III SESSIONE

EVOLUZIONE DELLA TECNOLOGIA NEL RAPPORTO MEDICO PAZIENTE

Moderatori: G. Lepore, I. Savulescu

Monitoraggio glicemico:

Nuovi parametri per medico e per paziente

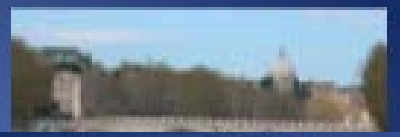
Dott.ssa Elisabetta Lovati

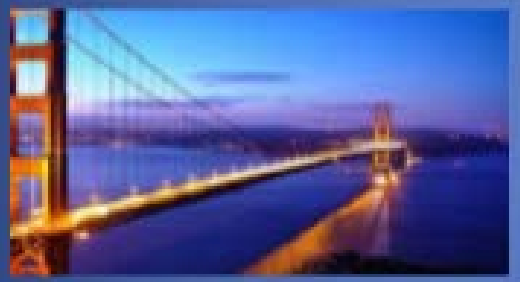
Resp. Amb. Endocrinologia e Diabetologia-
Cl. Medica I
Fond. IRCCS Policlinico San Matteo Pavia

La dott.ssa Lovati Elisabetta dichiara di aver ricevuto negli ultimi due anni compensi o finanziamenti dalle seguenti Aziende Farmaceutiche e/o Diagnostiche:

- **Roche Diabetes Care Italy**
- **Sanofy**

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.).





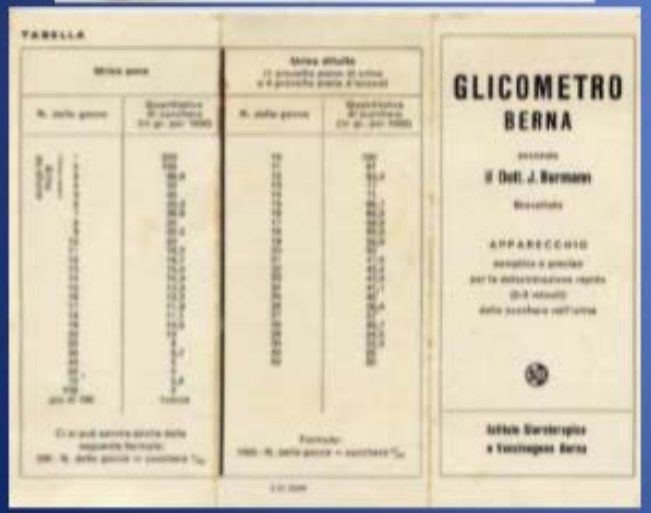

alamy stock photo

"Memoire"
Ha in memoria le unità di insulina da somministrare e le pratica a seconda dell'orario senza sbagliare

Usa e getta

Microinfusori realtime

Emoglukophot Erka




RAPID
GLUCO
TEST


104


106


29. 10. 20:32
5.3


100


106
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S

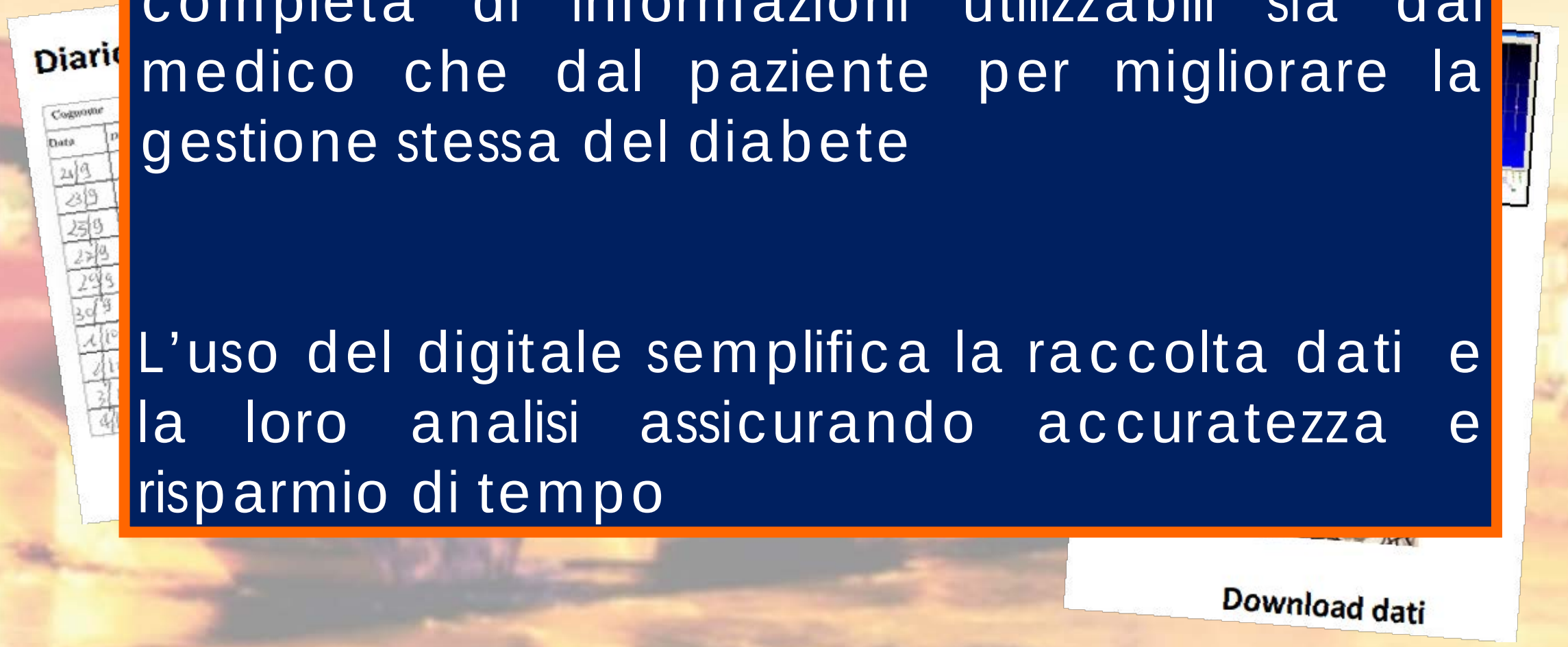
AUTOCONTROLLO (SMBG)

Il termine autocontrollo si riferisce alla pratica che comprende

- Misurazione strutturata della glicemia capillare (monitoraggio)
- Interpretazione del dato
- Intervento terapeutico

Lo scarico dati elettronico genera una serie più completa di informazioni utilizzabili sia dal medico che dal paziente per migliorare la gestione stessa del diabete

L'uso del digitale semplifica la raccolta dati e la loro analisi assicurando accuratezza e risparmio di tempo



DIARIO GLICEMIE CONSEGNATO IL 07/05

	Digiuno	1h dopo colazione	2h dopo colazione	Prima di pranzo	1h dopo pranzo	2h dopo pranzo	Prima di cena	1h dopo cena	2h dopo cena	Ore 23
1	x 88	x 114			100 g pane zuppa 2 fette					
2				x 72	x 180					
3	x 89						x 175	x 130		
4	x 87	x 135								
5	x 84				x 93					
6								x 130		
7	x 89	x 113								
8	89			x 76	x 114					
9							x 168	x 160 1 mezzena 2 fette		
10	x 76	x 119								
11	x 79				x 130					
12								x 134		
13	x 100			x 86			x 130			
14		x 139			x 134		86	x 137 195		
15	x 82						151	161		124

Si ricorda che le misurazioni vanno eseguite a digiuno, a 1e 2 h dopo l'**INIZIO** del pasto.

	Notte	Colazione		Pranzo		Cena		Ora di coricarsi
▲ Data	mg/dL	mg/dL	mg/dL	mg/dL	mg/dL	mg/dL	mg/dL	mg/dL
Mercoledì 08.05.2019		88						
		114						
Giovedì 09.05.2019		86		72	**181**		93	
					111			
Venerdì 10.05.2019			89	80			115	
							143	
Sabato 11.05.2019		87	139			97		
Domenica 12.05.2019			76		93			140
					86			
Lunedì 13.05.2019		84				115		
Martedì 14.05.2019	**197**	120			134		115	136
							102	
Mercoledì 15.05.2019		89	113			138	115	
Giovedì 16.05.2019		89	76	114	116		91	
Venerdì 17.05.2019		94		101		112	108	
							164	
Sabato 18.05.2019			76		**63**		114	
			119		**181**			
Domenica 19.05.2019			79	113	132			
Lunedì 20.05.2019		96		109	82	**142**		118
Martedì 21.05.2019		101		86	110		130	

Il calcolatore di bolo

- Quota di bolo correttivo
- Quota di bolo per coprire i Carboidrati
- Quota di adeguamento in base allo Stato salute
- Totale Bolo di insulina

iCGM/rtCGM

Da 5 valori/die a 1 valore ogni 5 minuti

SMBG: 5 controlli/die □ 150 valori/mese

CGM: 288/die □ 8640/mese

Icona menu

Icona profilo temp

Valore di glucosio attuale

Barra di stato

Freccia di tendenza

Unità di misura

Data e ora

Segnalazione di più eventi

Segnalazione di un evento (esercizio)

Calibrazione

Livello di avviso glucosio alto (linea tratteggiata rossa in alto)

Livello target glucosio alto (linea tratteggiata verde in alto)

Livello target glucosio basso (linea tratteggiata verde in basso)

Livello di avviso glucosio basso (linea tratteggiata rossa in basso)

Possibilità di visualizzare andamento in real time

Possibilità di avere allarmi
- **Di soglia**
- **Di velocità**
- **Predittivi**

A Simplified Approa… Using Rate… of Change Arrows to… With Real-Time Con… Monitoring

Journal of Diabetes Science and Technology
2017, Vol. 11(6) 1063–1069

David C. Klonoff, MD, FACP, F…
and David Kerr, MD, FRCPE[2]

Table 1c. Examples of manufacturer's (Medtronic) descriptions of rate of change arrows for their real-time continuous glucose monitoring devices, according to each product's user's guide.

