



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

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



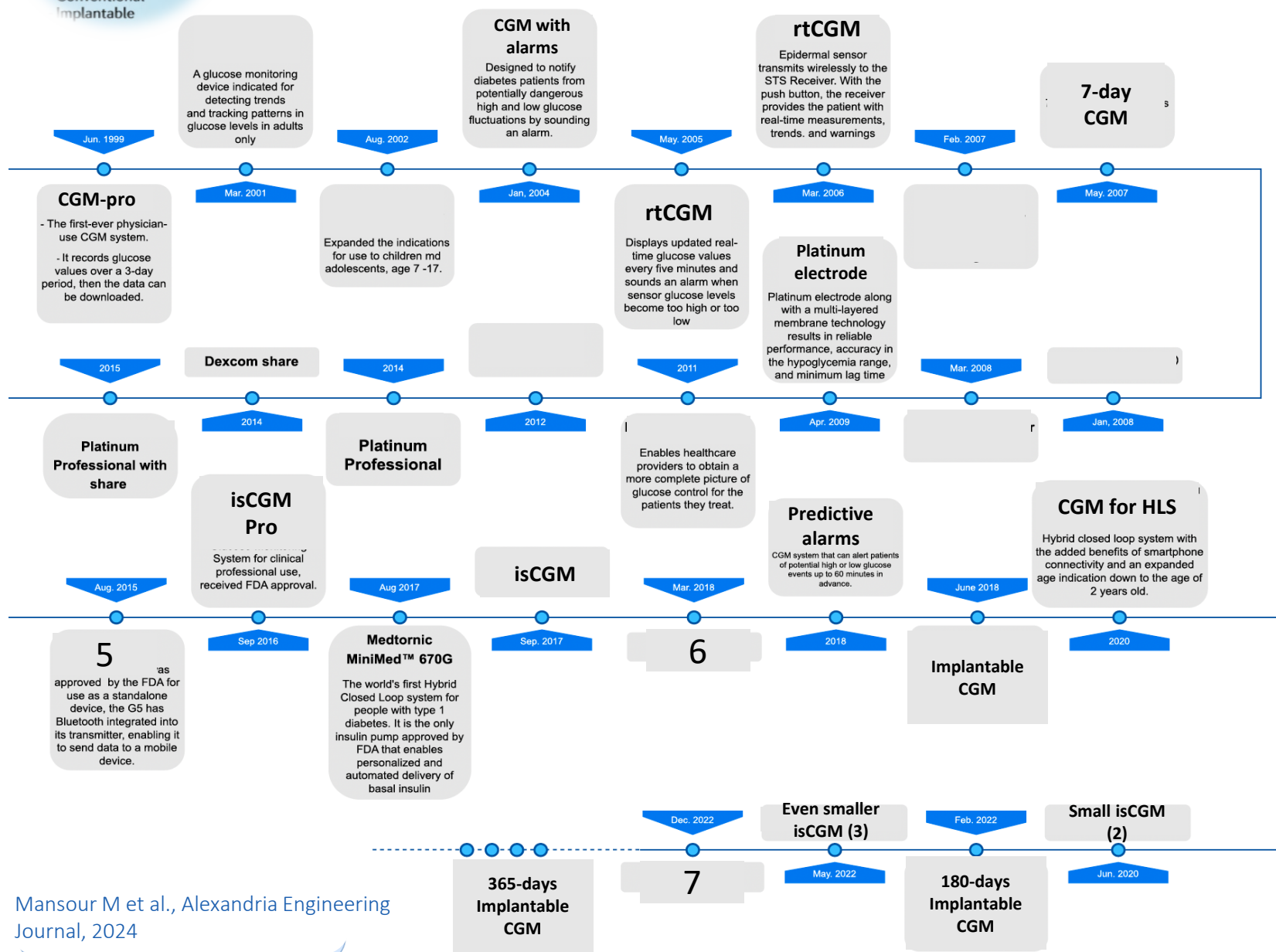
Technology in diabetes: four big areas

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

Insulin delivery • Insulin pen • Insulin pump - Conventional pump - Patch pump	Glucose sensing • Capillary blood glucose • Continuous glucose monitoring - Flash glucose monitoring - Conventional - Implantable
Data management • Health-care professional-centred - Data and/or web portals • Patient-centred - Data and/or web portals - Remote monitoring - Mobile apps	Glucose-responsive insulin delivery • Threshold-based suspension • Predictive low-glucose suspension • Hybrid single-hormone closed-loop

CGM landscape is rapidly evolving

- Glucose sensing
- Capillary blood glucose
 - Continuous glucose monitoring
 - Flash glucose monitoring
 - Conventional implantable



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 De

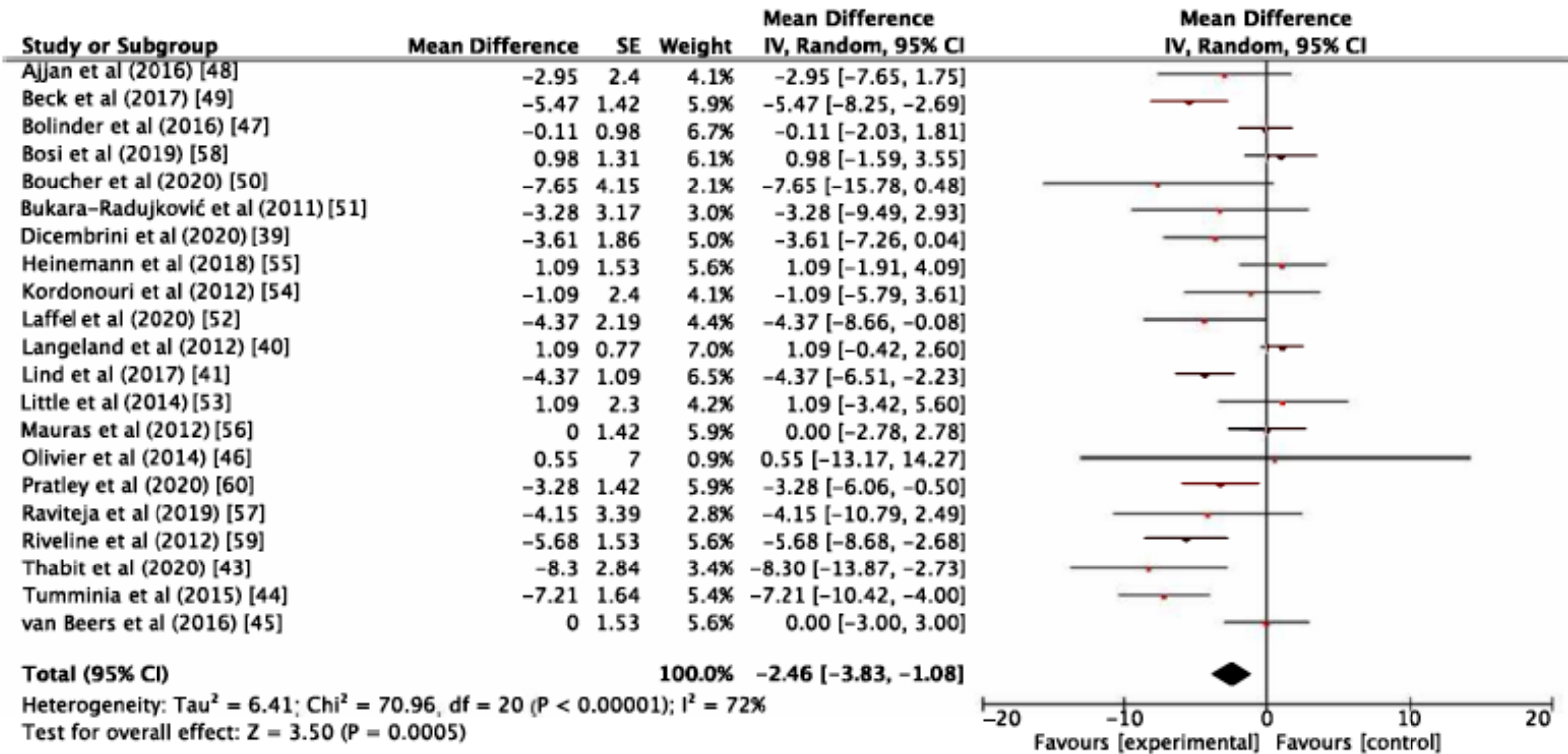
Table 1: Interference with CGM accuracy^{46-48,62,63}

