



Advanced Hybrid Closed Loop ed algoritmi

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Diapositiva preparata da CRISTINA BIANCHI e ceduta alla Società Italiana di Diabetologia.
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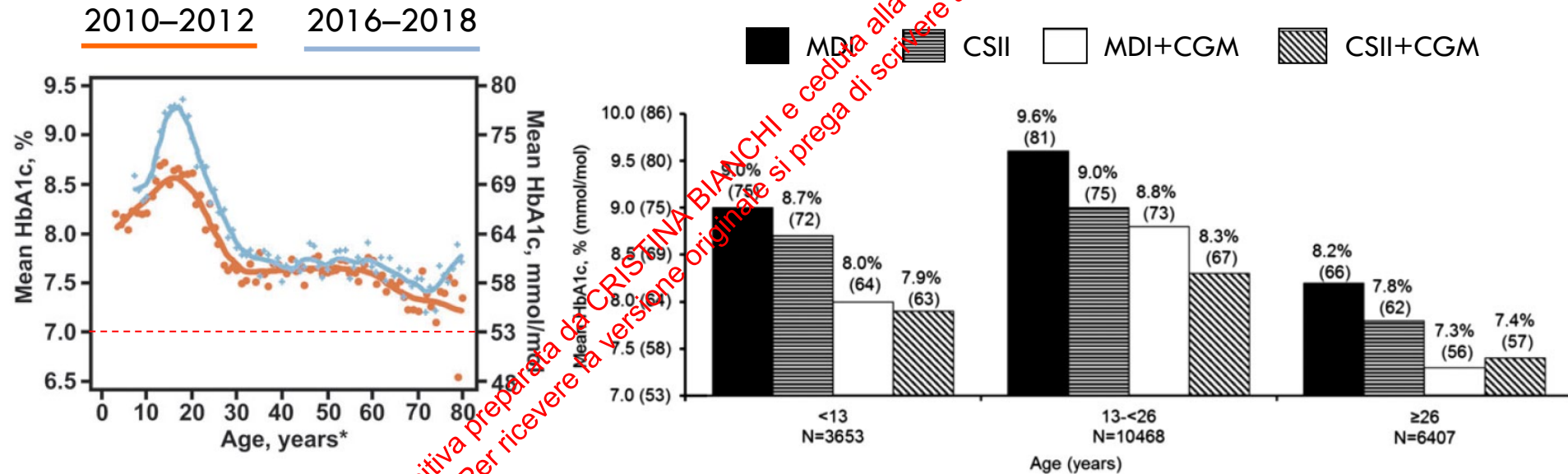
Cristina Bianchi, MD PhD