Medtronic MiniMed 670G[7]		Medtronic MiniMed 640G*[8,9,10]		Medtronic MiniMed 630G[11]	
↑↑↑	Rising at a rate of 3 mg/dL per minute or more	↑↑↑	Rising at a rate of 0.167 mmol/L per minute or more[8] / rising by about 3[9] or more[10] mmol/L over the last 20 minutes	↑↑↑	Rising at a rate of 3 mg/dL per minute or more
↑↑	Rising at a rate of 2 mg/dL per minute or more, but less than 3 mg/dL per minute	↑↑	Rising at a rate of 0.111 mmol/L per minute or more, but less than 0.167 mmol/L per minute[8] / rising by about 2-3 mmol/L over the last 20 minutes[9]	↑↑	Rising at a rate of 2 mg/dL per minute or more, but less than 3 mg/dL per minute
↑	Rising at a rate of 1 mg/dL per minute or more, but less than 2 mg/dL per minute	↑	Rising at a rate of 0.056 mmol/L per minute or more, but less than 0.111 mmol/L per minute[8] / rising by about 1-2 mmol/L over the last 20 minutes[9]	↑	Rising at a rate of 1 mg/dL per minute or more, but less than 2 mg/dL per minute
↓	Falling at a rate of 1 mg/dL per minute or more, but less	↓	Falling at a rate of 0.056 mmol/L per minute or more, but less than 0.111 mmol/L per minute[8] /	↓	Falling at a rate of 1 mg/dL per minute or more, but less than 2
↓↓	Falling at a rate of 2.0 mg/dL or more per minute	↓↓	Falling at a rate of 0.11 mmol/L (2.0 mg/dL) or more per minute	↓↓	Falling at a rate of 2.0 mg/dL (0.11 mmol/L) or more per minute

*This product has multiple descriptions of its rate of change arrows.[8,9,10]

Table 1d. Examples of manufacturer's (Senseonics) descriptions of rate of change arrows for their real-time continuous glucose monitoring device, according to the product's user's guide.

	Eversense*[15]
→	Gradually rising or falling glucose levels, falling or rising at a rate between 0.0 mg/dL and 1.0 mg/dL per minute
↗	Moderately rising glucose level, rising at a rate between 1.0 mg/dL and 2.0 mg/dL per minute
↘	Moderately falling glucose levels, falling at a rate between 1.0 mg/dL and 2.0 mg/dL per minute
↑	Very rapidly rising glucose levels, rising at a rate more than 2.0 mg/dL per minute
↓	Very rapidly falling glucose levels, falling at a rate more than 2.0 mg/dL per minute

*The app uses the last 20 minutes of continuous glucose data for calculating glucose trends.

…or their real-time continuous glucose monitoring

	Abbott Navigator II[4]
	…an 120 mg/dL per hour or 6.7 mmol/L per hour)
	…ween 60 and 120 mg/dL per hour or between …ur)
	…an 60 mg/dL per hour or 3.3 mmol/L per hour)
	…tween 60 and 120 mg/dL per hour or between …ur)
	…han 120 mg/dL per hour or 6.7 mmol/L per hour)

…for their real-time continuous glucose

	Dexcom G5 Mobile[6]
	…more than 3 mg/dL each minute (or more than …5 minutes)
	…/dL each minute (or up to 45 mg/dL in 15
	…1-2 mg/dL each minute (or up to 30 mg/dL in 15
	…creasing/decreasing more than 1 mg/dL per …p to 15 mg/dL in 15 minutes)
	…1-2 mg/dL each minute (or up to 30 mg/dL in 15
	…Falling 2-3 mg/dL each minute (or up to 45 mg/dL in 15 minutes)
↓↓	Rapidly falling more than 3 mg/dL each minute (or more than 45 mg/dL in 15 minutes)

Editorial

A Simplified Approach Using Rate of Change Arrows to Adjust Insulin With Real-Time Continuous Glucose Monitoring

David C. Klonoff, MD, FACP, FRCPE, Fellow AIMBE[1]
and David Kerr, MD, FRCPE[2]

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2017, Vol. 11(6) 1063–1069

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Table 4. Comparison of Existing and Suggested Approaches for Adjustment of Correction Insulin Boluses Based on Rate of Change Arrows From Real-Time Continuous Glucose Monitoring.

Rate of change (mg/dl/min)	JDRF/DirecNet 2008	Pettus/Edelman Survey 2015[19-21]	Scheiner Protocol 2015*[22]	Pettus/Edelman Protocol 2017*[23]	Klonoff/Kerr Protocol 2017
Rising 1-2 mg/dl/min	↑ 10%	—	Current glu value (no Δ)	Current glu value + 50	Current dose + 1 U
Rising 2-3 mg/dl/min	↑ 20%	111% higher	Current glu value + 25	Current glu value + 75	Current dose + 1.5 U
Rising >3 mg/dl/min	↑ 20%	140% higher	Current glu value + 50	Current glu value + 100	Current dose + 2 U
Change <1 mg/dl/min	No Δ	—			
Falling 1-2 mg/dl/min	↓ 10%	—	Current glu value (no Δ)	Current glu value – 50	Current dose – 1 U
Falling 2-3 mg/dl/min	↓ 20%	40% lower	Current glu value – 25	Current glu value – 75	Current dose – 1.5 U
Falling >3 mg/dl/min	↓ 20%	42% lower	Current glu value – 50	Current glu value – 100	Current dose – 2 U

Adapted from Pettus et al,[19] Pettus and Edelman,[20,21,23] and Scheiner.[22] glu=glucose. Δ = change. U=units. *Glucose values are all mg/dL

Table 5. A Simple Formula to Adjust an Insulin Bolus by Adding to or Subtracting From the Usual Dose to Cover a 45-Minute Window, Based on Rate of Change Arrows.

Rate of change of rising glucose indicated by an arrow(s) on a CGM	1 to 2 mg/dl/minute	2 to 3 mg/dl/minute	>3 mg/dl/minute
Dose of insulin to be added to a bolus dose	**1 unit**	**1.5 units**	**2 units**
Rate of change of falling glucose indicated by an arrow(s) on a CGM	1 to 2 mg/dl/minute	2 to 3 mg/dl/minute	>3 mg/dl/minute
Dose of insulin to be subtracted from a bolus dose	**1 unit**	**1.5 units**	**2 units**

1) I rates of change previsti vengono semplificati tenendo conto del punto medio:
   - 1-2 mg/dl/min: 1.5 mg/dl/min
   - 2-3 mg/dl/min: 2.5 mg/dl/min
   - >3 mg/dl/min: >3 mg/dl/min
2) La proiezione della glicemia attuale viene fatta a 45 minuti (media tra 30 e 60 min)
3) Segue che la glicemia dopo 45 min cambierà di:
   - 1-2 mg/dl/min: 67 mg/dl
   - 2-3 mg/dl/min: 112 mg/dl
   - >3 mg/dl/min: >135 mg/dl
4) Tendendo conto di una FSI medio nella popolazione adulta di 40 mg/dL/U (Walsh et al, *Diab Sci Tech* 2010) e ipotizzando (a scopo cautelativo) una FSI tra 67 e 75 mg/dL/U le unità di insulina da variare sarebbero:
   - 1-2 mg/dl/min: **1.0U**
   - 2-3 mg/dl/min: **1.5U**
   - >3 mg/dl/min: **2.0U**

esempio

- Glicemia pre-pasto di 190 mg/dL
- FSI di 40 mg/dL/U
- CHO:I di 15g/U
- Pasto con 90g di CHO
- ROC di 1-2 mg/dL/min in salita (↗)

cemia. However, for a child or for an adult who is either unusually sensitive to insulin or using less than 29 units total of insulin per day, then these proposed dose corrections could be potentially too great and this formula (Table 5) should not be used.

