

I SESSIONE: Il diabete diventa sempre più tech: evoluzione delle tecnologie

I sensori, facilitatori del percorso assistenziale e
del rapporto medico-paziente nel paziente
diabetico.

Quale ruolo dell'SMBG oggi?

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Policlinico P. Giaccone Palermo
Direttore Prof. G. Arnaldi



con il patrocinio di:



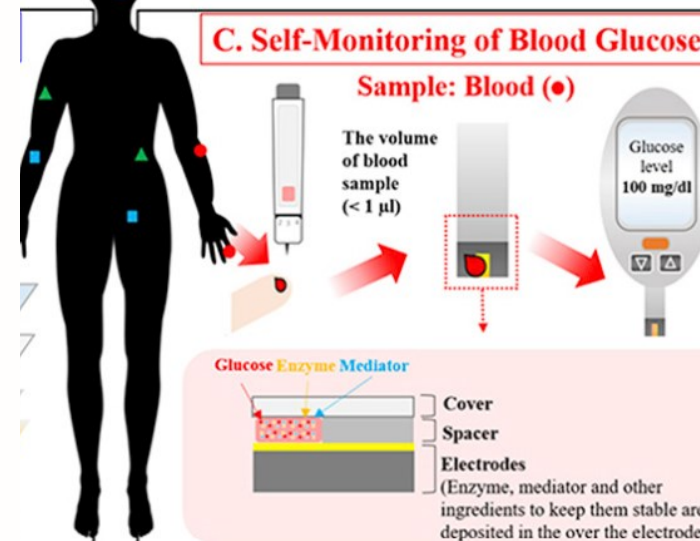
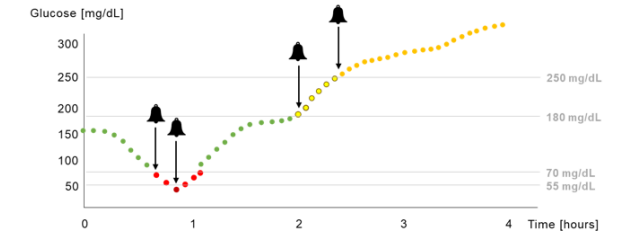
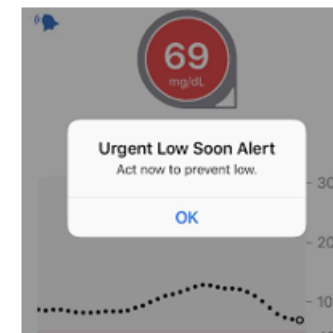
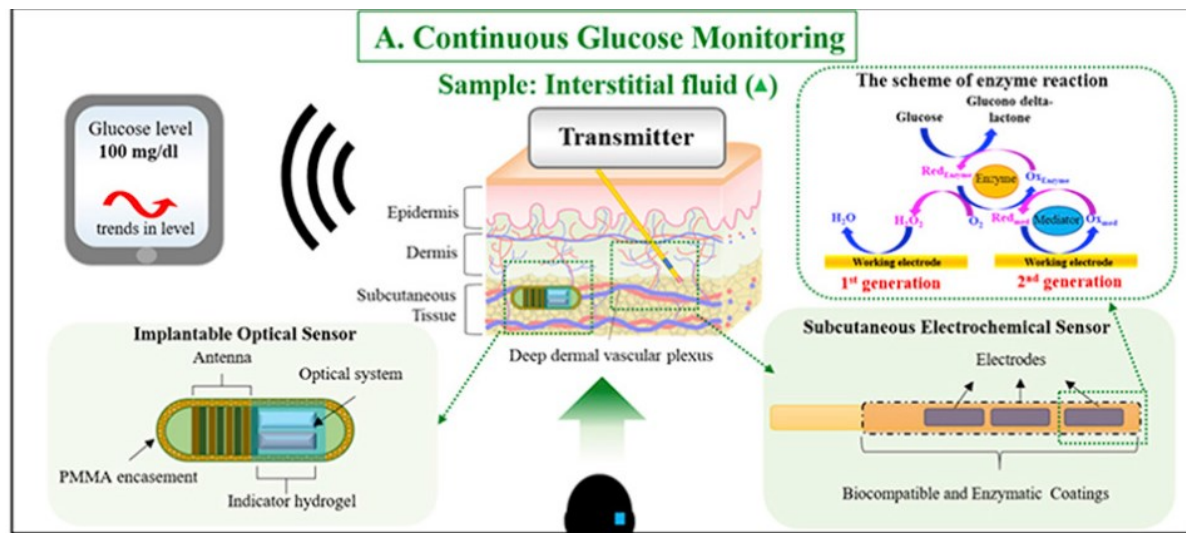
»» Il diabete oggi tra prevenzione,
nuovi farmaci e tecnologia:
un ponte verso il futuro

Palermo, 15/16 novembre 2024

Hotel La Torre

La Dr.ssa Enrica Vigneri dichiara di NON aver ricevuto negli ultimi due anni compensi o finanziamenti da Aziende Farmaceutiche e/o Diagnostiche

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.).



CONTROLLO DELLA GLICEMIA (mg/dl)

data	Colazione		Pranzo		Cena	
	prima	dopo 2 ore	prima	dopo 2 ore	prima	dopo 2 ore
11-10	170	168	123	240	202	156
12-10	183	168	175	230	172	
13-10	175	134	131	140	175	145
14-10	199	194	140	285	190	159
15-10	181	188	138	190	294	
16-10						

Annotazioni:

Lee I et al. Biosens Bioelectron. 2021;181:113054

7. Diabetes Technology: *Standards of Care in Diabetes—2024*

Diabetes Care 2024;47(Suppl. 1):S126–S144

–Continuous glucose monitoring devices

Type of CGM	Description
→ rtCGM	CGM systems that measure and display glucose levels continuously
→ isCGM with and without alarms	CGM systems that measure glucose levels continuously but require scanning for visualization and storage of glucose values
→ Professional CGM	CGM devices that are placed on the person with diabetes in the health care professional's office and worn for a discrete period of time (generally 7–14 days). Data may be blinded or visible to the person wearing the device. The data are used to assess glycemic patterns and trends. Unlike rtCGM and isCGM devices, these devices are clinic-based and not owned by the person with diabetes.

CGM, continuous glucose monitoring; isCGM, intermittently scanned CGM; rtCGM, real-time CGM.

