DIABETE OGGI
prevenzione e cura al centro del cambiamento

Update su sistemi di monitoraggio e metriche del glucosio

“Misura ciò che è misurabile e rendi misurabile ciò che non lo è

Galileo Galilei

“Solo ciò che è misurabile è migliorabile”

Thomas Samuel Kuhn

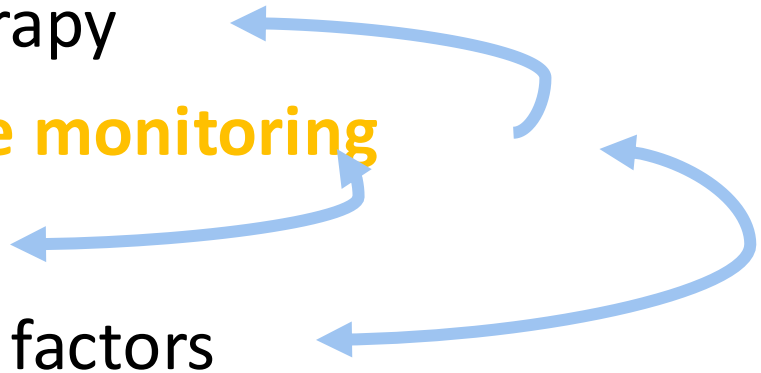
Ernesto Maddaloni

SAPIENZA UNIVERSITÀ DI ROMA

Google search for «Diabetes» images…

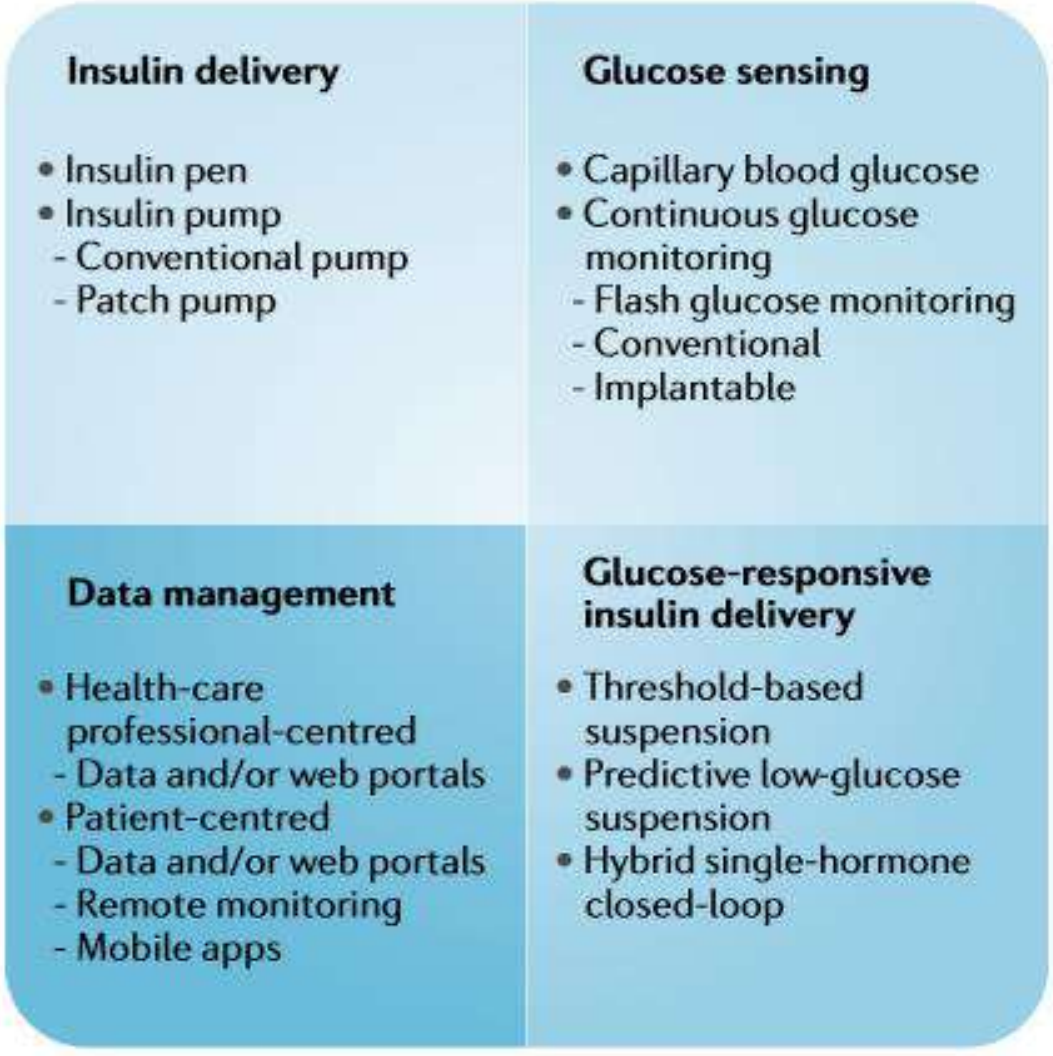
Barriers to glycemic control in diabetes

- Low adherence to pharmacotherapy
- **Low adherence to blood glucose monitoring**
- Poor self-management (DSME)
- Environmental and sociocultural factors
- Factors strictly related to the disease



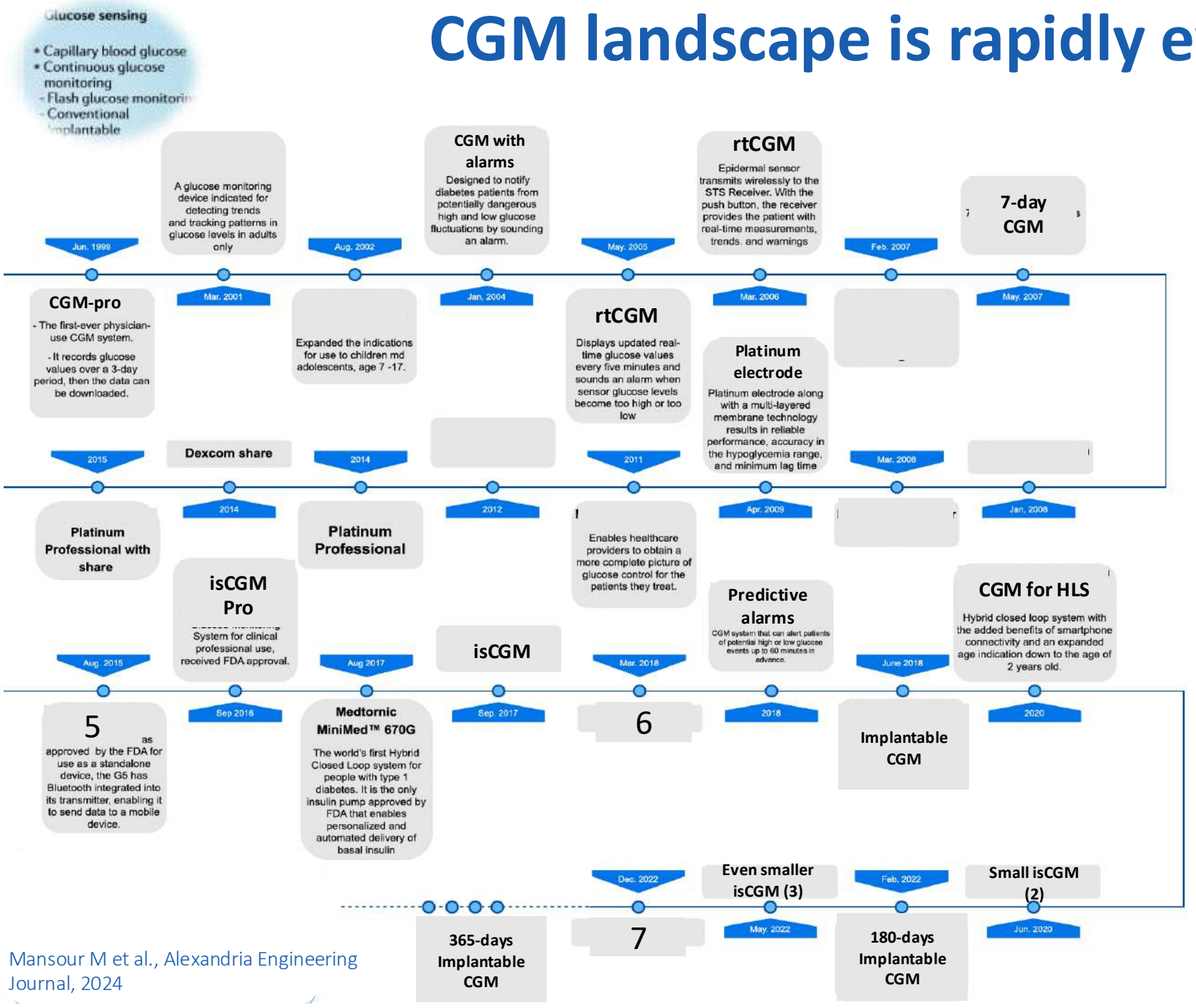
Technology in diabetes: four big areas

«The use of knowledge to turn resources into goods and services that society needs»