Battelino T et al., Lancet Diabetes Endocrinol 2023

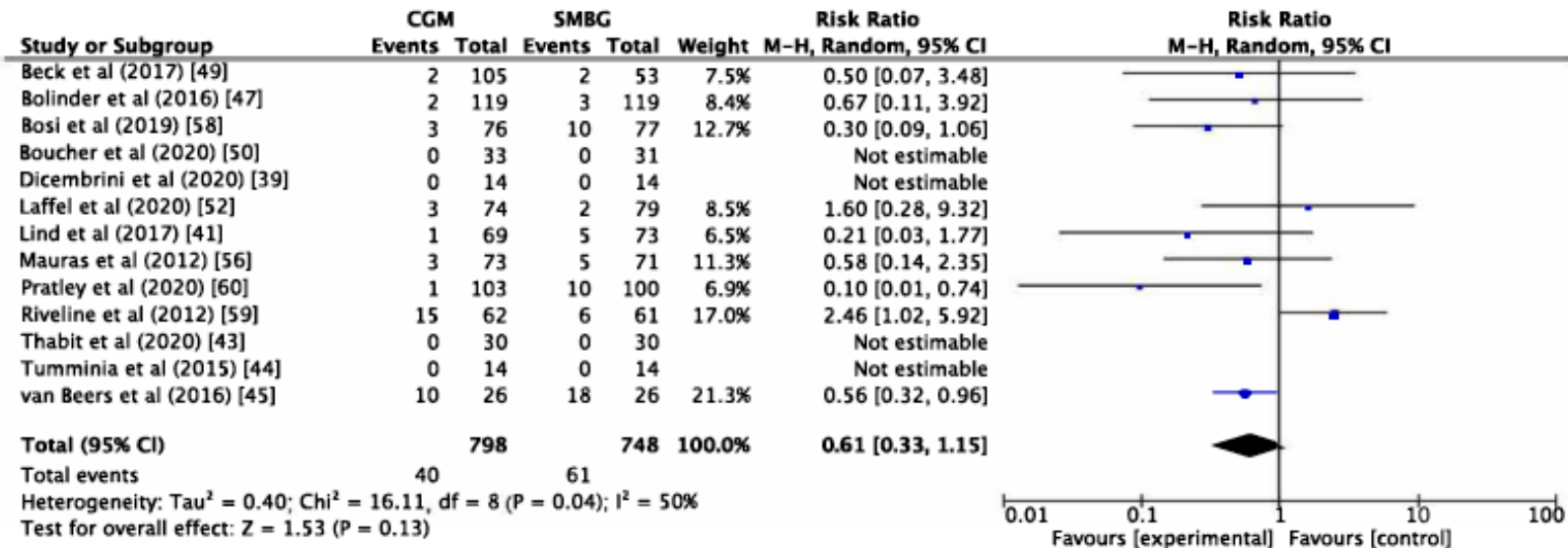
Effectiveness of continuous glucose monitoring in maintaining glycaemic control among people with type 1 diabetes mellitus: a systematic review of randomised controlled trials and meta-analysis

Evelyn Teo¹ • Norasyikin Hassan² • Wilson Tam¹ • Serena Koh¹

HbA1c



Hypoglycemias



ORIGINAL ARTICLE

Intermittently Scanned Continuous Glucose Monitoring for Type 1 Diabetes



P Adults with T1D and HbA1c 7.5%-11.0%



O HbA1c

I FGM

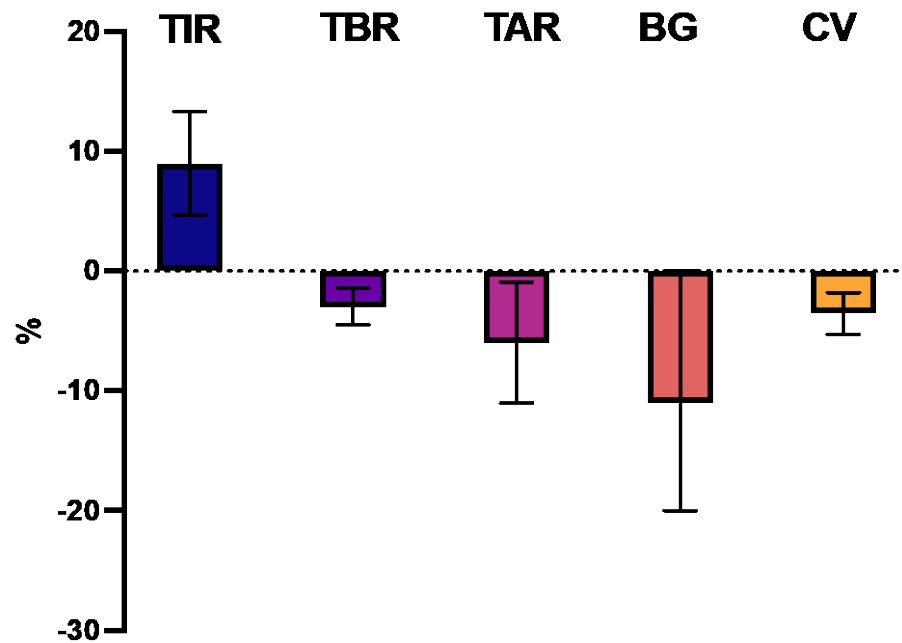
C SBMG

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

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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)	—