7. Diabetes Technology: *Standards of Care in Diabetes—2024*

Diabetes Care 2024;47(Suppl. 1):S126–S144

GENERAL DEVICE PRINCIPLES

Recommendations

- 7.1** Diabetes devices should be offered to people with diabetes. **A**
- 7.2** Initiation of continuous glucose monitoring (CGM) should be offered to people with type 1 diabetes early in the disease, even at time of diagnosis. **A**
- 7.3** Consider establishing competencies based on role in practice setting for health care professionals working with diabetes technology. **E**
- 7.4** The type(s) and selection of devices should be individualized based on a person's specific needs, preferences, and skill level. In the setting of an individual whose diabetes is partially or wholly managed by someone else (e.g., a young child or a person with cognitive impairment or dexterity, psychosocial, and/or physical limitations), the caregiver's skills and preferences are integral to the decision-making process. **E**

CONTINUOUS GLUCOSE MONITORING DEVICES

Recommendations

7.14 Real-time CGM (rtCGM) **A** or intermittently scanned CGM (isCGM) **B** should be offered for diabetes management in adults with diabetes on multiple daily injections (MDI) or CSII who are capable of using the devices

ADULTS ON MDI OR CSII

7.15 rtCGM **A** or isCGM **B** should be offered for diabetes management in adults with diabetes on basal insulin who are capable of using the devices

ADULTS ON BASAL INSULIN

Linea Guida della Associazione dei Medici Diabetologi (AMD), della Società Italiana di Diabetologia (SID) e della Società Italiana di Endocrinologia e Diabetologia Pediatrica (SIEDP)

La terapia del diabete mellito di tipo 1

Versione aggiornata a gennaio 2024



GRADO DI RACCOMANDAZIONE

Raccomandazione forte a favore dell'intervento, con qualità delle prove moderata.

In soggetti con diabete mellito di tipo 1 si raccomanda di utilizzare un sistema di monitoraggio in continuo del glucosio rispetto all'automonitoraggio glicemico capillare.

GRADO DI RACCOMANDAZIONE

Raccomandazione condizionata a favore dell'intervento, con qualità delle prove moderata.

In soggetti con diabete mellito di tipo 1 con storia di ipoglicemia severa o ipoglicemie inavvertite o con frequenti episodi di ipoglicemia si raccomanda di utilizzare sistemi di monitoraggio in continuo del glucosio dotati di avvisi predittivi rispetto a sistemi privi di avvisi predittivi.



Linea Guida della Società Italiana di Diabetologia (SID) e dell'Associazione dei Medici Diabetologi (AMD)

La terapia del diabete mellito di tipo 2

Versione aggiornata a dicembre 2022

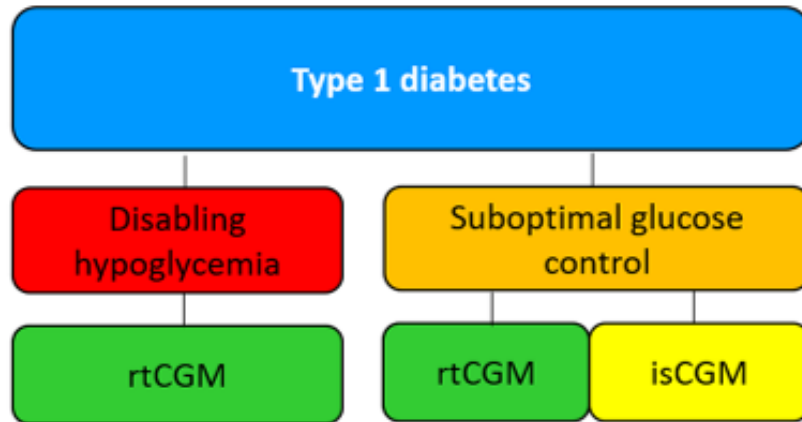
Linee Guida SID e AMD

6.2 Non si dà preferenza al CGM o al controllo glicemico capillare per la misurazione della glicemia nelle persone con DMT2 in trattamento insulinico *basal-bolus*.

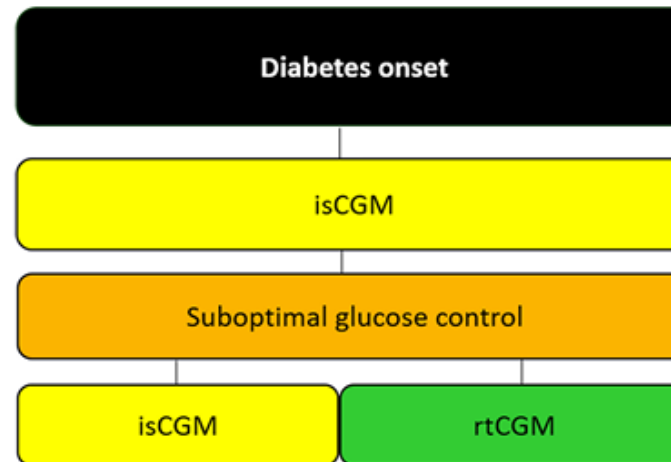
An updated algorithm for an effective choice of continuous glucose monitoring for people with insulin-treated diabetes

Maria Ida Maiorino ^{1,2} · Raffaella Buzzetti ³ · Concetta Irace ⁴ · Luigi Laviola ⁵ · Nicola Napoli ⁶ · Dario Pitocco ⁷ · Katherine Esposito ^{1,2} · on behalf of LIVE CGM working group

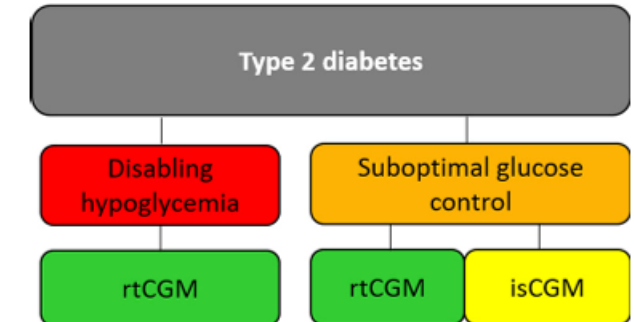
First scenario: type 1 diabetes



Second scenario: diabetes onset



Third scenario: type 2 diabetes



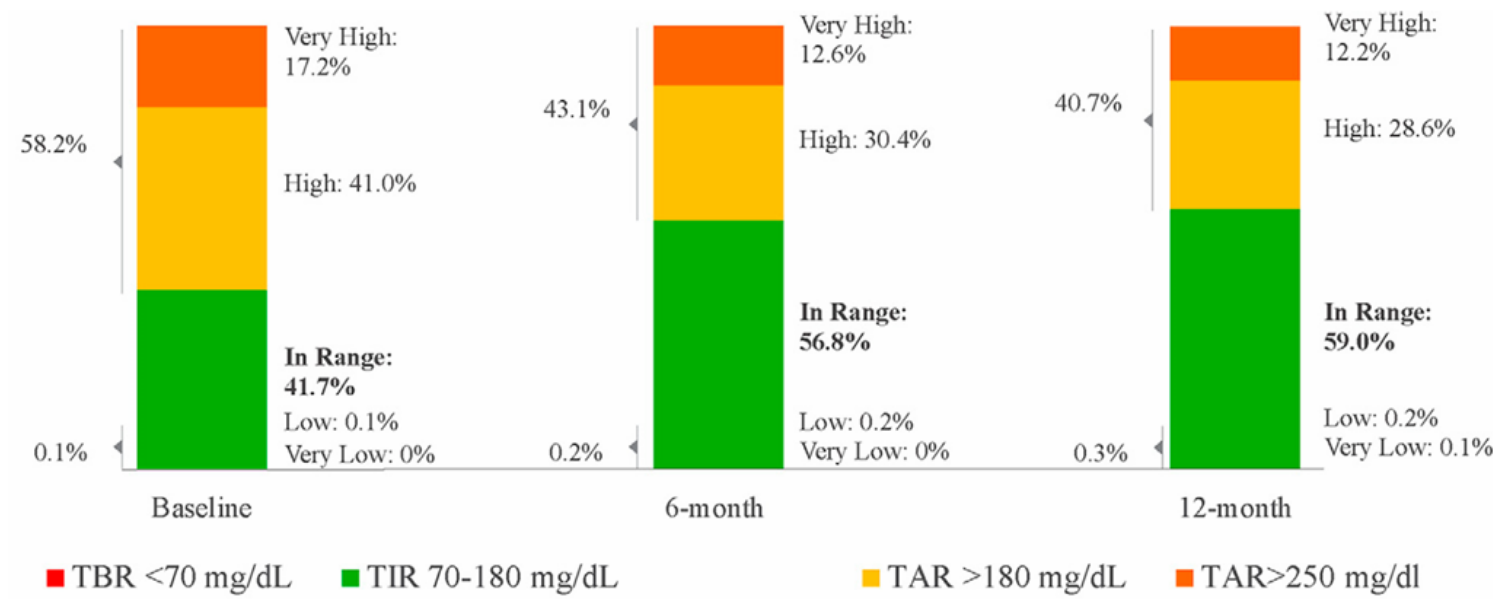
| Proposed use of CGM throughout the natural history of T2DM