Per il pasto: 6.0U

Correzione della glicemia: +1.5U → **8.5U**

Correzione della ROC: +1.0U

una variabile in più: il FSI

A Practical Approach to Using Trend Arrows on the CGM System for the Management of Adults With Diabetes

Grazia Aleppo,[1] Lori M. Laffel,[2] Andrew J. Ahmann,[3] Irl B. Hirsch,[4] Davida F. Kruger,[5] Anne Peters,[6] Ruth S. Weinstock,[7] and Dennis R. Harris[8]

Trend Arrows		Correction Factor* (CF)	Insulin Dose Adjustment (U)
Receiver	App		
⇈		<25 25–<50 50–<75 ≥75	+4.5 +3.5 +2.5 +1.5
↑		<25 25–<50 50–<75 ≥75	+3.5 +2.5 +1.5 +1.0
↗		<25 25–<50 50–<75 ≥75	+2.5 +1.5 +1.0 +0.5
→		<25 25–<50 50–<75 ≥75	No adjustment No adjustment No adjustment No adjustment
↘		<25 25–<50 50–<75 ≥75	-2.5 -1.5 -1.0 -0.5
↓		<25 25–<50 50–<75 ≥75	-3.5 -2.5 -1.5 -1.0
⇊		<25 25–<50 50–<75 ≥75	-4.5 -3.5 -2.5 -1.5

Da considerare per aggiustamenti:

- del bolo pre-pasto
- del bolo correttivo se oltre le 4 ore dal pasto precedente.

esempio

- Glicemia pre-pasto di 190 mg/dL
- FSI di 40 mg/dL/U
- CHO:I di 15g/U
- Pasto con 90g di CHO
- ROC di 1-2 mg/dL/min in salita (↗)

Per il pasto: 6.0U

Correzione della glicemia: +1.5U ⟶ **9.0U**

ROC in base a FSI: +1.5U

Trend Arrows		Correction Factor* (CF)	Insulin Dose Adjustment (U)
Receiver	App		
⇈		<25 25–<50 50–<75 ≥75	+4.5 +3.5 +2.5 +1.5
↑		<25 25–<50 50–<75 ≥75	+3.5 +2.5 +1.5 +1.0
↗		<25 25–<50 50–<75 ≥75	+2.5 +1.5 +1.0 +0.5
→		<25 25–<50 50–<75 ≥75	No adjustment No adjustment No adjustment No adjustment
↘		<25 25–<50 50–<75 ≥75	-2.5 -1.5 -1.0 -0.5
↓		<25 25–<50 50–<75 ≥75	-3.5 -2.5 -1.5 -1.0
⇊		<25 25–<50 50–<75 ≥75	-4.5 -3.5 -2.5 -1.5

un'altra variabile: il range glicemico

diabete di tipo 1

Scorecard Type 1 diabetes				Glucose level												
				<70 mg/dL[a] <3.9 mmol/L	70-180 mg/dL 3.9-10 mmol/L				180-250 mg/dL 10-13.9 mmol/L				>250 mg/dL >13.9 mmol/L				Ketone positive[b]
Change					Correction factor mg/dL mmol/L				Correction factor mg/dL mmol/L				Correction factor mg/dL mmol/L				
					<25 <1.4	25-<50 1.4-<2.8	50-<75 2.8-<4.2	>75 >4.2	<25 <1.4	25-<50 1.4-<2.8	50-<75 2.8-<4.2	>75 >4.2	<25 <1.4	25-<50 1.4-<2.8	50-<75 2.8-<4.2	>75 >4.2	
					Insulin units				Insulin units				Insulin units				
	⇈	⇈⇑	CU		+3.5	+2.5	+1.5	+1	+4.5	+3.5	+2.5	+1.5	+5	+4	+3	+2	Max corr[b]
↑	↑	⇈			+2.5	+2	+1	+0.5	+3.5	+2.5	+1.5	+1	+4	+3	+2	+1.5	Max corr[b]
↗	↗	↑			+1.5	+1	+0.5	+0.5	+2 .5	+1.5	+1	+0.5	+3	+2	+1.5	+1	Max corr[b]
→	→		1 fast-acting CU		+0	+0	+0	+0	+0	+0	+0	+0	+0	+0	+0	+0	Max corr[b]
↘	↘	↓	2 fast-acting CUs		−2.5	−1.5	−1	−0.5	−2	−1	−0.5	−0.5	−2.5	−1	−0.5	−0	Max corr[b]
↓	↓	⇊	2 fast-acting CUs		−3.5	−2.5	−1.5	−1	−3	−2	−1	−1	−3.5	−2	−1	−0.5	Max corr[b]
	⇊	⇊⇓	2 fast-acting CUs		−4.5	−3.5	−2.5	−1.5	−4	−3	−1.5	−1	−4	−2.5	−1	−0.5	Max corr[b]

Ziegler R et al, *J Diab Sci Tech*, 2019

esempio

Scorecard Type 1 diabetes			Glucose level												
		<70 mg/dL[a] <3.9 mmol/L	70-180 mg/dL 3.9-10 mmol/L				180-250 mg/dL 10-13.9 mmol/L				>250 mg/dL >13.9 mmol/L				Ketone positive[b]
Change			Correction factor mg/dL mmol/L				Correction factor mg/dL mmol/L				Correction factor mg/dL mmol/L				
			<25 <1.4	25-<50 1.4-<2.8	50-<75 2.8-<4.2	>75 >4.2	<25 <1.4	25-<50 1.4-<2.8	50-<75 2.8-<4.2	>75 >4.2	<25 <1.4	25-<50 1.4-<2.8	50-<75 2.8-<4.2	>75 >4.2	
			Insulin units				Insulin units				Insulin units				
	↑↑	↑↑↑	CU	+3.5	+2.5	+1.5	+1	+4.5	+3.5	+2.5	+1.5	+5	+4	+3	+2	Max corr[b]
↑	↑	↑↑		+2.5	+2	+1	+0.5	+3.5	+2.5	+1.5	+1	+4	+3	+2	+1.5	Max corr[b]
↗	↗	↑		+1.5	+1	+0.5	+0.5	+2.5	+1.5	+1	+0.5	+3	+2	+1.5	+1	Max corr[b]
→	→		1 fast-acting CU	+0	+0	+0	+0	+0	+0	+0	+0	+0	+0	+0	+0	Max corr[b]
↘	↘	↓	2 fast-acting CUs	−2.5	−1.5	−1	−0.5	−2	−1	−0.5	−0.5	−2.5	−1	−0.5	−0	Max corr[b]
↓	↓	↓↓	2 fast-acting CUs	−3.5	−2.5	−1.5	−1	−3	−2	−1	−1	−3.5	−2	−1	−0.5	Max corr[b]
	↓↓	↓↓↓	2 fast-acting CUs	−4.5	−3.5	−2.5	−1.5	−4	−3	−1.5	−1	−4	−2.5	−1	−0.5	Max corr[b]

Per il pasto: 6.0U

Correzione della glicemia: +1.5U ⟶ **9.0U**

ROC in base a FSI: +1.5U

Insulin Dose Adjustments Using the [redacted] System Trend Arrows in Adults: Pre-meal and Corrections ≥4 Hours Post-meal

Insulin Dose Adjustments

Trend Arrows	Correction Factor* (CF)			
	<25	25–<50	50–<75	≥75
↑	+3.5 units	+2.5 units	+1.5 units	+1.0 units
↗	+2.5 units	+1.5 units	+1.0 units	+0.5 units
→	No adjustment	No adjustment	No adjustment	No adjustment
↘	-2.5 units	-1.5 units	-1.0 units	-0.5 units
↓	-3.5 units	-2.5 units	-1.5 units	-1.0 units

Insulin dose adjustments using trend arrows do not replace standard calculations using ICR and CF. Adjustments are increases or decreases of rapid-acting insulin in addition to calculations using ICR and CF. Adjustments using trend arrows are an additional step to standard care.

*Correction factor (CF) is in mg/dL and indicates glucose lowering per unit of rapid-acting insulin.

Kudva YC, *Journal of the Endocrine Society*, Dec 2018

Pre-Exercise Planning for Aerobic and Mixed Exercise Using Trend Arrows in the [redacted] Systems

Pre-Exercise Glucose Concentration			
<100 mg/dL	100–180 mg/dL	181–250 mg/dL	>250 mg/dL
DO NOT Exercise *Ingest carbohydrate and/or wait until >100 mg/dL*	**Exercise Carefully** *Rescan every 30 minutes to avoid hypoglycemia*	**Exercise** *Rescan every 30 minutes to avoid hypoglycemia*	**DO NOT Exercise** *Correct and/or wait until ≤250 mg/dL*
↑ Wait until >100 mg/dL	↑ Rescan in 30 min	↑ Rescan in 30 min	↑ Correct to ≤180 mg/dL
↗ Wait until >100 mg/dL	↗ Rescan in 30 min	↗ Rescan in 30 min	↗ Correct to ≤180 mg/dL
→ Ingest 15 g carbohydrate	→ Consider ingesting 15 g carbohydrate*	→ Rescan in 30 min	→ Correct to ≤180 mg/dL
↘ Ingest 15 g carbohydrate	↘ Consider ingesting 15 g carbohydrate*	↘ Rescan in 30 min	↘ Wait until ≤250 mg/dL
↓ Ingest 30 g carbohydrate	↓ Consider ingesting 30 g carbohydrate*	↓ Consider ingesting 15 g carbohydrate	↓ Wait until ≤250 mg/dL

Le frecce di tendenza rappresentano il valore aggiunto nella gestione della glicemia per i pazienti che usano CGM

Le proposte di interpretazione sono molteplici, al crescere del numero di variabili che considerano diminuisce la semplicità di utilizzo da parte dei pazienti

L'educazione resta lo strumento fondamentale per ottimizzarne l'utilizzo

“La tecnologia non è nulla;
ciò che conta è avere fiducia nelle persone,
fiducia nel fatto che sono intelligenti
e che se dai loro gli strumenti,
faranno cose incredibili”.