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

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

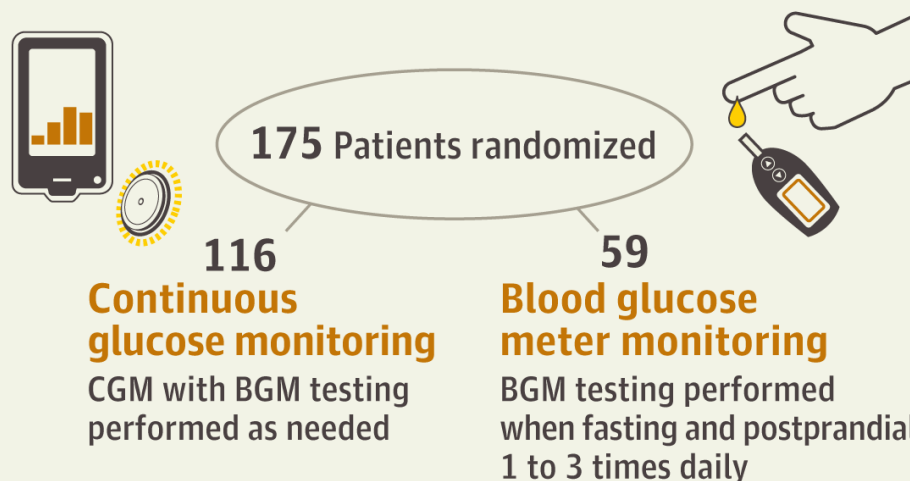
Mean age: **57 years**

LOCATIONS

15
Primary care practices in the US



INTERVENTION



PRIMARY OUTCOME

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

FINDINGS

Mean HbA_{1c} level at 8 months

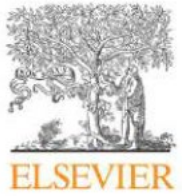
Continuous glucose monitoring

HbA _{1c}	Baseline	8 Months
	9.1%	8.0%

Blood glucose meter monitoring

HbA _{1c}	Baseline	8 Months
	9.0%	8.4%

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



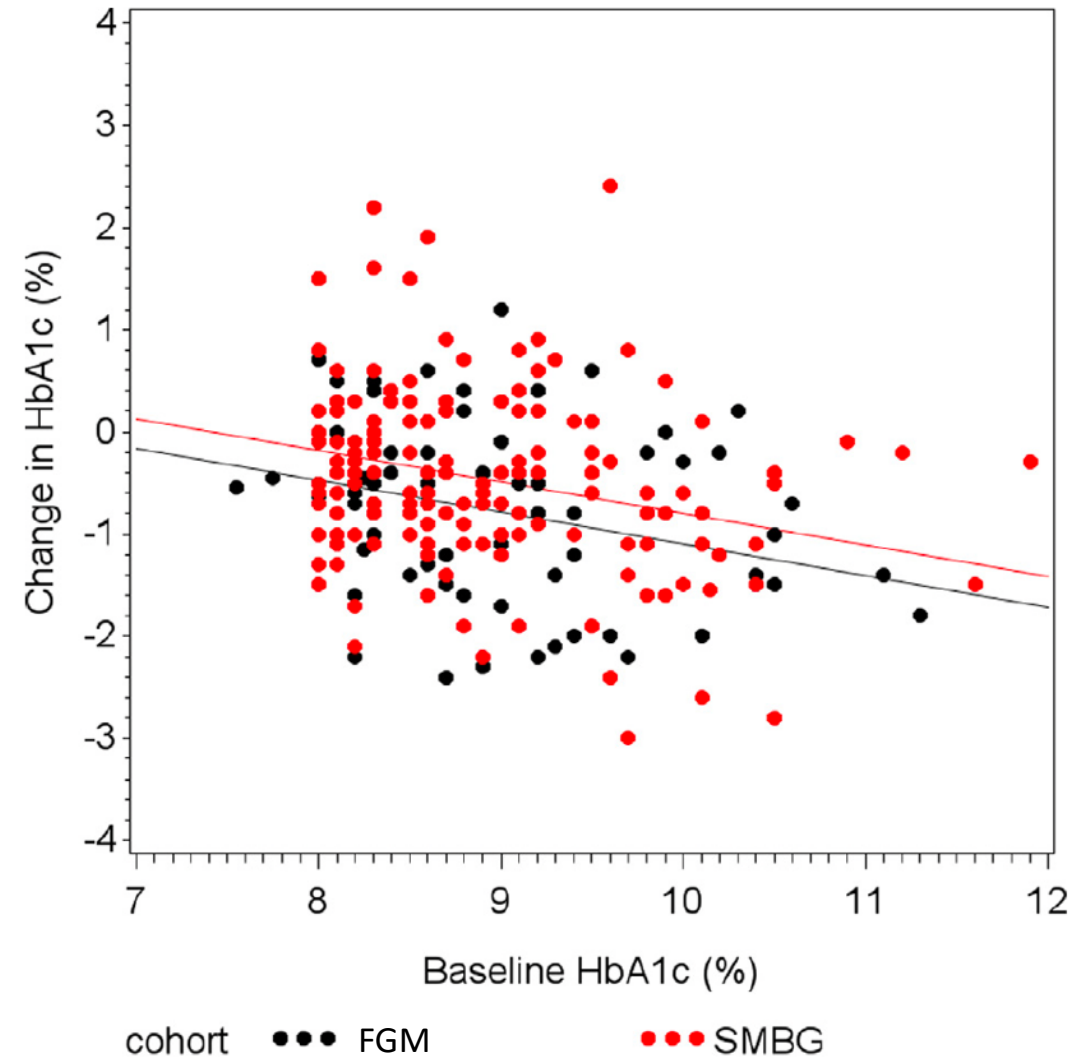
Contents available at ScienceDirect

Diabetes Research
and Clinical PracticeJournal homepage: www.elsevier.com/locate/diabresInternational
Diabetes
Federation

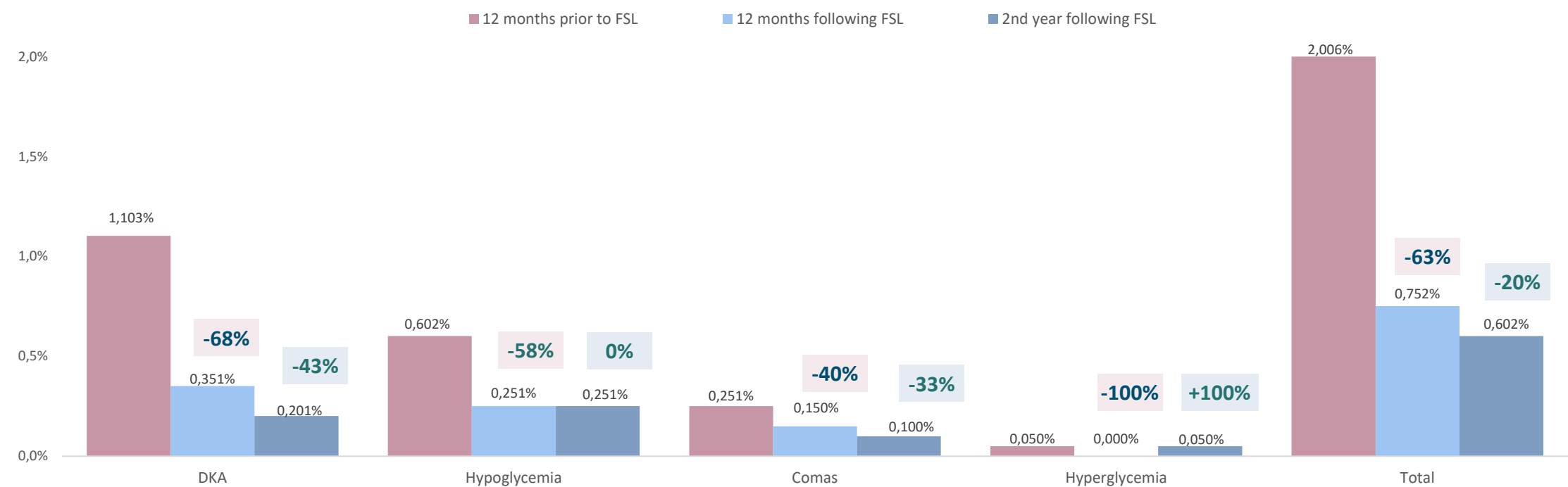
The use of flash glucose monitoring significantly improves glycemic control in type 2 diabetes managed with basal bolus insulin therapy compared to self-monitoring of blood glucose: A prospective observational cohort study

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 ($0.3\% \pm 0.12$ [$3 \text{ mmol/mol} \pm 1.3$, (mean $\pm$ SE)], $p = 0.0112$).
- The difference remained statistically significant after adjusting for confounders.