Group	At diagnosis and early disease	Management of stable disease	Long duration of disease ^a
All people with T2DM	Utilize CGM for 14 days after T2DM diagnosis Establish a baseline glucometric profile Provide education on the glycaemic response to diet and exercise in T2DM Decide on the initial treatment plan and therapy Evaluate the patient's early (14-day) response to T2DM treatment	Predict risk of microvascular complications Adjust therapy Manage glycaemic goals for time in range, time below range, time above range, glycaemic variability and glucose management indicator (CGM-defined HbA _{1c} correlate)	Facilitate T2DM therapy de-escalation in older and/or frail people with T2DM Prevent hypoglycaemia Reduce risk of cardiorenal complications (for example, chronic kidney disease) Reduce incidence and progression of microvascular disease Allow care workers to more effectively manage the care of people with T2DM
People with T2DM on: Multiple daily injections Basal insulin Premixed insulin Insulinotropic drugs ^b	Continuous access to CGM for daily use		
	Prevent hypoglycaemia Manage hyperglycaemia Support self-management	Prevention of hypoglycaemia Manage hyperglycaemia Facilitate periods of therapy escalation or de-escalation Support self-management	
People with T2DM on non-insulin therapy ^c	Intermittent use of CGM at least every 3 months, with HCP review		
	Reinforce education on glucose profiles, diet, physical activity and the effects of medication	Can be combined with a coincident HbA _{1c} test HCP can make decisions on whether to change therapy or not Predict changes in risk of microvascular complications People with T2DM can re-establish the behaviours of good self-management with support from CGM	

CGM, continuous glucose monitoring; HCP, health-care professional; T2DM, type 2 diabetes mellitus. ^aPeople with long-standing T2DM, with risk of consequent comorbid microvascular and macrovascular disease. ^bPeople with T2DM at increased risk of frequent hypoglycaemia confirmed during a CGM-led medical review. ^cCan include people on insulinotropic oral drugs with low risk of hypoglycaemia confirmed during a CGM-led medical review.

Ajjan R.A. et al. *Nature Reviews Endocrinology*. 2024 Jul; 20(7): 426-440 .

CGM USE IN NONINSULIN-TREATED TYPE 2 DIABETES



Data do not total 100% due to rounding.

FIG. 1. Time in ranges at baseline, 6 months, and 12 months for adults with noninsulin-treated T2D. T2D, type 2 diabetes.

Layne J. E. et al. Diabetes Technol Ther. 2024 Jun 21

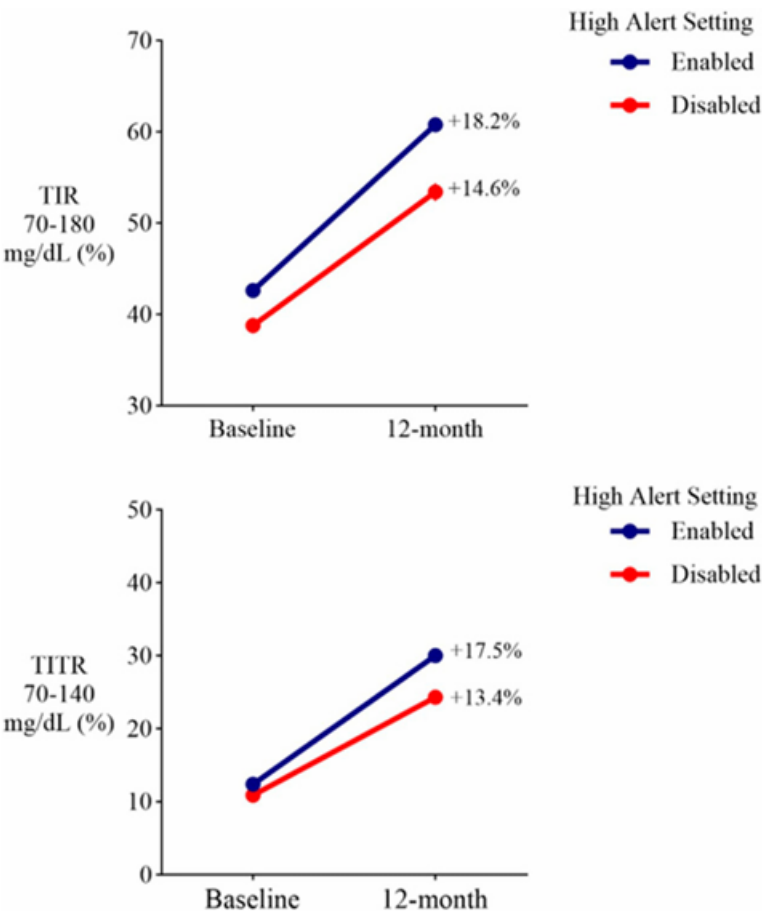


FIG. 2. Changes in TIR and TITR at 12 months in adults with noninsulin-treated T2D with the high alert enabled or disabled. Baseline and 12-month TIR and TITR in participants who had the high alert feature enabled are shown in blue ($n = 2,925$ patients; 76.2%) or who had the high alert feature disabled shown in red ($n = 915$; 23.8%) at 12 months. TIR, time in range; TITR, time in tight range.