Tauschmann M, et al. 2018

CGM landscape is rapidly evolving



Mansour M et al., Alexandria Engineering Journal, 2024

	Systems affected	Effect
Hydroxycarbamide		Sensor readings will be higher than actual glucose
Paracetamol		Sensor readings will be higher than actual glucose
Ascorbic Acid		Sensor readings will be higher than actual glucose at >500 mg per day
Alcohol		Sensor readings might be higher than actual glucose
Tetracycline		Sensor bias at therapeutic doses
Mannitol		Sensor bias at therapeutic doses

*As specified in the D

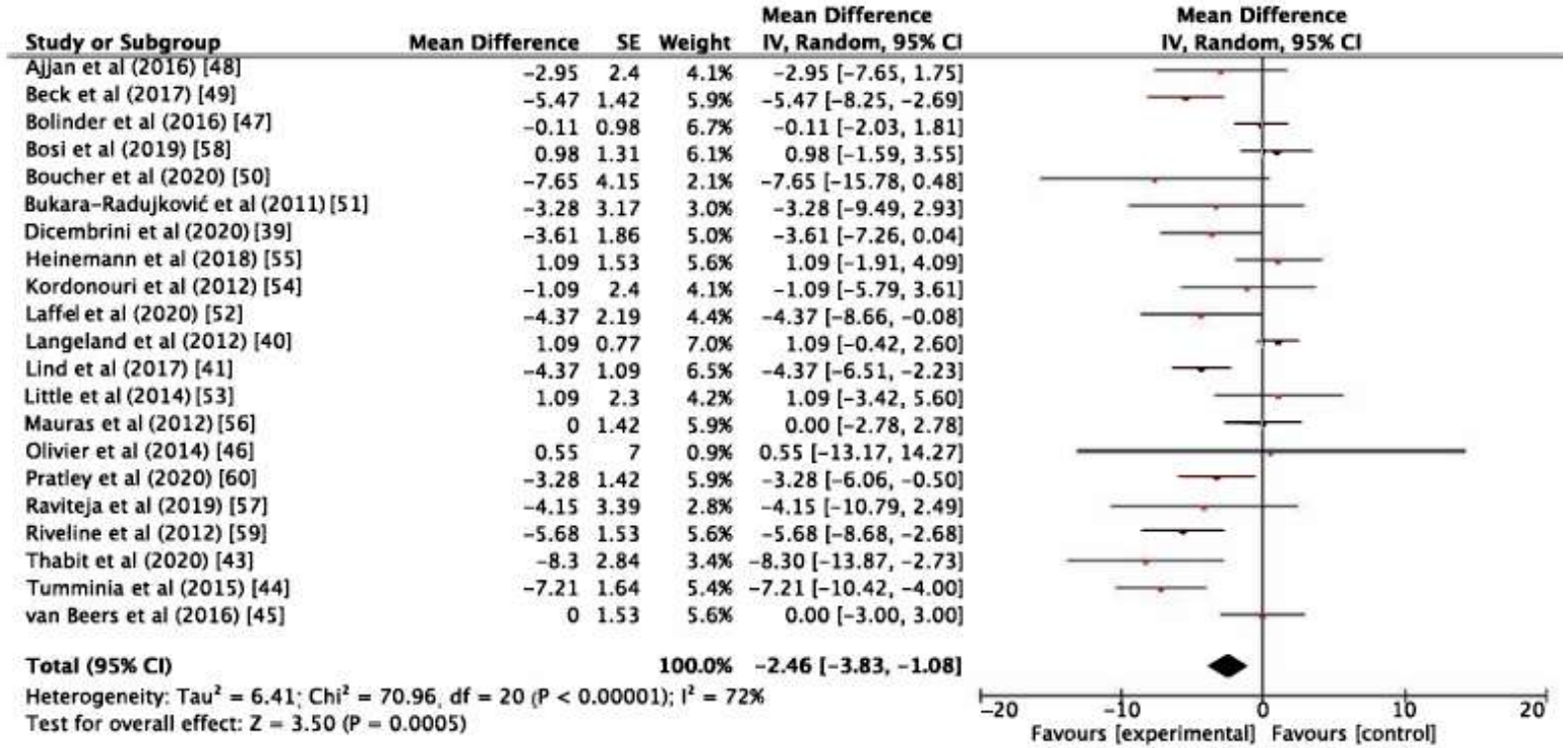
Table 1: Interference with CGM accuracy[46–48,62,63]

Battelino T et al., Lancet Diabetes Endocrinol 2023

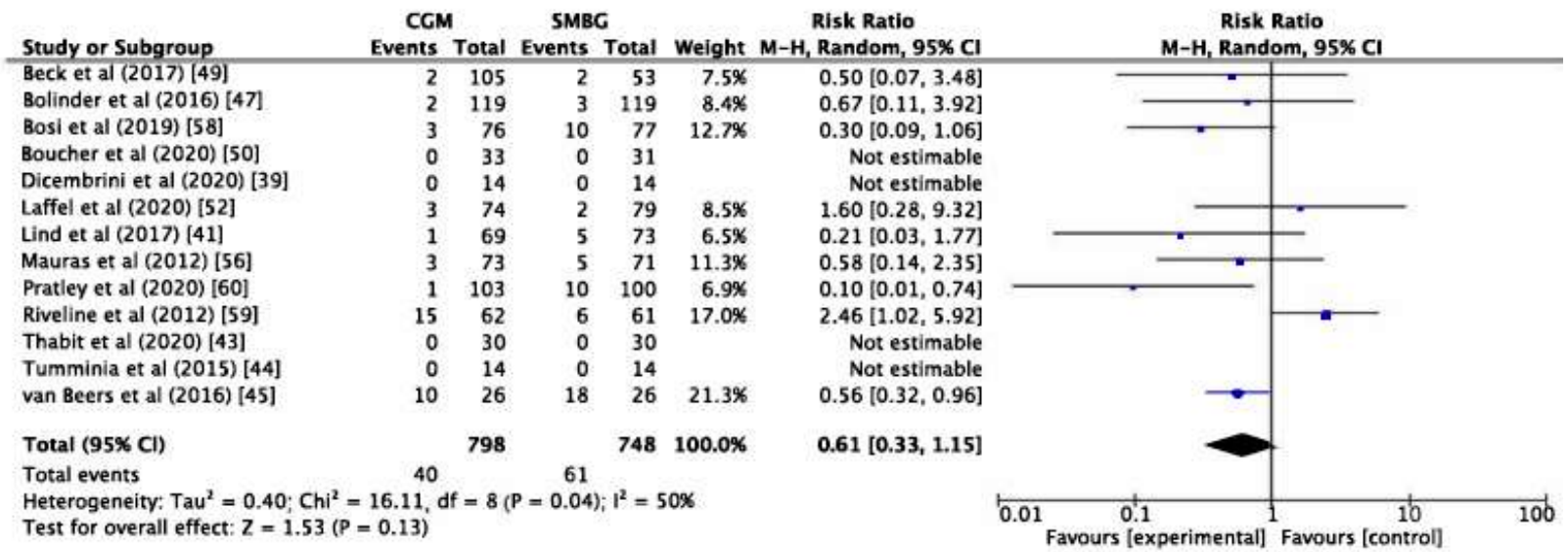
Effectiveness of continuous glucose monitoring in maintaining glycaemic control among people with type 1 diabetes mellitus: a systematic review of randomised controlled trials and meta-analysis

Evelyn Teo [1] · Norasyikin Hassan [2] · Wilson Tam [1] · Serena Koh [1]

HbA1c



Hypoglycemias



Teo E et al., Diabetologia 2022

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Intermittently Scanned Continuous Glucose Monitoring for Type 1 Diabetes

