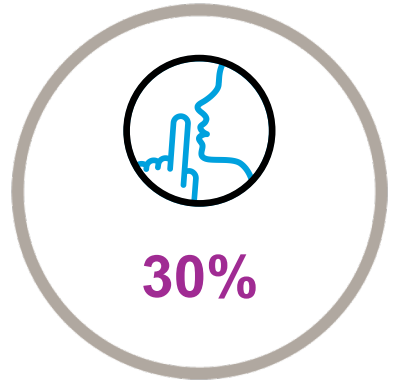
PwD report not sticking to routine

Resulted in >3 days of missed or incorrect dosing each month[c,3]



>60%

PwD say their treatment regimen is challenging and disruptive to everyday life[c,d,3]



30%

of people misrepresent or withhold information from providers due to fear of judgement[4]

Missing doses can reduce TIR and can increase TAR[1]

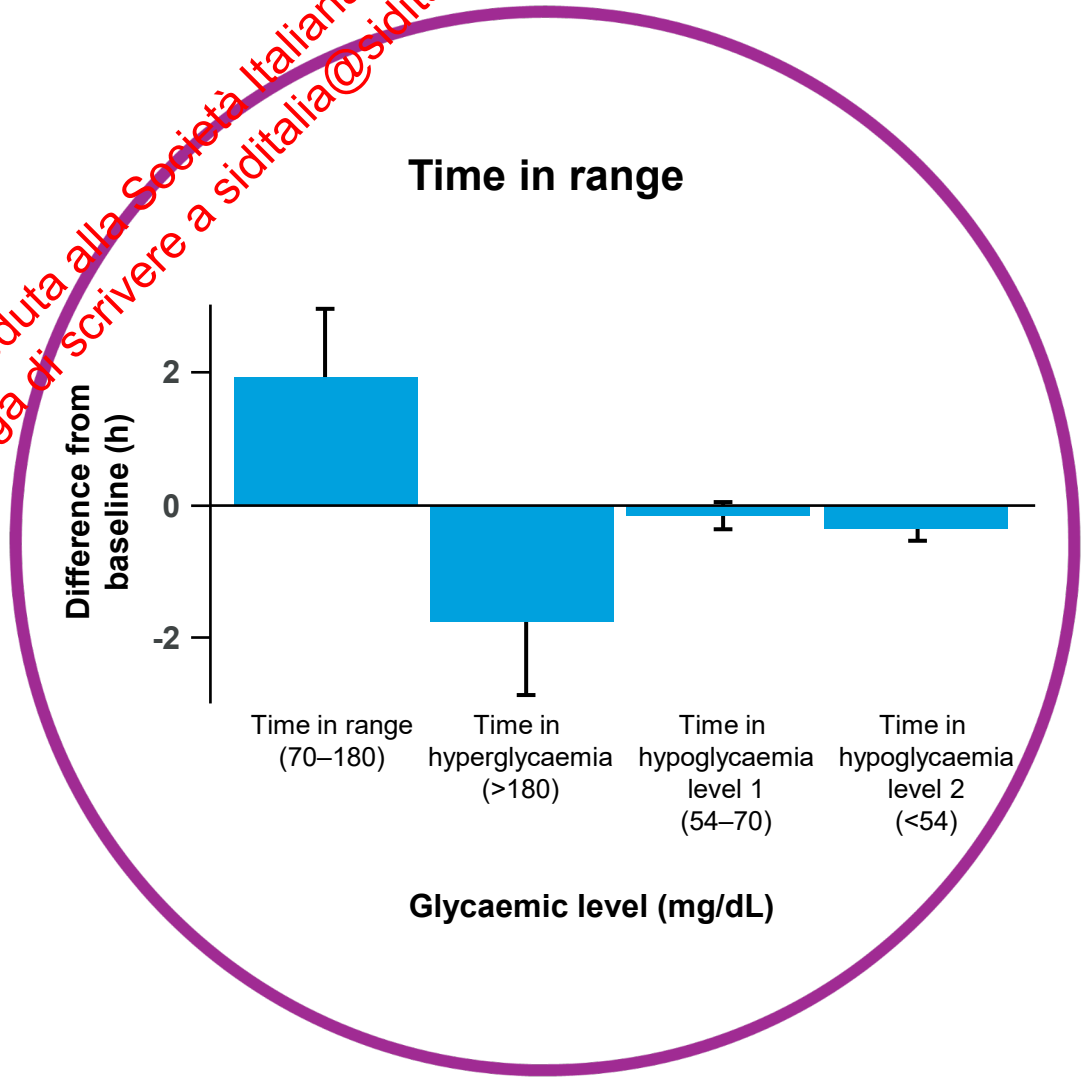
The complexity of DM treatment[5] can cause emotional distress and reduce medication adherence[6]

[a]A cross-sectional study in people with T1D or insulin-using people with T2D.
[b]A 12-week observational study in PwD with HbA1c ≥64 mmol/mol and taking three or more insulin boluses daily.
[c]An internet survey of 1250 physicians and a telephone survey of 1500 PwD.
[d]PwD considered that insulin regimen adherence was difficult because they were too busy, travelling, or reluctant to inject in public, their regimen involved too many injections, required administration at the same time each day or was too complicated.
DM, diabetes mellitus; HbA1c, glycated haemoglobin; PwD, people with diabetes; TAR, time above range; TIR, time in range; T1D, type 1 diabetes mellitus; T2D, type 2 diabetes mellitus.
[1]Edwards S, et al. Poster presented at: International Conference on ATTD; 19–22 February 2020; [2]Polonsky W, et al. In: International Conference on ATTD; 19–22 February 2020; [3]Peyrot M, et al. Diabetic Medicine. 2012;29(5): 682–689; [4]Beverly EA, et al. Diabetes Care. 2012;35(7): 1466–1472; [5]American Diabetes Association. Diabetes Care. 2019;42(Suppl 1): S1–S193; [6]Polonsky WH, et al. Patient Preference and Adherence. 2016;10: 1299–1307.

