

SCHOOL

SISTEMI AID IN GRAVIDANZA

AID: una soluzione per tutti

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Dichiarazione Conflitto d'Interessi

La sottoscritta Dott.ssa Cristina Bianchi

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

- Novonordisk

- Lilly

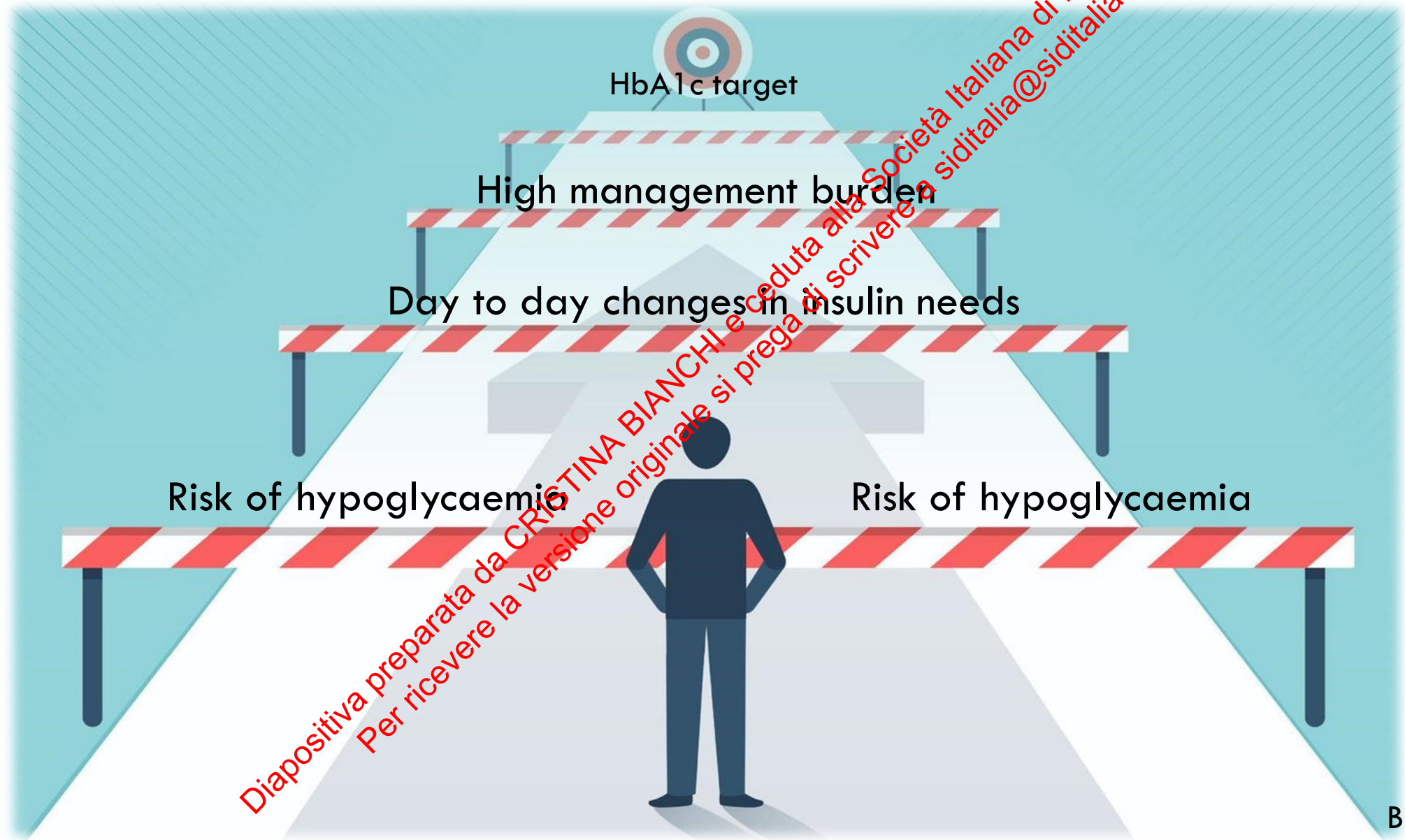
Dichiara altresì il proprio impegno ad astenersi, nell'ambito dell'evento, dal nominare, in qualsivoglia modo o forma, aziende farmaceutiche e/o denominazione commerciale e di non fare pubblicità di qualsiasi tipo relativamente a specifici prodotti di interesse sanitario (farmaci, strumenti, dispositivi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

Cristina Bianchi, MD PhD



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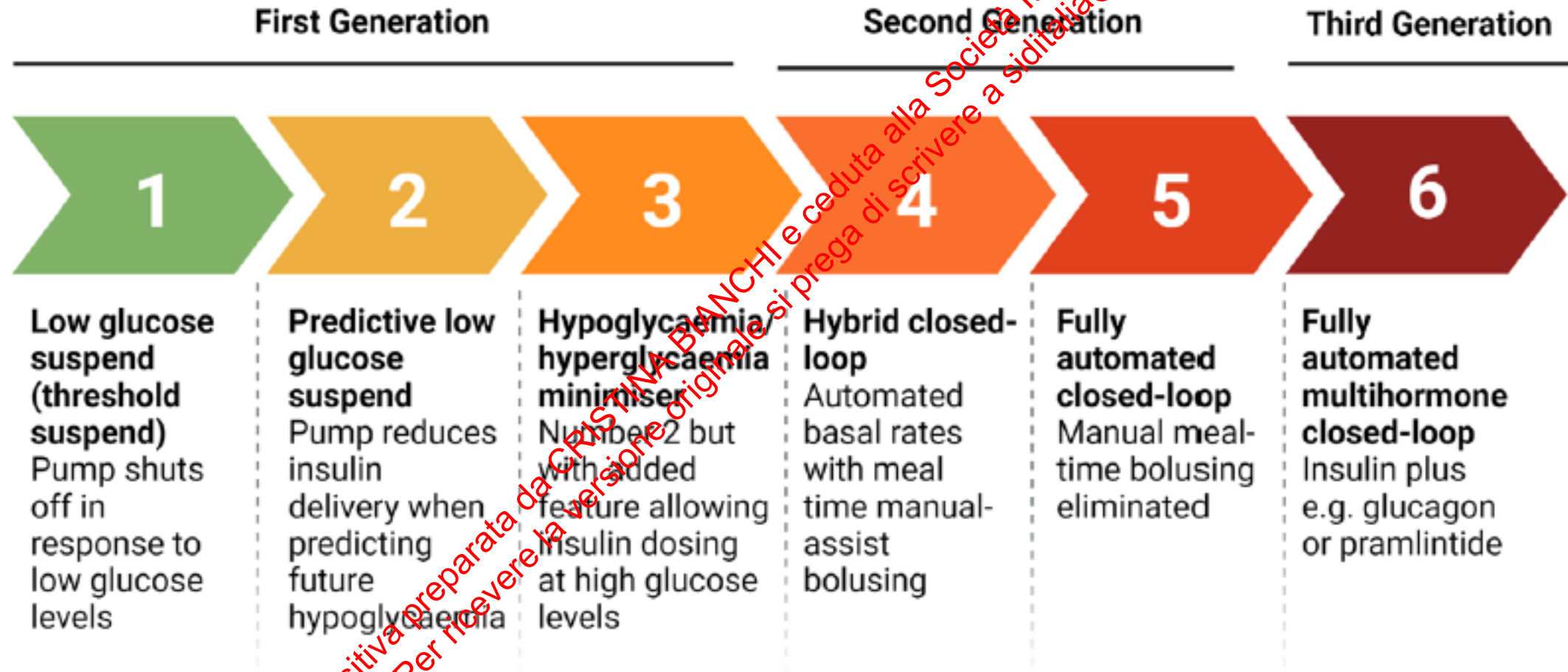
Barriers to achieve good glycaemic control



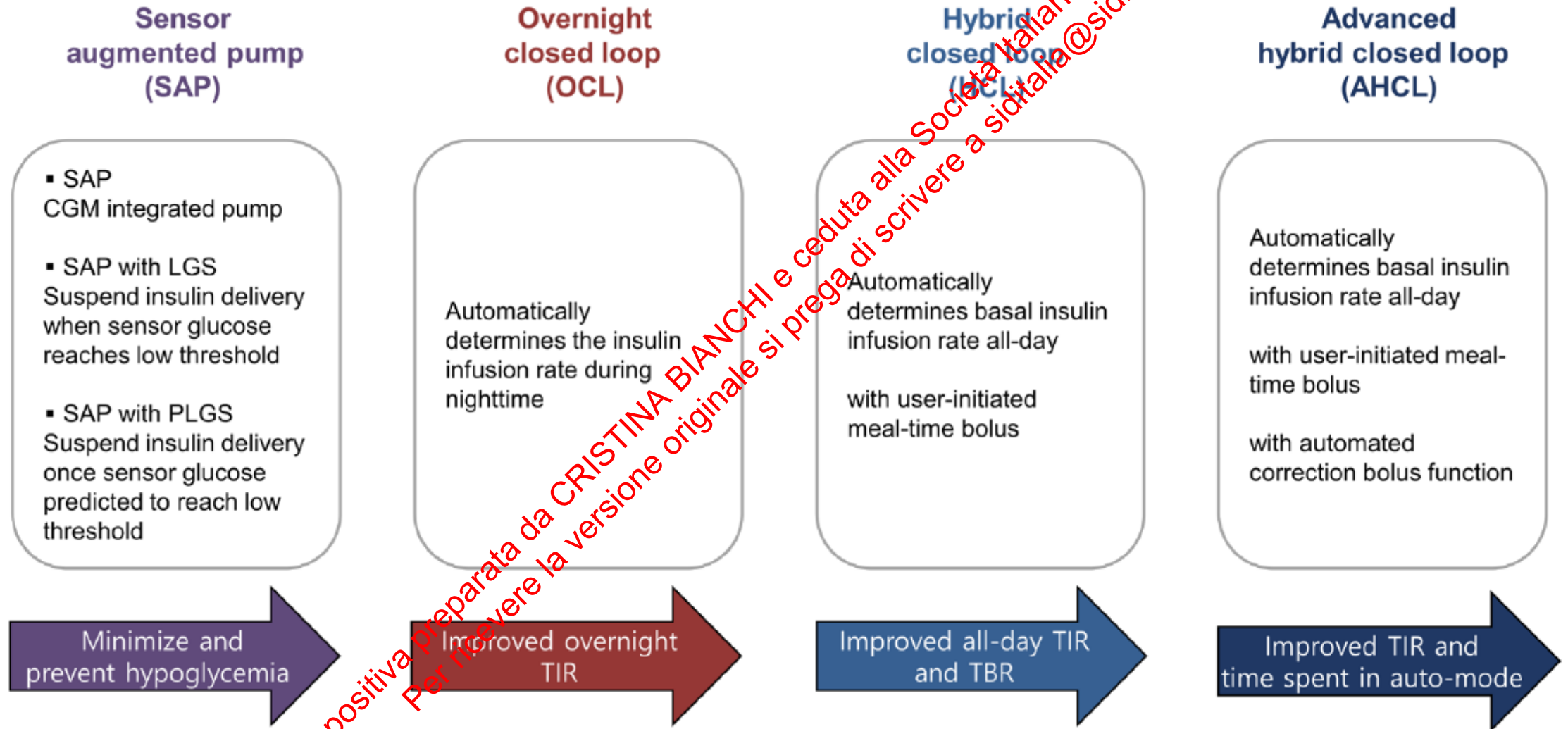
Timeline of development of the artificial pancreas system



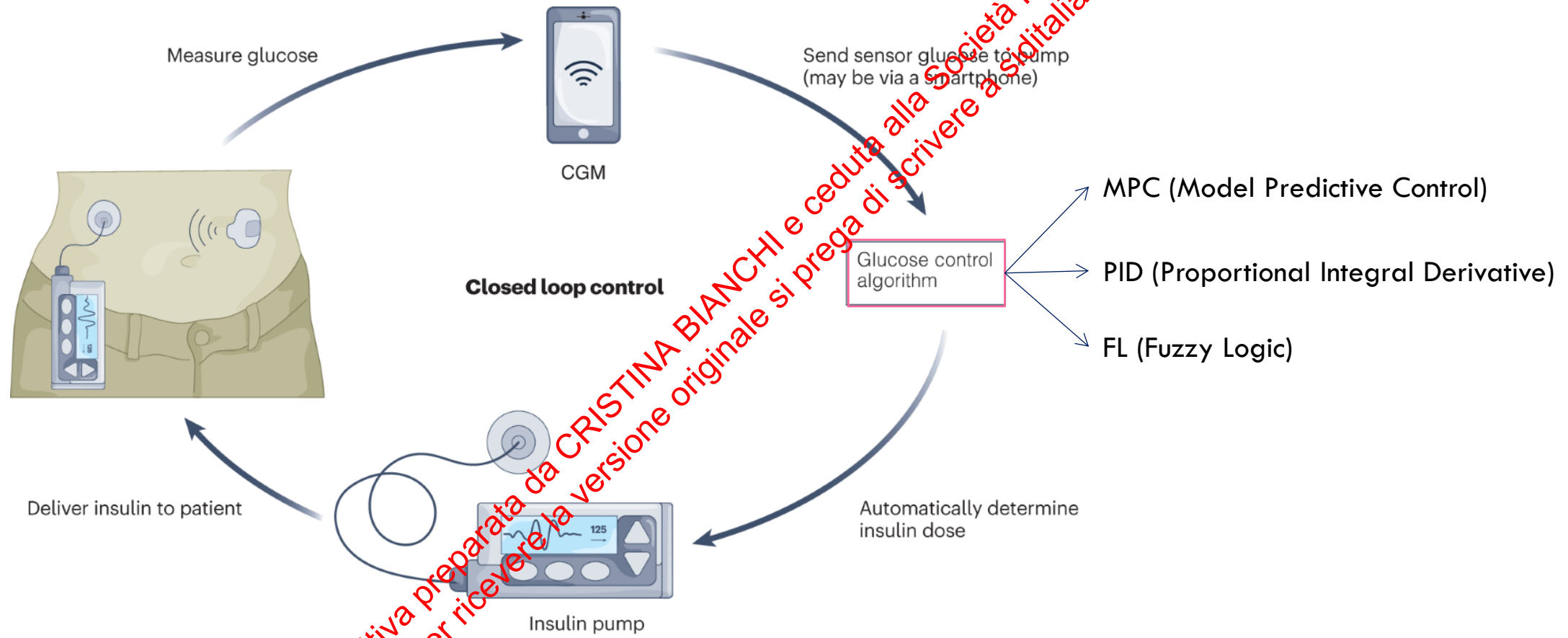
Developmental stages of artificial pancreas device systems originally described by JDRE