Clinical Targets for Continuous Glucose Monitoring Data

Interpretation: Recommendations From the International Consensus on Time in Range

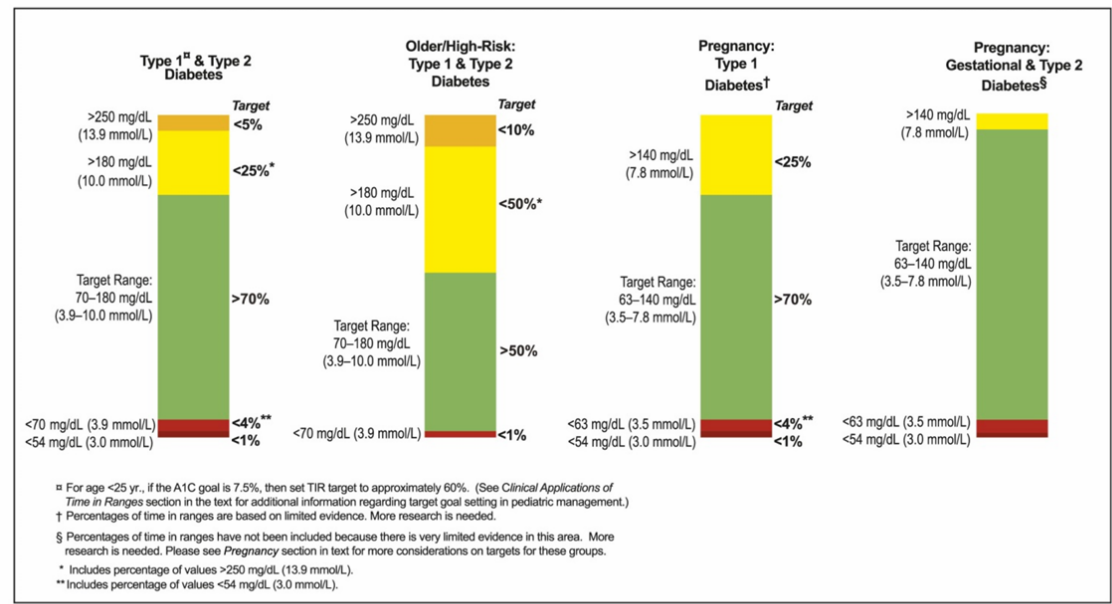


Figure 1—CGM-based targets for different diabetes populations.

Battelino T et al. Diabetes Care. 2019 Aug; 42(8): 1593-1603

Table 2—Standardized CGM metrics for clinical care: 2019	
1. Number of days CGM worn (recommend 14 days) (42,43)	
2. Percentage of time CGM is active (recommend 70% of data from 14 days) (41,42)	
3. Mean glucose	
4. Glucose management indicator (GMI) (75)	
5. Glycemic variability (%CV) target ≤36% (90)*	
6. Time above range (TAR): % of readings and time >250 mg/dL (>13.9 mmol/L)	Level 2
7. Time above range (TAR): % of readings and time 181–250 mg/dL (10.1–13.9 mmol/L)	Level 1
8. Time in range (TIR): % of readings and time 70–180 mg/dL (3.9–10.0 mmol/L)	In range
9. Time below range (TBR): % of readings and time 54–69 mg/dL (3.0–3.8 mmol/L)	Level 1
10. Time below range (TBR): % of readings and time <54 mg/dL (<3.0 mmol/L)	Level 2
Use of Ambulatory Glucose Profile (AGP) for CGM report	
CV, coefficient of variation. *Some studies suggest that lower %CV targets (<33%) provide additional protection against hypoglycemia for those receiving insulin or sulfonylureas (45,90,91).	

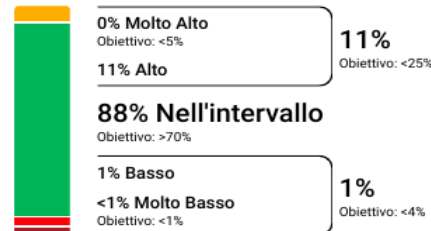
Ambulatory Glucose Profile (AGP): 3 Steps to an Action Plan

AGP

15 giorni | gio 3 ott 2024 - gio 17 ott 2024

Tempo negli intervalli Obiettivi per il diabete di tipo 1 e di tipo 2

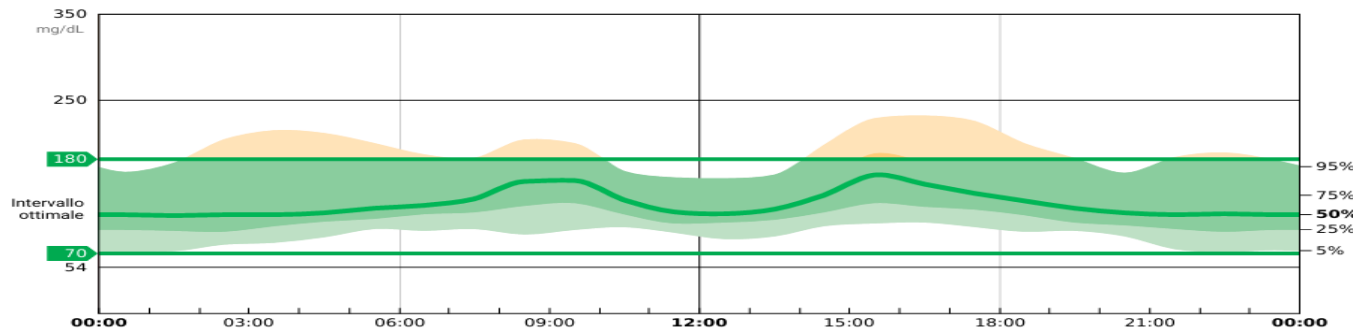
Ogni aumento del 5% nell'intervallo ottimale è clinicamente vantaggioso.
Ogni tempo 1% nell'intervallo = circa 15 minuti al giorno



Intervallo ottimale: 70-180 mg/dL
Molto alta: Al di sopra di 250 mg/dL
Molto bassa: Al di sotto di 54 mg/dL

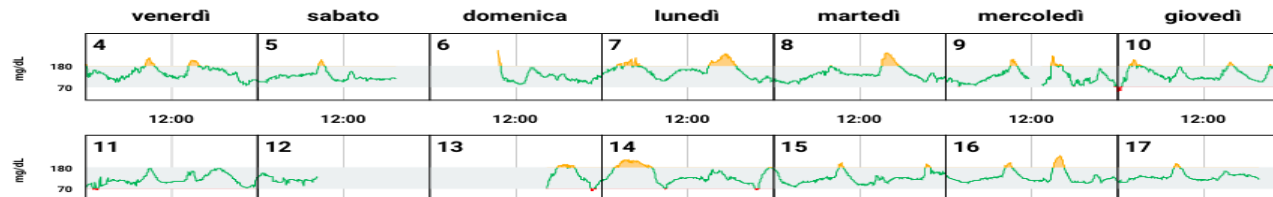
Ambulatory Glucose Profile (AGP)

AGP è un riepilogo dei valori del glucosio del periodo di riferimento, con la mediana (50%) e altri percentili mostrati come se si verificassero in un solo giorno.



Profilo del glucosio giornaliero

Ogni profilo giornaliero rappresenta un periodo da mezzanotte a mezzanotte.



Parametri del glucosio

Glucosio medio	133 mg/dL
Obiettivo: <154 mg/dL	
GMI	6,5%
Obiettivo: <7%	
Coefficiente di variazione	25,4%
Obiettivo: <36%	
Tempo di attività CGM	86,2%

Determine Where to Act

1. Determine if action is needed.

- Review time in ranges.
- Action is needed if Time in Range and Time Below Range are not at goal.
- More Green, Less Red (MGLR)**

2. Where is action needed?

- Review the AGP curve and daily views.
- Action is needed where the AGP curve is furthest from being **Flat Narrow and In-Range (FNIR)**.
- Treat hypoglycemia first.