Smart pens can lead to improved adherence and time in range

- Smart pens can support good injection behaviour, with fewer missed and more well-dosed mealtime injections and greater time in glycaemic range. This could lead to better glycaemic control
- Time spent in normal glycaemic range increased significantly from 9.2 to 11.1 hours/day (*P*<0.001)
- Reductions in hyperglycaemia and level 2 hypoglycaemia were also observed

Smart pen users with T1D saw a **43% decrease** (*P*=0.002) in the average daily number of missed mealtime doses



T1D, type 1 diabetes mellitus.

Adolfsson P, et al. Diabetes Technology & Therapeutics. 2020;22(10): 709–718.

From: **Association Between Treatment Adherence and Continuous Glucose Monitoring Outcomes in People With Diabetes Using Smart Insulin Pens in a Real-World Setting**

Association Between Treatment Adherence and Continuous Glucose Monitoring Outcomes in People With Diabetes Using Smart Insulin Pens in a Real-World Setting

METHODS

Retrospective real-world analysis of observational data[a] from **3,945** adults with diabetes[b] from **16 countries** (**Europe** and **Japan**) self-administering basal[c] and bolus[d] insulin using a smart insulin pen (NovoPen 6 or NovoPen Echo Plus) alongside CGM.[e]

Treatment adherence and **smart insulin pen engagement** were assessed over 14-day periods through **missed basal**[f] and **missed bolus**[g] insulin doses, and **frequency of data uploads**.[h]

RESULTS

Mean frequency (number) and estimated probability (%) of occurrence over a 14-day period

Missed basal insulin doses: 0.19
Missing ≥ 1 basal dose: 17.6% (95% CI: 16.5%, 18.7%)

Missed bolus insulin doses: 6.0
Missing ≥ 1 bolus dose: 99.1% (95% CI: 98.7%, 99.4%)

Over a 14-day period, one **missed basal** insulin dose or one **missed bolus** insulin dose was associated with:

- a significant decrease in the percentage of **TIR (3.9–10.0 mmol/L)** of **−2.8%** and **−1.7%**
- a significant increase in **GMI score** of **+0.2%** and **+0.1%**

Smart insulin pen engagement was positively associated with **glycemic outcomes**.

- Over a 14-day period, **1 day with at least one data upload** was associated with a significant increase (**+0.5%**) in percentage of **TIR (3.9–10.0 mmol/L)**.

These data highlight the challenges of adhering to basal-bolus insulin treatment in a real-world setting. **Missing two basal or four bolus insulin doses** over a 14-day period was associated with a **clinically relevant decrease of > 5%** in the percentage of **TIR (3.9–10.0 mmol/L)**.

[a]Data collection period: March 23, 2021–July 8, 2022. Consented to sharing anonymous data. [c]Insulin degludec. [d]Insulin aspart or fast-acting insulin aspart. [e]Data from smart insulin pens and CGM devices were aggregated into 14-day periods. [f]A missed basal insulin dose was defined as a window of > 40 h between two consecutive doses. [g]A missed bolus insulin dose was defined as a meal with no bolus insulin injection within the window of 15 min before to 1 h after the start of a meal, with meals detected from the CGM signal. [h]The number of days with a data upload was used as a proxy for smart insulin pen engagement. CGM, continuous glucose monitoring; GMI, glucose management indicator; SD, standard deviation; TBR, time below range; TIR, time in range.