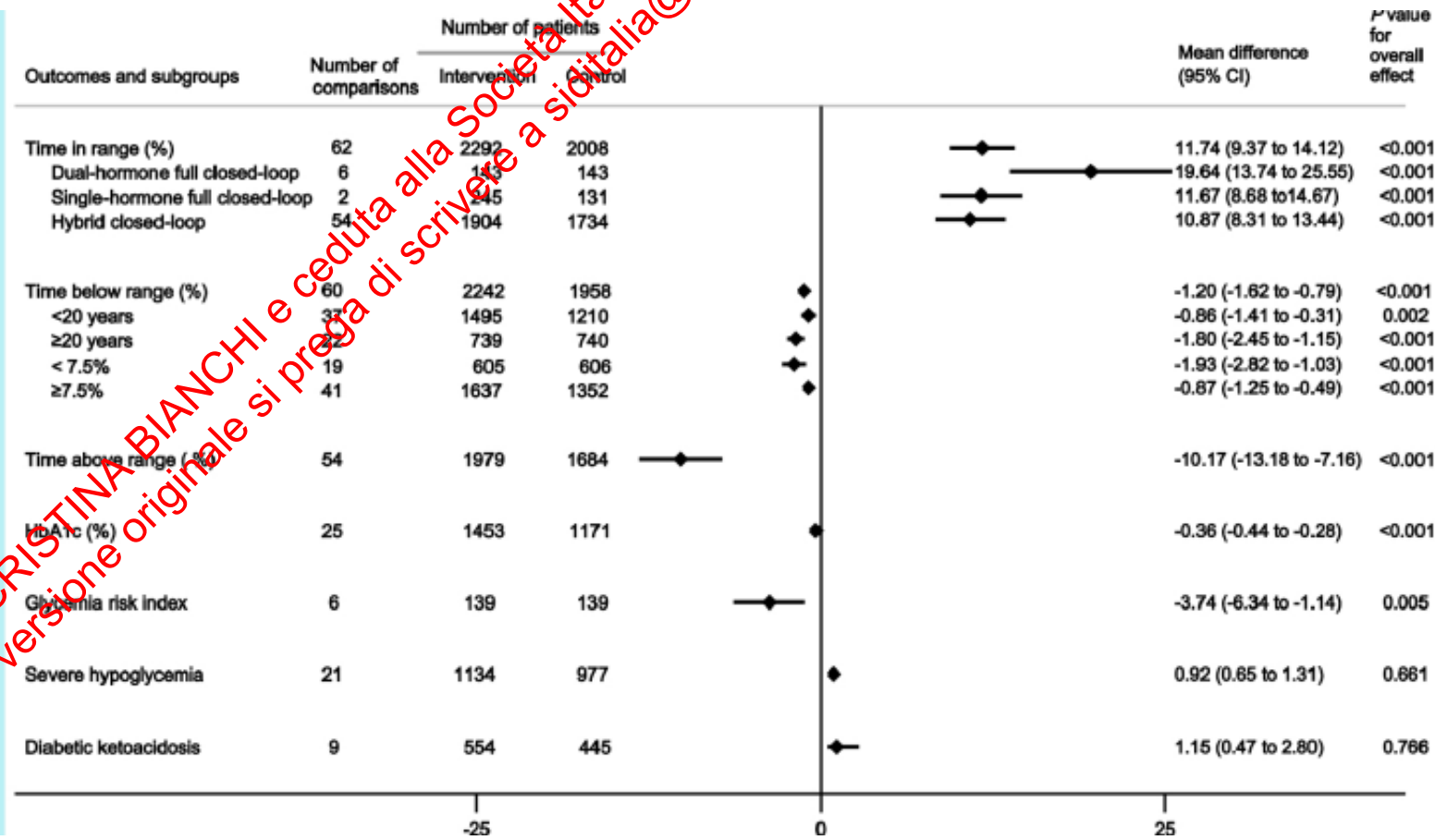
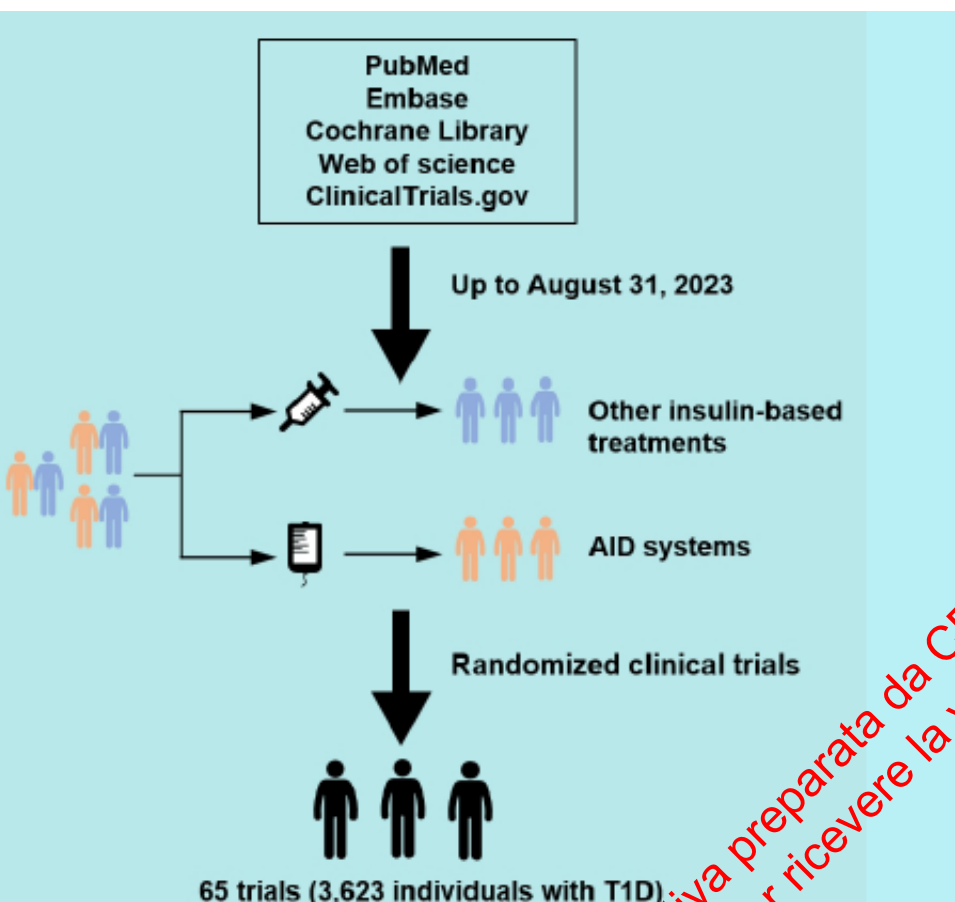
Key features of SAP and artificial pancreas systems