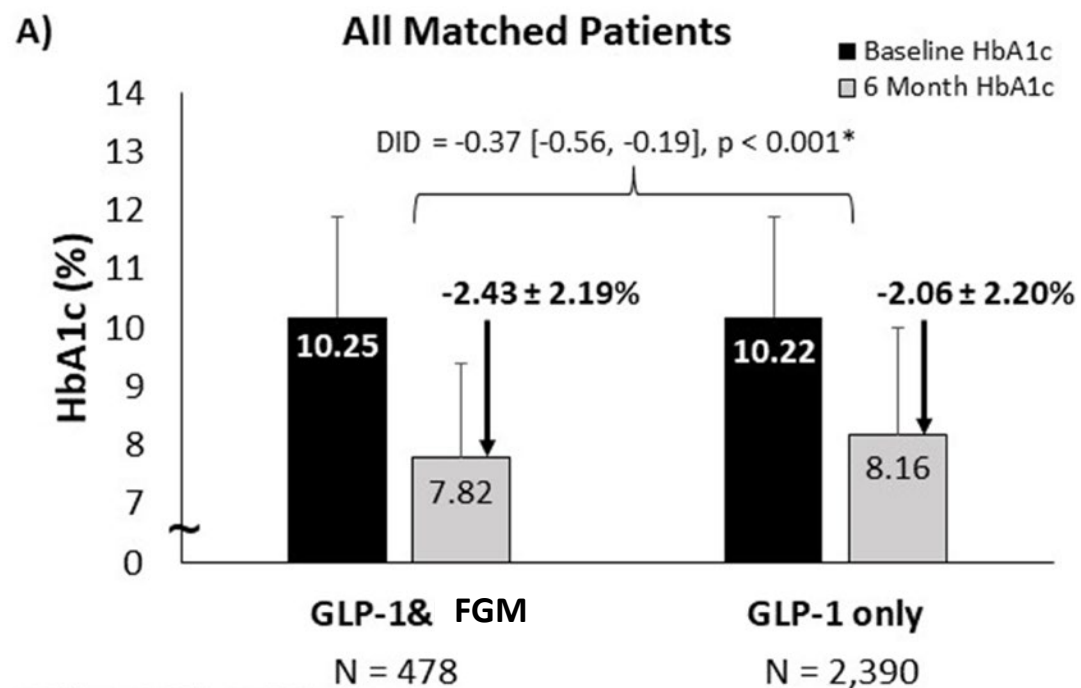
RELIEF Study (T2B): in people with T2D on Basal Insulin (n=5933)there was a significant reduction in the hospitalization rate for acute diabetes-associated events 1 and 2 years after FGM starting



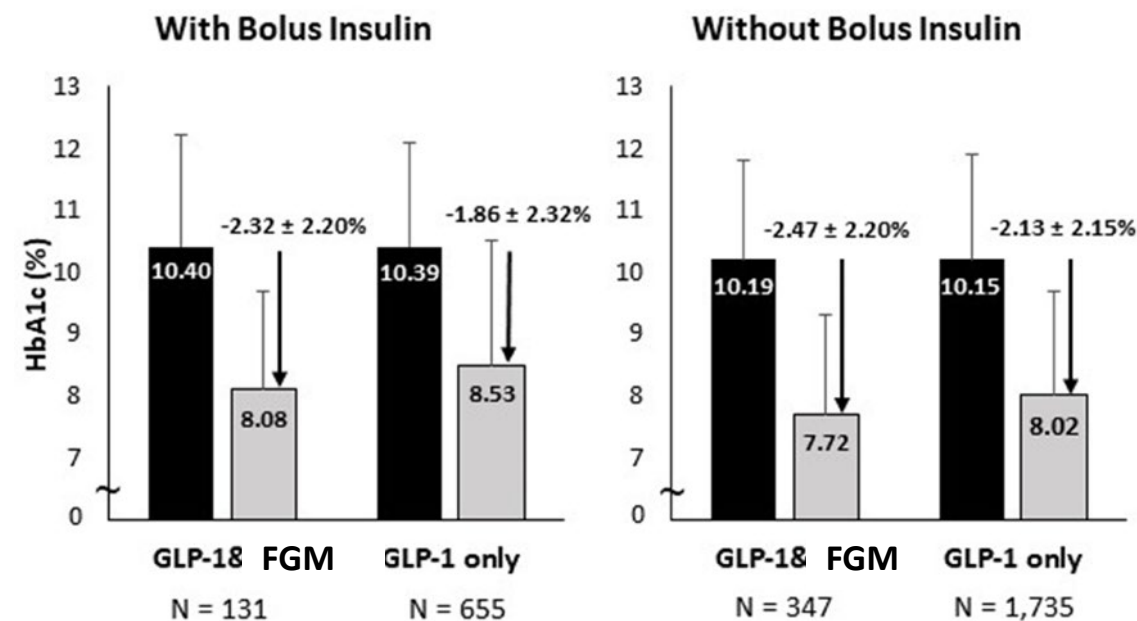
Abbreviazioni: ADE: eventi acuti correlate al diabete; DKA: Ketoacidosi diabetica; T2B: Pazienti di tipo 2 in terapia con Insulina Basale

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 Viridi, MD,⁴ and Eden Miller, DO⁵



B)



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. Aijan,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. Stocken³

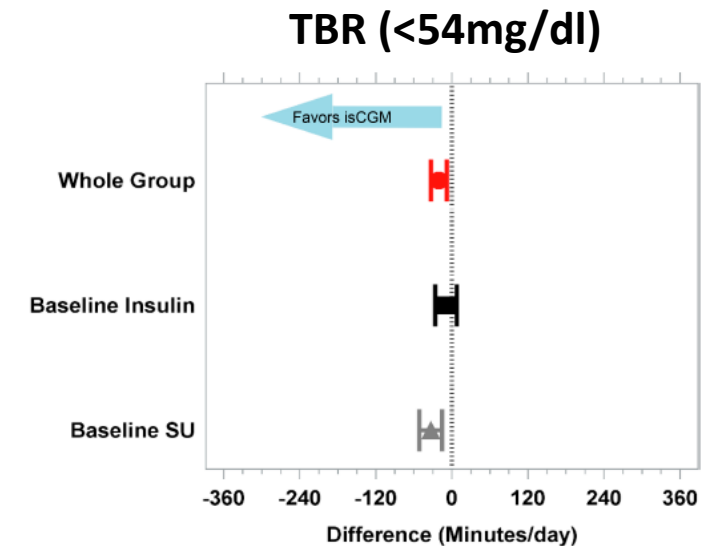
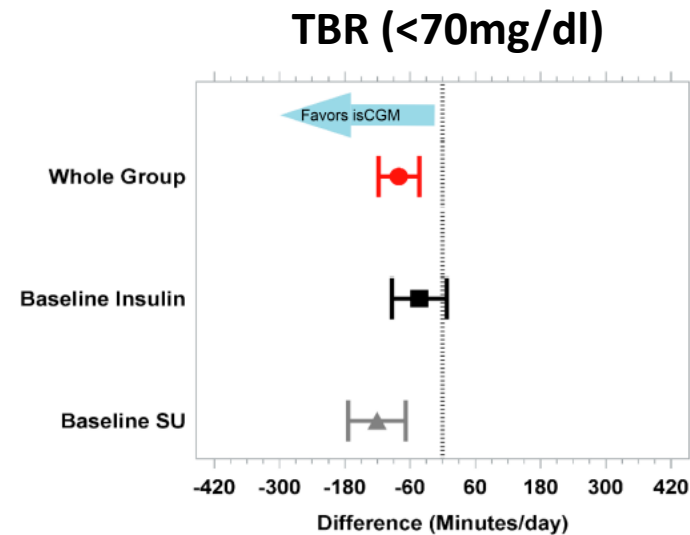
Diabetes Care 2023;46:441–449 | <https://doi.org/10.2337/dc22-1219>