Diabetes Care. 2024;47(6):995-1003. doi:10.2337/dc23-2176

diabetology

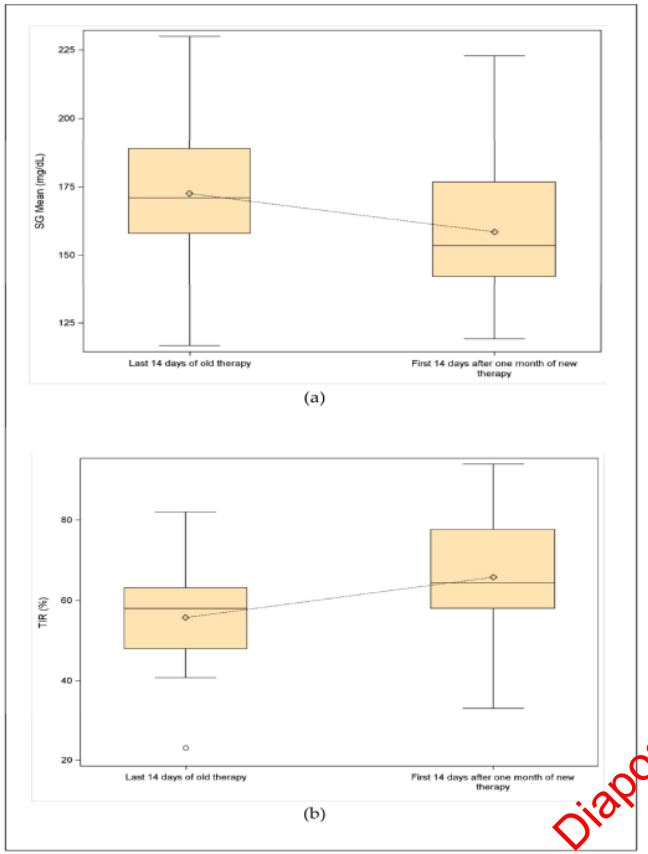
MDPI

Conclusions: The transition to the Smart MDI system significantly enhanced glycemic control by lowering mean glucose levels and increasing TIR. These findings highlight its efficacy in improving hyperglycemia management while maintaining a stable risk of hypoglycemia.

Article

Real-World Life Analysis of a Continuous Glucose Monitoring and Smart Insulin Pen System in Type 1 Diabetes: A Cohort Study

Paola Pantanetti [1,†], Giovanni Cangelosi [1,*,†], Sara Morales Palomares [2], Gaetano Ferrara [3], Federico Biondini [4], Stefano Mancin [5,*], Gabriele Caggianelli [6], Mauro Parozzi [7], Marco Sguanci [8,‡] and Fabio Petrelli [9,‡]



(a) Change in SG mean from standard MDI to Smart MDI;

(b) Change in TIR from standard MDI to Smart MDI.

Table 5. Comparison Between Standard MDI and Medtronic Smart MDI.

Measure	Summary Statistics	Last 14 Days of Old Therapy (n = 17)	First 14 Days After One Month of New Therapy (n = 17)	p-Value
SG mean (mg/dL)	Available Measures (%)	17 (100.0%)	17 (100.0%)	0.035
	Mean ± SD	172.5 ± 25.3	158.5 ± 26.5	
	Median (IQR)	171.0 (158.0–189.0)	153.5 (142.2–176.7)	
	Min–Max	116.7–230.0	119.2–222.9	

Sensor Glucose (SG) decreased from 171.0 mg/dL to 153.5 mg/dL (p = 0.035)

TAR (%)	Min–Max	0.5–43.0	0.0–38.6	0.015
	Available Measures (%)	17 (100.0%)	17 (100.0%)	
	Mean ± SD	40.3 ± 15.0	31.4 ± 16.3	
	Median (IQR)	39.0 (35.0–46.0)	34.2 (19.8–41.3)	
	Min–Max	5.9–76.0	5.4–66.0	

Time In Range (TIR) increased from 58.0% to 64.4% (p = 0.005)

TIR (%)	Available Measures (%)	17 (100.0%)	17 (100.0%)	0.005
	Mean ± SD	55.7 ± 13.7	65.8 ± 15.6	
	Median (IQR)	58.0 (48.0–63.2)	64.4 (58.0–77.6)	
	Min–Max	23.0–82.0	33.1–93.9	

Time above range (TAR; >180 mg/dL) decreased from 39.0% to 34.2% (p = 0.015)

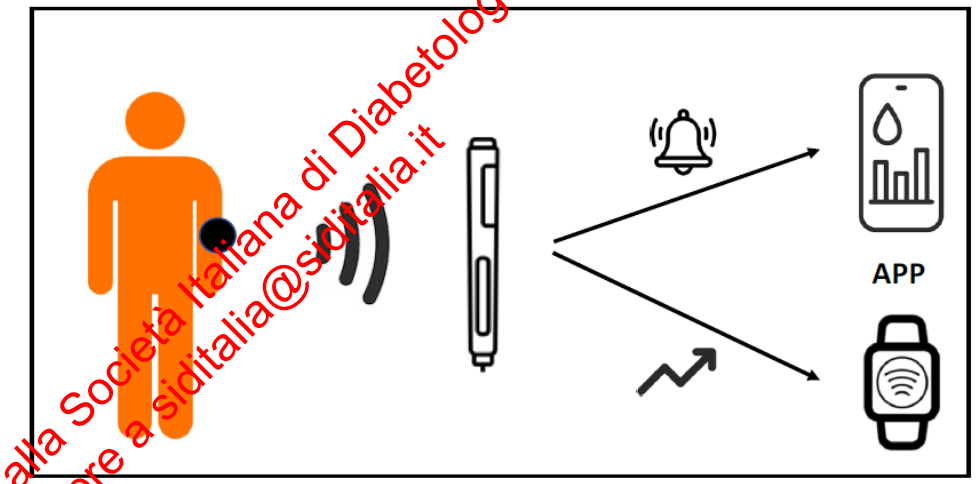
Review Article

The Utility of Smart Multiple Daily Injection Systems in Intensive Insulin-Treated People With Diabetes: An Italian Expert Consensus

Journal of Diabetes Science and Technology
1–10

DOI: 10.1177/19322968251316577
journals.sagepub.com/home/dst
Sage

Francesco Giorgino, MD[1], Riccardo Bonfanti, MD[2], Filomena Castaldo, MD[3], Concetta Irace, MD[4], Andrea Laurenzi, MD[5,6], Claudio Maffeis, MD[7], Giovanni Pappagallo, PhD[8], Dario Pitocco, MD[9], Ivana Rabbone, MD[10], Emanuela Zarra, MD[11], and Andrea Enzo Scaramuzza, MD[12]



Improved Adherence to Insulin Therapy

1. Adherence to insulin therapy is often problematic but can be improved by an administration tracking system (dosage, timing, timing with respect to meals, and forgotten boluses).
2. A Smart MDI system allows programming of reminders, alerts, and alarms related to insulin bolus administration/glycemic values and suggests appropriate interventions.
3. The ability to record the therapy administered and highlight errores or inadequacies retrospectively can help people with diabetes to manage their therapy.