Advanced Hybrid Closed-Loop

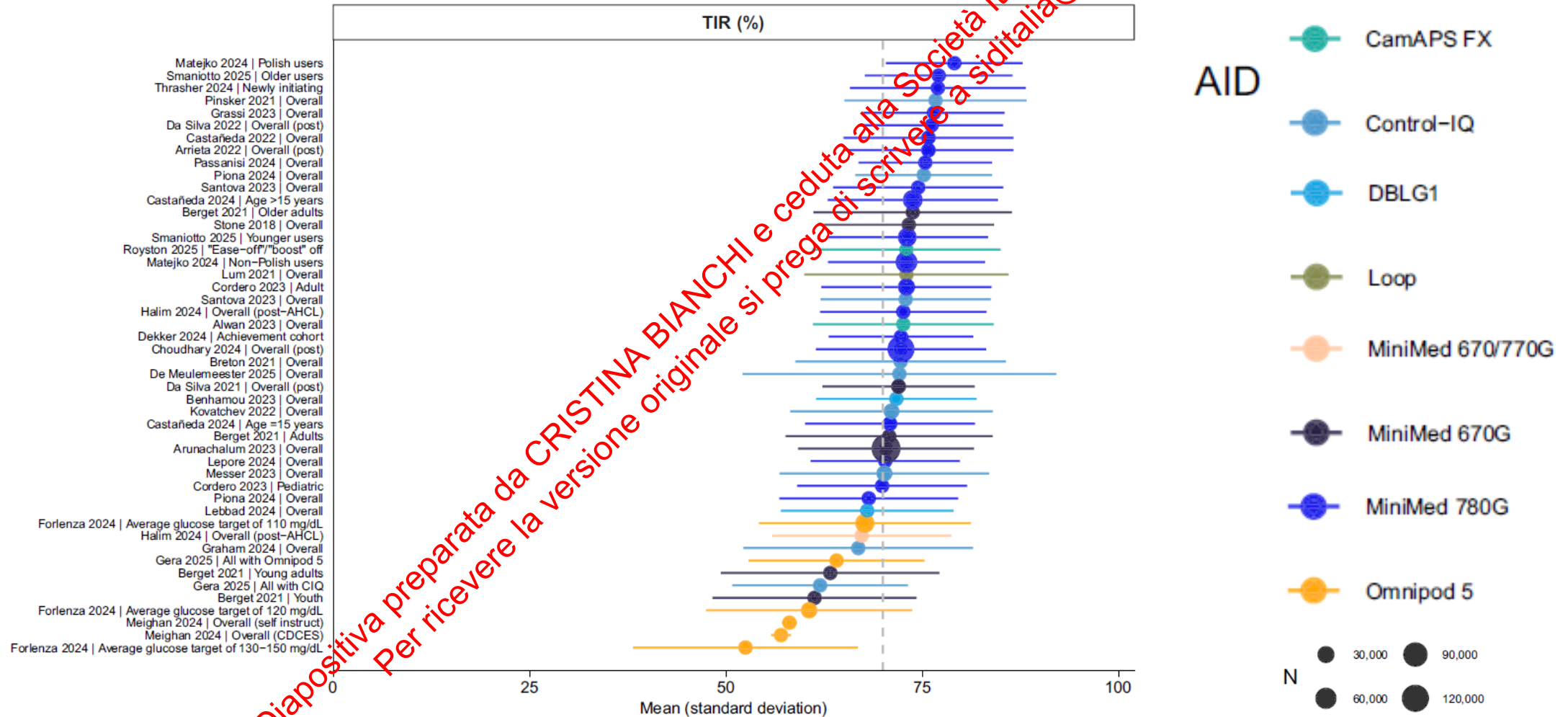


Automated insulin delivery systems in Type 1 Diabetes: a meta-analysis



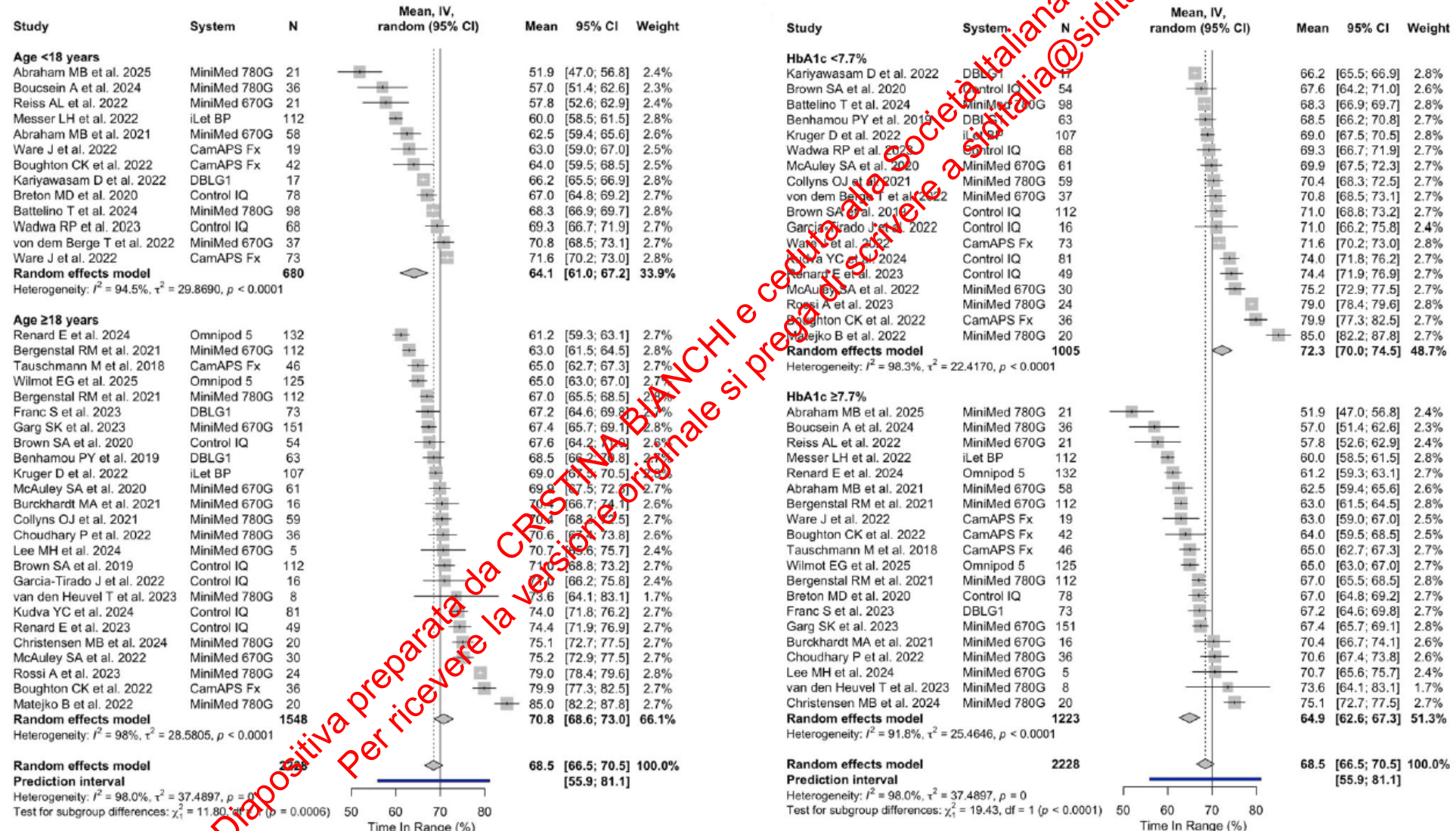
Automated insulin delivery systems in Type 1 Diabetes: a meta-analysis of of real-world evidence

34 studies with 635463 users; MiniMed 780G (16), Control-IQ (9), MiniMed 670G (6), and other systems (≤ 3 studies each)



Automated insulin delivery systems in Type 1 Diabetes

37 studies 2228 involving subjects treated with seven different HCL systems
(CamAPS Fx, Control IQ, DBLG1, iLet BP, MiniMed 670G, MiniMed 780G and Omnipod 5)

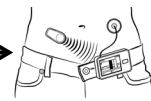


AID systems in Type 1 Diabetes: quality of life



Multicenter longitudinal
real-life study

257 people with type 1 diabetes
on insulin pump (>65% PLGS) +
CGM



Hybrid closed loop (tslim X2 with Control-IQ)

Follow-up:
6 months

Variables	Adolescents n = 55			Adults n = 202		
	T0	M6	Δ M6 - M0	T0	M6	Δ M6 - M0
PAID score (Diabetes distress)	33.2 ± 18.6	34.6 ± 23.5	1.4 ± 19.4	46.9 ± 18.8	39.9 ± 20.8	-6.9 ± 18.1**
ADDQOL score (Quality of life)	1.1 ± 1.0	1.3 ± 1.1	0.2 ± 0.8	0.6 ± 1.0	0.9 ± 1.0	0.3 ± 0.9**
PSS score (Stress)	17.2 ± 7.0	17.1 ± 7.0	-0.1 ± 5.0	17.4 ± 6.6	15.8 ± 6.8	-1.6 ± 5.8**
GAD 7 score (Anxiety)	6.7 ± 5.3	6.1 ± 5.4	-0.6 ± 3.5	6.5 ± 5.1	5.9 ± 5.1	-0.6 ± 4.3*
FSS score (Fatigue)	30.8 ± 11.9	31.0 ± 10.5	0.1 ± 11.0	34.3 ± 14.8	34.4 ± 15.5	0.1 ± 14.0
HFS II score (Fear of hypoglycemia)	8.2 ± 3.0	6.9 ± 3.5	-1.2 ± 3.7*	6.2 ± 2.8	5.2 ± 3.2	-1.0 ± 3.0**
Godin score (Physical activity)	37.3 ± 22.6	43.4 ± 25.5	6.0 ± 18.9*	24.1 ± 17.9	26.5 ± 20.3	2.4 ± 19.2
PSQI score (Sleep)	5.5 ± 3.4	6.1 ± 3.3	-0.3 ± 2.5	6.4 ± 3.2	6.2 ± 3.2	-0.3 ± 2.6
QSP9 score (Depression)	7.5 ± 5.3	7.6 ± 5.7	0.1 ± 4.0	6.2 ± 5.0	5.7 ± 4.8	-0.5 ± 3.8

* p<0,05; **p<0,001

Type 1 Diabetes and A1D use at different stages of life



Children/adolescents



Pregnancy

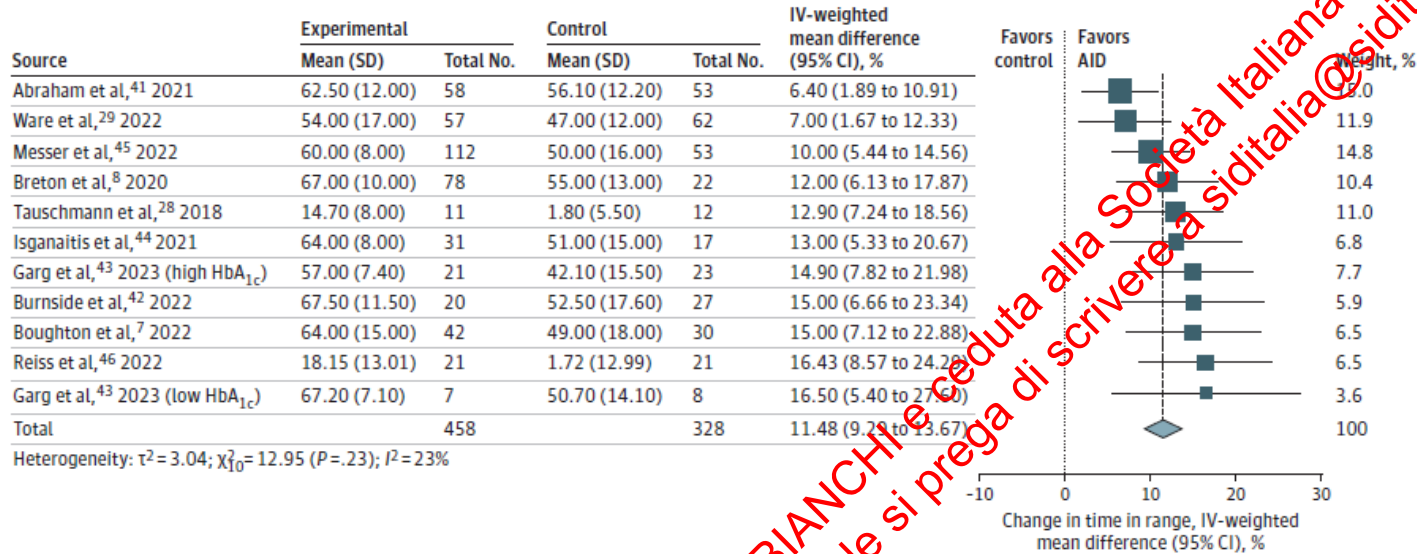


Elderly

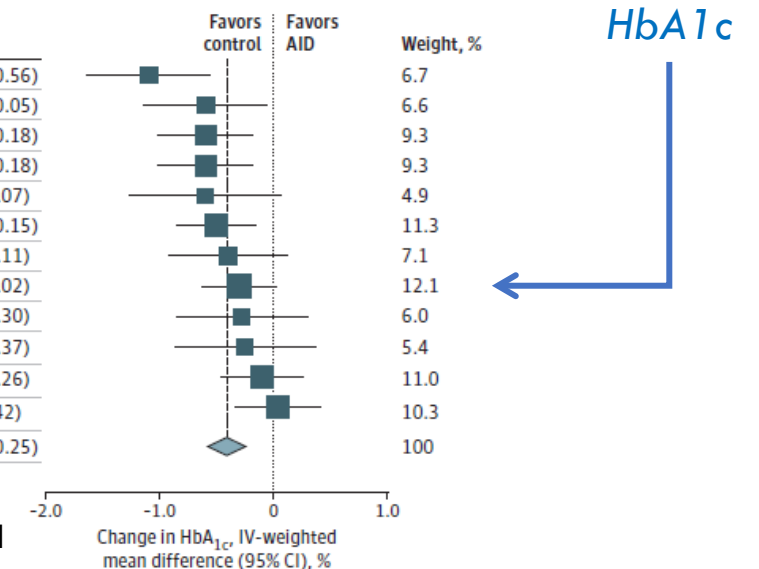
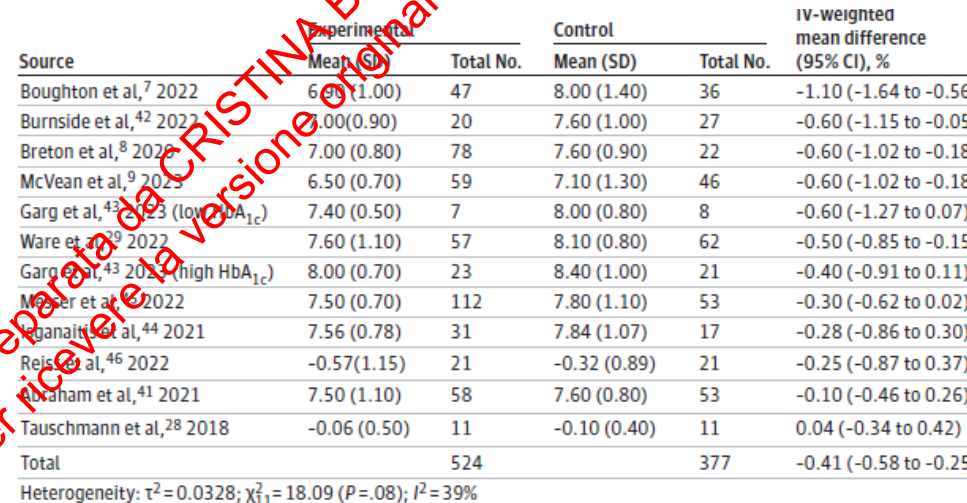
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AID use in children and adolescents with Type 1 Diabetes: a meta-analysis

Time in range



Use of AID systems by youth with Type 1 Diabetes was associated with clinically meaningful improvements in multiple measures of glucose management, including the risk of both hyperglycemia and hypoglycemia.



Type 1 Diabetes and AID use at different stages of life



Children/adolescents



Pregnancy



Elderly

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Challenges of AID in pregnancy



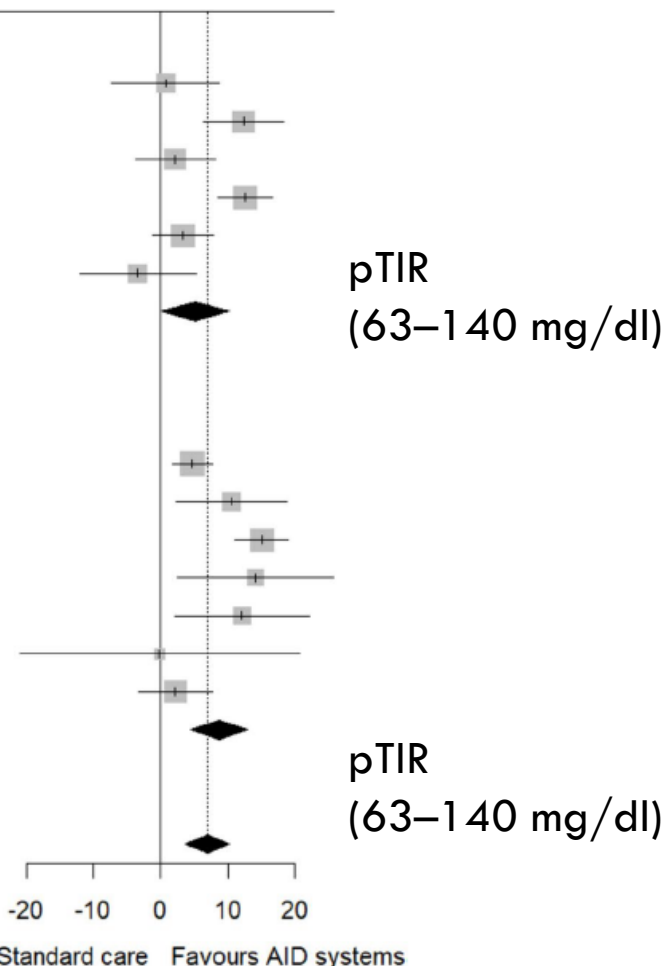
Implementing AID use during pregnancy requires unique configurations including:

- ability to safely achieve the tighter pregnancy TIR before conception and throughout gestation,
- algorithm adaptability to changes in insulin sensitivity throughout gestation,
- assertive postprandial insulin delivery, including a mechanism to respond to changes in glycemia postprandially,
- more aggressive glucose targets without an increased risk of maternal hypoglycemia,
- ability to rapidly adapt to changes in insulin requirements postpartum (through setting adjustments and algorithm adaptation)
- user-friendly, regardless of an individual's health care status or literacy, to maximize benefits and reduce risks throughout gestation.