Steve Jobs

Incremento della quantità di dati a disposizione

DATA MANAGEMENT

Percorso strutturato che parte da una visione generale per arrivare ad individuare la situazione particolare

1. Visione generale permette
   - individuare andamento medio di una giornata;
   - individuare gli scostamenti con una prima valutazione visiva della variabilità glicemica sia intragiornaliera che intergiornaliera

2. Analisi del particolare permette
   - analisi delle aree prandiali (fase pre- prandiale, fase post-prandiale tardiva, iperglicemia post-prandiale)
   - area notturna

Diabetes Care Volume 40, December 2017

International Consensus on Use of Continuous Glucose Monitoring

Diabetes Care 2017;40:1631–1640 | https://doi.org/10.2337/dc17-1600

Thomas Danne,[1] Revital Nimri,[2] Tadej Battelino,[3] Richard M. Bergenstal,[4] Kelly L. Close,[5] J. Hans DeVries,[6] Satish Garg,[7] Lutz Heinemann,[8] Irl Hirsch,[9] Stephanie A. Amiel,[10] Roy Beck,[11] Emanuele Bosi,[12] Bruce Buckingham,[13] Claudio Cobelli,[14] Eyal Dassau,[15] Francis J. Doyle III,[15] Simon Heller,[16] Roman Hovorka,[17] Weiping Jia,[18] Tim Jones,[19] Olga Kordonouri,[1] Boris Kovatchev,[20] Aaron Kowalski,[21] Lori Laffel,[22] David Maahs,[13] Helen R. Murphy,[23] Kirsten Nørgaard,[24] Christopher G. Parkin,[25] Eric Renard,[26] Banshi Saboo,[27] Mauro Scharf,[28] William V. Tamborlane,[29] Stuart A. Weinzimer,[29] and Moshe Phillip[2]

Table 1—Key metrics for CGM data analysis and reporting

CGM metric	Measures	ATTD consensus
1	Mean glucose	√ (calculated)
	Severe hypoglycemia*	Clinical diagnosis: event requiring assistance (level 3)
	Percentage of time in hypoglycemic ranges, mg/dL (mmol/L)	
2	Clinically significant/very low/immediate action required	<54 (<3.0) (level 2)
3	Alert/low/monitor	<70–54 (<3.9–3.0) (level 1)
	Percentage of time in target range, mg/dL (mmol/L)	
4	Default	70–180 (3.9–10.0)
	Secondary	70–140 (3.9–7.8)
	Percentage of time in hyperglycemic ranges, mg/dL (mmol/L)	
5	Alert/elevated/monitor	>180 (>10) (level 1)
6	Clinically significant/very elevated/immediate action required	>250 (>13.9) (level 2)
	Diabetic ketoacidosis*	Clinical diagnosis: ketones, acidosis, and usually hyperglycemia (level 3)
	Glycemic variability	
7	Primary glycemic variability	CV
	Stable	CV <36%,
	Unstable	CV ≥36%
	Secondary glycemic variability	SD
8	eA1C	√ (calculated)
9	Three time blocks: sleep, wake, 24 h	12:00 A.M.–6:00 A.M., 6:00 A.M.–12:00 A.M., 12 A.M.–12:00 A.M.
	Recommended data sufficiency	
10	Collection period (minimum no. of weeks)	2
11	Percentage of expected CGM readings (minimum percentage)	70–80 (10 of 14 days)
12	Episodes of hypoglycemia/hyperglycemia (minimum no. of minutes) (with beginning and end of episode defined)	15 min
13	Area under the curve	√ (calculated)
14	Risk of hypoglycemia and hyperglycemia	LBGI/HBGI recommended
15	Standardized CGM visualization of data	AGP recommended

*Severe hypoglycemia (level 3) and diabetic ketoacidosis (level 3) are not key CGM metrics per se. However, these conditions are included in the table because they are important clinical categories that must be assessed and documented.

Introduzione nuovi parametri controllo glicemico

Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range

Diabetes Care 2019;42:1593–1603 | https://doi.org/10.2337/dci19-0028

Tadej Battelino,[1] Thomas Danne,[2] Richard M. Bergenstal,[3] Stephanie A. Amiel,[4] Roy Beck,[5] Torben Biester,[2] Emanuele Bosi,[6] Bruce A. Buckingham,[7] William T. Cefalu,[8] Kelly L. Close,[9] Claudio Cobelli,[10] Eyal Dassau,[11] J. Hans DeVries,[12,13] Kim C. Donaghue,[14] Klemen Dovc,[1] Francis J. Doyle III,[11] Satish Garg,[15] George Grunberger,[16] Simon Heller,[17] Lutz Heinemann,[18] Irl B. Hirsch,[19] Roman Hovorka,[20] Weiping Jia,[21] Olga Kordonouri,[2] Boris Kovatchev,[22] Aaron Kowalski,[23] Lori Laffel,[24] Brian Levine,[9] Alexander Mayorov,[25] Chantal Mathieu,[26] Helen R. Murphy,[27] Revital Nimri,[28] Kirsten Nørgaard,[29] Christopher G. Parkin,[30] Eric Renard,[31] David Rodbard,[32] Banshi Saboo,[33] Desmond Schatz,[34] Keaton Stoner,[35] Tatsuiko Urakami,[36] Stuart A. Weinzimer,[37] and Moshe Phillip[28,38]

Diabetes care Volume 42, August 2019

Target clinici per l'interpretazione dei dati relativi al monito… glicemico in co… Raccoma… interv…

Diabetes Care 2… …doi.org/10.2337/dci19-0028

Semplificato a solo 10 l'elenco dei parametri più importanti ottenibili dai dati CGM fondamentali per la valutazione del compenso metabolico

Tadej Battelino,[1] Thomas Danne,[2]
Richard M. Bergenstal,[3]
Stephanie A. Amiel,[4] Roy Beck,[5]
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and Moshe Phillip[28,38]

Analisi del dato

Tabella 2: metriche CGM standardizzate per l'assistenza clinica: 2019

1. Numero di giorni di utilizzo del dispositivo CGM (raccomandati 14 giorni) (42,43)	
2. Percentuale di tempo con CGM attivo (raccomandato il 70% dei dati nei 14 giorni) (41,42)	
3. Glicemia media	
4. Indicatore di controllo glicemcio (GMI) (75)	
5. Variabilità glicemica (% CV) target ≤36% (90)*	
6. Tempo al di sopra del range (TAR): % di letture e tempo > 250 mg/dL (> 13,9 mmol/L)	Livello 2
7. Tempo al di sopra del range (TAR): % di letture e tempo tra 181-250 mg/dL (10,1-13,9 mmol/L)	Livello 1
8. Tempo in range (TIR): % di letture e tempo tra 70-180 mg/dL (3,9-10,0 mmol/L)	Nel range
9. Tempo al di sotto del range (TBR): % di letture e tempo tra 54-69 mg/dL (3,0-3,8 mmol/L)	Livello 1
10. Tempo al di sotto del range (TBR): % di letture e tempo < 54 mg/dL (< 3,0 mmol/L)	Livello 2

Uso del profilo glicemico ambulatoriale (AGP) per il report CGM

Analisi del dato: tempo di utilizzo

1. Numero di giorni di utilizzo del dispositivo CGM (raccomandati 14 giorni) (42,43)
2. Percentuale di tempo con CGM attivo (raccomandato il 70% dei dati nei 14 giorni) (41,42)

Analisi del dato: media glicemica

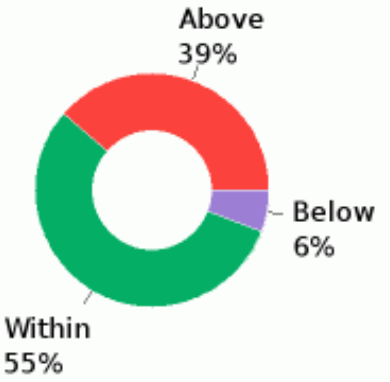
3. Glicemia media

ott 11 2019 - ott 24 2019 — **Data ultima sinc: Giovedì Ott 24 2019 2:46**

CGM (mg/dl)

CGM readings summary	
Average (mg/dl)	169
Median (mg/dl)	161
AUC high > 180 mg/dl	23
AUC low < 70 mg/dl	1
Highest value (mg/dl)	Hi
Lowest value (mg/dl)	41
Standard deviation (SD)	72
Values per day	271.4
Number of values	3800
Values above goal (180 mg/dl)	1478
Values within goal (70-180 mg/dl)	2096
Values below goal (70 mg/dl)	226
Average daily CGM sensor duration	22:35 (94%)
Total CGM sensor duration	13 days 04:40

Interval	*Avg*	*#*	*SD*
00:00-06:00	147	1009	63
06:00-08:00	141	316	50
08:00-10:00	156	301	53
10:00-12:00	143	336	49
12:00-14:00	172	315	60
14:00-16:00	199	312	65
16:00-18:00	171	311	80
18:00-20:00	145	322	68
20:00-22:00	233	302	72
22:00-24:00	231	306	81



Statistiche sulla

164	7,3%	Esposizione glicemica

< 54 mg/dL	< 70 mg/dL	70 - 180 mg/dL	> 180 mg/dL	> 250 mg/dL
0,3%	1,9%	60,5%	37,6%	8,9%

Intervalli glicemici

37,9%	62	Variabilità glicemica

95,0%	Sufficienza dei dati

entuale
npo di
ità CGM

Analisi del dato:

Dai dati ricavati da 10-14 giorni di CGM si estrapola il valore medio del glucosio ed usando una formula standard derivata dalle letture del glucosio da una popolazione di diabetici il dato ottenuto è l' eA1C

In molti pazienti questo dato è sovrapponibile al dato di HbA1C misurato in laboratorio, in altri è fortemente discordante… questo può essere un forte elemento di frustrazione

Glucose Management Indicator (GMI): A New Term for Estimating A1C From Continuous Glucose Monitoring