Objective

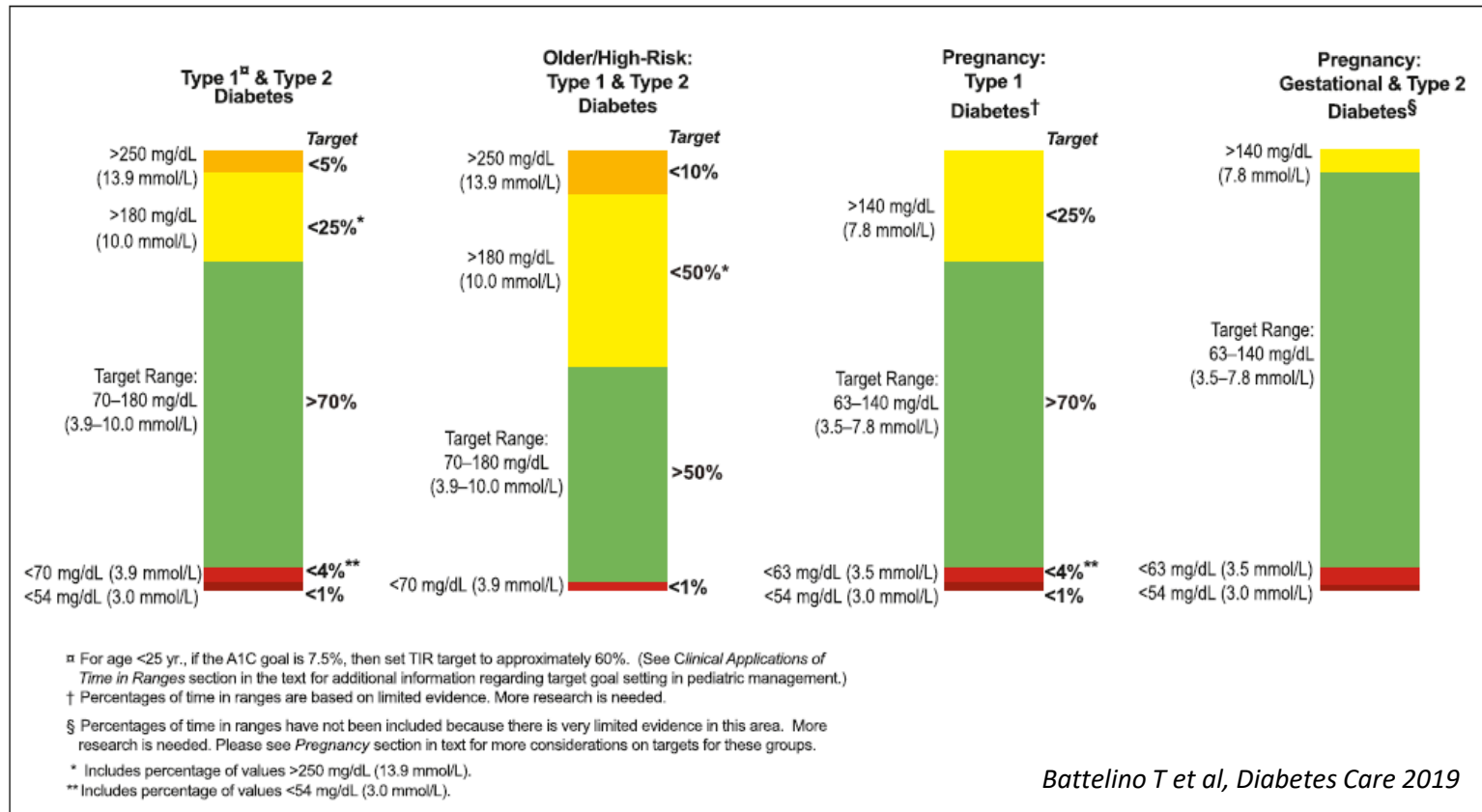
To analyze the impact of isCGM on glycemic and patient-related outcomes in individuals with T2D and recent myocardial infarction and assess cost effectiveness.

Population

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



CGM-based targets: recommendations for clinical practice



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 Weinzierl, 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 (<3.0 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 $\geq 5\%$ (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)

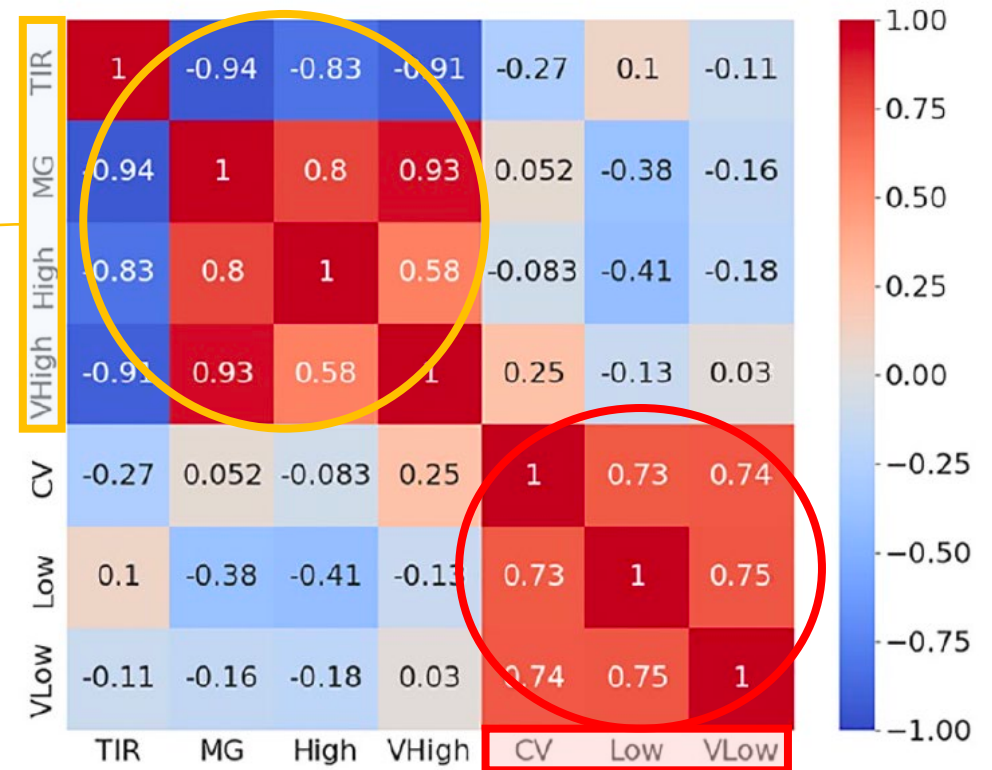
Glycemia Risk Index (GRI): a single-number summary of the quality of glycemia

- 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.

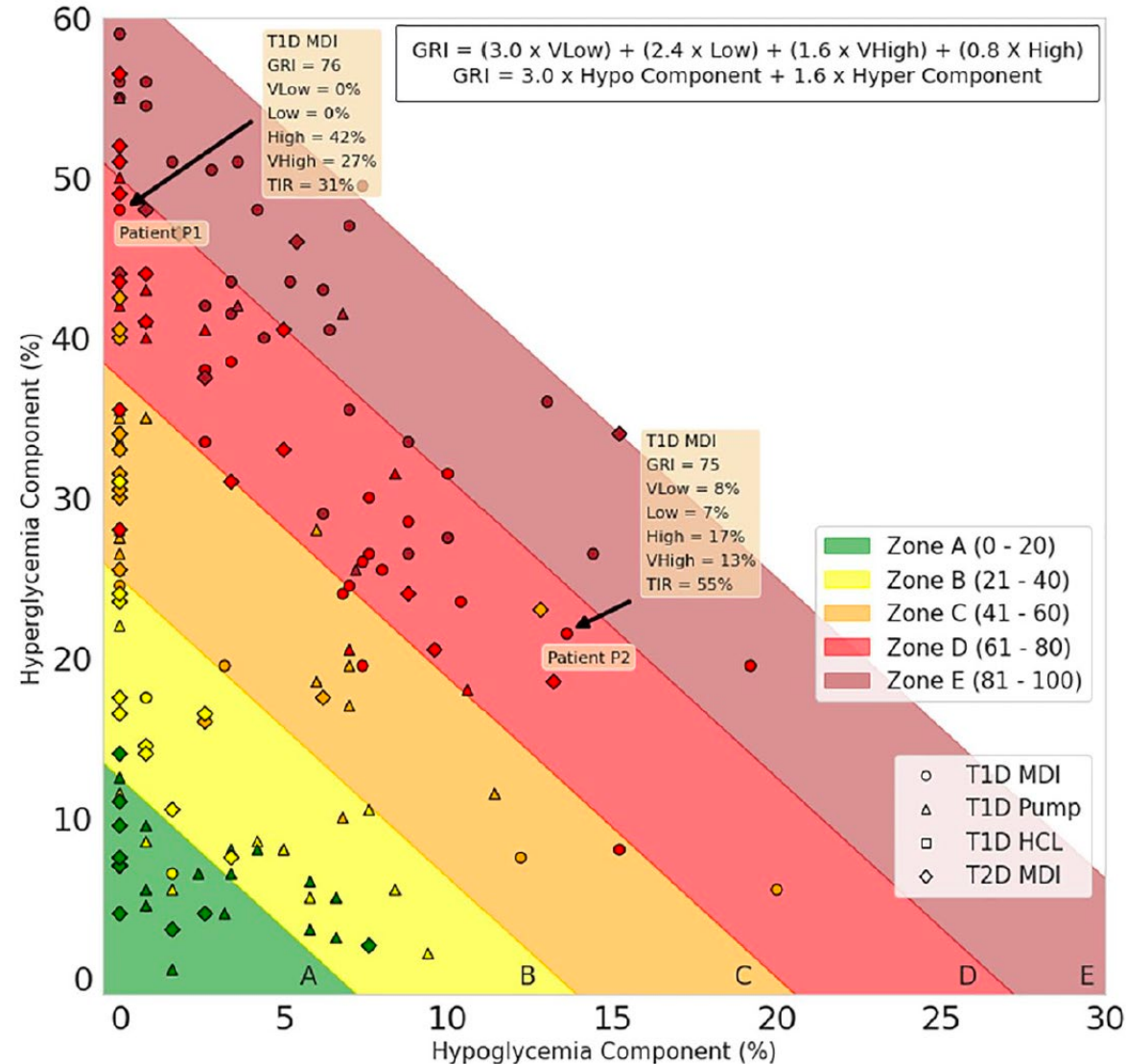
PCA was conducted to uncover the essential components of glycemic control