The Patient - Patient-Centered Outcomes Research (2023) 16:127–138
https://doi.org/10.1007/s40271-022-00610-x

ORIGINAL RESEARCH ARTICLE

Patients' Preferences for Connected Insulin Pens: A Discrete Choice Experiment Among Patients with Type 1 and Type 2 Diabetes

Jaein Seo[1] · Sebastian Heidenreich[2] · Esraa Aldalooj[2] · Jiat Ling Poon[3] · Erik Spaepen[4] · Elizabeth L. Eby[3] · Rachel S. Newson[5]

Accepted: 3 November 2022 / Published online: 28 November 2022

Key Points for Decision Makers

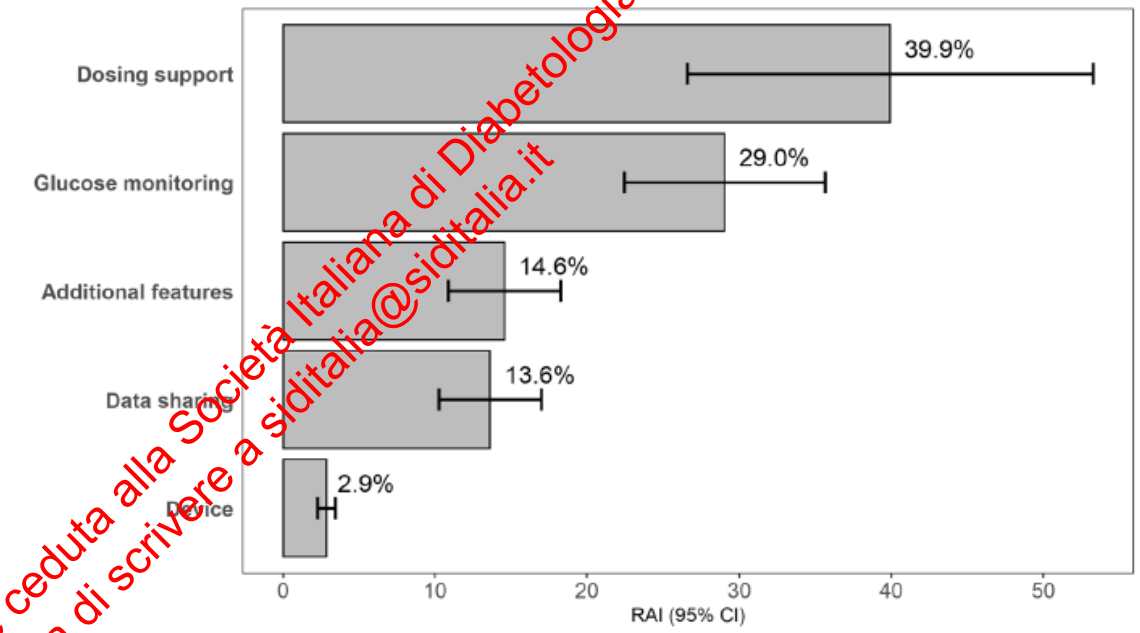
This study of adults with diabetes in the USA and UK showed that most (75%) would prefer to inject insulin with an insulin pen connected to a mobile app, rather than with a non-connected insulin pen.

Most people in the study preferred connected insulin pens over non-connected pens because they can automatically log insulin doses and record glucose levels.

A minority (9%) remained skeptical of connected insulin pens but could be convinced if the pens offered features beyond insulin dose and glucose logging, while others (16%) would not use any connected insulin pen.

https://doi.org/10.1007/s40271-022-00610-x

Relative attribute importance (RAI)



Characteristic	Overall ($N = 540$)	USA ($N = 336$)	UK ($N = 204$)
Previous use of an app for diabetes, *n* (%)			
Currently using one app	106 (19.6)	61 (18.2)	45 (22.1)
Currently using more than one app	15 (2.8)	6 (1.8)	9 (4.4)
Not using anymore	31 (5.7)	20 (6.0)	11 (5.4)
Not used any, but willing to try	286 (53.0)	179 (53.3)	107 (52.5)
Not used any, and not willing to try	102 (18.9)	70 (20.8)	32 (15.7)
Diabetes app functions, *n* (%)[a]			
Blood sugar tracking	136 (25.2)	77 (22.9)	59 (28.9)
Insulin dose tracking	60 (11.1)	26 (7.7)	34 (16.7)
Data sharing with healthcare provider	78 (14.4)	43 (12.8)	35 (17.2)
Potential recipients of data sharing, *n* (%)[a]			
Healthcare professional	475 (88.0)	301 (89.6)	174 (85.3)
I would not share my data	52 (9.6)	28 (8.3)	24 (11.8)
Reasons for not sharing data, *n* (%)[a]			
Concern about data privacy	28 (5.2)	19 (5.7)	9 (4.4)
Prefer sharing manually/verbally	23 (4.3)	10 (3.0)	13 (6.4)