Richard M. Bergenstal,[1] Roy W. Beck,[2] Kelly L. Close,[3] George Grunberger,[4] David B. Sacks,[5] Aaron Kowalski,[6] Adam S. Brown,[7] Lutz Heinemann,[8] Grazia Aleppo,[9] Donna B. Ryan,[10] Tonya D. Riddlesworth,[2] and William T. Cefalu[11]

https://doi.org/10.2337/dc18-1581

$$\text{GMI}\ (\%) = 3.31 + 0.02392 \times [\text{mean glucose in mg/dL}]$$

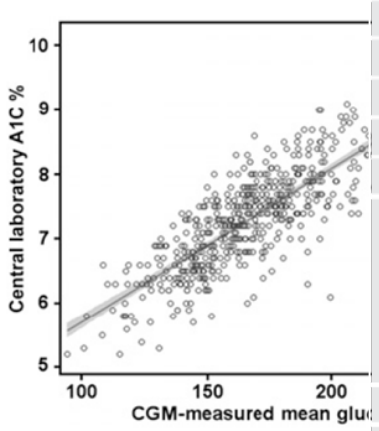


Figure 1—Plot of CGM-mea
cose concentration vs. cen
measured A1C used to comp
to estimate GMI, combining
randomized trials using the
sor with 505 software (*N* = 5
the Supplementary Data. T
represents the 95% CI of the
The regression equation to co
3.31 + 0.02392 × [mean gluc
GMI (mmol/mol) = 12.71 + 4
glucose in mmol/L]. A calcul
GMI is available at www.ja
www.AGPreport.org/agp/link

Table 1—GMI calculated for various CGM-derived mean glucose concentrations

CGM-derived mean glucose (mg/dL)	GMI (%)*
100	5.7
125	6.3
150	6.9
175	7.5
200	8.1
225	8.7
250	9.3
275	9.9
300	10.5
350	11.7

CGM-measured mean glucose (mmol/L)	GMI (mmol/mol)†
5	36.2
6	40.9
7	45.7
8	50.4
9	55.1
10	59.8
12	69.2
14	78.6
16	88.0
18	97.4

*GMI (%) = 3.31 + 0.02392 3 [mean glucose in mg/dL]. †GMI (mmol/mol) = 12.71 + 4.70587 3 [mean glucose in mmol/L]. A calculator to compute GMI is available at www.jaeb.org/gmi and www.AGPreport.org/agp/links.

Diabetes Care 2018;41:2275-2280

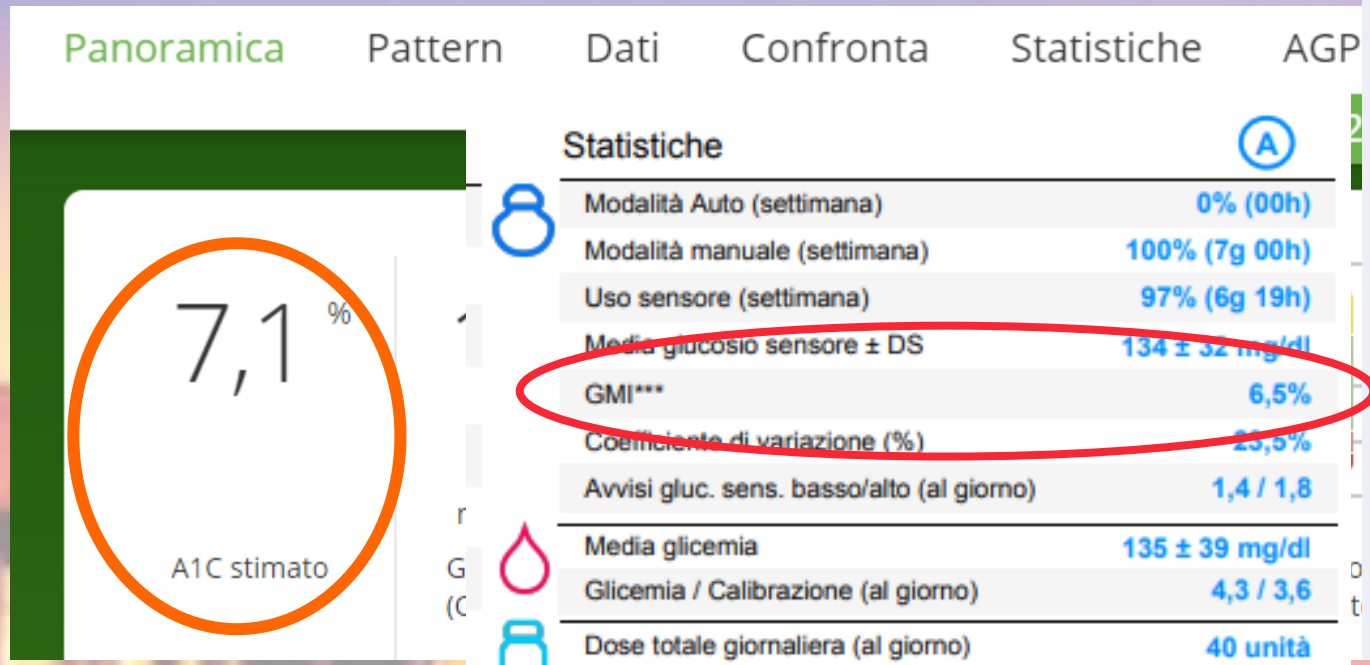
Analisi del dato: indicatore di controllo glicemico (GMI)

4. Indicatore di controllo glicemcio (GMI) (75)

I LIMITI DELL'HbA1c

- VI SONO IMPORTANTI DIFFERENZE RAZZIALI
- NON E' AFFIDABILE NEI PAZIENTI CON ANEMIA, EMOGLOBINOPATIE, CARENZA DI FERRO E IN GRAVIDANZA
- NON FORNISCE INFORMAZIONI SUL NUMERO DI IPOGLICEMIE O IPERGLICEMIE
- NON RIFLETTE LE RAPIDE VARIAZIONI DI GLICEMIE (in sintesi non da indicazioni sulla variabilità glicemica)

L'HbA1c in media sovrastima il controllo glicemico medio nella razza nera, sottostima nella bianca



Statistiche

Modalità Auto (settimana)	0% (00h)
Modalità manuale (settimana)	100% (7g 00h)
Uso sensore (settimana)	97% (6g 19h)
Media glucosio sensore ± DS	134 ± 32 mg/dl
GMI***	6,5%
Coefficiente di variazione (%)	23,5%
Avvisi gluc. sens. basso/alto (al giorno)	1,4 / 1,8
Media glicemia	135 ± 39 mg/dl
Glicemia / Calibrazione (al giorno)	4,3 / 3,6
Dose totale giornaliera (al giorno)	40 unità
Insulina tramite bolo (al giorno)	25U (62%)
Insul. Basale Auto/Basale (al giorno)	15U (38%)
Sostituzione set	Ogni 1,0 giorni
Sostituzione serbatoio	Ogni 2,6 giorni
Pasto (al giorno)	3,1
Carboidrati immessi (al giorno)	208 ± 35 g
Tempo insulina attiva	4:00 ore

ale attivo

Molto bass			Alto	Molto alta	Tempo CGM attivo
< 54 mg/dL			150 - 250 mg/dL	> 250 mg/dL	
2 %	8 %	68 %	21 %	1 %	96 %

Media periodo: **122 mg/dL**

Valore massimo: **306 mg/dL** (26/11/2020 23:43)

Valore minimo: **41 mg/dL** (01/12/2020 06:18)

Deviazione standard (SD): **43 mg/dL**

Coefficiente di variazione (CV): **36 %**

Glucose management indicator (GMI): **6.2 %**

Analisi del dato: COEFFICIENTE DI VARIAZIONE

5. Variabilità glicemica (% CV) target ≤36% (90)*

COEFFICIENTE DI VARIAZIONE

- DS DIVISO MEDIA

- ES: MEDIA GLICEMIA 134
  DS 55
  CV 55/134: 41%

- STIMA DELLA VARIABILITA' GLICEMICA
  STABILE < 36%
  INSTABILE > 36%

Toward Defining the Threshold Between Low and High Glucose Variability in Diabetes

Louis Monnier,[1] Claude Colette,[1] Anne Wojtusciszyn,[2] Sylvie Dejager,[3] Eric Renard,[2] Nicolas Molinari,[4] and David R. Owens[5]