A parallel-group, multicenter, randomized, controlled trial

P Adults with T1D and HbA1c 7.5%-11.0%

O HbA1c

I FGM

C SBMG

Table 2. Glycated Hemoglobin Levels at Baseline and at 24 Weeks.*

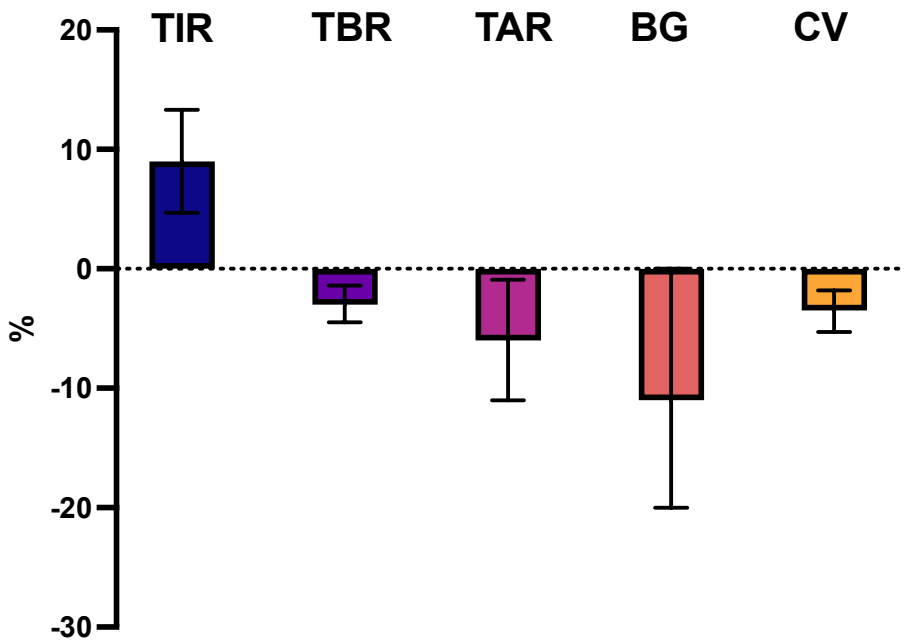
Outcome	Baseline		24 Weeks		Adjusted Mean Between-Group Difference or Odds Ratio (95% CI)†	P Value
	Intervention Group (N=78)	Usual-Care Group (N=78)	Intervention Group (N=72)	Usual-Care Group (N=69)		
Glycated hemoglobin level						
Percent	8.7±0.9	8.5±0.8	7.9±0.8	8.3±0.9	−0.5 (−0.7 to −0.3)	<0.001
≤7.5% — no. (%)	1 (1)	3 (4)	26 (36)	15 (22)	2.47 (1.08 to 5.68)	—
≤7.0% — no. (%)	NA‡	NA‡	11 (15)	5 (7)	2.43 (0.76 to 7.78)	—
Change in glycated hemoglobin level from baseline — percentage points	NA	NA	−0.8±0.8	−0.2±0.6	−0.5 (−0.7 to −0.3)	<0.001
Reduction in glycated hemoglobin level from baseline — no. (%)						
≥0.5 percentage points	NA	NA	46 (64)	21 (30)	4.74 (2.10 to 10.71)	—
≥1.0 percentage points	NA	NA	25 (35)	8 (12)	4.30 (1.67 to 11.09)	—

Leelarathna L et al., NEJM 2022

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Intermittently Scanned Continuous Glucose Monitoring for Type 1 Diabetes



Compared to usual care, participants randomized to FGM showed:

- Higher TIR: **+9.0** (4.7 to 13.3)*
- Lower TBR: **−3.0** (−4.5 to −1.4)*
- Lower TAR: **−6.0** (−11.0 to −0.9)*
- Lower mean blood glucose (BG): **−11** (−20 to 0)*
- Lower coefficient of variation (CV): **−3.5** (−5.3 to −1.8)*

*Adjusted mean difference with (95% CI) are shown

Modified from Leelarathna L et al., NEJM 2022

JAMA Network™

QUESTION For adults with poorly controlled type 2 diabetes treated with basal insulin without prandial insulin in primary care practices, does continuous glucose monitoring (CGM) improve hemoglobin A_{1c} (HbA_{1c}) levels compared with blood glucose meter (BGM) monitoring?

CONCLUSION This randomized clinical trial found there was a significantly greater decrease in HbA_{1c} level over 8 months with CGM than with BGM monitoring.

POPULATION

88 Women
87 Men

Adults with type 2 diabetes treated with basal insulin without prandial insulin

Mean age: **57 years**

LOCATIONS

15
Primary care practices in the US

INTERVENTION

175 Patients randomized

116
Continuous glucose monitoring
CGM with BGM testing performed as needed

59
Blood glucose meter monitoring
BGM testing performed when fasting and postprandial 1 to 3 times daily

PRIMARY OUTCOME

HbA_{1c} level at 8 months adjusted for the baseline value

FINDINGS

Mean HbA_{1c} level at 8 months

Continuous glucose monitoring		Blood glucose meter monitoring	
HbA_{1c}		HbA_{1c}	
Baseline	8 Months	Baseline	8 Months
9.1%	▶ 8.0%	9.0%	▶ 8.4%

Risk-adjusted difference was significant,
−0.4% (95% CI, −0.8% to −0.1%)

Martens T, Beck RW, Bailey R, et al; MOBILE Study Group. Effect of continuous glucose monitoring on glycemic control in patients with type 2 diabetes treated with basal insulin: a randomized clinical trial. *JAMA*. Published online June 2, 2021. doi:10.1001/jama.2021.7444

DIABETES RESEARCH AND CLINICAL PRACTICE 183 (2022) 109172

Contents available at ScienceDirect

Diabetes Research and Clinical Practice

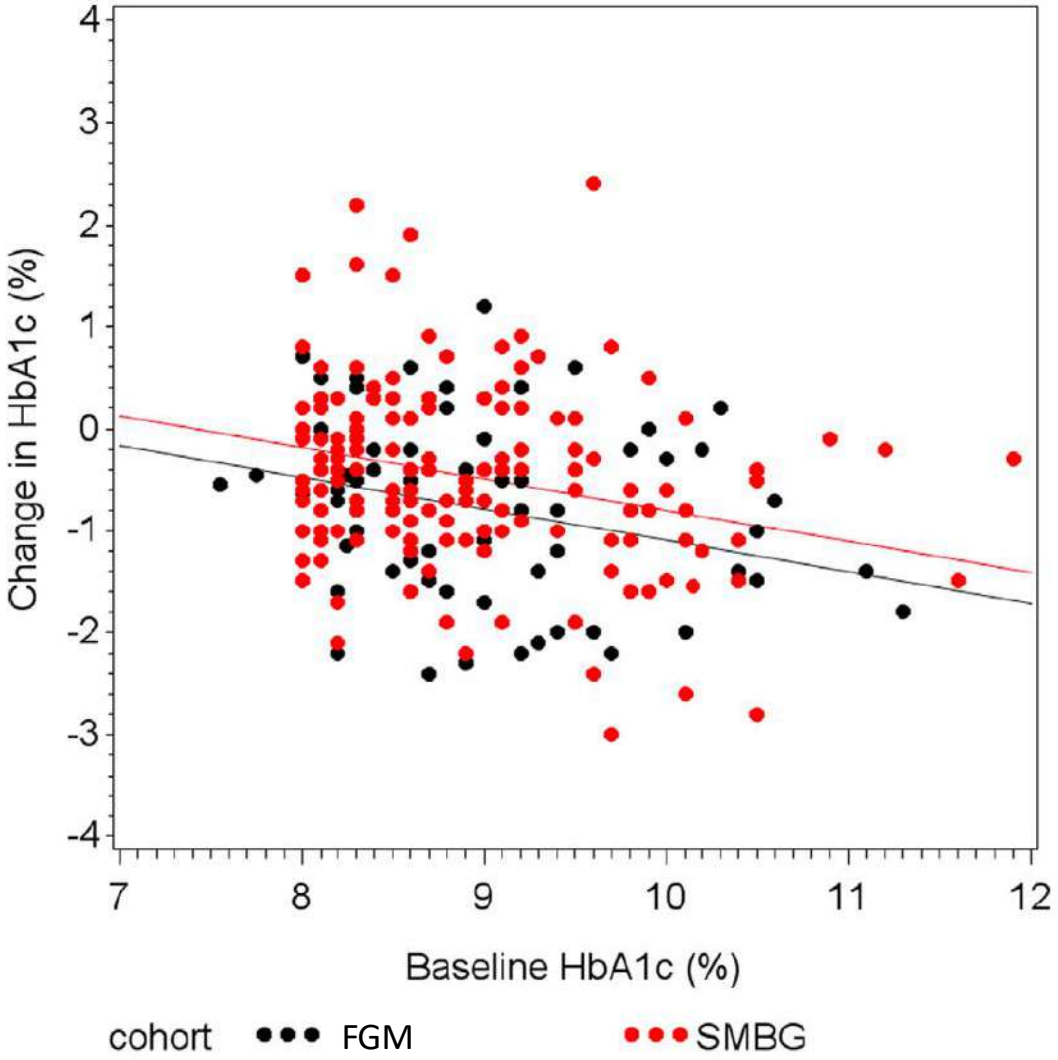
journal homepage: www.elsevier.com/locate/diabres

International Diabetes Federation

The use of flash glucose monitoring significantly improves glycemic control in type 2 diabetes managed with basal bolus insulin therapy compared to self-monitoring of blood glucose: A prospective observational cohort study