AID use in pregnant women with Type 1 Diabetes: a meta-analysis

33 studies
involving 450 participants

Study or Subgroup	Total	AID systems Mean SD	Total	Standard care Mean SD	Mean Difference IV, Random, 95% CI	Mean Difference IV, Random, 95% CI
Randomized controlled trials						
Murphy 2011	12	77.25 8.86	12	76.50 11.00	0.75 [-7.24; 8.74]	
Stewart 2016	17	70.50 8.86	17	58.15 8.86	12.35 [6.39; 18.31]	
Stewart 2018	17	62.30 8.86	17	60.10 8.86	2.20 [-0.76; 8.16]	
Lee 2023	61	68.20 10.50	63	55.60 12.46	12.60 [8.54; 16.66]	
Benhalima 2024	46	66.50 10.00	49	63.20 9.40	3.30 [-1.22; 7.82]	
Polsky 2024	12	60.10 11.08	12	63.46 10.75	-3.36 [-12.09; 5.37]	
Total (95% CI)	165		170		5.19 [0.06; 10.32]	
Heterogeneity: $\tau^2 = 31.02$; $\chi^2 = 23.18$, $df = 5$ ($P = 0.0003$); $I^2 = 78.4\%$						
Observational studies						
Albert 2023	6	66.25 2.73	6	61.50 2.34	4.75 [1.87; 7.63]	
Dodesini 2023	8	64.99 9.24	8	54.40 7.70	10.59 [2.27; 18.91]	
Guibert 2023	13	60.33 5.78	13	45.25 6.27	15.08 [11.10; 19.06]	
Levy 2023	10	78.62 9.27	10	64.50 16.30	14.10 [2.50; 25.70]	
Fresa 2024	6	79.91 5.59	6	67.75 11.31	12.16 [2.07; 22.25]	
Nandam 2024	6	67.90 15.70	2	68.10 12.00	-0.20 [-21.04; 20.64]	
Quirós 2024	59	66.73 13.03	53	64.53 16.00	2.20 [-3.24; 7.64]	
Total (95% CI)	108		98		8.71 [4.51; 12.90]	
Heterogeneity: $\tau^2 = 16.99$; $\chi^2 = 24.08$, $df = 6$ ($P = 0.0005$); $I^2 = 75.1\%$						
Total (95% CI)	273		268		7.01 [3.72; 10.30]	
Heterogeneity: $\tau^2 = 23.54$; $\chi^2 = 47.83$, $df = 12$ ($P < 0.0001$); $I^2 = 74.9\%$						
Test for subgroup differences: $\chi^2 = 1.08$, $df = 1$ ($P = 0.2980$)						



AID use in pregnant women with Type 1 Diabetes

- The CIRCUIT Randomized Clinical Trial



Multicenter
open-label
randomised
trial



Since June 2021
Up to July 2024



94 pregnant women with Type 1 diabetes
before 14 weeks' gestation

AID system (Tandem with Control IQ)

Pre-trial insulin delivery method + CGM

Follow-up:
until 6 weeks
postpartum

Mean percentage of time
in pregnancy-specific glucose range

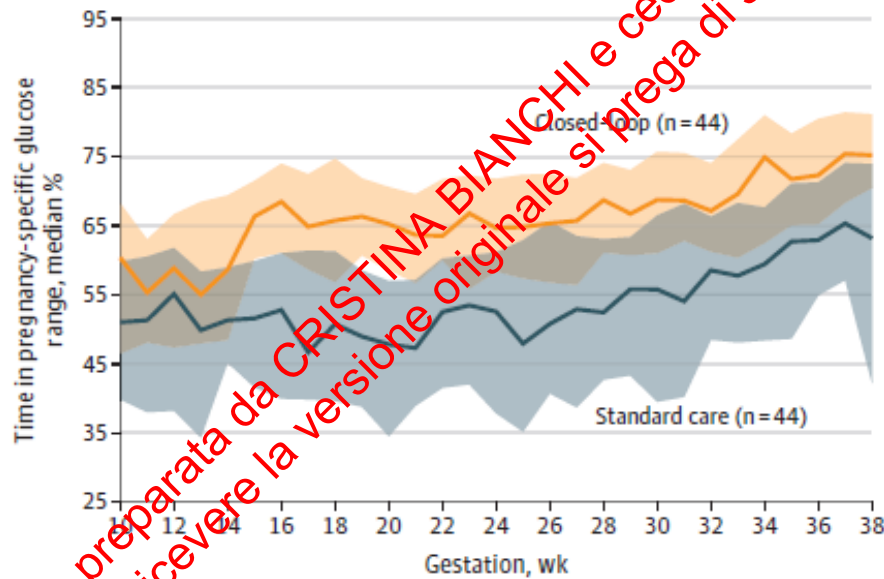
Closed-loop system **65.4%**

Standard care **50.3%**

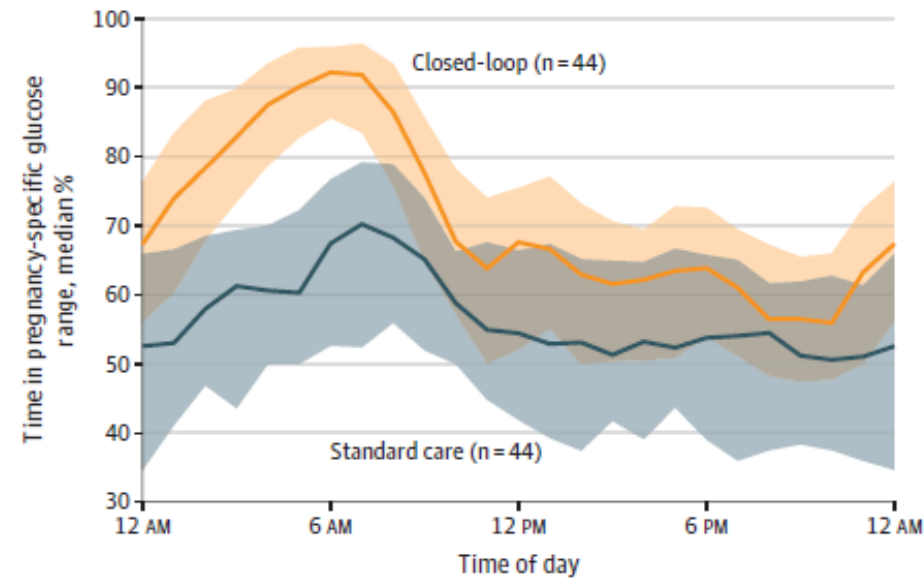
The closed-loop system significantly increased
time in the pregnancy-specific glucose range
by 3 hours per day:

Mean adjusted difference, **12.5%**
(95% CI, 9.5% to 15.6%); $P < .001$

Time in pregnancy-specific glucose range by gestational week of pregnancy



Time in pregnancy-specific glucose range by time of day



Type 1 Diabetes and AID use at different stages of life



Children/adolescents



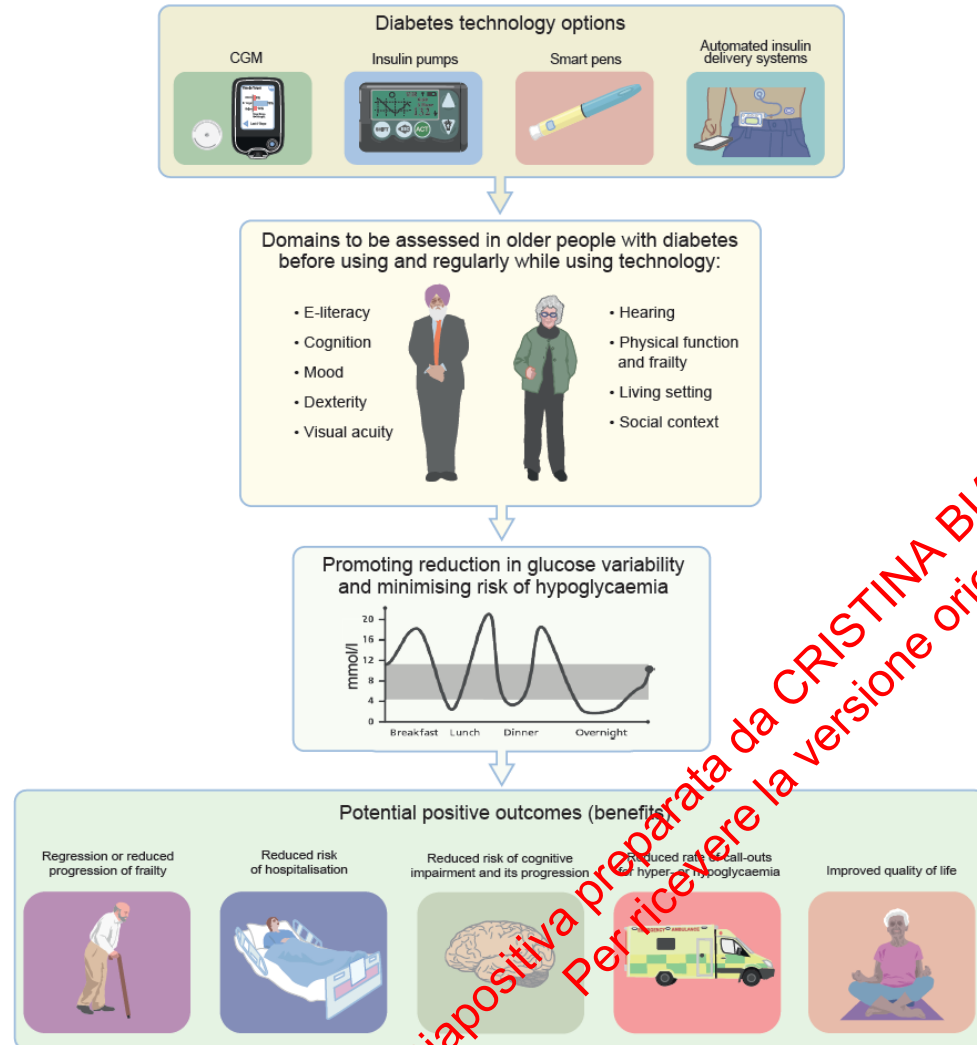
Pregnancy



Elderly

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Benefits of technology in older people with diabetes and key barriers to its use