Diabetes Care 2017;40:832–838 | https://doi.org/10.2337/dc16-1769

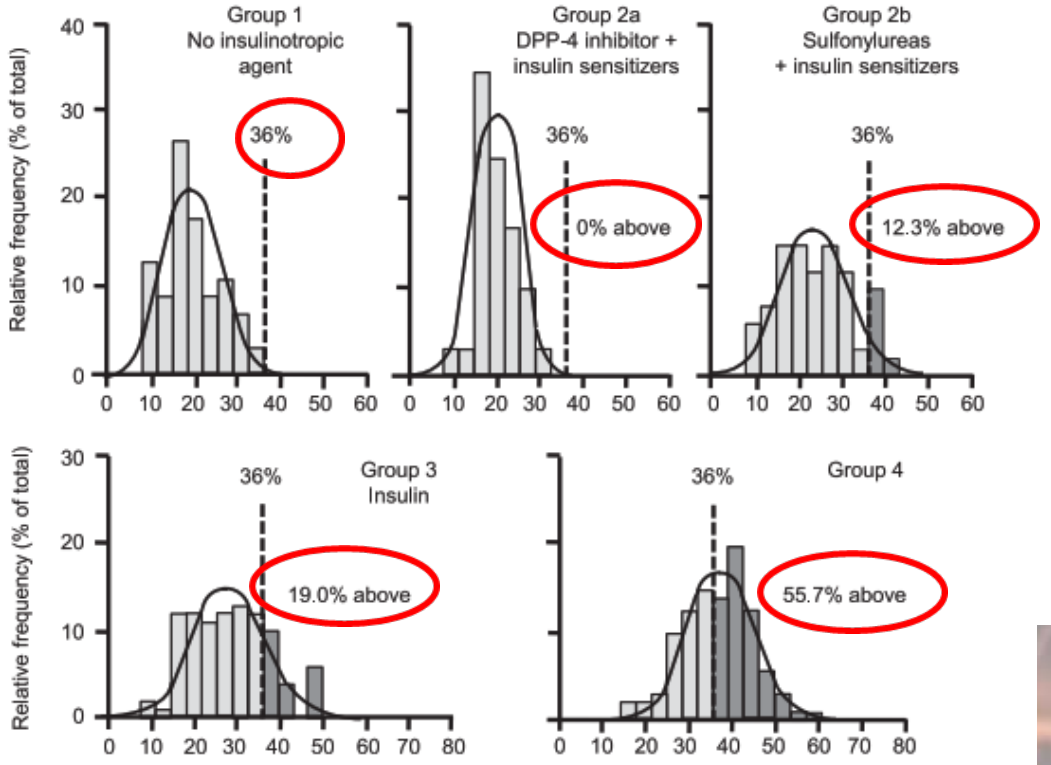
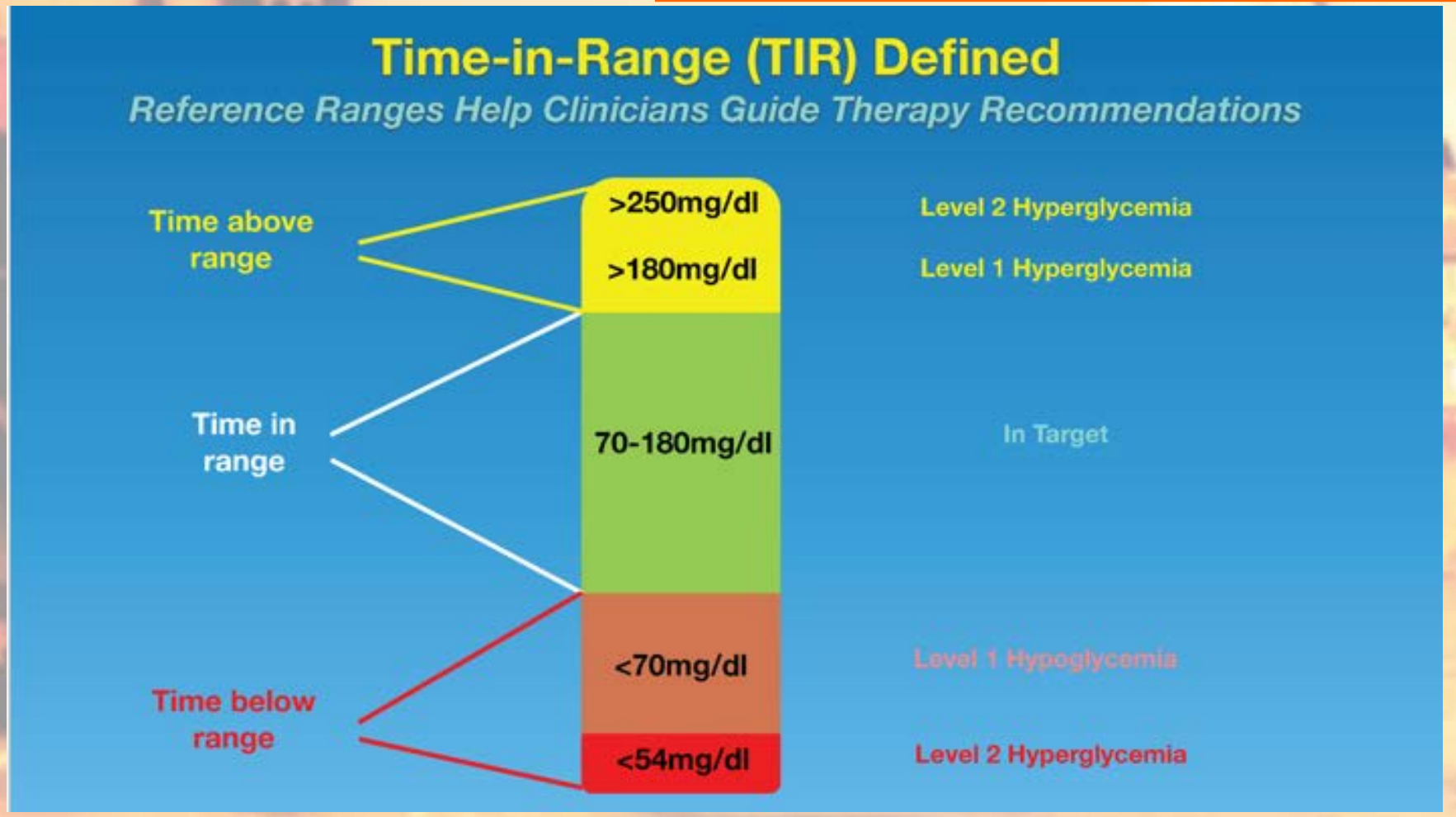
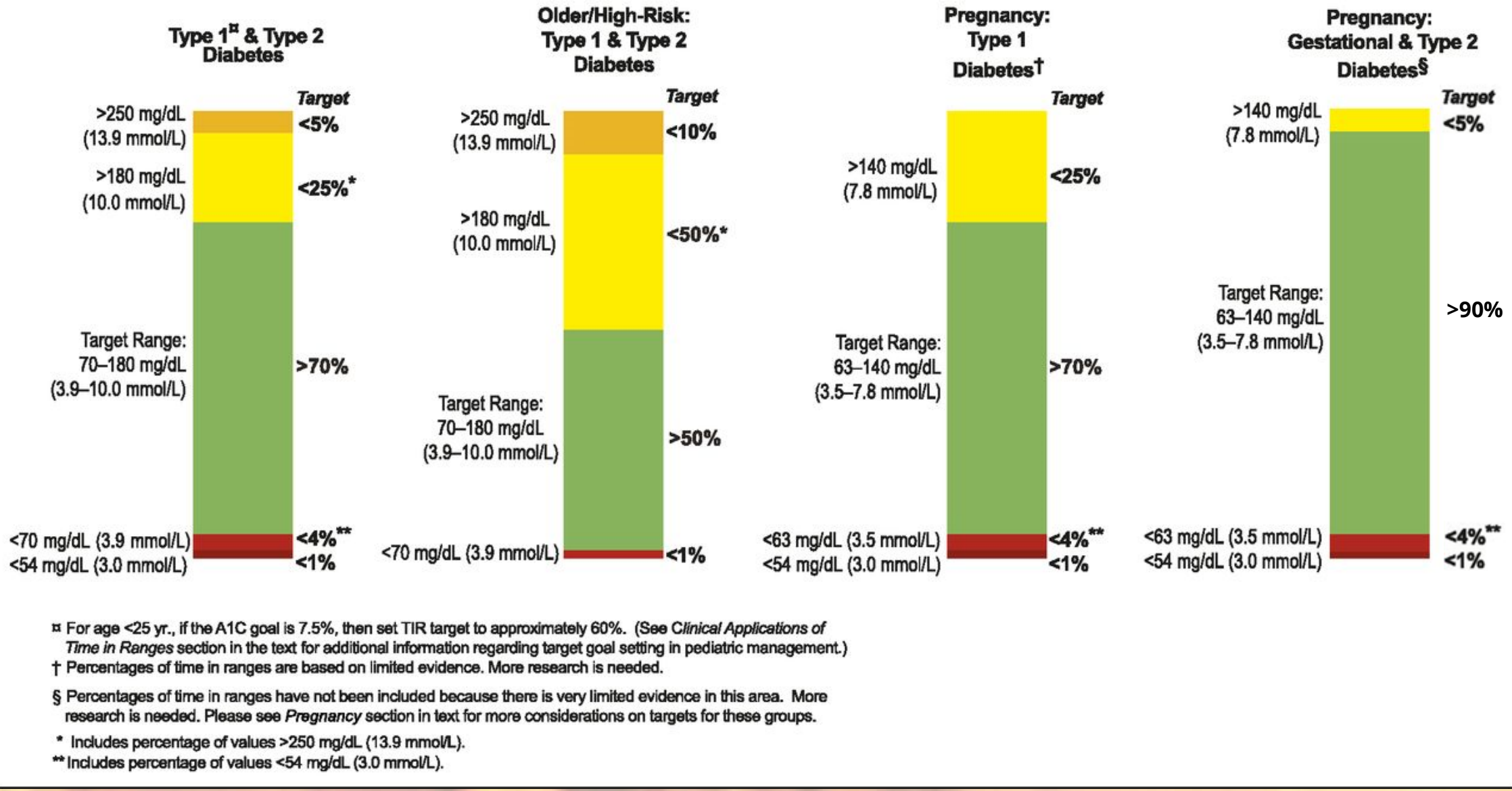


Figure 1—Histograms of relative frequency distributions for %CVs for glucose in the five groups of persons with either type 2 (groups 1, 2a, 2b, and 3) or type 1 diabetes (group 4). The upper limit of the distribution of %CV ($\%CV_{max1}$ = 36%) in group 1 (no insulinotropic agent) is taken as reference to discern stable from unstable diabetes. In the four other groups, the percentages of patients above this threshold value of 36% are indicated as appropriate in the corresponding panels.