Hyperglycemia-related metrics
-Hyperglycemia principal dimension

Hypoglycemia-related metrics
-Hypoglycemia principal dimension

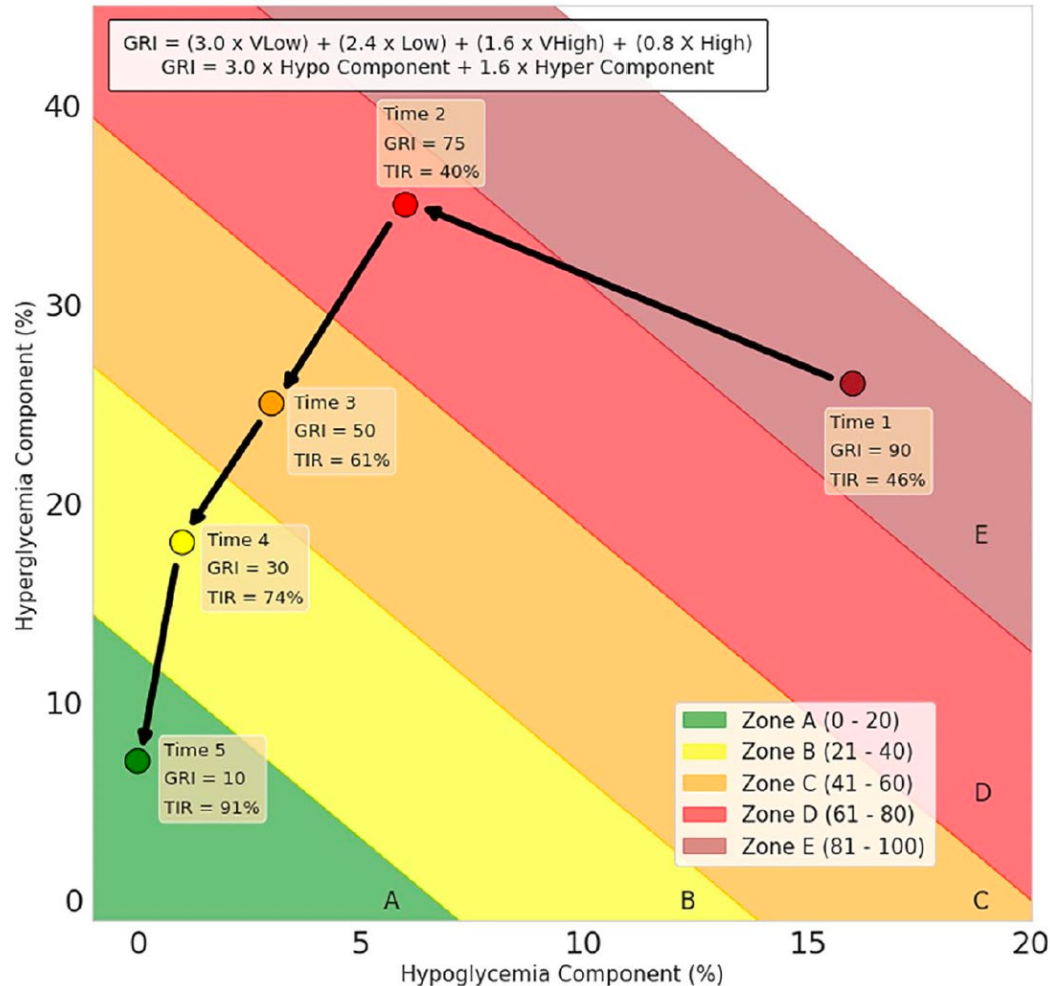


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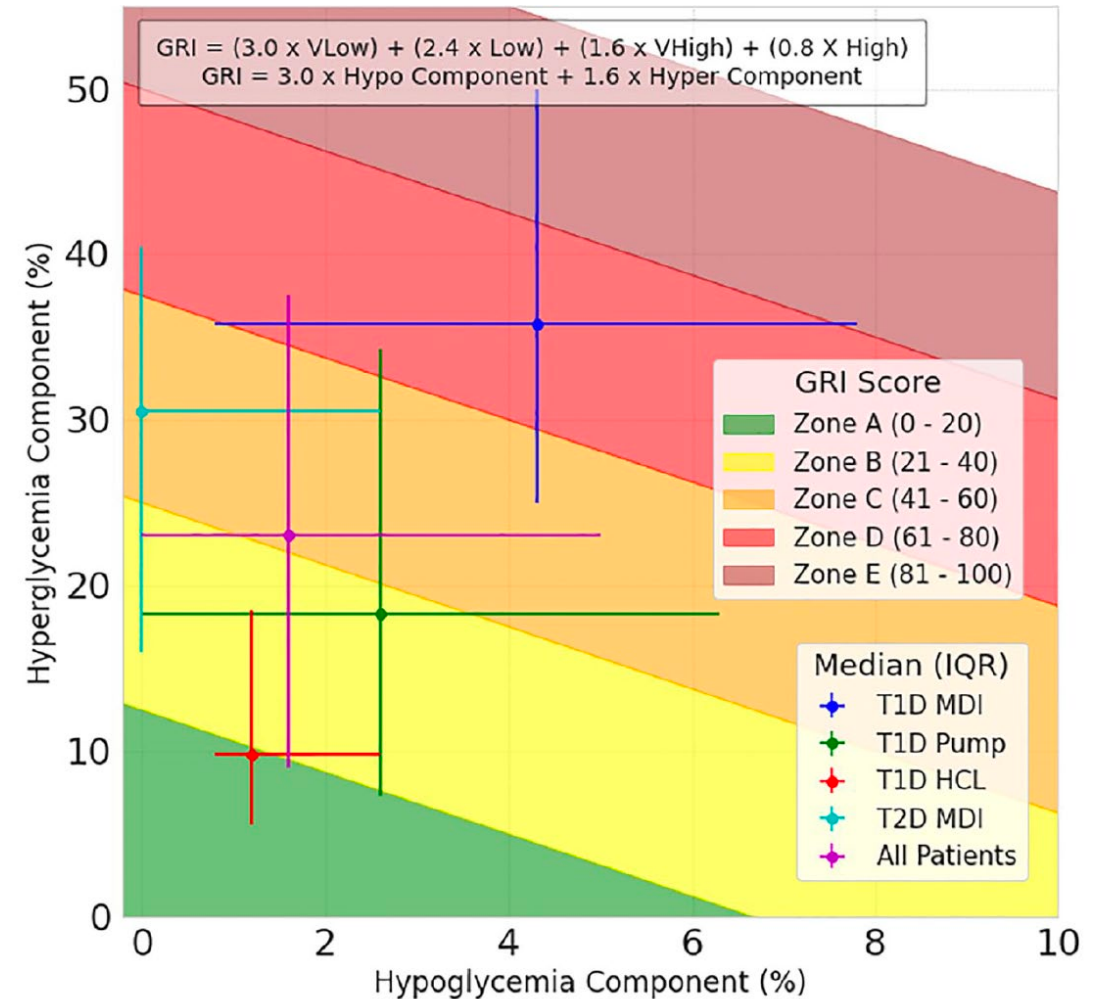