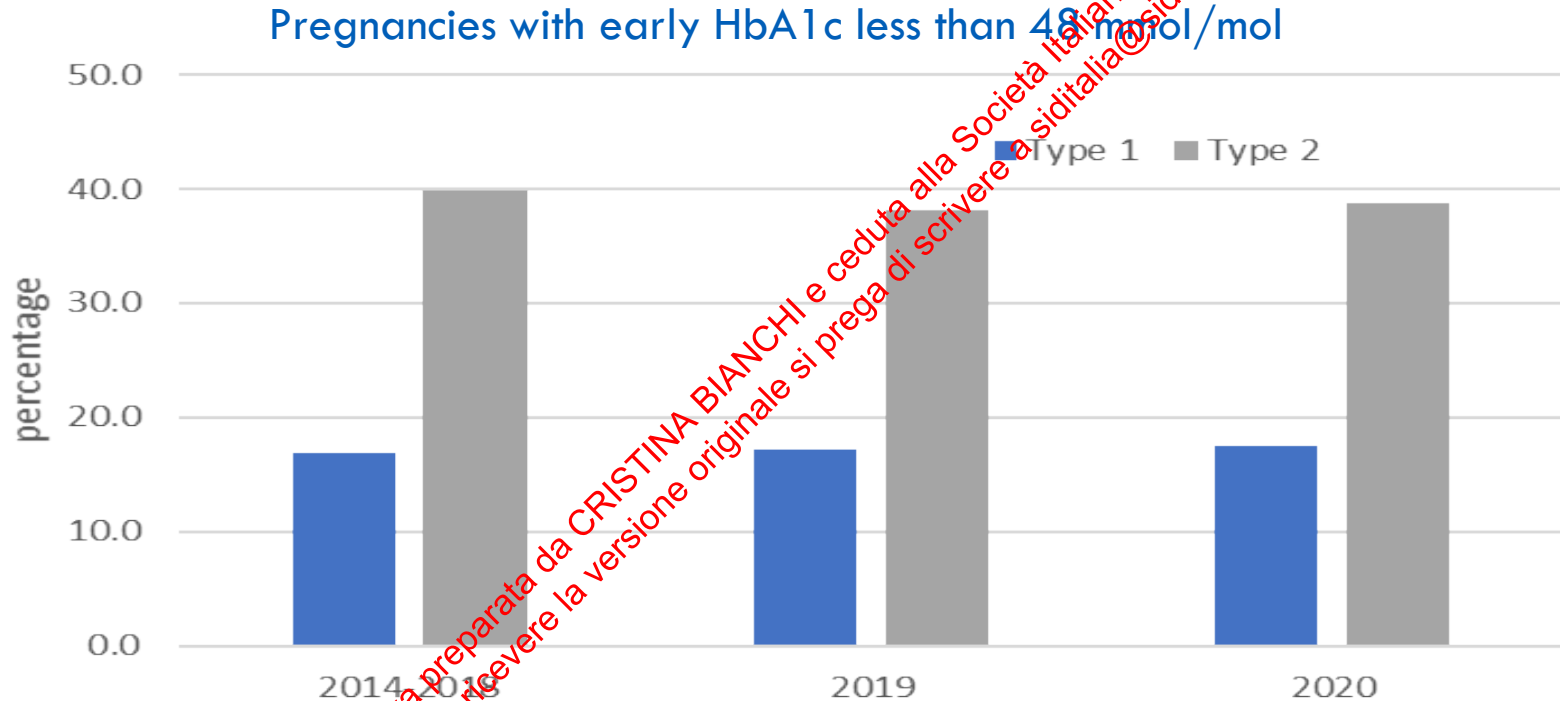
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State of Type 1 Diabetes Management

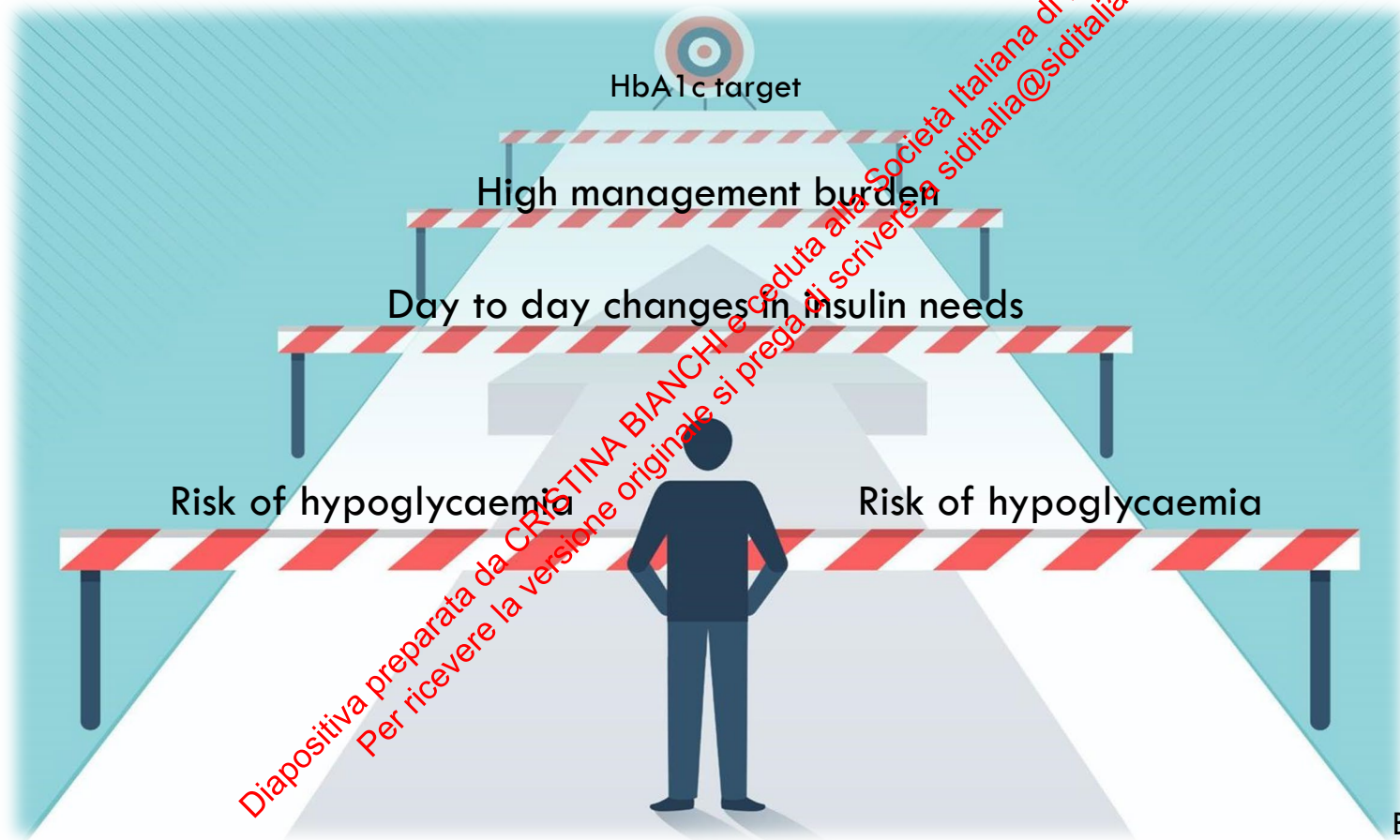
22,697 US registry participants (age 1–93 years) collected between 2016 and 2018, compared with data collected in 2010–2012 for 25,529 US registry participants