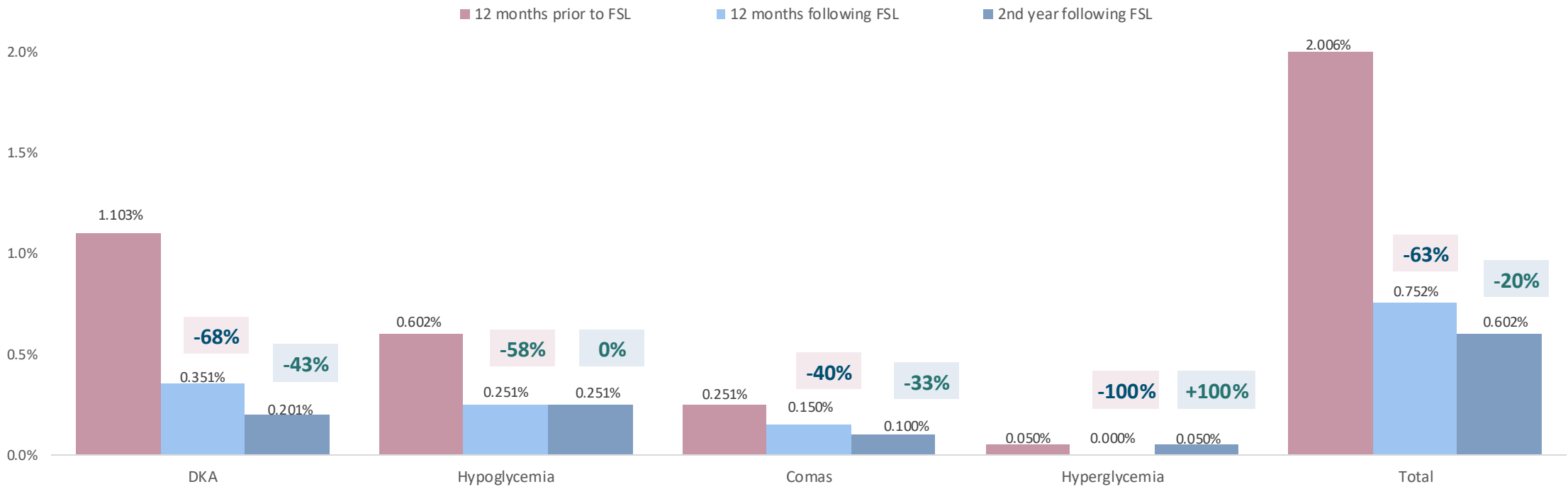
E. Bosi [a,*], G. Gregori [b], C. Cruciani [c], C. Irace [d], P. Pozzilli [e], R. Buzzetti [f]

- After 3–6 months, 234 complete cases (83 FSL, 151 SMBG users) demonstrated significantly reduced HbA1c for FSL use compared to SMBG (0.3% ± 0.12 [3 mmol/mol ± 1.3, (mean ± SE)], p = 0.0112).
- The difference remained statistically significant after adjusting for confounders.



Bosi E et al., Diabetes Research & Clinical Practice 2022

RELIEF Study (T2B): in people with T2D on Basal Insulin (n=5933)there was a significant reduction in the hospitalization rate for acute diabetes-associated events 1 and 2 years after FGM starting

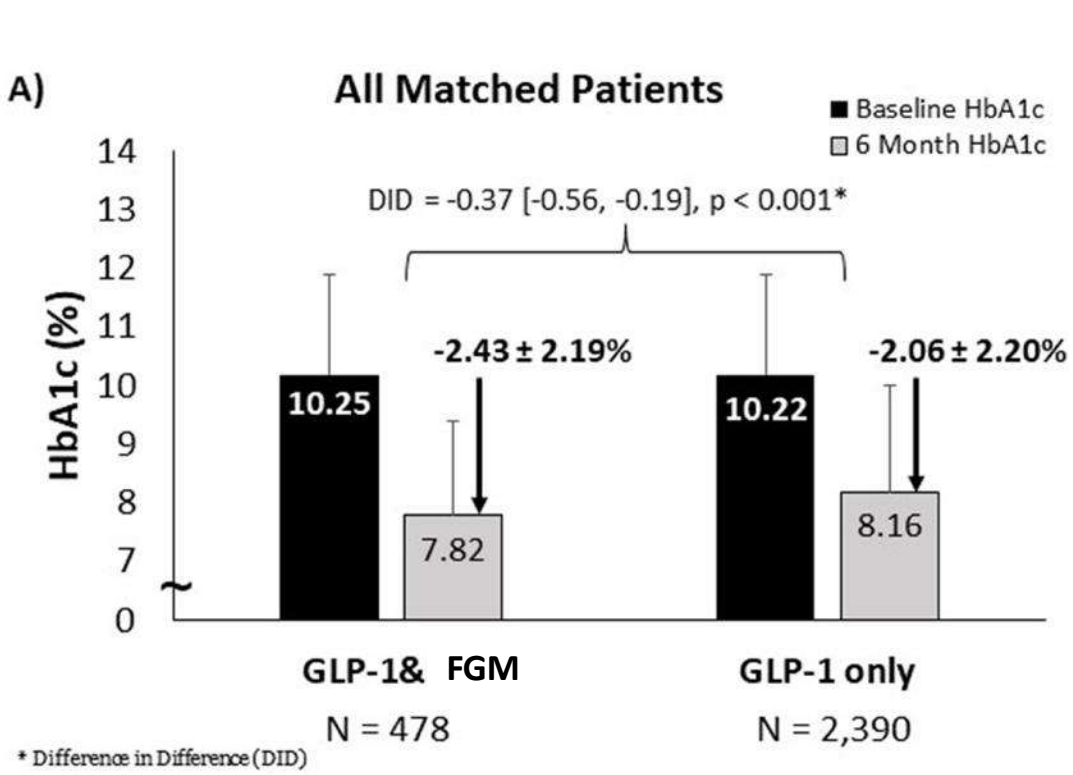


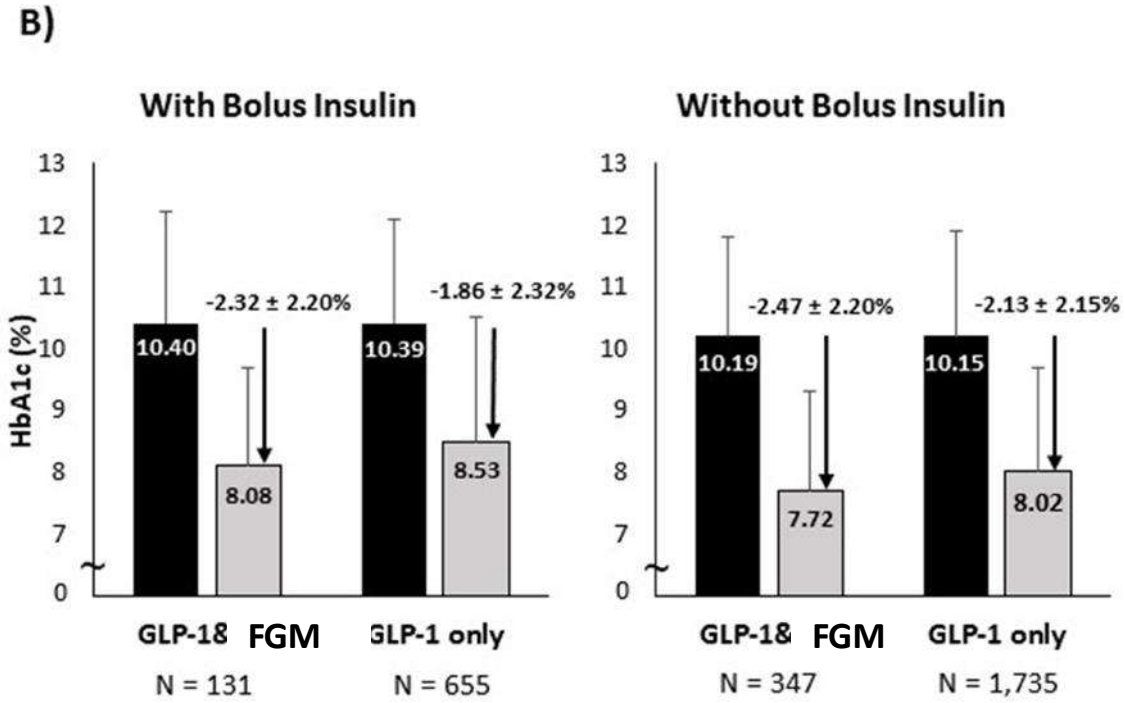
Abbreviazioni: ADE: eventi acuti correlate al diabete; DKA: Ketoacidosi diabetica; T2B: Pazienti di tipo 2 in terapia con Insulina Basale

Guerci B. Diabetes Technol Ther. 2023 Jan;

Initiating GLP-1 Therapy in Combination with FGM Provides Greater Benefit Compared with GLP-1 Therapy Alone

Eugene E. Wright, Jr. MD,[1] Gregory J. Roberts, BS,[2] Joyce S. Chuang, PhD,[3] Yelena Nabutovsky, MS,[3] Naunihal Virdi, MD,[4] and Eden Miller, DO[5]





Diabetes Technol Ther. 2024 May 31. doi: 10.1089/dia.2024.0015. Epub ahead of print. PMID: 38669474

Multicenter Randomized Trial of Intermittently Scanned Continuous Glucose Monitoring Versus Self-Monitoring of Blood Glucose in Individuals With Type 2 Diabetes and Recent-Onset Acute Myocardial Infarction: Results of the LIBERATES Trial

Ramzi A. Ajjan,[1] Simon R. Heller,[2] Colin C. Everett,[3] Armando Vargas-Palacios,[4] Ruchi Higham,[2] Linda Sharples,[5] Diana A. Gorog,[6,7] Alice Rogers,[8] Catherine Reynolds,[1] Catherine Fernandez,[2] Pedro Rodrigues,[4] Thozhukat Sathyapalan,[9] Robert F. Storey,[10] and Deborah D. Stocken[3]

Diabetes Care 2023;46:441–449 | https://doi.org/10.2337/dc22-1219

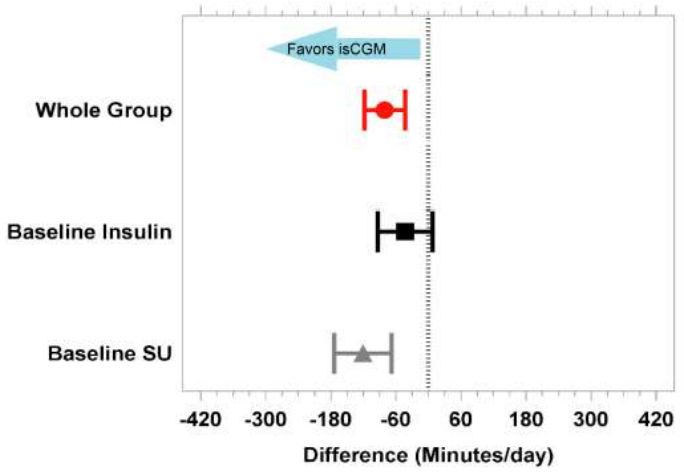
Objective

To analyze the impact of isCGM on glycemic and patient-related outcomes in individuals with T2D and recent myocardial infarction and assess cost effectiveness.