[a]Responses were not mutually exclusive

Experience using an app for diabetes

Facilitating Positive Behaviors and Well-being to Improve Health Outcomes

Table 5.7—Psychosocial concerns and their association with diabetes-related outcomes in adults with type 1 diabetes

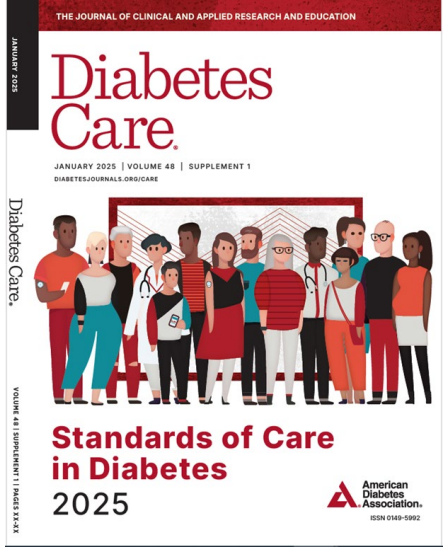
	Increased A1C	Increased blood pressure	Increased cholesterol	Increased macrovascular complications	Increased microvascular complications	Decreased self-care behaviors	Comorbid psychosocial concerns	Decreased quality of life	Increased mortality
Diabetes distress (406,528–530)	+++	?	+	+++	+++	+++	+++	+++	?
Depression and depressive symptoms (528,529,531,532)	+++	?	+++	+++	+++	+++	+++	+++	+++
Anxiety (359,533,534)	+++	?	?	?	?	+++	+++	+++	?
Disordered eating behaviors (insulin omission) (535,536)	+++	?	?	?	+++	+++	+++	+++	+++
Serious mental illness (schizophrenia, personality disorders) (537–539)	+++	?	+	+++	+++	?	+++	?	+++
Cognitive impairment (540–544)	+++	+++	+++	+++	+++	++	+++	?	+++

+++, strong evidence (consistent findings in multiple studies of good methodological quality or one study of excellent methodological quality); ++, moderate evidence (consistent findings in multiple studies of fair methodological quality or one study of good methodological quality); +, limited evidence (evidence from one study of fair methodological quality); ?, no data available.

Table 5.8—Psychosocial concerns and their association with diabetes-related outcomes in adults with type 2 diabetes

	Increased A1C	Increased blood pressure	Increased dyslipidemia	Increased macrovascular complications	Increased microvascular complications	Decreased self-care behaviors	Comorbid psychosocial concerns	Decreased quality of life	Increased mortality
Diabetes distress (545–551)	+++	+	+	+++	+++	+++	+++	+++	+++
Depression and depressive symptoms (552–559)	+++	++	+++	+++	+++	+++	+++	+++	+++
Anxiety (358,408,553,560–563)	+++	++	+	+++	+	+++	+++	+++	+++
Disordered eating behaviors (binge eating disorder, night eating syndrome) (564–567)	+/–	?	?	?	?	+	+++	+++	?
Serious mental illness (schizophrenia, bipolar disorder) (568–575)	+/–	?	?	+++	+++	+++	+++	+++	+++
Cognitive impairment (576–583)	+++	+++	+++	+++	+++	+++	+++	+++	+++

+++, strong evidence (consistent findings in multiple studies of good methodological quality or one study of excellent methodological quality); ++, moderate evidence (consistent findings in multiple studies of fair methodological quality or one study of good methodological quality); +, limited evidence (evidence from one study of fair methodological quality); +/–, inconclusive evidence; ?, no data available.



Facilitating Positive Heath Behaviors and Well-being to Improve Health Outcomes:
Standards of Care in Diabetes - 2025. Diabetes Care 2025;48(Suppl. 1):S86-S127

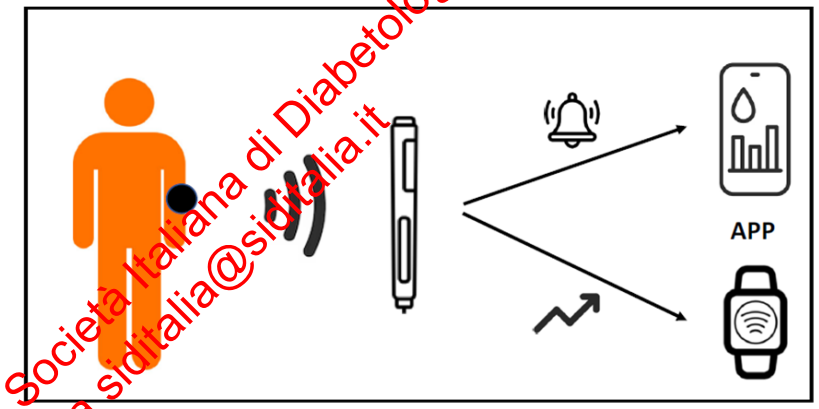
Review Article

The Utility of Smart Multiple Daily Injection Systems in Intensive Insulin-Treated People With Diabetes: An Italian Expert Consensus