AID in older adults with Type 1 Diabetes



Multicenter
randomized
crossover trial



Since Sept. 2020
Up to Dec. 2022

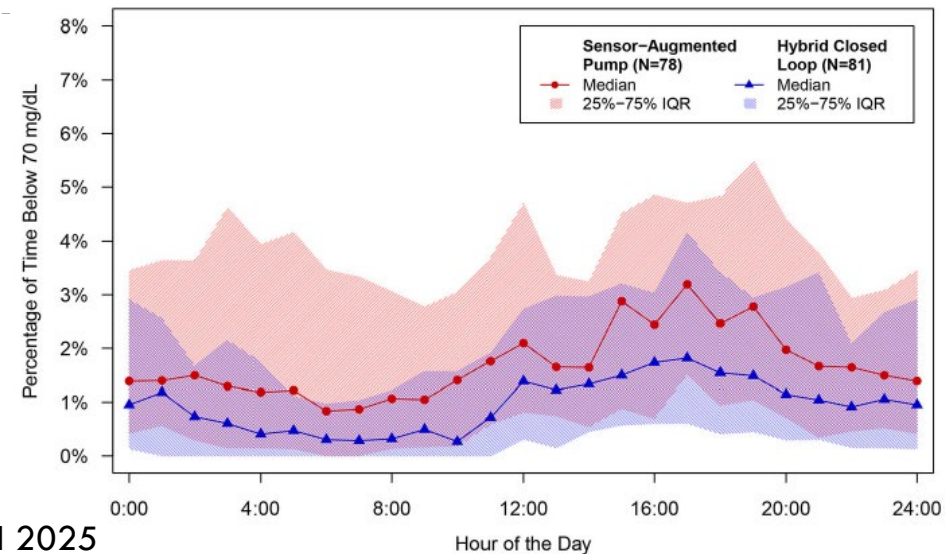
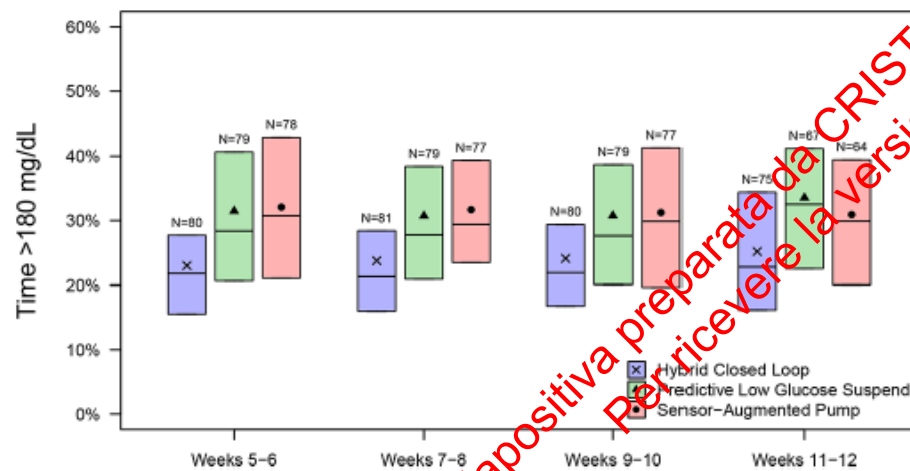
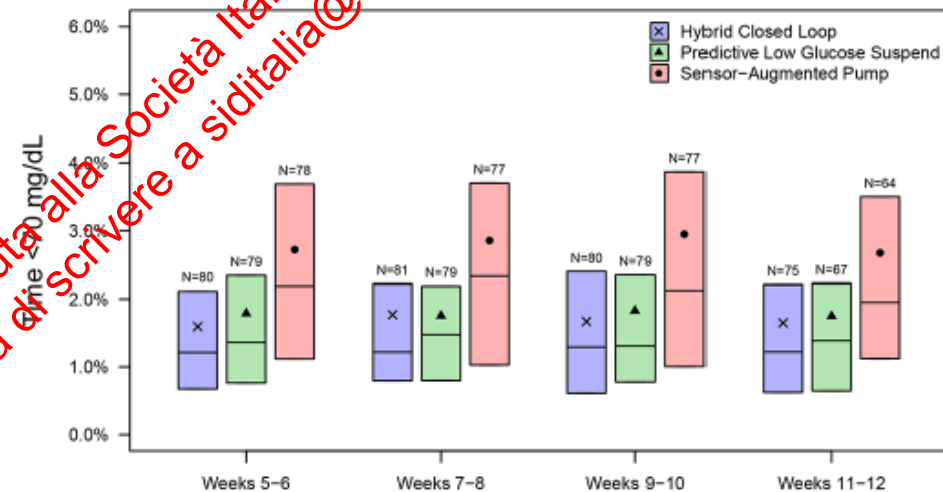
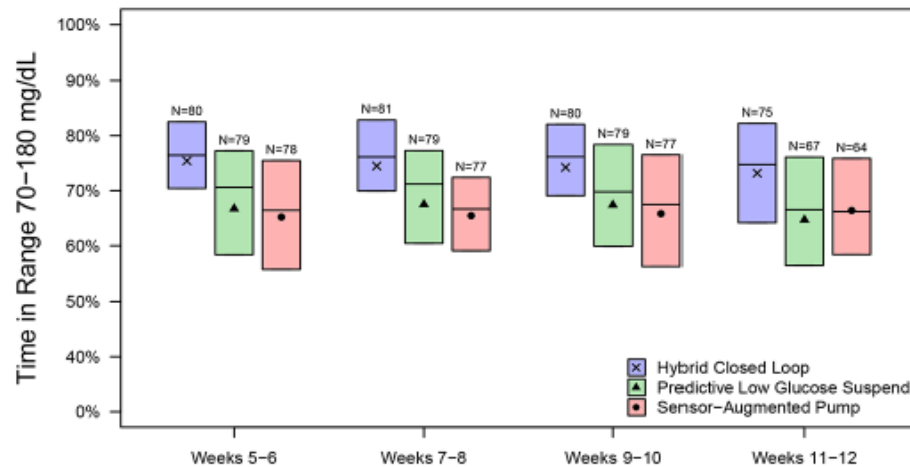
82 adults (65–86 years)
with type 1 diabetes

Three
12-week
periods

Hybrid closed loop (HCL - t:slim X2 with Control-IQ)

Predictive low glucose suspend (PLGS- t:slim pump X2 with Basal-IQ)

Sensor-augmented pump (SAP - t:slim X2 pump + CGM without automation)



Type 1 Diabetes and AID use at different stages of life



Children/adolescents



Pregnancy



Elderly



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AID systems use: different scenarios



Type 2 diabetes



Chronic kidney disease/dialysis



Awareness hypoglycemia

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AID system use in type 2 diabetes

- The 2IQP Study -



Multicenter
randomised
trial



Since June 2023
Up to June 2024

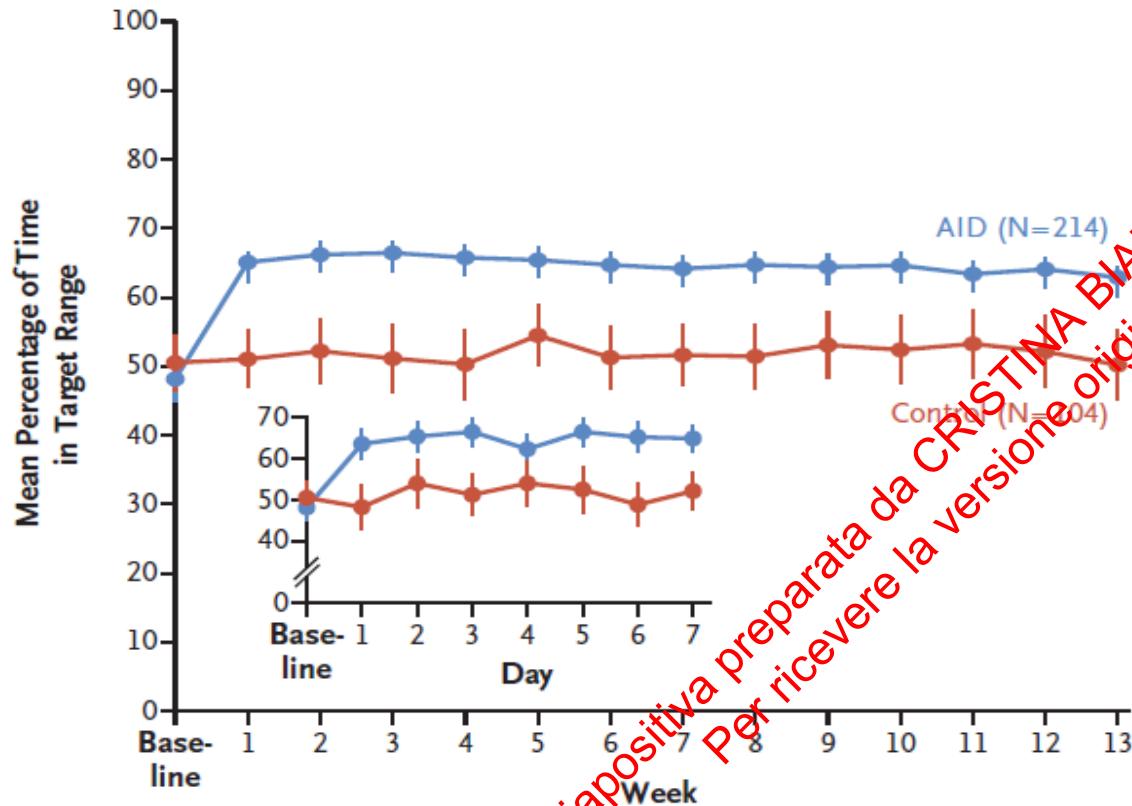
319 individuals
with insulin-treated type 2 diabetes

AID system (Tandem with Control IQ)

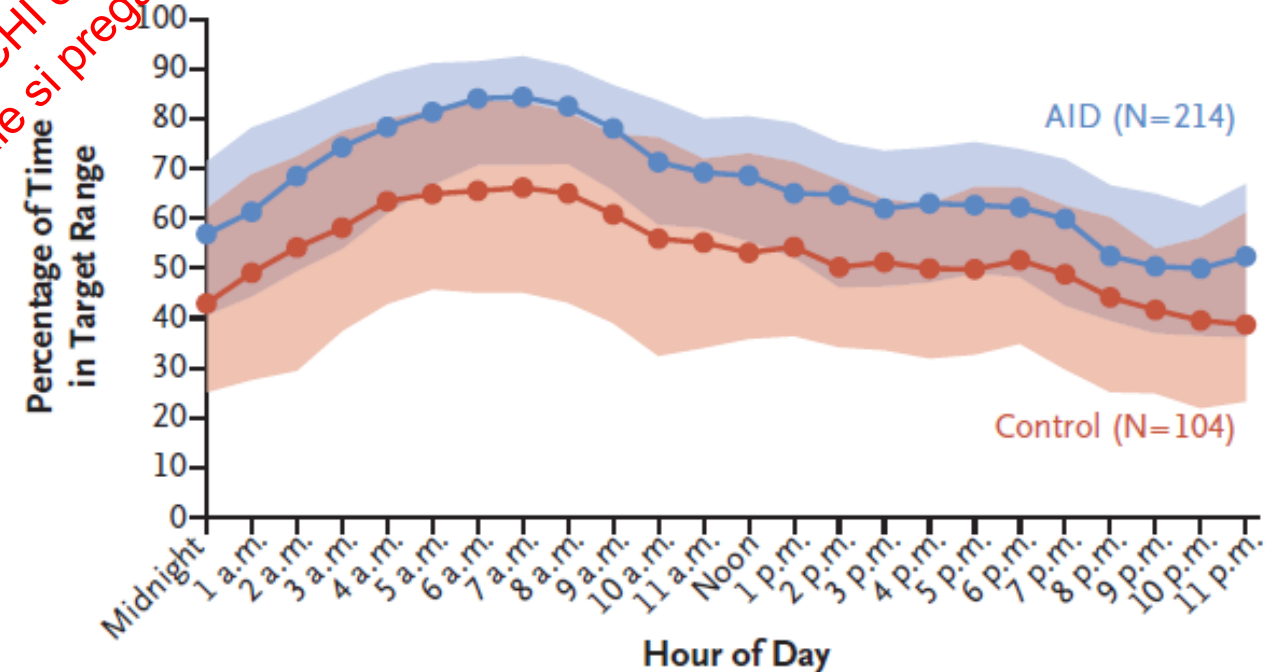
Pre-trial insulin delivery method + CGM

Follow-up:
13 weeks

Time in glucose target range (70 to 180 mg/dl) over 13 weeks



Time in glucose target range according to hour of day over 13 weeks



AID system use in type 2 diabetes



Multicenter
randomised
trial

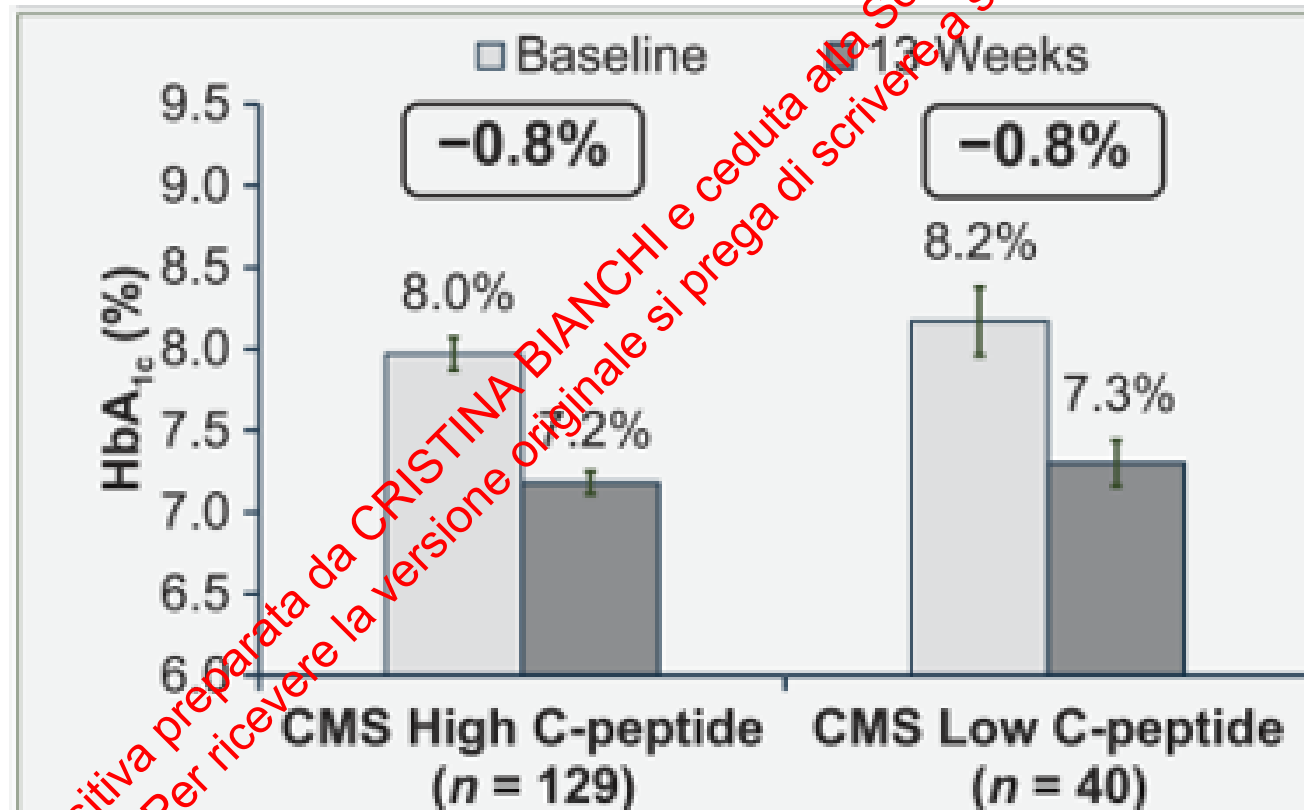


Since June 2023
Up to June 2024

254 individuals
With type 2 diabetes
treated with AID system
(Tandem with Control IQ)