3. Act on the data.

- Adjust lifestyle and medications to achieve **MGLR** and **FNIR**.
- Adjust, adjust, adjust!**

AGP report three-step action plan. ©2022 HealthPartners Institute, International Diabetes Center.

STATISTICHE E TARGET GLUCOSIO

26 giugno 2024 - 9 luglio 2024

14 Giorni

STEP 1 Tempo in cui il sensore è attivo:

99%

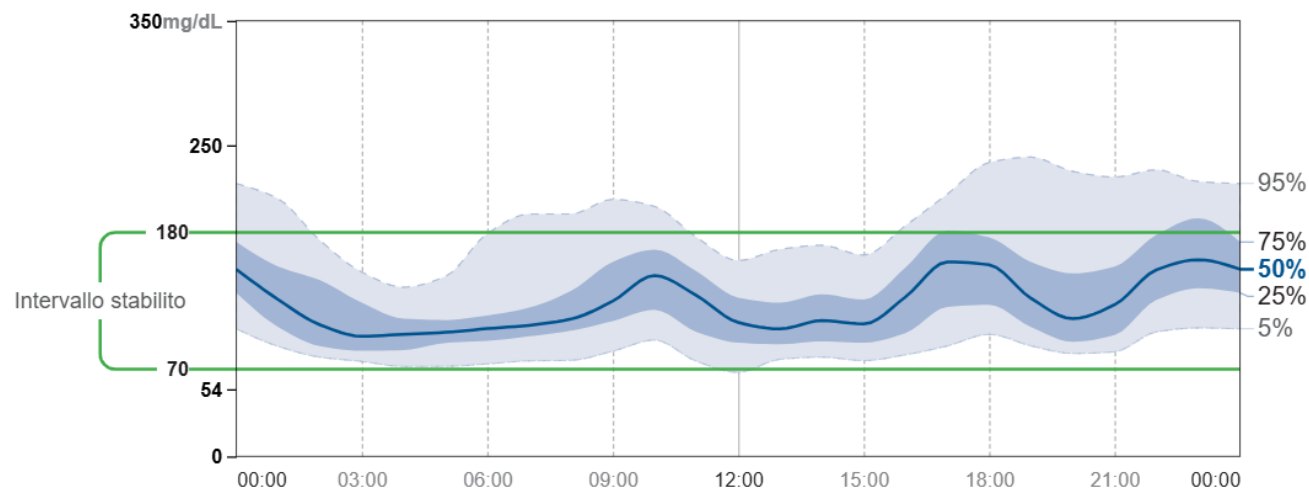
Intervalli e target per

Diabete tipo 1 o tipo 2

Intervalli di glucosio	Target % di letture (Ora/Giorno)
Intervallo stabilito 70-180 mg/dL	Superiore a 70% (16h 48min.)
Inferiore a 70 mg/dL	Inferiore a 4% (58min.)
Inferiore a 54 mg/dL	Inferiore a 1% (14min.)
Superiore a 180 mg/dL	Inferiore a 25% (6h)
Superiore a 250 mg/dL	
Ogni aumento del 5% d	

PROFILO DI GLUCOSIO AMBULATORIALE (AGP)

AGP è un riepilogo dei valori di glucosio del periodo di riferimento, con la mediana (50%) e gli altri percentili mostrati come se si fossero verificati in un solo giorno.



TEMPO NEGLI INTERVALLI



STEP 3

STEP 2 Indicatore di gesti

Variabilità del glucosio
Definito come percentuali

STEP 4

Di Molfetta S. et al. Diabetes Research Clinical Practice 187 (2022) 109867

STATISTICHE E TARGET GLUCOSIO

26 giugno 2024 - 9 luglio 2024

14 Giorni

Tempo in cui il sensore è attivo:

99%

Intervalli e target per

Diabete tipo 1 o tipo 2

Intervalli di glucosio	Target % di letture (Ora/Giorno)
Intervallo stabilito 70-180 mg/dL	Superiore a 70% (16h 48min.)
Inferiore a 70 mg/dL	Inferiore a 4% (58min.)
Inferiore a 54 mg/dL	Inferiore a 1% (14min.)
Superiore a 180 mg/dL	Inferiore a 25% (6h)
Superiore a 250 mg/dL	

Ogni aumento del 5% del temp

Diario giornaliero

26 giugno 2024 - 9 luglio 2024 (14 Giorni)

Valore medio del glucosio

MER 26 giu

Indicatore di gestione

STEP 5 Variabilità del glucosio

Definito come percentuale del

- Glucosio mg/dL
- Max
- min
- Carb. grammi
- Insulina ad azione rapida

GIO 27 giu

- Glucosio mg/dL
- Max
- min
- Carb. grammi
- Insulina ad azione rapida

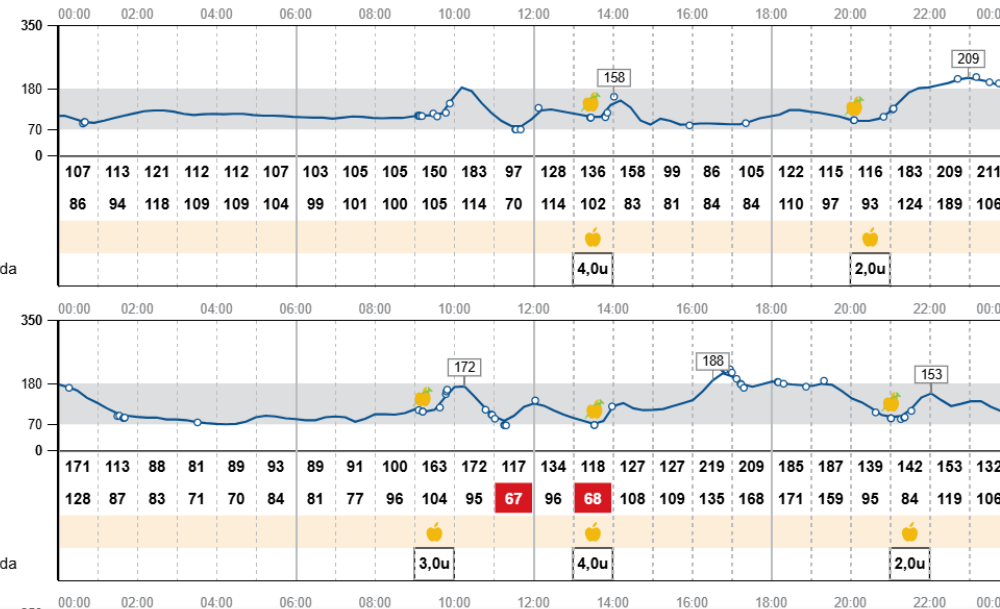
TEMPO NEGLI INTERVALLI



1% (14min.)