Journal of Diabetes Science and Technology
1–10

DOI: 10.1177/19322968251316577
journals.sagepub.com/home/dst
Sage

Francesco Giorgino, MD[1], Riccardo Bonfanti, MD[2], Filomena Castaldo, MD[3], Concetta Irace, MD[4], Andrea Laurenzi, MD[5,6], Claudio Maffeis, MD[7], Giovanni Pappagallo, PhD[8], Dario Pitocco, MD[9], Ivana Rabbone, MD[10], Emanuela Zarra, MD[11], and Andrea Enzo Scaramuzza, MD[12]

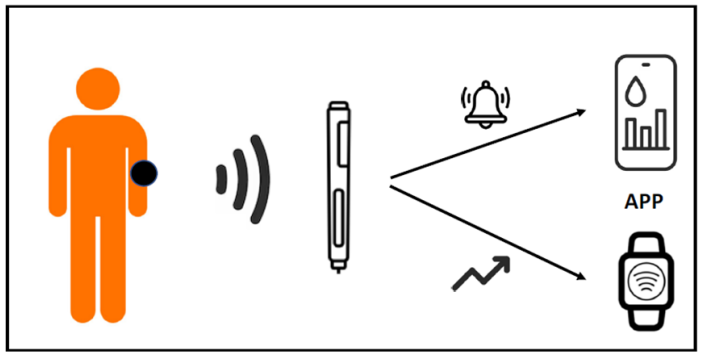


Influence on Quality of Life and Other Patient-Reported Outcomes

1. Reducing time in hyper/hypoglycemia and increasing time in range improves QoL, and a Smart MDI system can help achieve these therapeutic goals while reducing fear of hypoglycemia.
2. The use of Smart MDI promotes patient-diabetologist interactions, reduces patient workload by removing the need to compile electronic diaries, facilitates retrospective data analysis that increases patient awareness of disease management, helps the patient define mealtime insulin doses and corrective boluses, and provides insulin bolus reminders. Clinical studies will establish whether these have a relevant impact on QoL.

Prevention of Hypoglycemic Events and Related Anxiety

1. Assessing IOB can reduce the risk of hypoglycemia from insulin stacking.
2. Use of a Smart MDI system may reduce hypoglycemia by integrating glucose sensor data in the calculation and suggesting the correct insulin dose.
3. These characteristics of a Smart MDI system may reduce fear and anxiety regarding hypoglycemic events.



- DTSQs
- SF12
- SF36

Ultimi 14 gg della precedente terapia MDI

Primi 14 gg della terapia SMART MDI

Caratteristiche cliniche e demografiche dei pazienti inclusi nell'osservazione

Parametri	T1D (n=33)
M/F	15/18
Diabete mellito tipo 1, % pz	100
Età, anni	29,2 ± 10,9
Durata diabete, anni	16,8 ± 11,7
TIR (70-180 mg/dl), %	50,5 ± 20,8
TAR (181-250 mg/dl), %	27,9 ± 12,1
TAR (> 250 mg/dl), %	19,8 ± 16,2
TBR (54-69 mg/dl), %	1,6 ± 1,6
TBR (<54 mg/dl), %	0,1 ± 0,4
GMI, %	7,5 ± 0,8
CV, %	35,5 ± 7,7

I valori sono espressi come media ± deviazione standard.
Abbreviazioni: TIR, time in range; TAR, time above range, TBR, time below range, GMI, glucose management indicator, CV, coefficient di variazione

Diabetes Treatment Satisfaction Questionnaire (DTSQ)

Università degli Studi della Campania *Luigi Vanvitelli*

Parametri	T0	T1	*p*	*p ΔM vs ΔF*
Q 1,4,5,6,7 e 8	26.182 ± 5.593	28.818 ± 3.844	0,026	0,757
Q 2	4 (3,4)	3 (2,4)	0,005	0,019
Q 3	3 (2,4)	3 (1,4)	0,966	0,061

I valori sono espressi come media ± deviazione standard o come mediana (range interquartile).
Abbreviazioni: T0: Terapia multiniettiva tradizionale, T1: Terapia multiniettiva con SmartMDI.
ΔM: delta maschi, ΔF: delta femmine. Q: questions del DTSQs

Il primo parametro valuta il «gradimento del trattamento» e consiste in 6 domande che riguardano:

- *Soddisfazione per il trattamento attuale*
- *Flessibilità*
- *Convenienza*
- *Comprensione del diabete*
- *Raccomandazione del trattamento agli altri*
- *Volontà di continuare*

Il secondo parametro è costituito da due domande che valutano il carico derivante:

- *dall'iperglicemia (Q2)*
- *dall'ipoglicemia (Q3)*

Nicolucci A, Giorgino R, Cucinotta D, et al. Validation of the Italian version of the WHO Well-Being Questionnaire (WHO-WBQ) and the WHO-Diabetes Treatment Satisfaction Questionnaire (WHO-DTSQ) Diabetes Nutr. Metab. 2004;17:235–243.