high C-peptide
low C-peptide

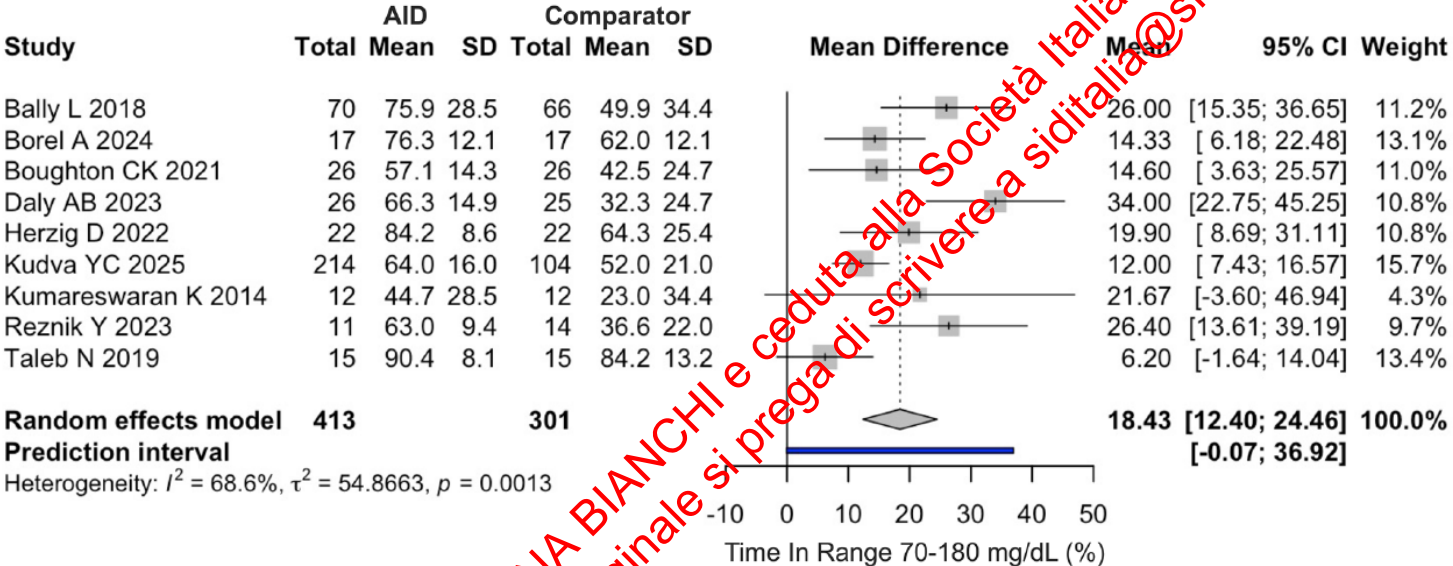
Follow-up:
13 weeks



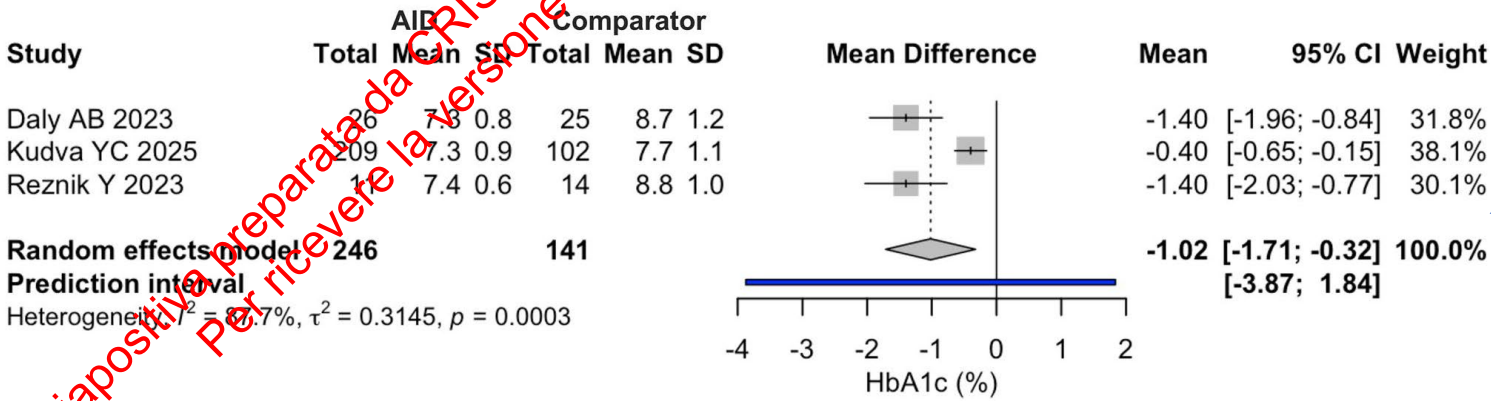
AID system use in type 2 diabetes: a meta-analysis of RCT

9 studies, accounting for 714 adults with type 2 diabetes

Time in range



HbA1c



AID systems use: different scenarios



Type 2 diabetes



Chronic kidney disease/dialysis



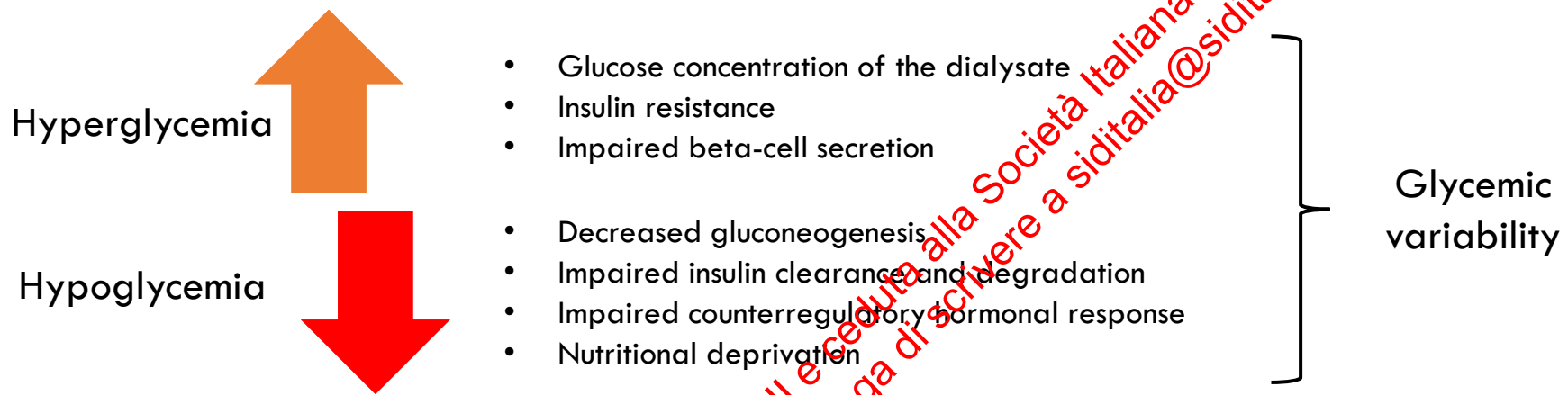
Awareness hypoglycemia



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Use of AID systems in end stage kidney disease/haemodialysis:

mitigating features of AID against pathophysiological challenges of diabetes management in ESKD



Pathophysiological challenges in ESKD	AID mitigating feature
• Increased risk of hypoglycemia	• Automatic suspension of insulin delivery upon detection of impending hypoglycaemia • Low glucose alarms helpful in nocturnal hypoglycemia or cases of impaired hypoglycemia awareness • Algorithms can be adjusted to prevent hypoglycemia on dialysis days by altering glucose target or by using 'activity/exercise mode'
• Impaired insulin clearance	• Most systems allow adjustment of active insulin time
• Increased insulin resistance • High glucose variability	• Automatic adjustment of basal insulin and correction bolus delivery factor at every few minutes based on CGM and pump data. • Healthcare professionals can access AID data illuminating discernible patterns in insulin requirements glucose variability, allowing for meaningful intervention thereby reducing the risk of clinical inertia due to the complexity of glycemic profile

Abbreviations: ESKD = End stage kidney disease, AID = Automated insulin delivery, CGM = Continuous glucose monitor.

AID system in patients with diabetes and CKD/hemodialysis



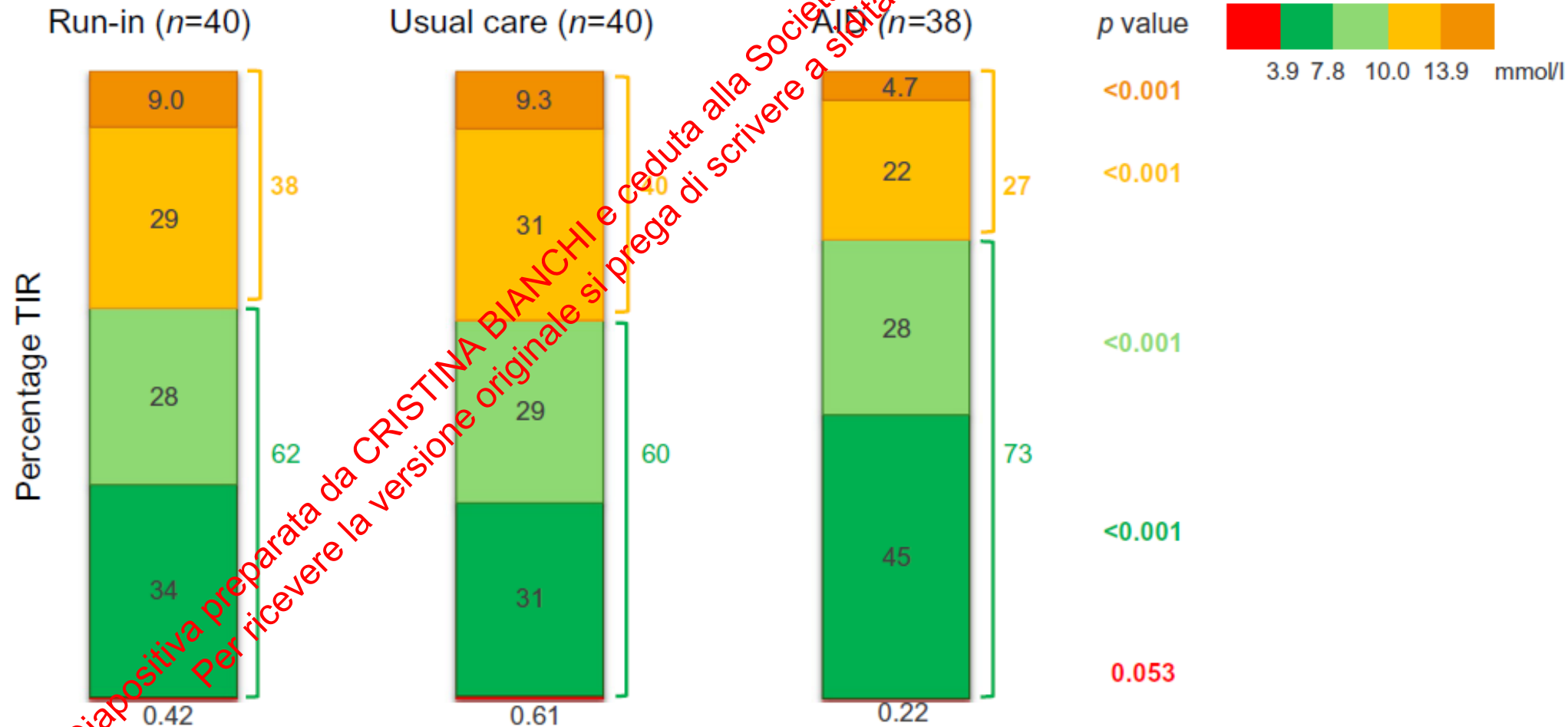
Randomised
crossover trial



40 individuals
(24 type 1 diabetes, 16 type 2 diabetes)
with advanced CKD/ hemodialysis