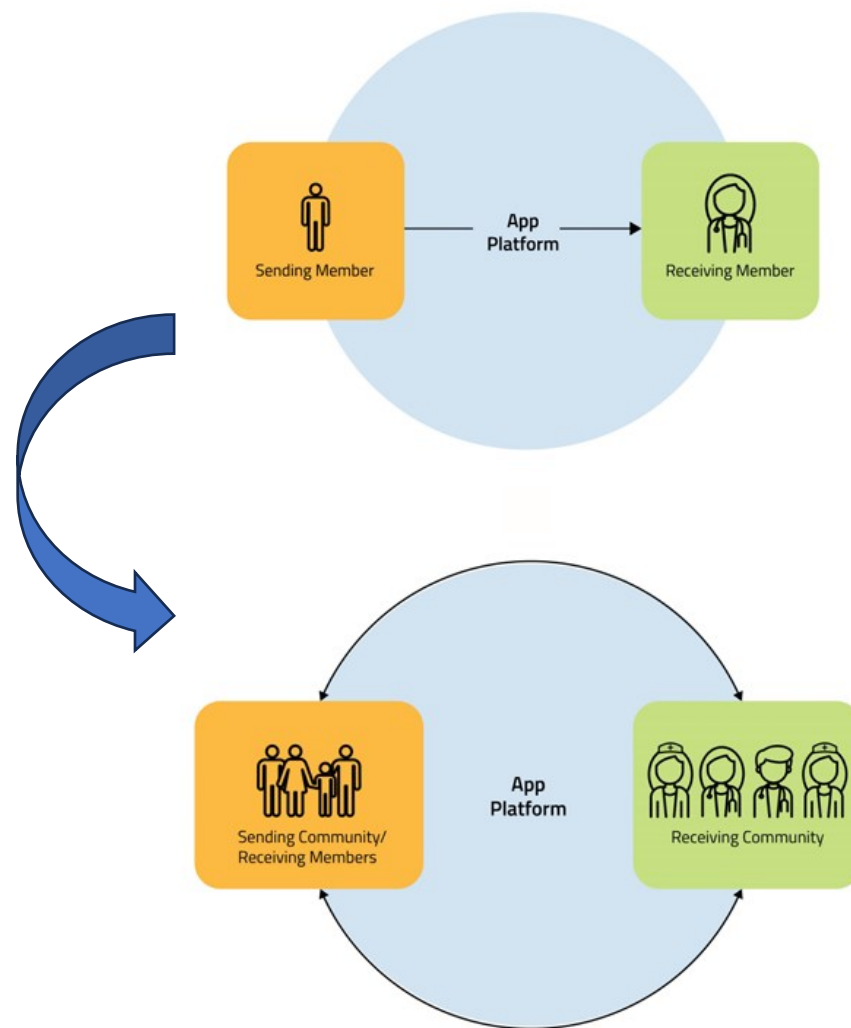
0% (0min.)

STEP 6



Di Molfetta S. et al. Diabetes Research Clinical Practice 187 (2022) 109867

Circular Flow



Malandrullo I et al. Int J Mol Sci 2020 Nov 3; 21(21): 8243.

The Digital/Virtual Diabetes Clinic:
The Future Is Now—Recommendations
from an International Panel on Diabetes
Digital Technologies Introduction

Moshe Phillip, MD,^{1,2} Richard M. Bergenstal, MD,³ Kelly L. Close, BA,⁴
Thomas Danne, MD,⁵ Satish K. Garg, MD,⁶ Lutz Heinemann, PhD,⁷ Irl B. Hirsch, M
Boris P. Kovatchev, PhD,⁹ Lori M. Laffel, MD,¹⁰ Viswanathan Mohan, MD,¹¹
Christopher G. Parkin, MS,¹² and Tadej Battelino, MD¹³

Diabetes Technol Ther. 2021 Feb;23(2):146-154.

DIGITAL/VIRTUAL DIABETES CLINIC

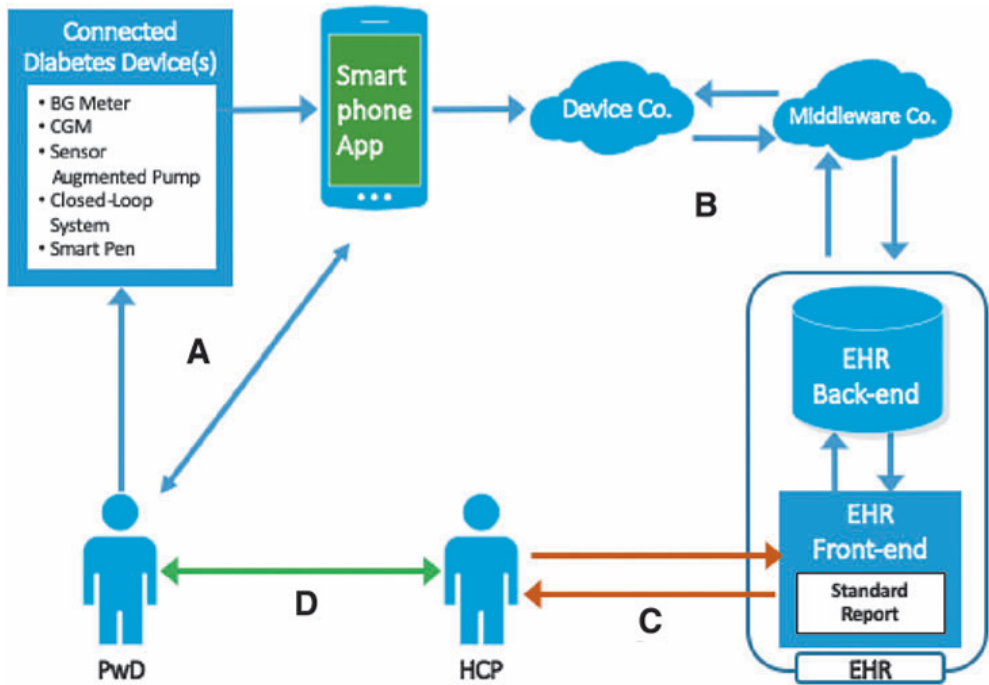
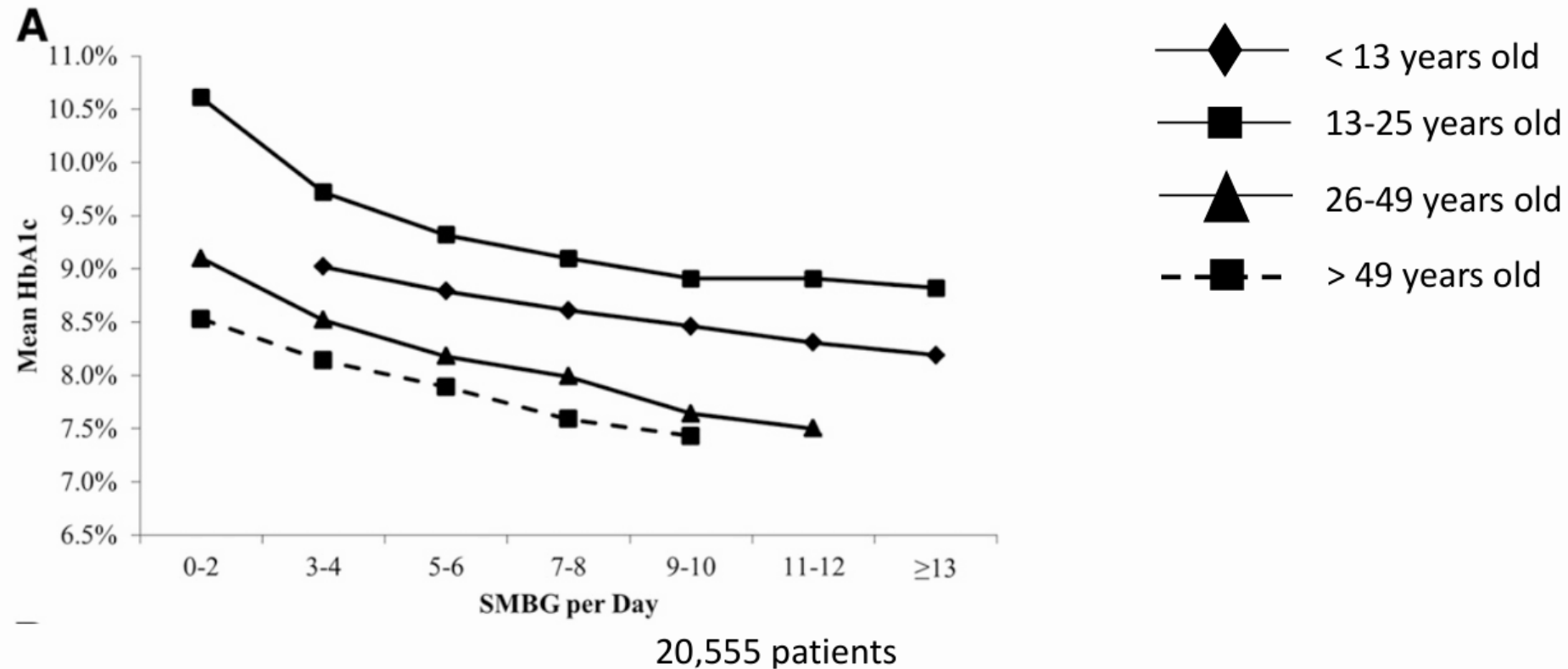