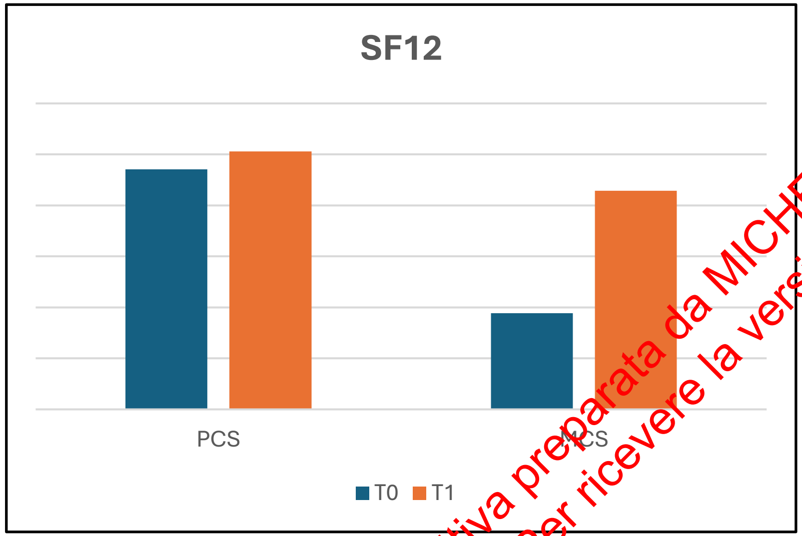
Università
degli Studi
della Campania
Luigi Vanvitelli

SF12

Il questionario SF-12 (Short form health survey) consiste in 12 domande finalizzate alla valutazione della salute fisica e mentale.

Parametri	T0	T1	p	p Δ M vs Δ F
PCS	51.413 (48.453, 54.780)	52.112 (45.467, 55.893)	0,7217	0,035
MCS	45.772 (35.40, 51.99)	50.57 (31.99, 56.75)	0,106	0,332

I valori sono espressi come mediana (range interquartile).
Abbreviazioni: T0: Terapia multiniettiva tradizionale, T1: Terapia multiniettiva con SmartMDI.
ΔM: delta maschi, ΔF: delta femmine. PCS: State of Physical health, MCS: State of Mental health



MCS *(State of Mental health) analizza specifici aspetti della salute mentale:*

PCS *(State of Physical health) analizza specifici aspetti della salute fisica:*

- *Vitalità*
- *Attività fisica*
- *Attività sociali*
- *Limitazione di ruolo dovute alla salute fisica*
- *Stato emotivo*
- *Dolore fisico*
- *Stato mentale*
- *Salute generale*
- *Salute generale*

Ware J Jr, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Med Care. 1996 Mar;34(3):220-33. doi: 10.1097/00005650-199603000-00003. PMID: 8628042.

SF36

Parametri	T0	T1	p	p Δ M vs Δ F
Funzionamento fisico	95 (85, 100)	100 (80, 100)	0,426	0,004
Limitazioni del ruolo dovute alla salute fisica	100 (50, 100)	100 (100, 100)	0,03	0,016
Limitazioni di ruolo dovute a problemi emotivi	100 (33.3, 100)	100 (33.3, 100)	0,91	0,016
Energia/fatica	70 (50, 75)	75 (55, 75)	0,142	0,017
Benessere emotivo	72 (44, 76)	68 (52, 84)	0,235	0,515
Funzionamento sociale	75 (62.5, 87.5)	75 (75, 87.5)	0,304	0.172
Dolore	90 (57.5, 100)	100 (67.5, 100)	0,266	0.061
Salute generale	55 (45, 70)	55 (50, 70)	0,045	<0.001
Cambiamento di salute	50 (50, 75)	75 (75, 100)	0,006	0.028

I valori sono espressi come mediana (range interquartile).
Abbreviazioni: T0: Terapia multiniettiva tradizionale, T1: Terapia multiniettiva con SmartMDI.
ΔM: delta maschi, ΔF: delta femmine.

*L'**SF-36** (Short form health survey) è un questionario generico, multidimensionale, costituito da 36 domande suddivisibili in 8 domini che permettono di cogliere l'impatto della malattia su varie dimensioni della qualità di vita.*

Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care. 1992 Jun;30(6):473-83. PMID: 1593914.

Benefits of Engagement with Diabetes Technology

- Avoidance of hypoglycemia or hyperglycemia using CGM with alarms[1]
- Improved awareness and engagement[1,2]
- Help with remembering to take insulin[1]
- Help with insulin dose calculation to avoid underdosing or overdosing[1]