State of Diabetes management in early pregnancy



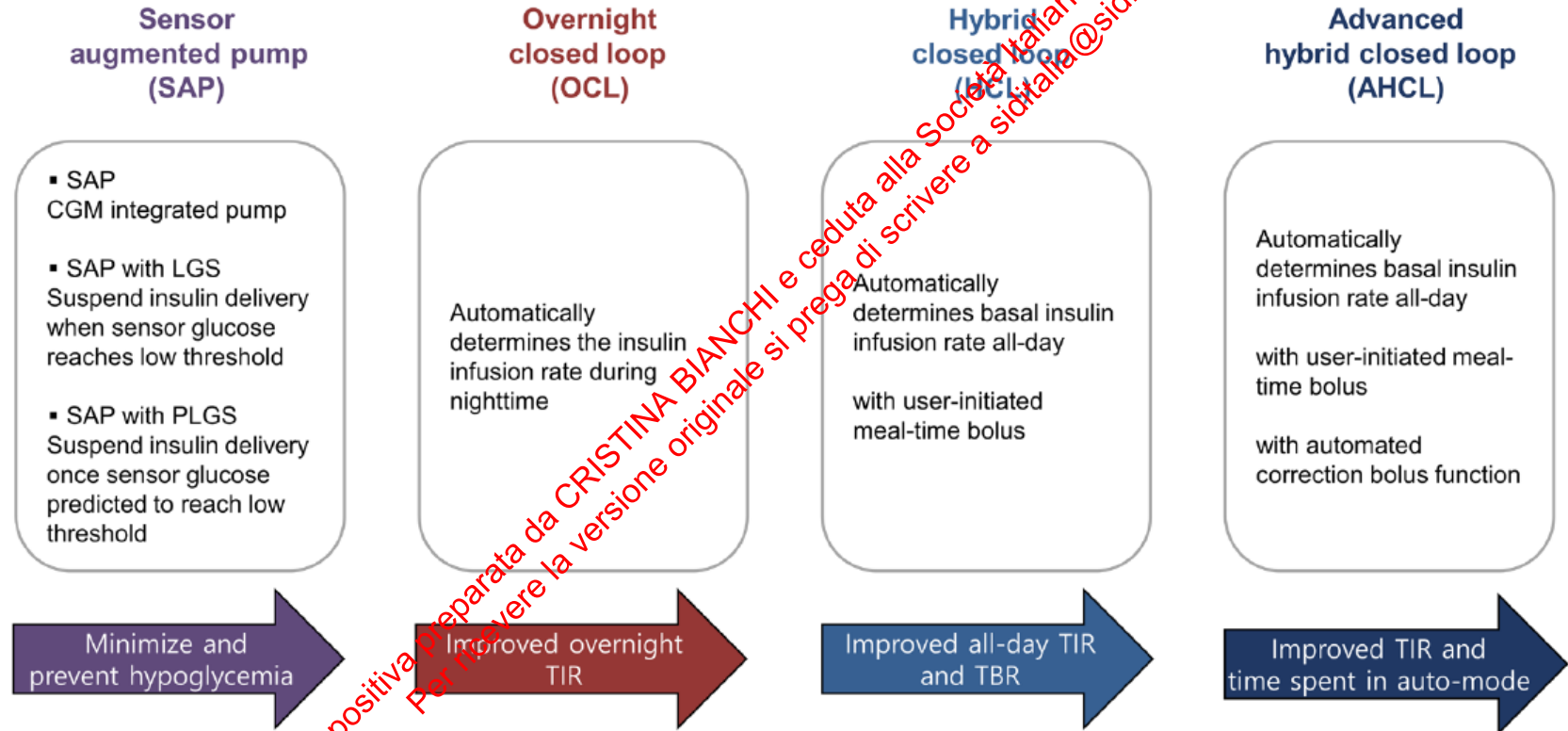
Barriers to achieve good glycaemic control in Type 1 Diabetes