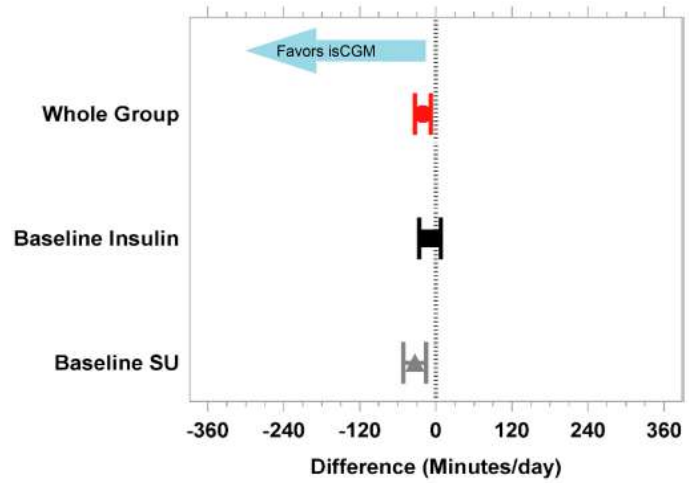
Population

People with acute MI and T2D who were on sulphonylurea and/or insulin

TBR (<70mg/dl)

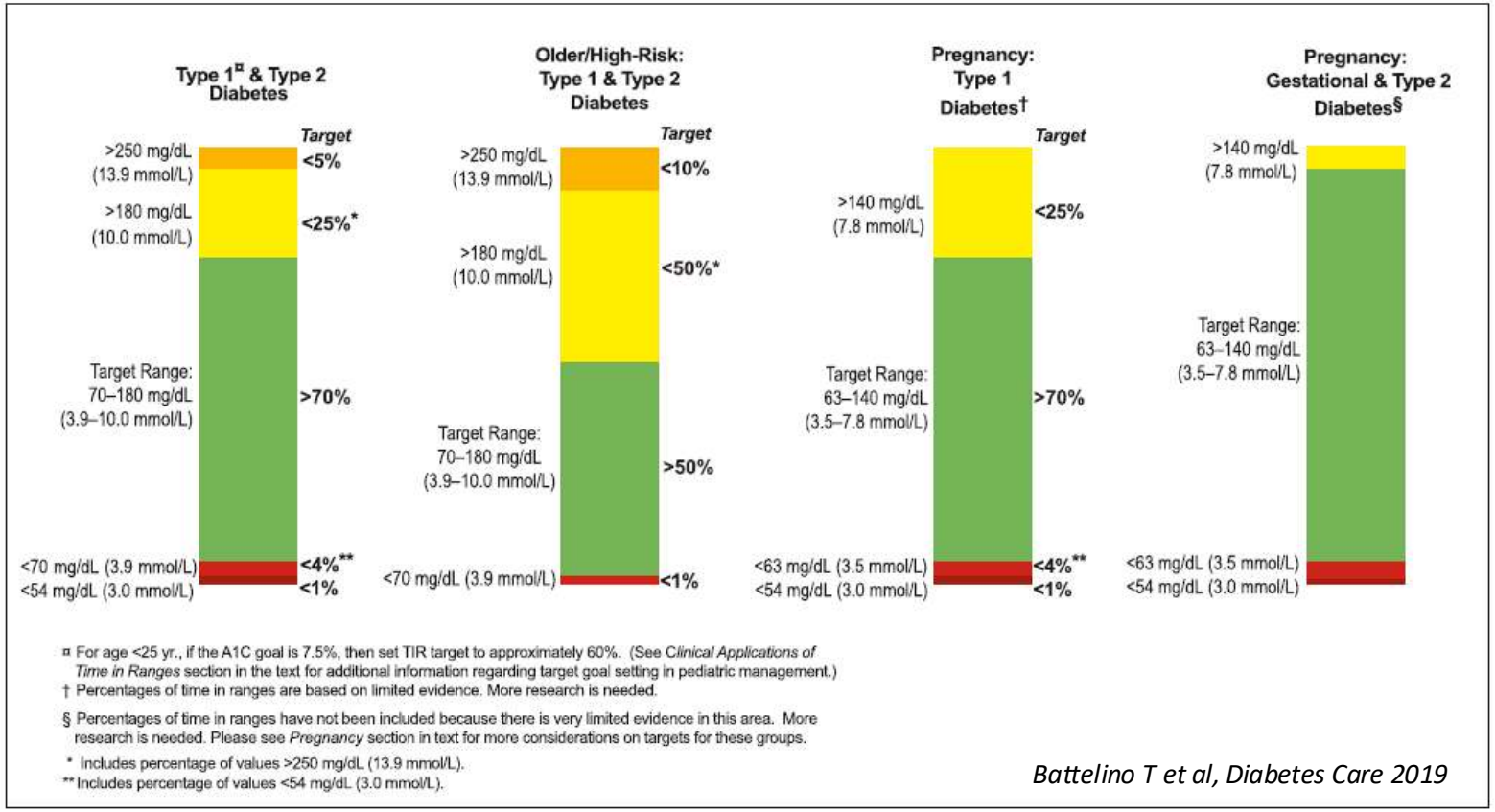


TBR (<54mg/dl)



Aijan RA et al., Diabetes Care 2023

CGM-based targets: recommendations for clinical practice



¤ 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).

Battelino T et al, Diabetes Care 2019

Continuous glucose monitoring and metrics for clinical trials: an international consensus statement

Tadej Battelino, Charles M Alexander, Stephanie A Amiel, Guillermo Arreaza-Rubin, Roy W Beck, Richard M Bergenstal, Bruce A Buckingham, James Carroll, Antonio Ceriello, Elaine Chow, Pratik Choudhary, Kelly Close, Thomas Danne, Sanjoy Dutta, Robert Gabbay, Satish Garg, Julie Heverly, Irl B Hirsch, Tina Kader, Julia Kenney, Boris Kovatchev, Lori Laffel, David Maahs, Chantal Mathieu, Dídac Mauricio, Revital Nimri, Rimei Nishimura, Mauro Scharf, Stefano Del Prato, Eric Renard, Julio Rosenstock, Banshi Saboo, Kohjiro Ueki, Guillermo E Umpierrez, Stuart A Weinzimer, Moshe Phillip

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	Units and quantity
Core endpoints	
Time in range 70–180 mg/dL (3·9–10·0 mmol/L)	Percentage of time in range; amount of time (hours and minutes)
Time below range <70 mg/dL (<3·9 mmol/L), including readings of <54 mg/dL (<3·9 mmol/L)	Percentage of time below range; amount of time (hours and minutes)
Time below range <54 mg/dL (<3·0 mmol/L)	Percentage of time below range; amount of time (hours and minutes)
Time above range >180 mg/dL (>10·0 mmol/L), including readings of >250 mg/dL (<13·9 mmol/L)	Percentage of time above range; amount of time (hours and minutes)
Time above range >250 mg/dL (>13·9 mmol/L)	Percentage of time above range; amount of time (hours and minutes)
Coefficient of variation	Percentage coefficient of variation intraday (ie, within 24 h) and interday (ie, over multiple days)
SD of mean glucose	SD
Mean sensor glucose	mg/dL (mmol/L)

- A difference of ≥5% (absolute percentage points) in time in range is considered clinically meaningful for an individual participant in a clinical study and 3% is considered clinically meaningful for a treatment group difference in mean time in range (B)[84]