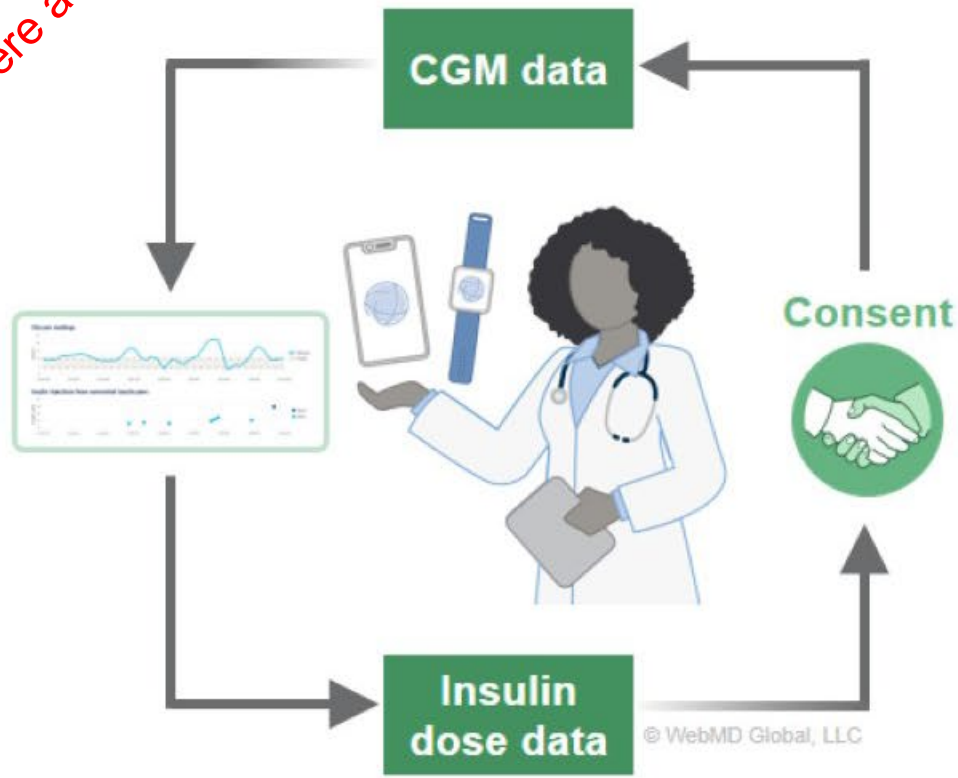
1. Klonoff DC, et al. J Diabetes Sci Technol. 2018;12:551-553; 2. Faculty insight, Julia Mader, MD.

SMART MDI

Benefits of connected pens for patients, HCPs and health systems[1]

People with diabetes	▪ Safety and hypoglycemia avoidance ▪ Smartphone app supports dosing reminders ▪ Software updates deliver frequently improved digital tools ▪ Data integration with glucose sensing
HCPs	▪ Automatic data capture facilitates retrospective review ▪ Machine learning can support therapeutic decisions
Health systems	▪ Identify and support high-risk patients ▪ Connected data ecosystem promotes asynchronous care

Linking insulin dosing to CGM with connected pens[2]



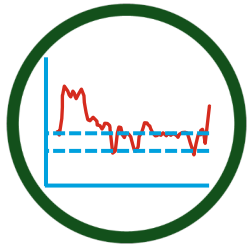
CGM, continuous glucose monitoring; HCP, healthcare provider

1. Kompala T, et al. J Diabetes Sci Technol. 2022;16:596-604; 2. Grunberger G, et al. Endocr Pract. 2021;27:505-537

Key take-aways

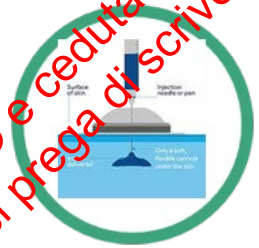
Il tempo e lo sforzo necessari per tenere **traccia delle dosi di insulina** possono essere impegnativi[1] .

I principali **vantaggi del CGM** includono il monitoraggio dei dati del glucosio in tempo reale per le persone con diabete e l'accesso a report completi per i loro sanitari (incluse **escursioni glicemiche dovute ad omissione di boli)**



Le dosi di insulina mancanti possono ridurre il TIR e aumentare il tempo al di sopra del range (TAR)[2]

La complessità della terapia antidiabete può causare disagio emotive e ridurre aderenza. **La SMART MDI può portare a una migliore aderenza e ad un aumento del TIR[5] .**



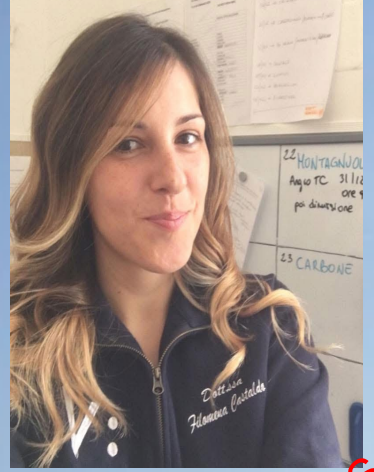
Chiunque sperimenti sfide emotive legate alla terapia iniettiva, come **paura, ansia e stress o il loro impatto fisico, può trarre beneficio da SMART MDI**. Tale sistema può facilitare anche la somministrazione di dosi aggiuntive di insulina (ad es. nei boli di correzione).

I diari elettronici possono aiutare gli operatori sanitari e persone con diabete ad **ottimizzare il tempo**. Le soluzioni digitali **aiutano ad affrontare le sfide** nella gestione del diabete

HCP, healthcare provider.

[1]Peyrot M, et al. Diabetic Medicine. 2012;29(5): 682–689; [2]Edwards S, et al. Poster presented at: International Conference on ATTD; 19–22 February 2020; [3]American Diabetes Association. Diabetes Care. 2019;42 Suppl 1: S1–S193; [4]Polonsky WH, et al. Patient Preference and Adherence. 2016;10: 1299–1307; [5]Adolfsson P, et al. Diabetes Technology & Therapeutics. 2020;22(10): 709–718; [6]Hinnen DA, et al. Journal of Diabetes Science and Technology. 2015;9(2): 293–301; [7]Warshaw H, et al. The Diabetes EDUCATOR. 2020;46(S4): 3S–20S.





Tecnologia per la Gestione e la Cura del diabete
UOC Endocrinologia e Malattie del Metabolismo
AOU Università degli Studi della Campania
Luigi Vanvitelli

Università degli Studi della Campania Luigi Vanvitelli

AOV Azienda Ospedaliera Universitaria Luigi Vanvitelli