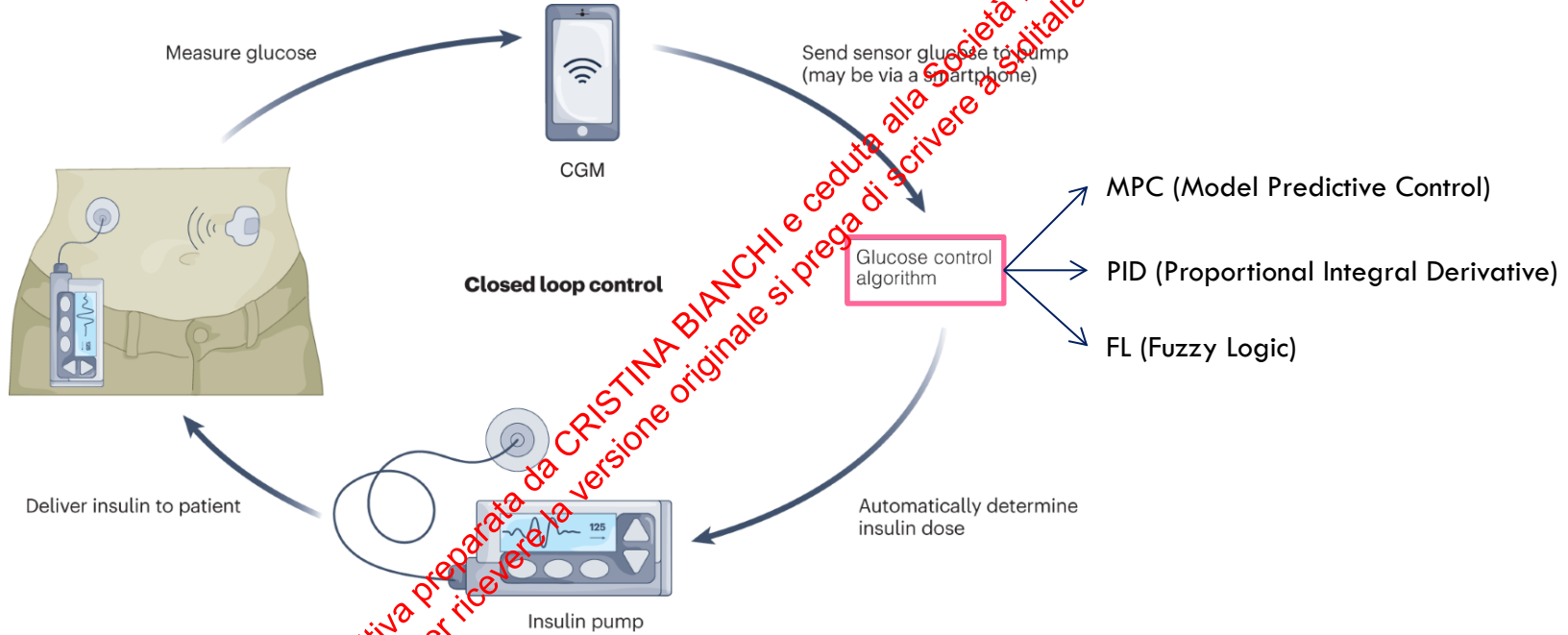
Timeline of development of the artificial pancreas system