AID followed by
usual care with CGM
Reverse sequence

each for 8 weeks



Use of AID systems in end stage kidney disease/haemodialysis



Study (Year)	Design/Setting	Population	AID System/Algorithm	Comparator	Follow-up Duration	Key Glycemic Outcomes	Hypoglycemia Findings	Notes
Chaudhry et al. 2024	Single-center case series	4 adults with T1D on HD	Medtronic MiniMed 780 G SmartGuard	Pre-HD baseline	4.5 months (2–9 months)	↑TIR; ↓time above range	No change in TBR; no severe hypoglycemia	Feasibility of AID in HD; real-world outpatient use First evidence in T1D
Pavlou et al. 2025	Real-world multi-center case series	9 adults with T1D on HD	Omnipod 5 SmartAdjust & Medtronic 780 G SmartGuard	Pre-AID baseline	7 months (1.5–25 months)	TIR ↑ 39.7 → 59.8%; ↓GV; ↓HbA1c	No significant TBR change	First real-world evidence of significant benefit with AID in a T1D dialysis population
Boughton et al. 2021	RCT open label 2-center crossover trial	26 adults with T2D on HD (outpatient)	Cambridge fully closed-loop	Standard insulin therapy	2 × 20 days (crossover)	TIR ↑ 37.7 → 52.8%; ↓mean glucose	↓TBR ($p = 0.04$); no severe events	Only RCT; robust evidence of benefit
Bally et al. 2019	Post-hoc inpatient analysis of open label RCT	17 adults with T2D on HD (in hospital)	Fully closed-loop insulin delivery	Conventional insulin therapy	8 days	↑TIR +37.6%; ↓GV (28.4 vs 32.3%)	No increase in hypoglycemia	Post-hoc analysis of a short-term inpatient study; improved stability

Note: ↑ indicates increase; ↓ indicates decrease.
Abbreviations: TIR = Time in Range; TBR = Time Below Range; GV = Glucose Variability; HD = Hemodialysis; ESKD = End Stage Kidney Disease RCT = Randomized Controlled Trial.

AID system in patients with type 1 DM and CKD on hemodialysis



Real-world data



9 individuals with type 1 diabetes and
ESKD on hemodialysis
using AID systems



Follow-up: 7 months

	Mean pre-AID (±SD)	Mean post-AID (±SD)	Difference post-AID (Δ)	P-value
TIR (%)	39.7 (±17.1)	59.8 (±18.1)	20.1	0.001
Time in very high range (%)	30.4 (±19.5)	14.3 (±12.3)	-16.1	0.01
TBR (%)	4 (±5.4)	1.4 (±1.3)	-2.6	0.1
Mean BG (mmol/L)	13.1 (±2.4)	9.8 (±1.9)	-3.3	0.0002
GV (%) [†]	39.8 (±3.8)	33.8 (±6.5)	-6	0.01
TDI (IU) [‡]	35.8 (±12.2)	29.6 (±7.1)	-6.2	0.05
Hemodialysis day TIR (%) [§]	32.7 (±17.7)	62.3 (±14.9)	29.6	0.002
Hemodialysis day TDI (IU) [¶]	27.3 (±7.5)	26.9 (±5.8)	-0.32	0.43
HbA1c (mmol/mol) ^{††}	78.6 (±12.8)	56.1 (±8.5)	-22.5	0.003
Weight ^{‡‡}	74.8 (±19.6)	71.8 (±15.9)	-2.5	0.23

AID systems in patients with diabetes undergoing dialysis

- The AID-DIAL-CAL Study -

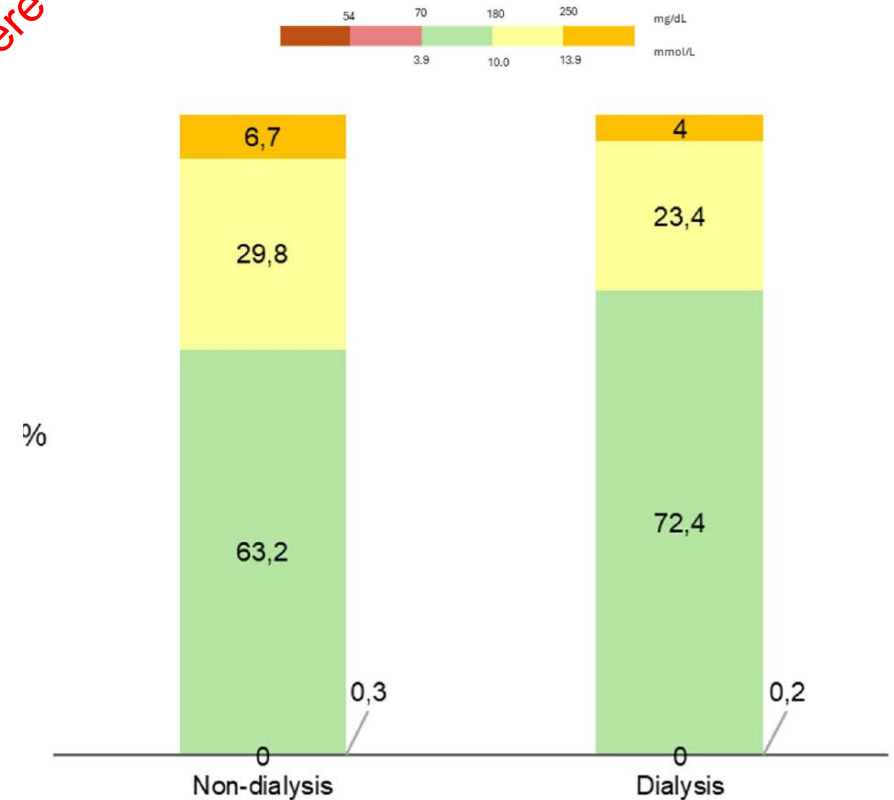


Longitudinal retrospective
pilot real-world analysis



14 individuals
(2 type 1 diabetes, 12 type 2 diabetes)
on hemodialysis
in AID therapy (MiniMed 780G)

Follow-up:
3 - 12 months



AID systems in patients with diabetes undergoing dialysis

- The AID-DIAL-CAL Study -



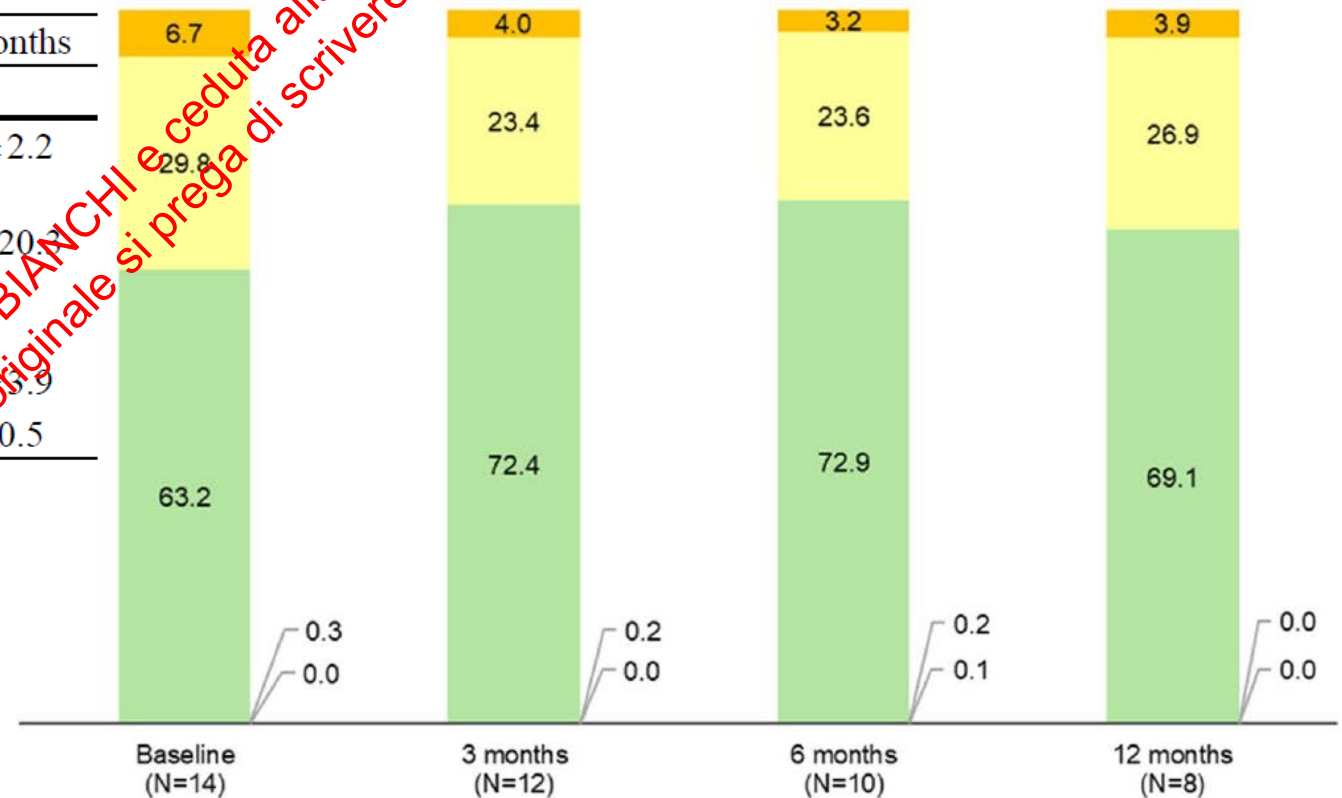
Longitudinal retrospective
pilot real-world analysis



14 individuals
(2 type 1 diabetes, 12 type 2 diabetes)
on hemodialysis on hemodialysis
in AID therapy (MiniMed 780G)

Follow-up:
3 - 12 months

	Baseline	3-months	6-months	12-months
	N= 14	N= 14	N= 10	N= 8
Sensor use (%)	81.3±20.3	93.7±4.9	88.8±12.6	95.5±2.2
Mean sensor glucose (mg/dl)	169.9±19.1	156.9±21.3	158±10.7	161±20.2
CV (%)	26.6±5	26.5±3.9	28.8±6.5	25.5±3.9
GMI (%)	7.4±0.5	7.1±0.5	7.1±0.3	7.2±0.5



AID systems in patients with diabetes undergoing dialysis

- The AID-DIAL-CAL Study -



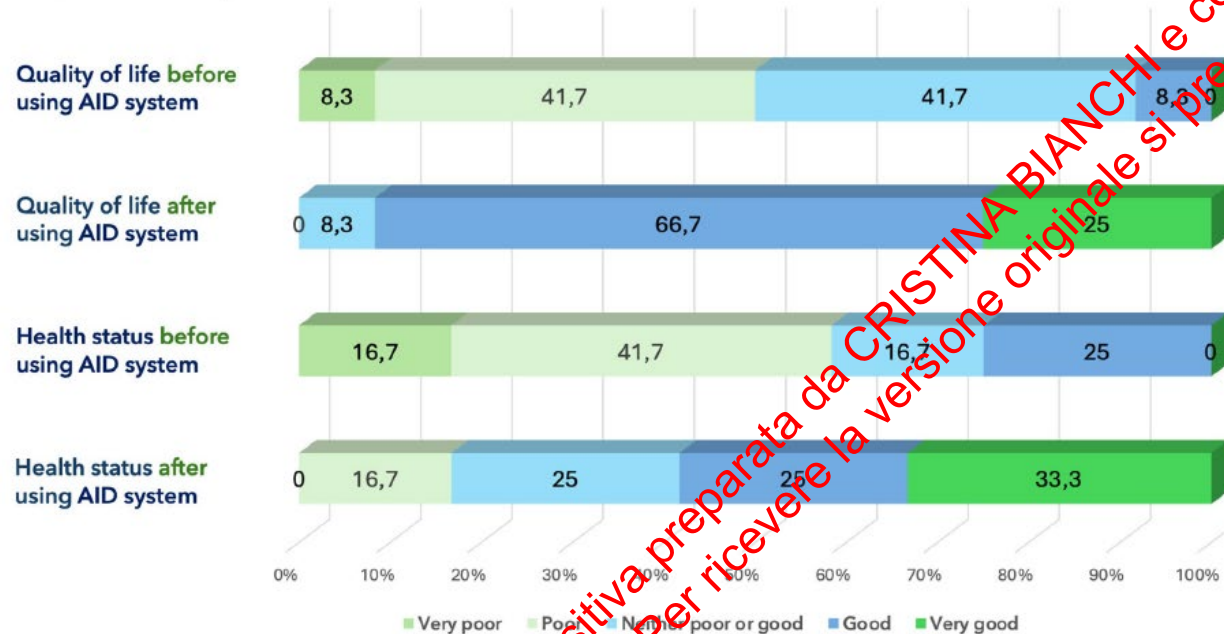
Longitudinal retrospective
pilot real-world analysis