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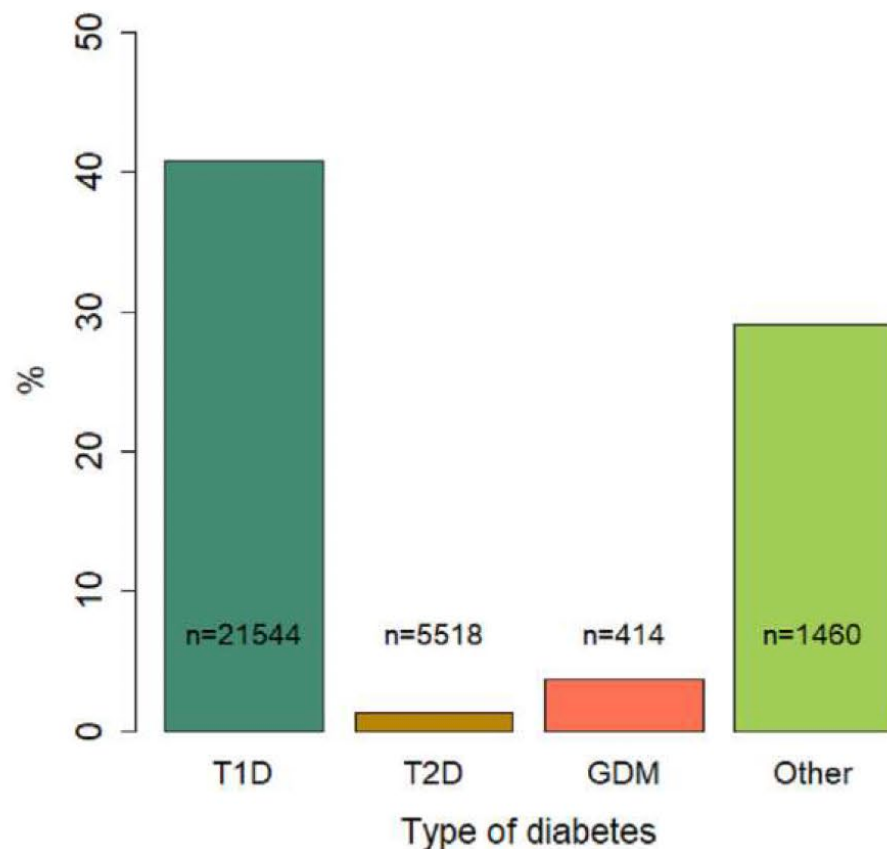
Changes of GRI over time



GRI to differentiate groups of patients



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

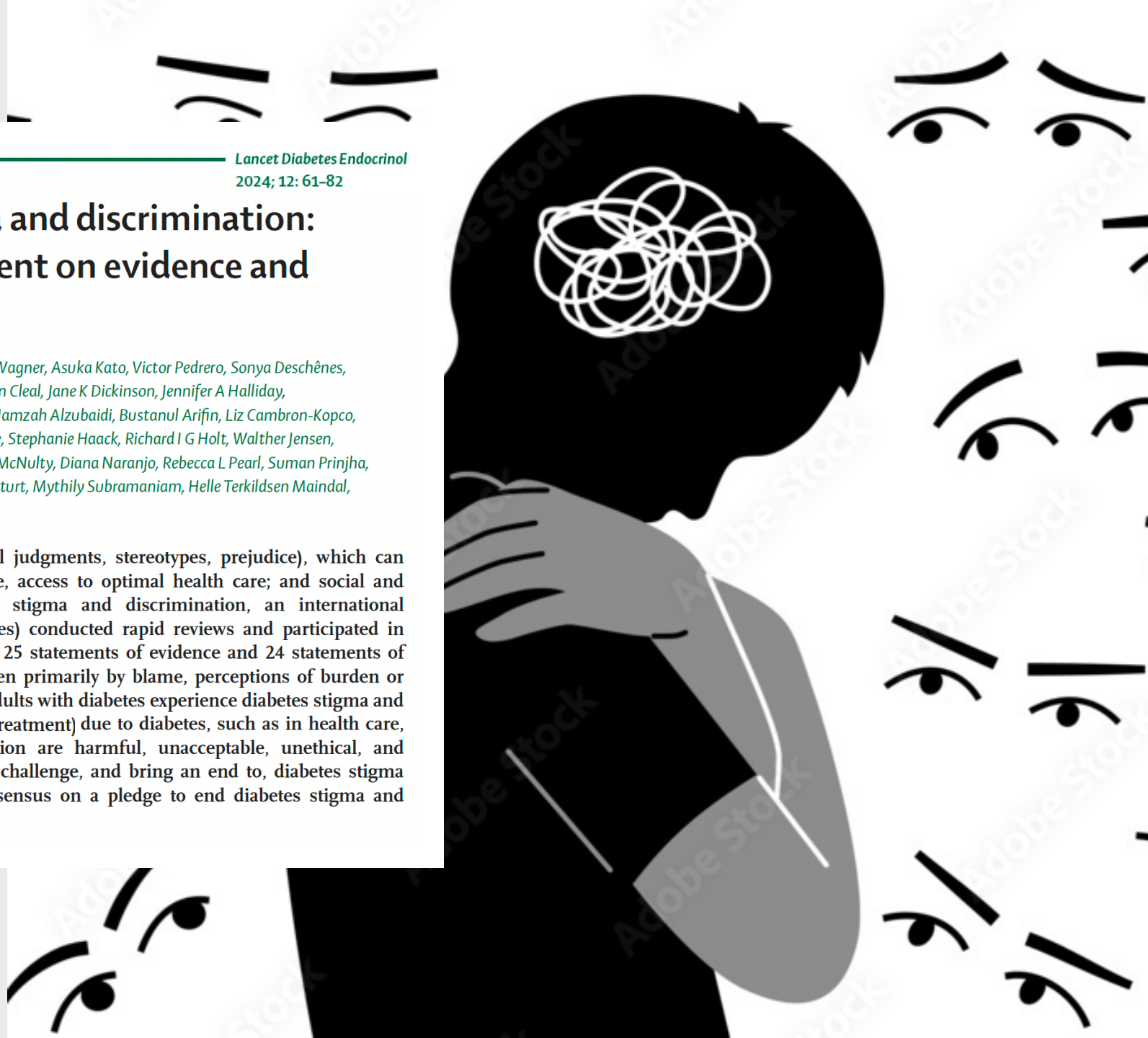
*Pitocco D. et al. Working group of Diabetes and Technology
AMD-SID-SIEDP NMCD Vol. 32 Issue 10 2022*



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.