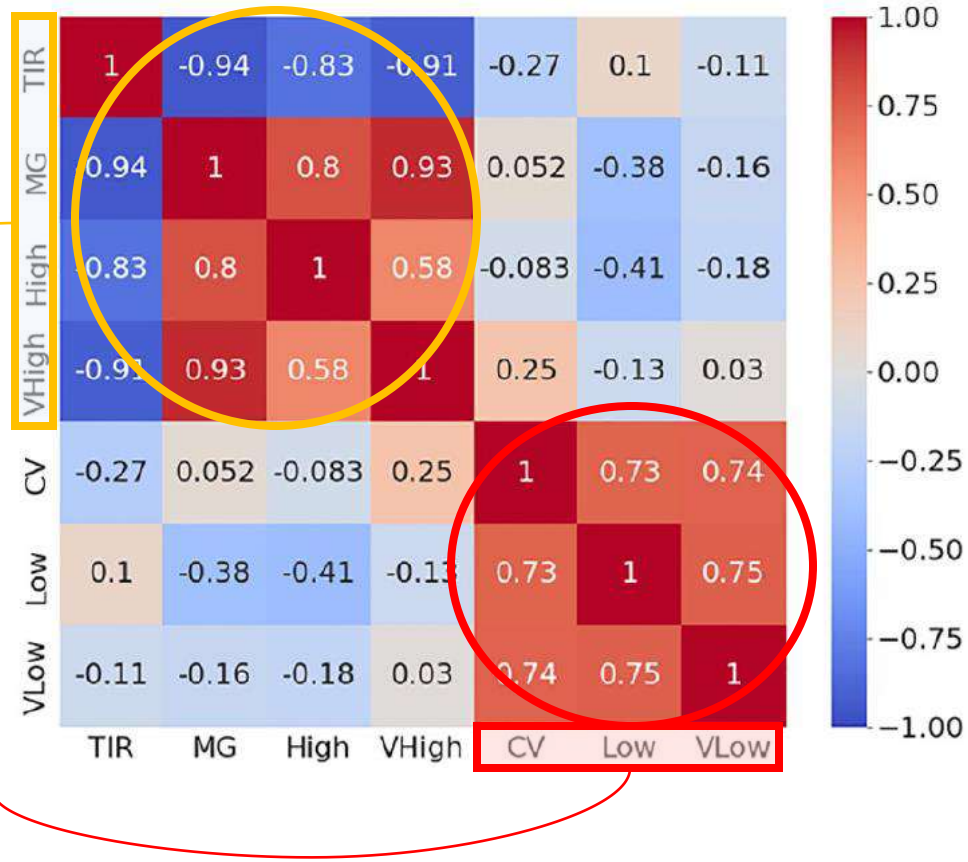
- Studies can be powered to detect a minimum 3% change in mean time in range between study groups (E)

Battelino T et al., Lancet Diabetes Encocrinol 2023

Glycemia Risk Index (GRI): a single-number summary of the quality of glycemia

- Data from 14-day CGM from 225 adults
  - T1D on pump (including AHCLS) or MDI
  - T2D on MDI
- 330 expert diabetologists ranked CGM tracings from best to worst in terms of glucose control quality.

PCA was conducted to uncover the essential components of glycemic control

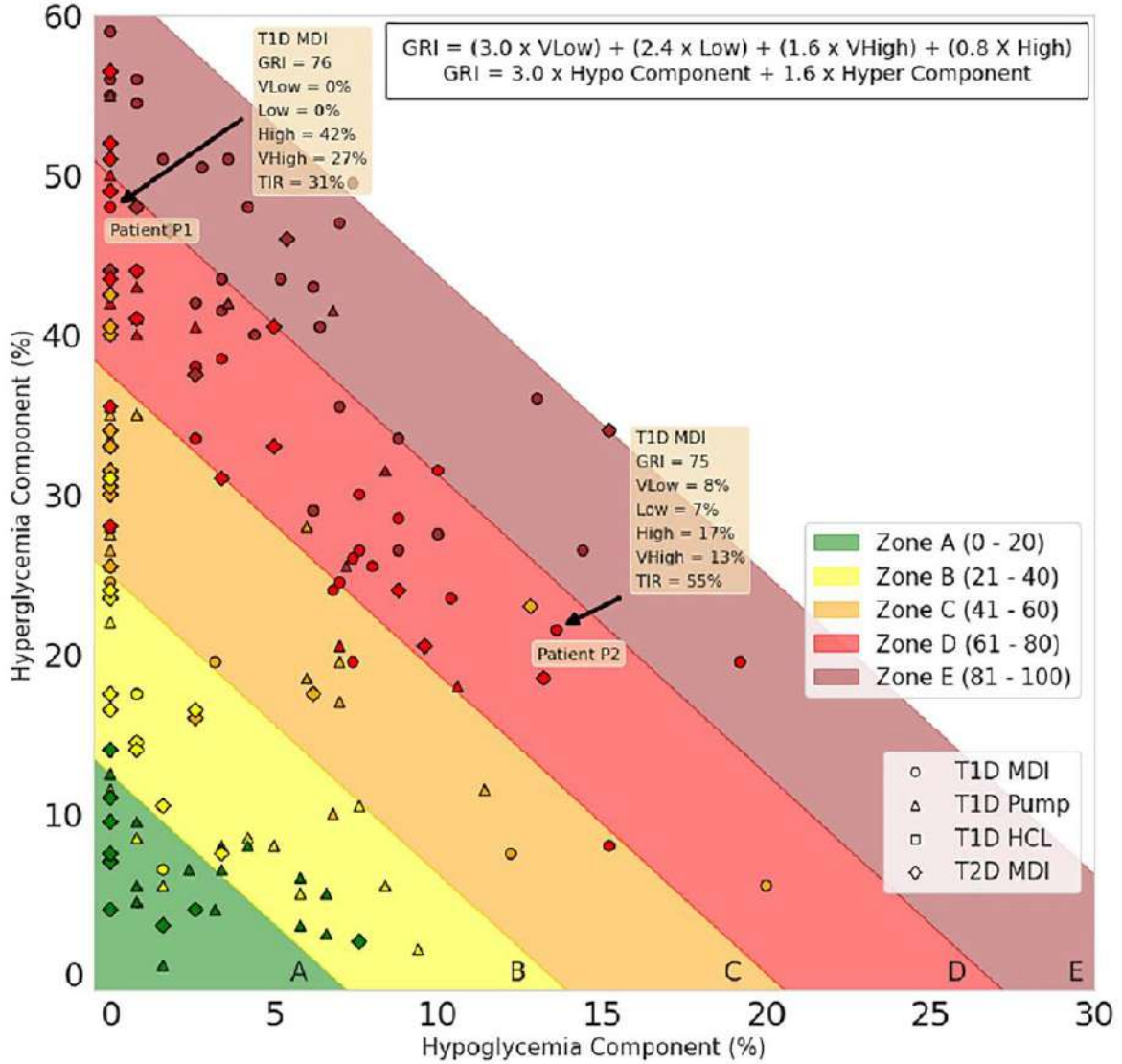


Hyperglycemia-related metrics
-Hyperglycemia principal dimension

Hypoglycemia-related metrics
-Hypoglycemia principal dimension

Klonoff DC et al., J Diabetes Science Technology 2023

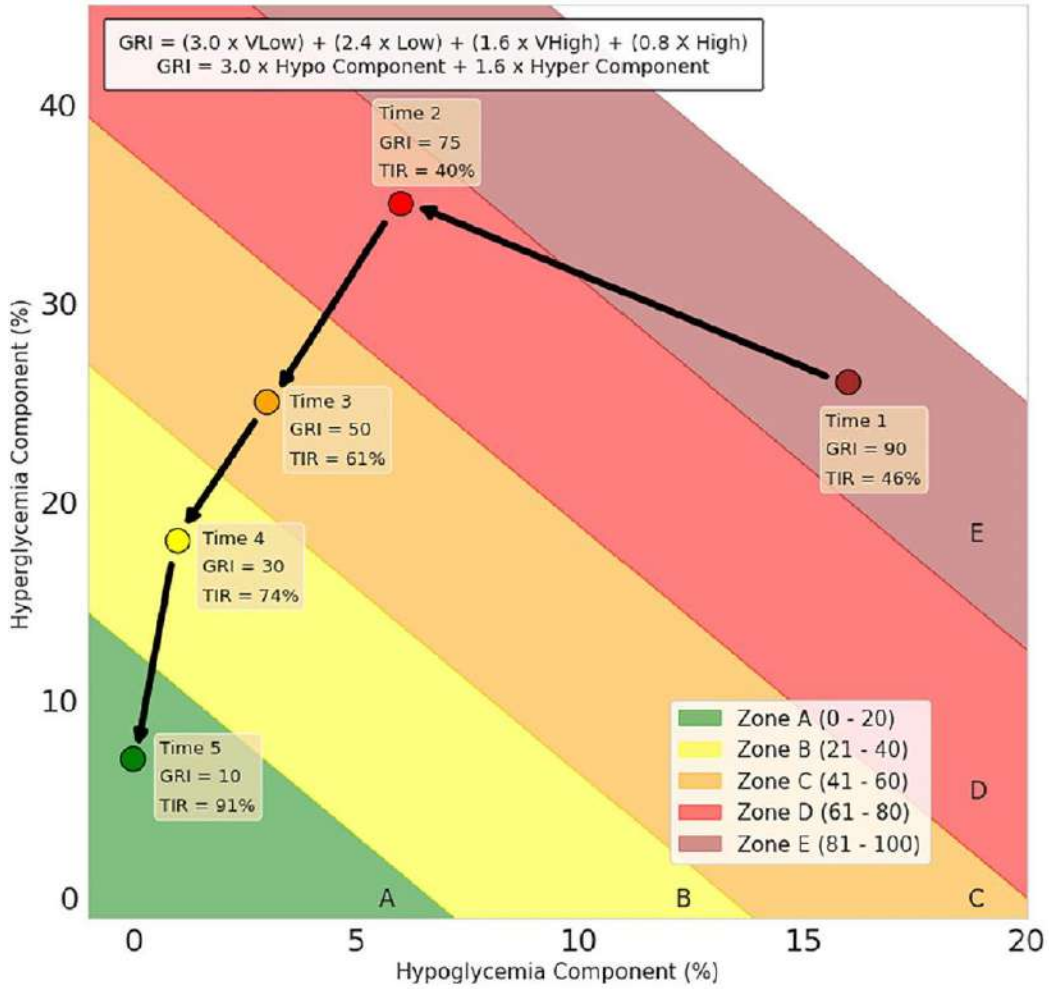
Glycemia Risk Index (GRI): a single-number summary of the quality of glycemia