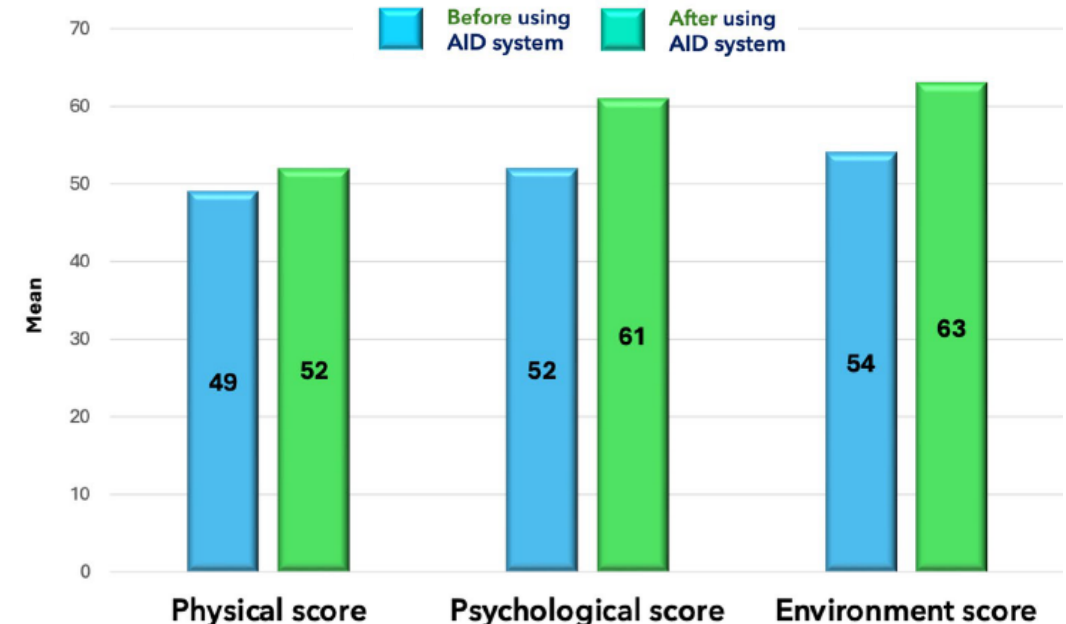
14 individuals
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on hemodialysis on hemodialysis
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Follow-up:
3 - 12 months

PWD on dialysis using AID system: Quality of life
WHOQoL-Bref questionnaire



PWD on dialysis using AID system: Quality of life
WHOQoL-Bref questionnaire



AID systems use: different scenarios



Type 2 diabetes



Chronic kidney disease/dialysis

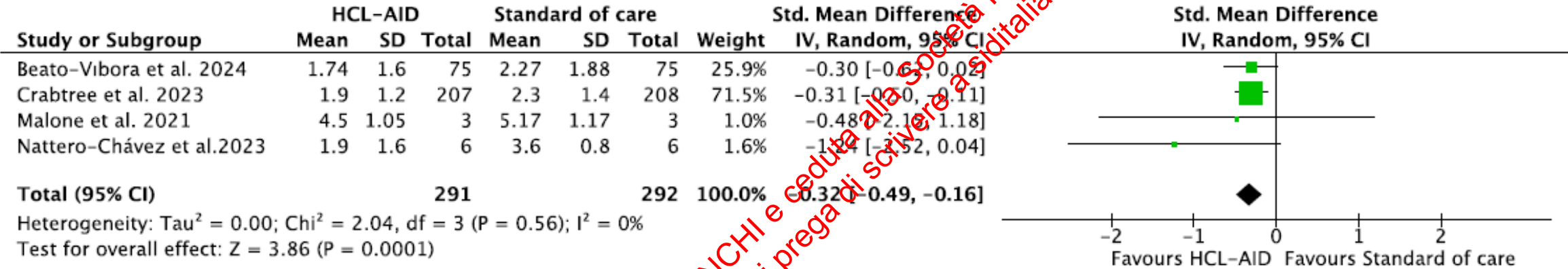


Awareness hypoglycemia

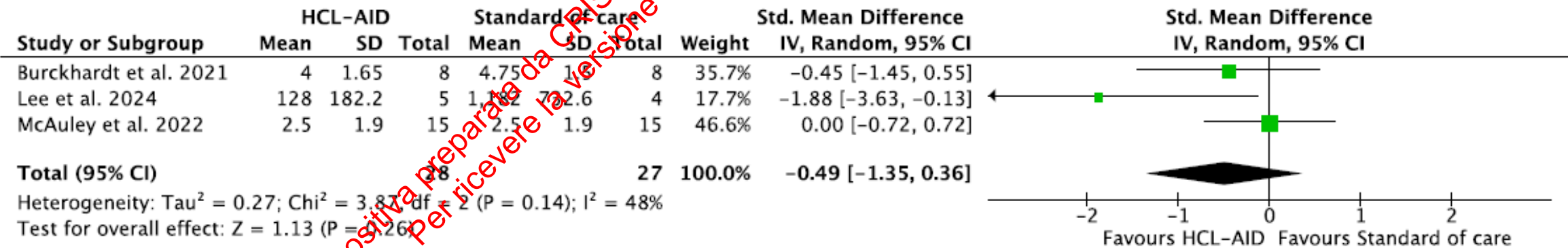
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AID and hypoglycaemia awareness in type 1 diabetes: a metanalysis

Observational studies



Randomised controlled studies



AID systems use: different scenarios



Type 2 diabetes



Chronic kidney disease/dialysis



Awareness hypotension



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AID: other scenarios



Diabetes post-pancreasectomy/pancreatitis



Cystic fibrosis



Prolonged fasting/Ramadan



Gastropancyesis/enteral nutrition



Intellectual diasability



Hospitalization



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AID: guidelines

7.25a AID systems are the preferred insulin delivery method over MDI, CSII, and sensor-augmented pumps in people with type 1 diabetes, **A** adults with type 2 diabetes, **A** children and adolescents with type 2 diabetes, **E** and those with other forms of insulin-deficient diabetes. **B, C, D, E** Choice of an AID system should be made based on the individual's circumstances, preferences, and needs. **E**

7.25b Consider AID systems for select people with type 2 diabetes treated with basal insulin not achieving individualized glycemic goals. **B** Choice of an AID system should be made based on the individual's circumstances, preferences, and needs. **E**

15.19 Automated insulin delivery (AID) systems with pregnancy-specific glucose targets are recommended for pregnant individuals with type 1 diabetes. **A**

15.20 AID systems without pregnancy-specific glucose targets or a pregnancy-specific algorithm may be considered for select pregnant individuals with type 1 diabetes when used with assistive techniques and working with experienced health care teams. **B**

7.3b When prescribing an automated insulin delivery (AID) system, people with diabetes and their caregivers must receive education on how to use and troubleshoot the system. This education should occur at regular intervals as needed. Education should include utilization of the integrated system and its data, including uploading or sharing data to monitor and adjust therapy. **C**

7.5 People with diabetes using CGM, continuous subcutaneous insulin infusion (CSII), and/or AID for diabetes management should have continued access to devices across third-party payors, regardless of age or A1C levels. **E**

7.6 Children and adolescents should be supported at school in the use of diabetes technology, such as CGM systems, CSII, connected insulin pens, and AID systems. **E**

7.7 For adults with diabetes using diabetes technology, reasonable accommodations in educational and work settings should include having sufficient time to manage their devices and respond to high and low glucose levels. **E**

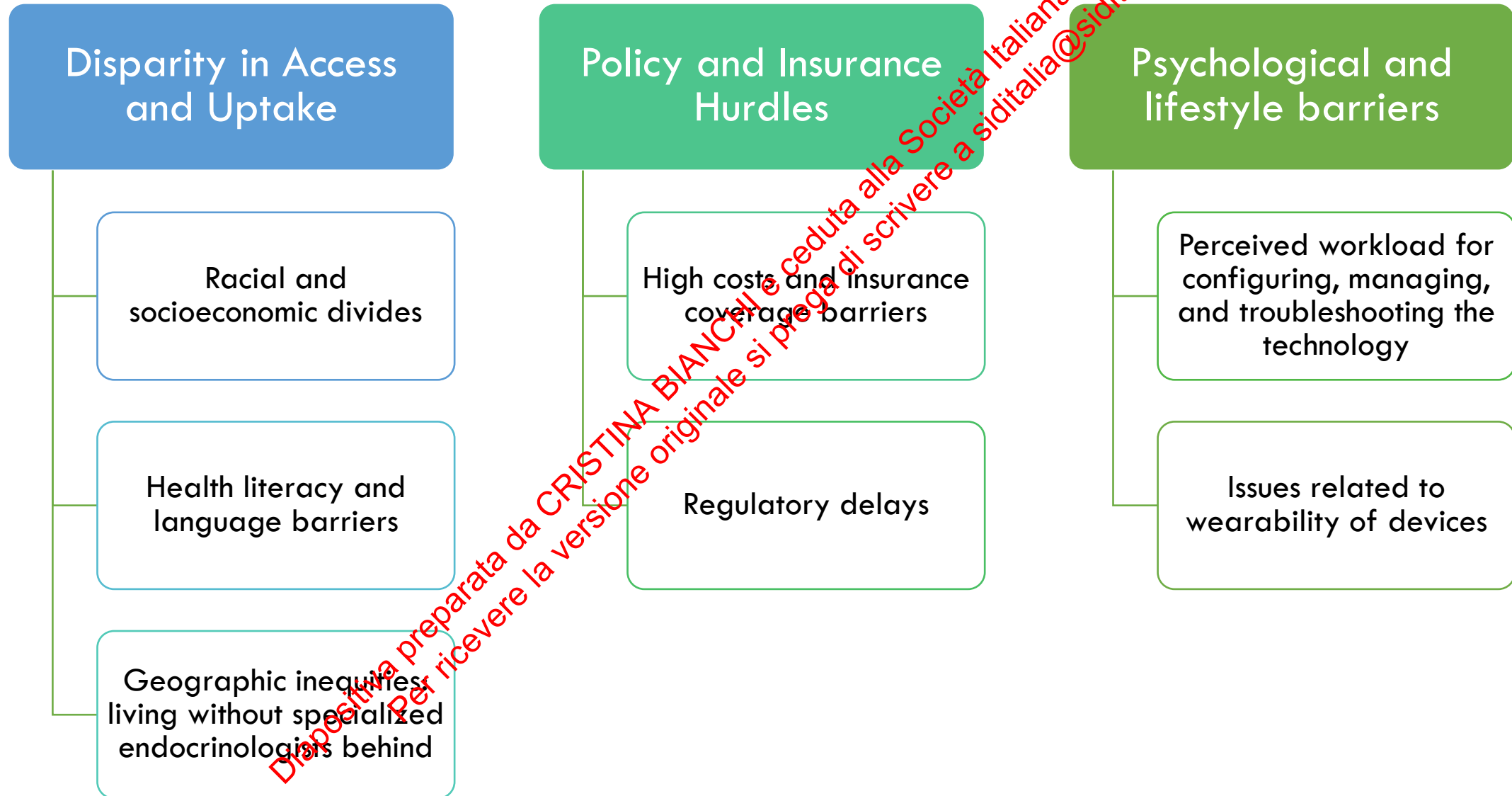
7.8 Consider early initiation, including at diagnosis, of CGM, CSII, and AID depending on a person's or caregiver's needs and preferences. **C**

7.8a There should be no requirement of C-peptide level, **B** the presence of islet autoantibodies, **B** or duration of insulin treatment **C** before initiation of CSII or AID.

7.9 Standardized reports for all CGM, CSII, AID, and connected insulin devices with a minimum of a single-page report, such as the standardized CGM report and weekly summary, should be available and utilized. Options for daily and weekly reports and raw data should be available. **E**

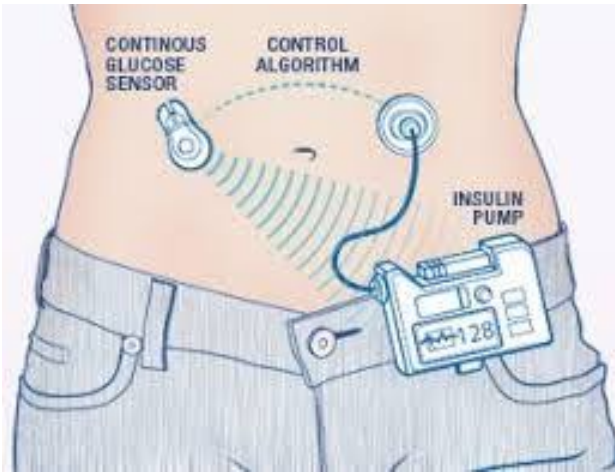
AID systems are for everyone, but...is everyone for AID?

Despite the clinical benefits, several factors prevent universal adoption:



Conclusions: the aid of AID

- ✓ Technological advances are transforming the management of type 1 diabetes at all ages, including pregnancy.
- ✓ The automated nature of closed loop and its ability to adapt to real-time glucose levels may improve glucose control and quality of life across a range of populations, making it a viable choice for many, if not all.
- ✓ However, for optimal use of diabetes technology, it is essential to improve the knowledge and skills of both healthcare professionals and users.
- ✓ Inequities in diabetes technology access and utilization remain a critical public health barrier, directly widening the gap in health outcomes based on race, socioeconomic status, and geography.





**Thanks
for listening!**

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