FIG. 1. Conceptual representation of D/VDC information flow and feedback. (A) Data from the device(s) are automatically transmitted to a smartphone app, which provides immediate feedback to the user. (B) The app transfers the data to the EHR via cloud-based, device-specific software and middleware. (C) HCP then access the data, which are presented in standardized formats. HCP enter any therapy changes into the EHR and (D) contact the patient to set up an in-clinic visit or schedule a remote consultation via one of the telemedicine tools. D/VDC, digital/virtual diabetes clinic; EHR, electronic health record; HCP, health care professional.

Evidence of a Strong Association Between Frequency of Self-Monitoring of Blood Glucose and Hemoglobin A1c Levels in T1D Exchange Clinic Registry Participants

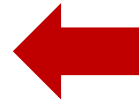


Miller K.M. et al. Diabetes Care 2013; 36(7): 2009-2014

7. Diabetes Technology: *Standards of Care in Diabetes—2024*

Diabetes Care 2024;47(Suppl. 1):S126–S144 | <https://doi.org/10.2337/dc24-S007>

- suspicion that CGM is inaccurate
- for calibration (is needed)
- disruption in CGM transmission
- a warning message appears
- glucose levels are changing rapidly (>2 mg/dl/min)



BLOOD GLUCOSE MONITORING

Recommendations

7.9 People with diabetes should be provided with blood glucose monitoring (BGM) devices as indicated by their circumstances, preferences, and treatment. People using CGM devices must also have access to BGM at all times. **A**

7.10 People who are taking insulin and using BGM should be encouraged to check their blood glucose levels when appropriate based on their insulin therapy. This may include checking when fasting, prior to meals and snacks, after meals, at bedtime, in the middle of the night, prior to, during, and after exercise, when hypoglycemia is suspected, after treating low blood glucose levels until they are normoglycemic, when hyperglycemia is suspected, and prior to and while performing critical tasks such as driving. **B**

7.12 Although BGM in people on non-insulin therapies has not consistently shown clinically significant reductions in A1C levels, it may be helpful when altering meal plans, physical activity plans, and/or medications (particularly medications that can cause hypoglycemia) in conjunction with a treatment adjustment program. **E**



Linea Guida della Società Italiana di Diabetologia (SID) e dell'Associazione dei Medici Diabetologi (AMD)

La terapia del diabete mellito di tipo 2

Versione aggiornata a dicembre 2022

Linee Guida SID e AMD

6.1 Si suggerisce un monitoraggio glicemico strutturato (con uno schema predefinito di glicemie capillari da eseguire) per i soggetti con DMT2.

6.2 Non si dà preferenza al CGM o al controllo glicemico capillare per la misurazione della glicemia nelle persone con DMT2 in trattamento insulinico *basal-bolus*.

Effects of Structured Versus Unstructured Self-Monitoring of Blood Glucose on Glucose Control in Patients With Non-insulin-treated Type 2 Diabetes: A Meta-Analysis of Randomized Controlled Trials

Edoardo Mannucci, MD¹, Alessandro Antenore, MD¹,
Francesco Giorgino, MD, PhD², and Marina Scavini, MD, PhD³