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

four in five adults with diabetes experience diabetes stigma

Jane Speight*, Elizabeth Holmes-Truscott*, Mattias
Susan J Guzman, Kevin L Joiner, Shengxin Liu, Ingha Wilmang, Kate M Dabbott, Bryan Clea, Jane K Dickinson, Jennifer A Hamdy,
Eimear C Morrissey, Giesje Neefs, Shane O'Donnell, Anna Serlachius, Per Winterdijk, Hamzah Alzubaidi, Bustanul Arifin, Liz Cambron-Kopco,
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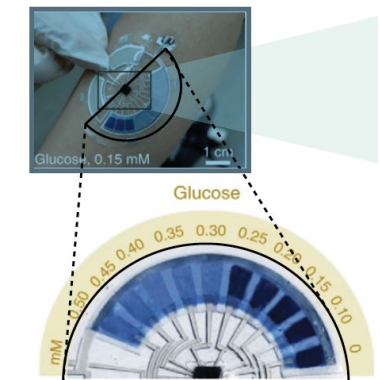
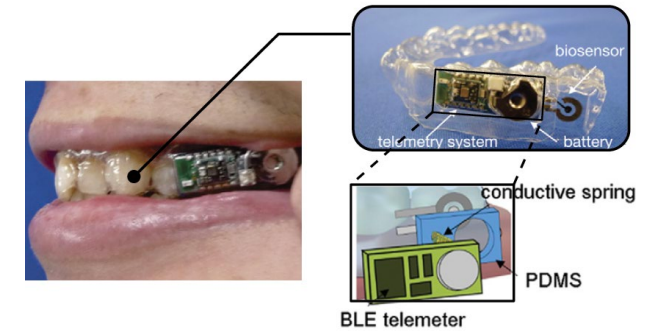
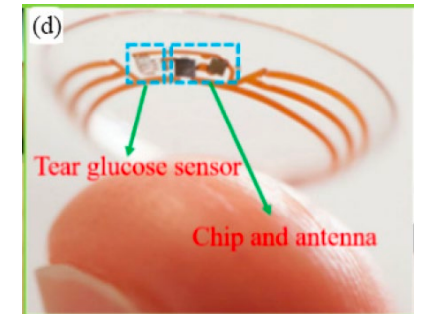
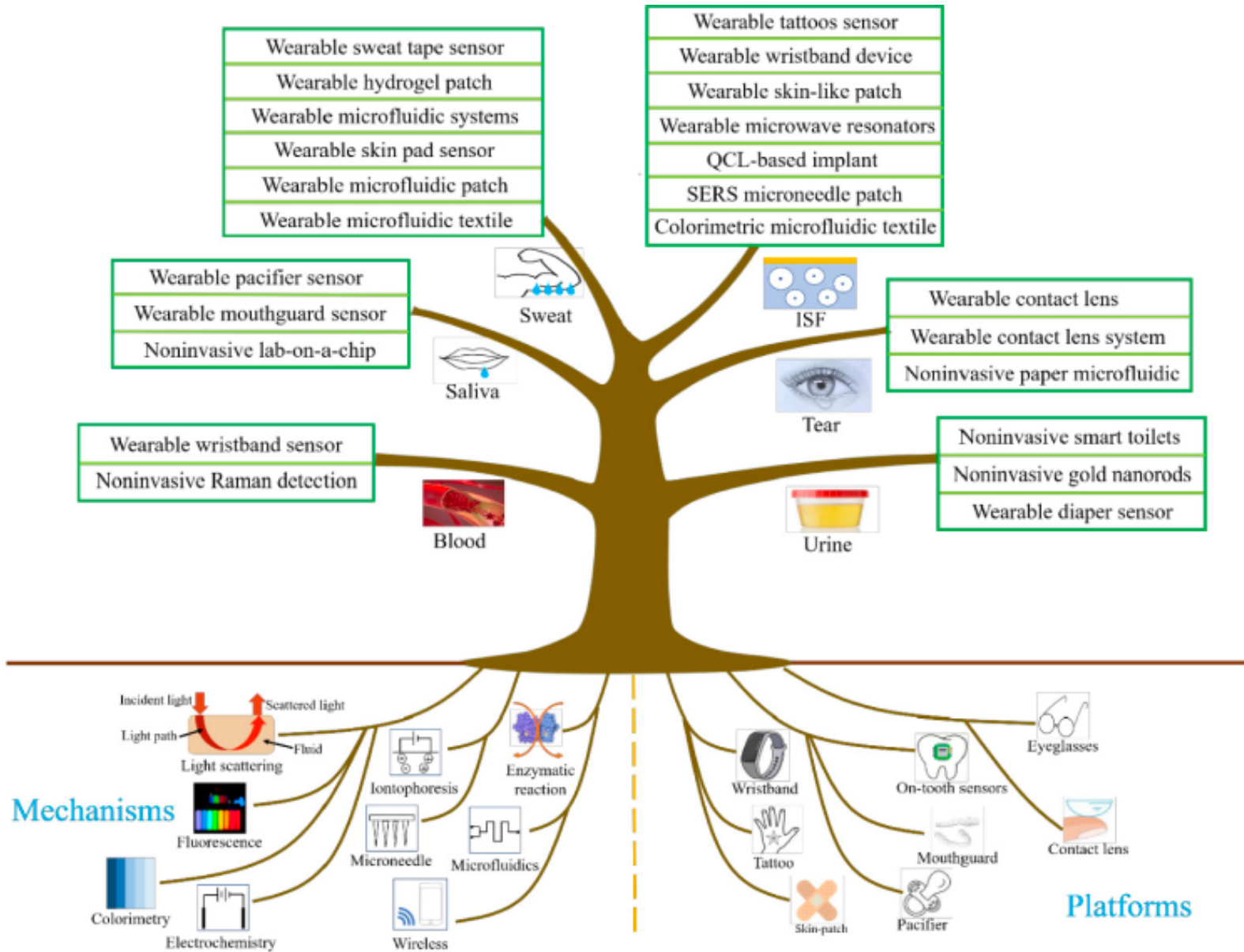
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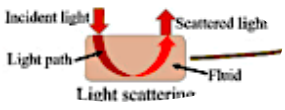
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one in five experience discrimination (ie, unfair and prejudicial treatment)

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.

The future of glucose sensors

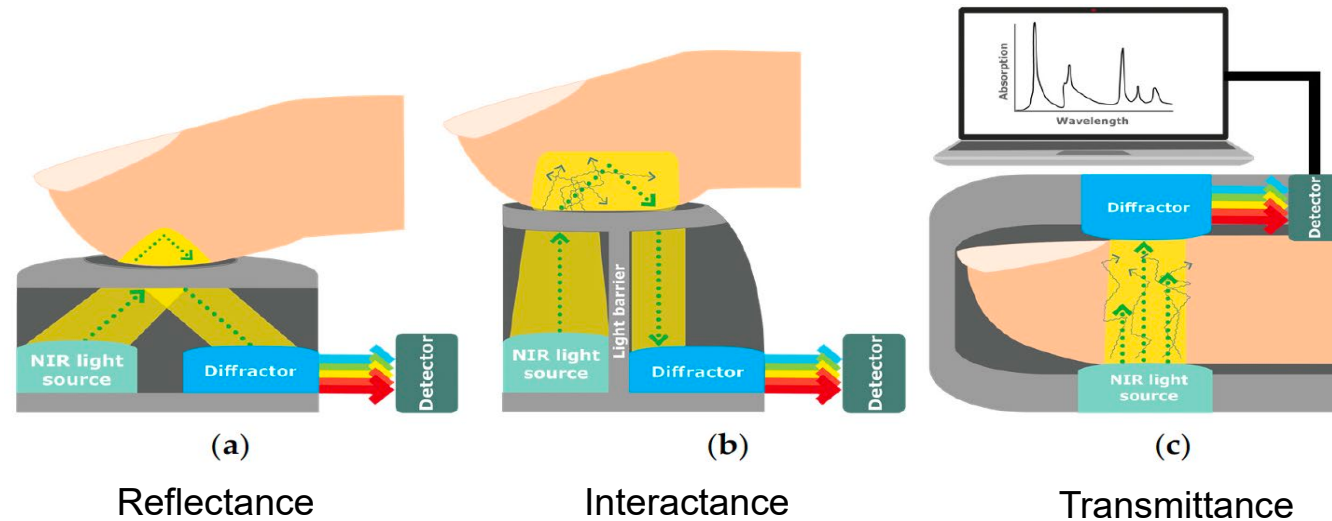




Near InfraRed (NIR) Spectroscopy for CGM

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.



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

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!

MAKE IT WORK!