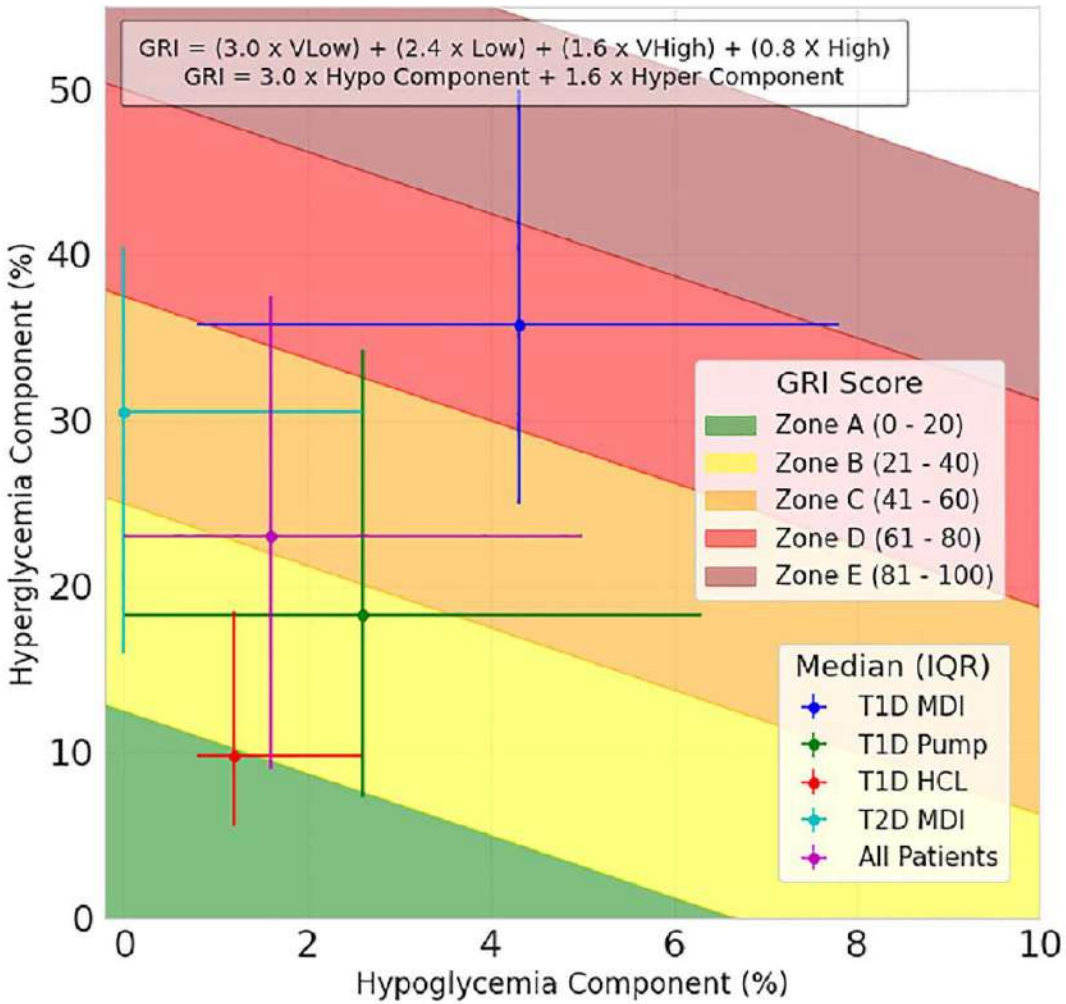
Klonoff DC et al., J Diabetes Science Technology 2023

Glycemia Risk Index (GRI): a single-number summary of the quality of glycemia

Changes of GRI over time

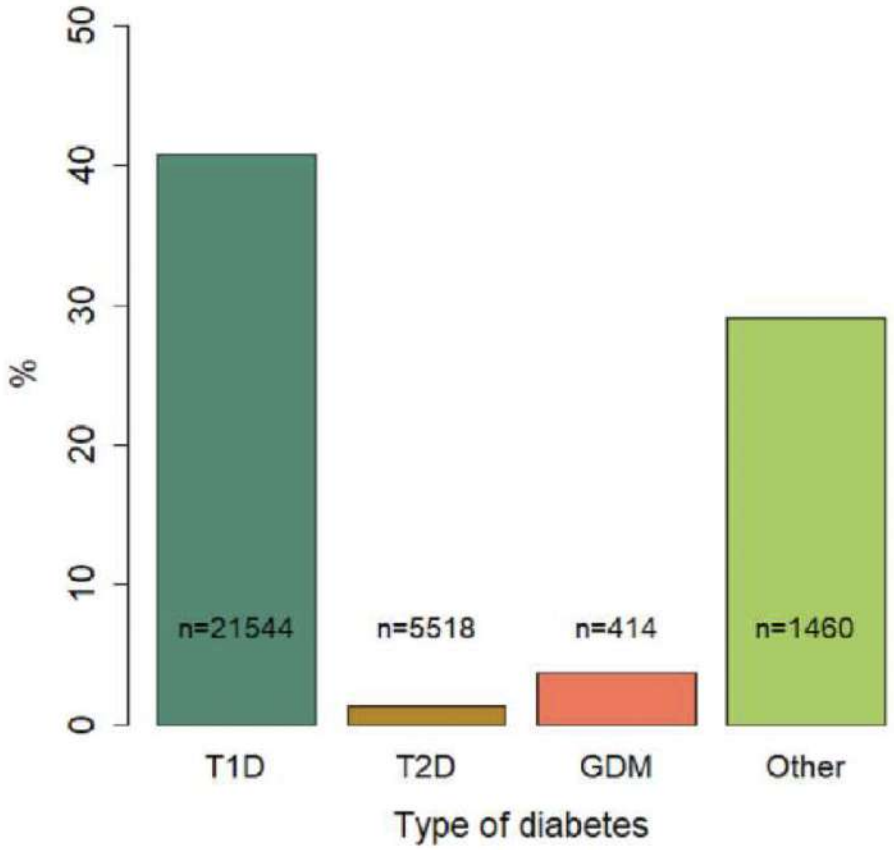


GRI to differentiate groups of patients



Klonoff DC et al., J Diabetes Science Technology 2023

CGM in Italia non è ancora utilizzato abbastanza (o come vorrebbero le linee guida)



507.386 n. pazienti totali (il 86,4% con DM2)

28.936 n. pazienti con CGM

Pitocco D. et al. Working group of Diabetes and Technology AMD-SID-SIEDP NMCD Vol. 32 Issue 10 2022

Lancet Diabetes Endocrinol
2024; 12: 61–82

Bringing an end to diabetes stigma and discrimination: an international consensus statement on evidence and recommendations

Jane Speight, Elizabeth Holmes-Truscott*, Matthew Garza, Renza Scibilia, Sabina Wagner, Asuka Kato, Victor Pedrero, Sonya Deschênes, Susan J Guzman, Kevin L Joiner, Shengxin Liu, Ingrid Willaing, Katie M Babbott, Bryan Cleal, Jane K Dickinson, Jennifer A Halliday, Eimear C Morrissey, Giesje Nefs, Shane O'Donnell, Anna Serlachius, Per Winterdijk, Hamzah Alzubaidi, Bustanul Arifin, Liz Cambron-Kopco, Corinna Santa Ana, Emma Davidsen, Mary de Groot, Maartje de Wit, Phyllisa Deroze, Stephanie Haack, Richard I G Holt, Walther Jensen, Kamlesh Khunti, Karoline Kragelund Nielsen, Tejal Lathia, Christopher J Lee, Bridget McNulty, Diana Naranjo, Rebecca L Pearl, Suman Prinjha, Rebecca M Puhl, Anita Sabidi, Chitra Selvan, Jazz Sethi, Mohammed Seyam, Jackie Sturt, Mythily Subramaniam, Helle Terkildsen Maindal, Virginia Valentine, Michael Vallis, Timothy C Skinner*

People with diabetes often encounter stigma (ie, negative social judgments, stereotypes, prejudice), which can adversely affect emotional, mental, and physical health; self-care, access to optimal health care; and social and professional opportunities. To accelerate an end to diabetes stigma and discrimination, an international multidisciplinary expert panel (n=51 members, from 18 countries) conducted rapid reviews and participated in a three-round Delphi survey process. We achieved consensus on 25 statements of evidence and 24 statements of recommendations. The consensus is that diabetes stigma is driven primarily by blame, perceptions of burden or sickness, invisibility, and fear or disgust. On average, four in five adults with diabetes experience diabetes stigma and one in five experience discrimination (ie, unfair and prejudicial treatment) due to diabetes, such as in health care, education, and employment. Diabetes stigma and discrimination are harmful, unacceptable, unethical, and counterproductive. Collective leadership is needed to proactively challenge, and bring an end to, diabetes stigma and discrimination. Consequently, we achieved unanimous consensus on a pledge to end diabetes stigma and discrimination.