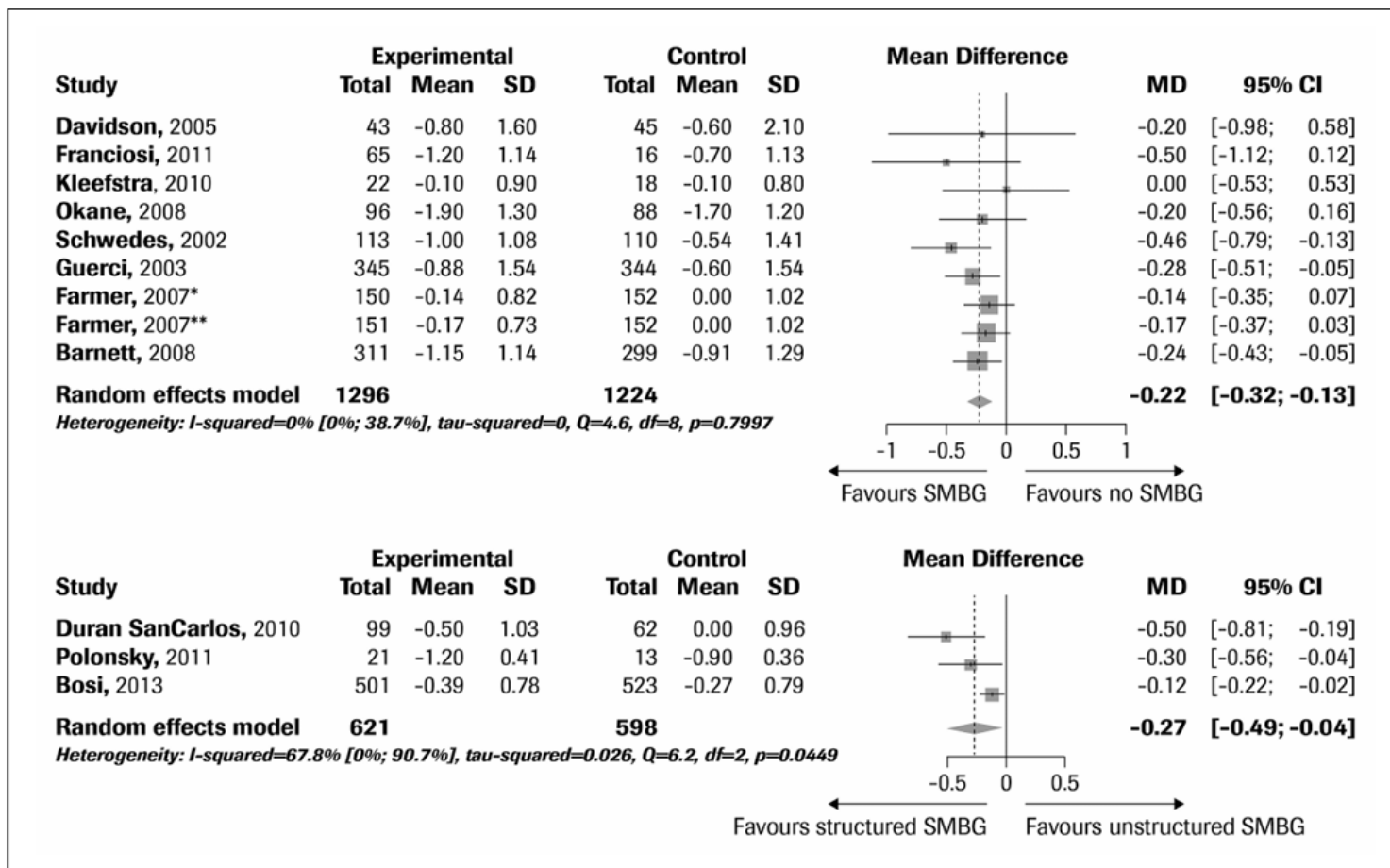


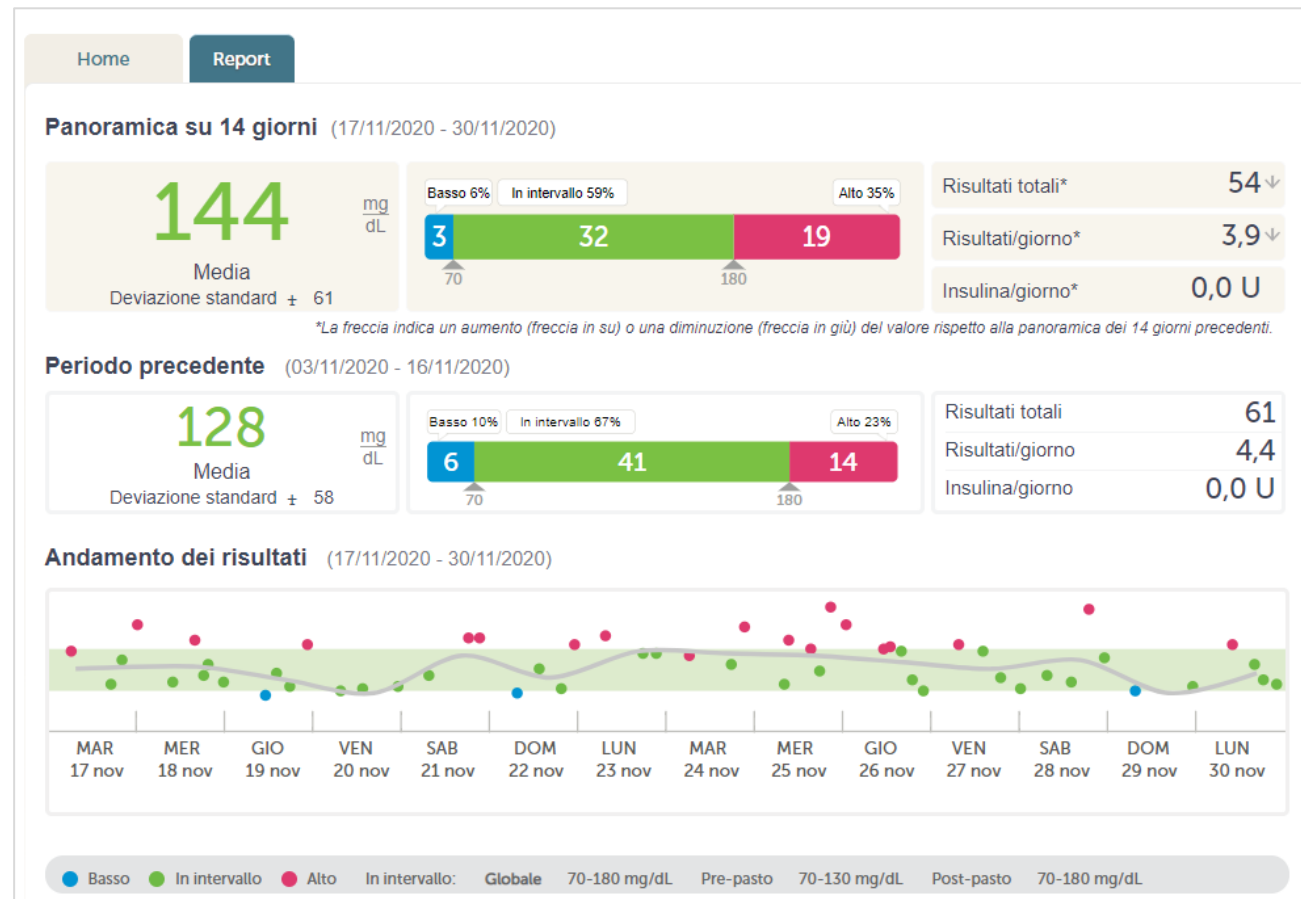
Figure 2. Forest plot of mean HbA1c differences in studies comparing SMBG vs no SMBG (upper panel) or structured SMBG vs unstructured SMBG (lower panel).



Mobile App per pazienti



Web App per operatori
sanitari



CONCLUSIONI

- I sistemi di monitoraggio in continuo del glucosio sono uno strumento indispensabile per una valutazione più omnicomprensiva del compenso glicemico ed hanno rivoluzionato l'approccio al diabete, rendendo il paziente sempre più parte attiva nella gestione terapeutica della propria malattia nella quotidianità.
- Le evidenze scientifiche a supporto dei benefici sono sempre maggiori e aprono la strada a raccomandazioni cliniche sempre più ampie, a favore di un numero crescente di persone con diabete.
- La continua diffusione di soluzioni digitali e l'immediatezza della condivisione delle informazioni, anche da remoto, hanno modificato la relazione tra medico e paziente e l'ecosistema in cui essi operano.
- Il monitoraggio capillare del glucosio (SBMG) deve essere garantito a tutti i pazienti che dispongono di CGM. Nei pazienti non insulino-trattati si suggerisce un monitoraggio di tipo strutturato che potrebbe essere facilitato dall'utilizzo di glucometri che permettano la condivisione dei dati con il team medico in modo da rendere il flusso di lavoro più efficace e anche da remoto.

Grazie per l'attenzione