Analisi del dato:

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





¤ For age <25 yr., if the A1C goal is 7.5%, then set TIR target to approximately 60%. (See *Clinical Applications of Time in Ranges* section in the text for additional information regarding target goal setting in pediatric management.)

† Percentages of time in ranges are based on limited evidence. More research is needed.

§ Percentages of time in ranges have not been included because there is very limited evidence in this area. More research is needed. Please see *Pregnancy* section in text for more considerations on targets for these groups.

* Includes percentage of values >250 mg/dL (13.9 mmol/L).

** Includes percentage of values <54 mg/dL (3.0 mmol/L).

Table 5—Estimate of A1C for a given TIR level based on type 1 diabetes and type 2 diabetes studies

Beck et al. (26) (n = 545 participants with type 1 diabetes)			Vigersky and McMahon (27) (n = 1,137 participants with type 1 or type 2 diabetes)	
TIR 70–180 mg/dL (3.9–10.0 mmol/L)	A1C, % (mmol/mol)	95% CI for predicted A1C values, %	TIR 70–180 mg/dL (3.9–10.0 mmol/L)	A1C, % (mmol/mol)
20%	9.4 (79)	(8.0, 10.7)	20%	10.6 (92)
30%	8.9 (74)	(7.6, 10.2)	30%	9.8 (84)
40%	8.4 (68)	(7.1, 9.7)	40%	9.0 (75)
50%	7.9 (63)	(6.6, 9.2)	50%	8.3 (67)
60%	7.4 (57)	(6.1, 8.8)	60%	7.5 (59)
70%	7.0 (53)	(5.6, 8.3)	70%	6.7 (50)
80%	6.5 (48)	(5.2, 7.8)	80%	5.9 (42)
90%	6.0 (42)	(4.7, 7.3)	90%	5.1 (32)
Every 10% increase in TIR = ~0.5% (5.5 mmol/mol) A1C reduction			Every 10% increase in TIR = ~0.8% (8.7 mmol/mol) A1C reduction	

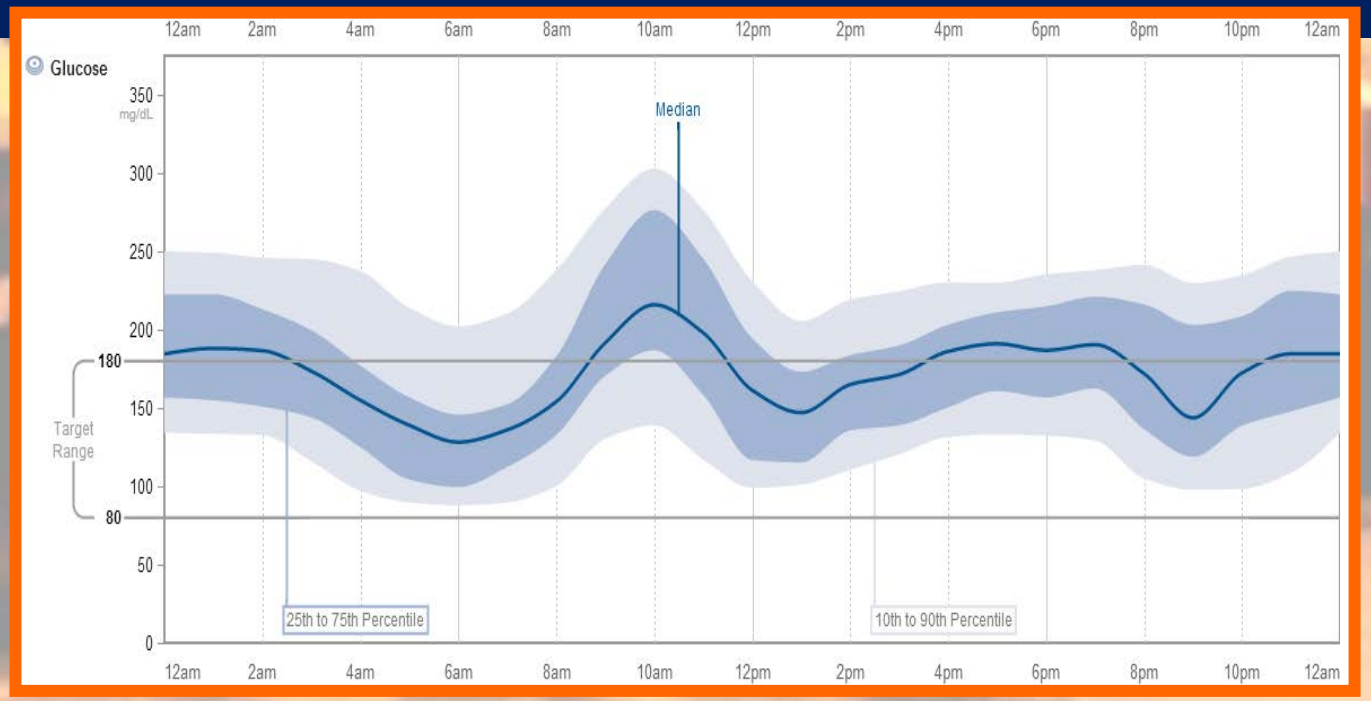
The difference between findings from the two studies likely stems from differences in number of studies analyzed and subjects included (RCTs with subjects with type 1 diabetes vs. RCTs with subjects with type 1 or type 2 diabetes with CGM and SMBG).

Analisi del dato: AGP

Uso del profilo glicemico ambulatoriale (AGP) per il report CGM

AMBULATORY GLUCOSE PROFILE (AGP)

E' UN'ISTANTANEA VISIVA DELLA GIORNATA TIPO DEL PAZIENTE CHE, UTILIZZANDO I DATI AD ALTA DENSITA', MOSTRA I TREND IPO- ED IPERGLICEMICI AL DI LA' DEI RISULTATI DELL'HbA1c PR FACILITARE UNA MIGLIORE EDUCAZIONE E TERAPIA DEL PAZIENTE



* Mazze RS. Making sense of glucose monitoring technologies from SMBG to CGM. Diabetes Technology and Therapeutics 2005;7(5):784-7

captūrAGP™

PDY Example - CGM Tests = 3285
26 Nov 2012 - 10 Dec 2012 (14.0 days)

Glucose Statistics

GLUCOSE EXPOSURE		GLUCOSE VARIABILITY		Dangerously Low	Very Low	Low	GLUCOSE RANGES In Target Range	High	Very High	Dangerously High	DATA SUFFICIENCY
Avg Glucose mg/dL	Estimated HbA1c	SD mg/dL	IQR mg/dL	Below 50 mg/dL	Below 60 mg/dL	Below 70 mg/dL	70 - 180 mg/dL	Above 180 mg/dL	Above 250 mg/dL	Above 400 mg/dL	Avg Tests/Day
169	**7.5%**	**90**	**110**	**9.4%**	**12.9%**	**15.7%**	**41.0%**	**43.3%**	**19.5%**	**0.9%**	**235**
88 - 116 *	< 6 *	10 - 26 *	13 - 29 *	0 *	0 *	< 4 *	> 90 *	< 6 *	0 *	0 *	Max 288

GLUCOSE EXPOSURE CLOSE-UP

	Wake 6 AM to 12 AM	Sleep 12 AM to 6 AM	24 Hours
AUC - Hourly (mg/dL)•h	**177**	**104**	**159**
	89 - 121 *	85 - 109 *	89 - 113 *

VARIABILITY CLOSE-UP

Coefficient of Variation	Avg Δ Median Curve mg/dL/hr
53.3%	**16.4**
19 - 25 *	2 - 5 *

HYPOGLYCEMIA AND HYPERGLYCEMIA EPISODES CLOSE-UP

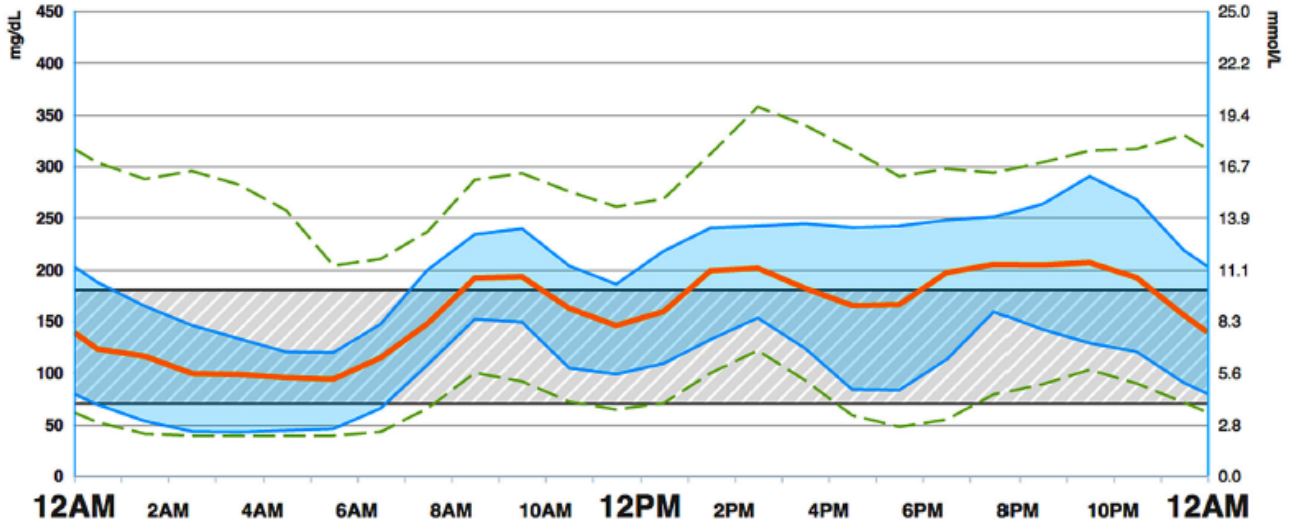
	< 50	< 60	< 70	> 180	> 250	> 400
Avg Hours Per Day	**2.2**	**3.0**	**3.7**	**10.1**	**4.6**	**0.2**
Mean Episodes/Day	**1.4**	**1.9**	**2.2**	**3.3**	**1.9**	**0.3**
Mean Duration (Hours)	**1.5**	**1.6**	**1.7**	**3.1**	**2.3**	**0.9**

* Episode = at least 10 minutes of consecutive measurements within a range

* Indicates reference ranges, which are derived from normal reference population means ± 2 standard deviations. The five curves below represent frequency distributions of glucose data plotted according to time without regard to date.