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four in five adults with diabetes experience diabetes stigma

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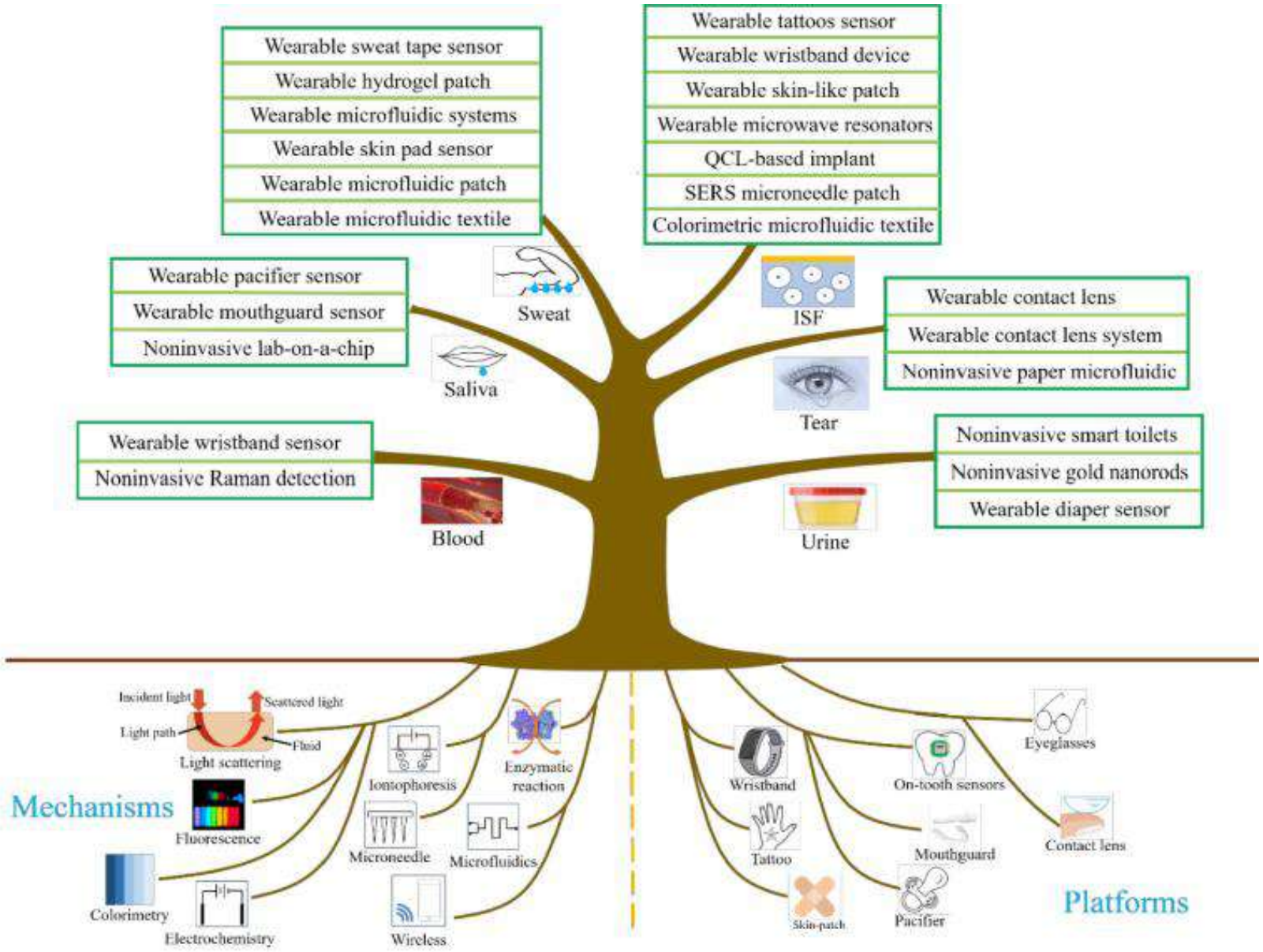
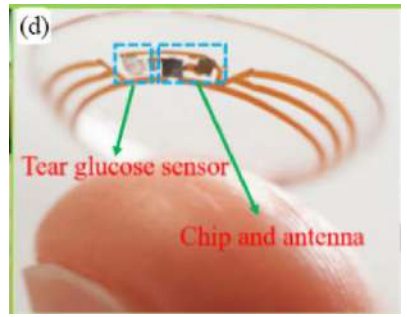
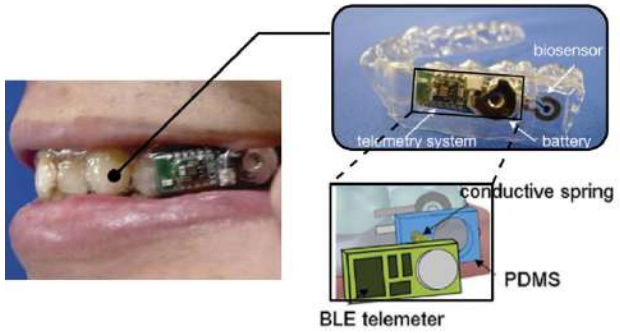
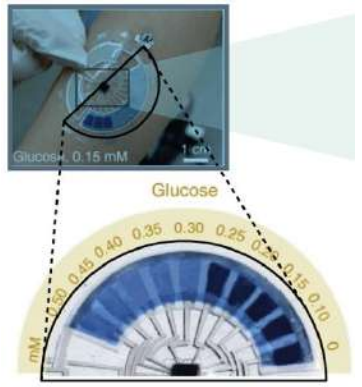
The future of glucose sensors

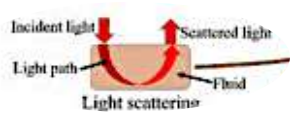








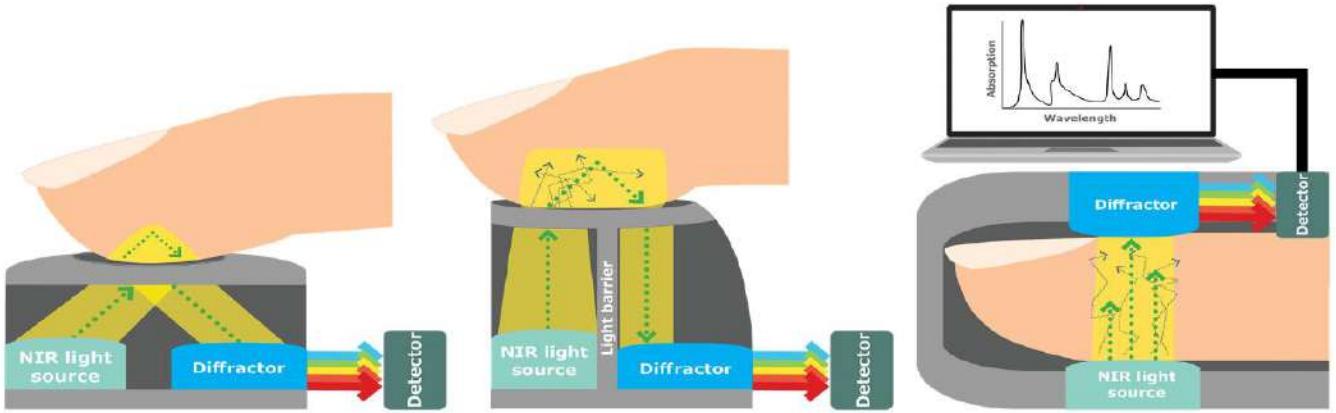
Peng Z et al., Journal of Innovative Optical Health Sciences, 2022



Near InfraRed (NIR) Spectroscopy for CGM

Shines light in the range of 750 nm to 2.5 µm onto the skin, and the reflected light is measured

Glucose molecules can absorb light, resulting in changes in the intensity of the reflected light at specific wavelengths, which are used to estimate the glucose concentration.



(a) Reflectance (b) Interactance (c) Transmittance

Further research on NIR is needed to account for:

- the diffusion processes of different substances within the tissue that may impact glucose levels' measurement.
- physiological parameters and environment factors: thickness, temperature, skin (tone and melanin), substances in the tissue (fat, protein, and water), and ambient light intensity

Di Filippo D et al., Sensors 2023

Considerazioni finali

Nuove tecnologie a supporto dei pazienti con diabete e degli HCP stanno rivoluzionando la gestione della patologia

La digitalizzazione dei dati circa il controllo glicemico giornaliero è elemento chiave nella gestione moderna del diabete mellito

Il monitoraggio glicemico in continuo con digitalizzazione del dato è già di per sé un efficace intervento terapeutico digitale in diabetologia

La rivoluzione tecnologica del glucose sensing non è ancora terminata!

Davies MJ, et al. *Diabetes Care* 2022;.

MAKE IT WORK!

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