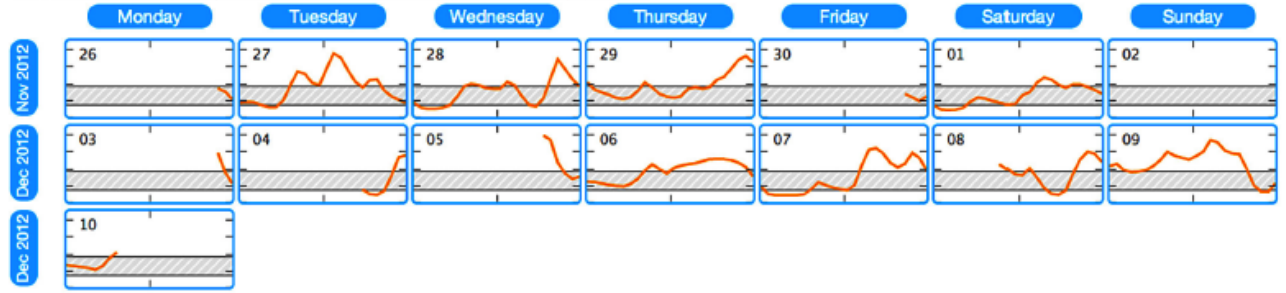
CGM · Data Point · 50% - Median · 25/75% - IQR · 10/90% · Target Range

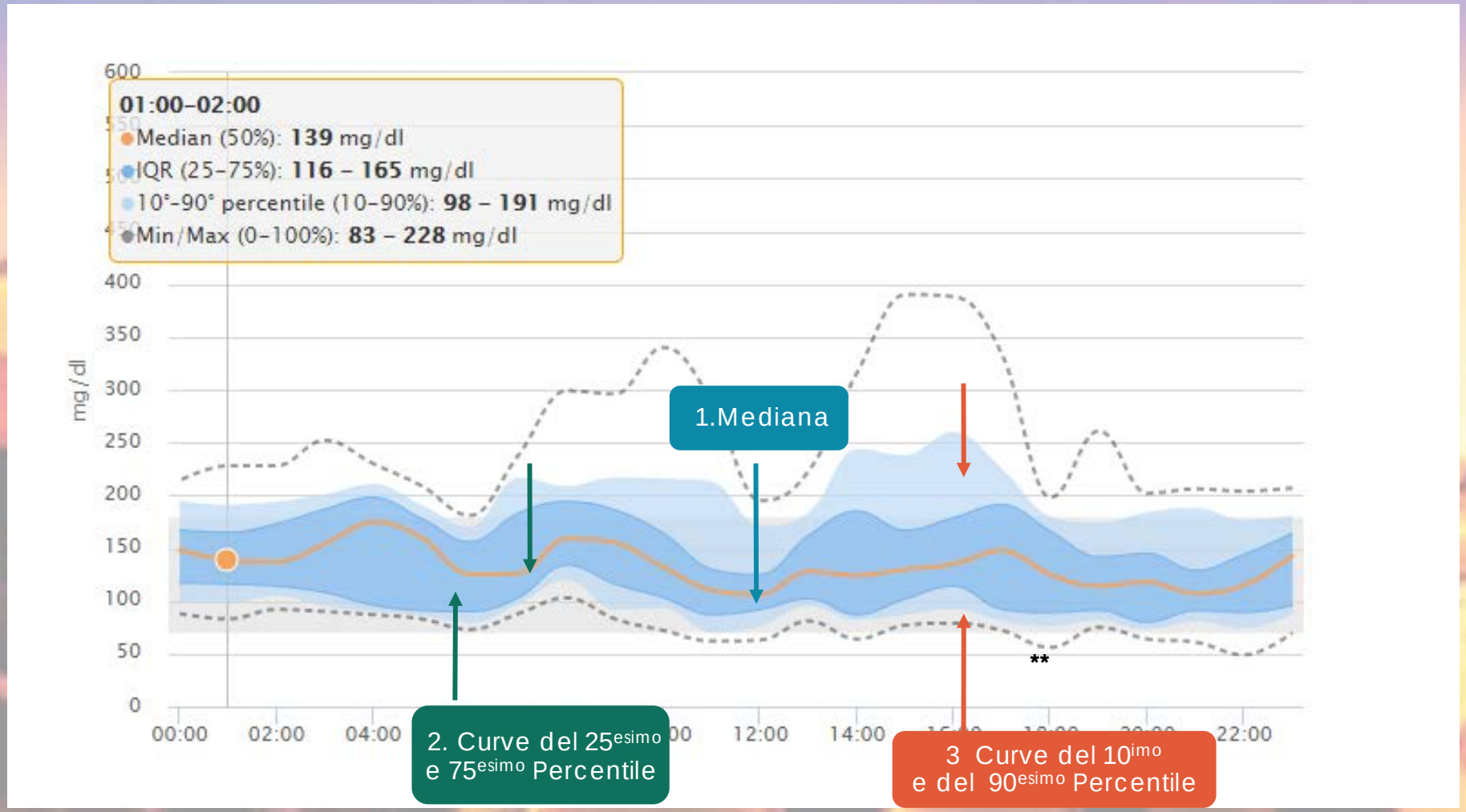
Ambulatory Glucose Profile



The Y axis scale and target range are the same as on the Ambulatory Glucose Profile graph above.

Daily Glucose Profile





1, Curva Mediana (50esimo percentile) mostra il valore mediano per ogni punto temporale.

1. Le curve immediatamente sopra e sotto la curva mediana definiscono **lo scarto interquartile (Interquartile Range – IQR)**. L'IQR mostra l'ampiezza del 50% dei valori glicemici giornalieri, notturni, e postprandiali.

1. **Le curve di 10imo e 90esimo percentile ai lati della mediana**, tengono traccia della escursioni glicemiche, ovvero Il 10% di tutti i valori glicemici più bassi del 10imo percentile e il 10% più alti del 90esimo percentile.

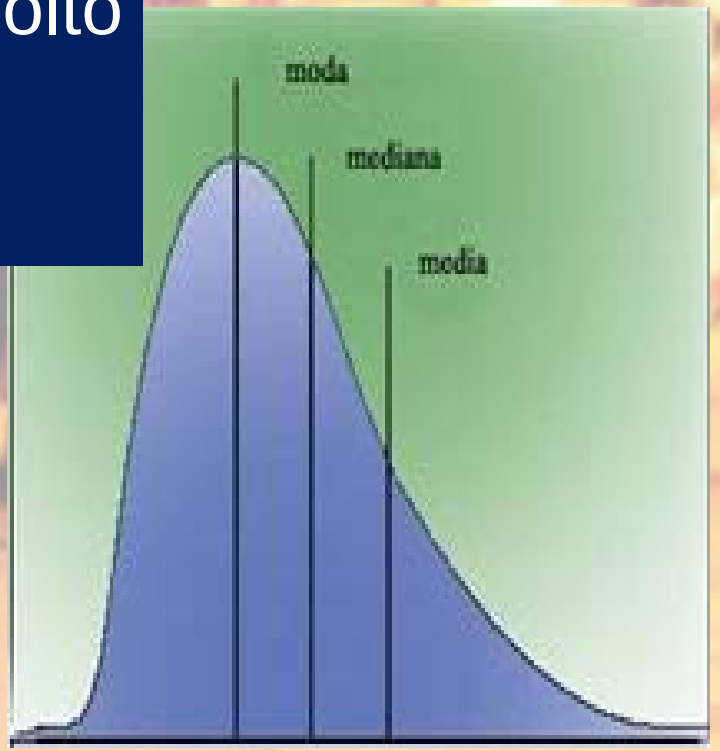
LA MEDIANA

Il concetto di mediana ci viene dalla statistica e rappresenta il valore di mezzo rispetto ad una serie di numeri che vengono ordinati in modo crescente o decrescente. Rappresenta molto meglio la realtà rispetto alla media, quando i valori sono molto differenti tra loro.

Esempio:

100
120
600

Mediana = 120
Media = 273



MOLTEPLICITA’ DEI REPORTS

Selezionare il più importante per le priorità del paziente

Crearsi delle sequenze di analisi


Glicemia media
TAR
TIR
Forniscono una proiezione di quello che sarà il dato di HbA1C
Tutte sono influenzate dal grado di iperglicemia
TBR
quindi
ncentrare
nto terapeutico
Le metriche ottenute dal CGM sono fondamentali per una terapia personalizzata
GMI
Fornisce informazioni sulla variazione dell'HbA1C dopo un cambio di terapia nel breve tempo

Grazie per la Vostra attenzione