Key features of SAP and artificial pancreas systems

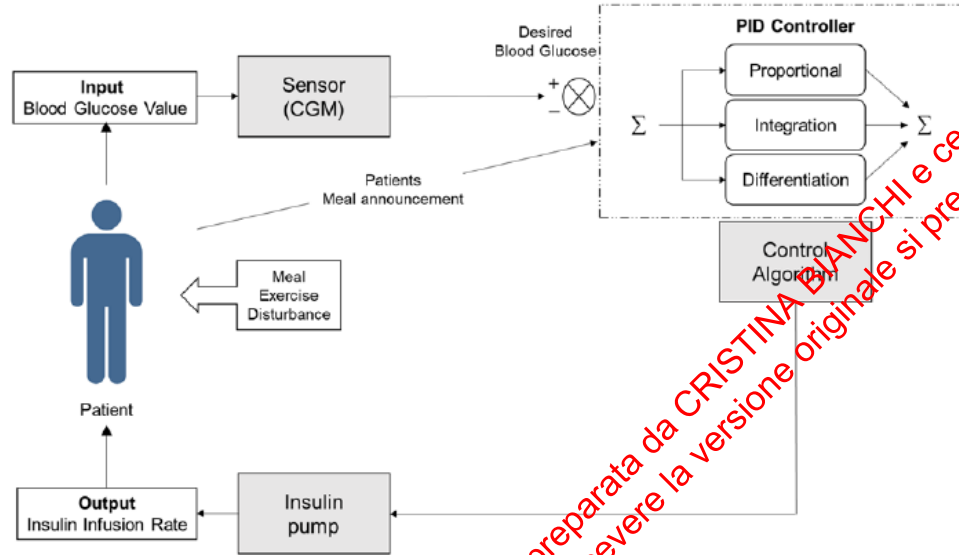


Advanced Hybrid Closed-Loop



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Control algorithms of artificial pancreas system: proportional integral derivative control (PID) algorithm



PID controllers modify insulin rates by evaluating glucose excursions from three perspectives:

- proportional component: deviation from target glucose
- integral component: area under the curve between measured and target glucose level
- derivative component: rate of change of measured glucose levels

Control algorithms of artificial pancreas system: proportional integral derivative control (PID) algorithm



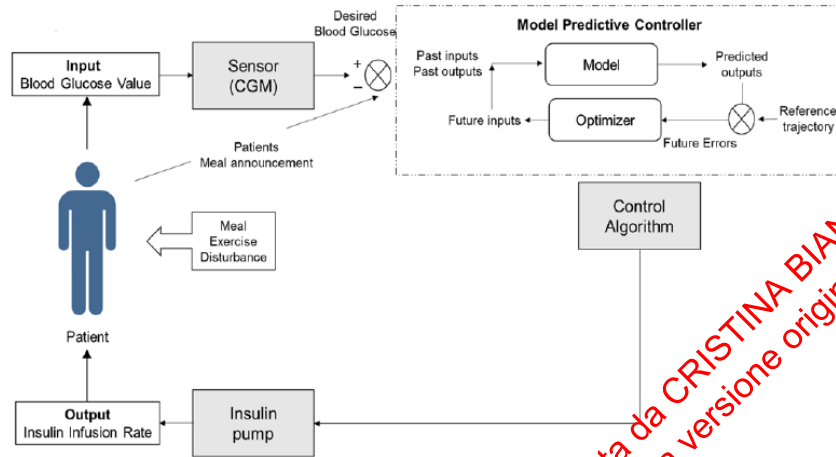
“derivative component” corresponds to the future, predicting the future direction of changes in the glucose level

“integral component” corresponds to the past to see the area deviating from the target in the previous trajectory

“proportional component” corresponds to the present because it detects how far away the glucose level is from the target right now

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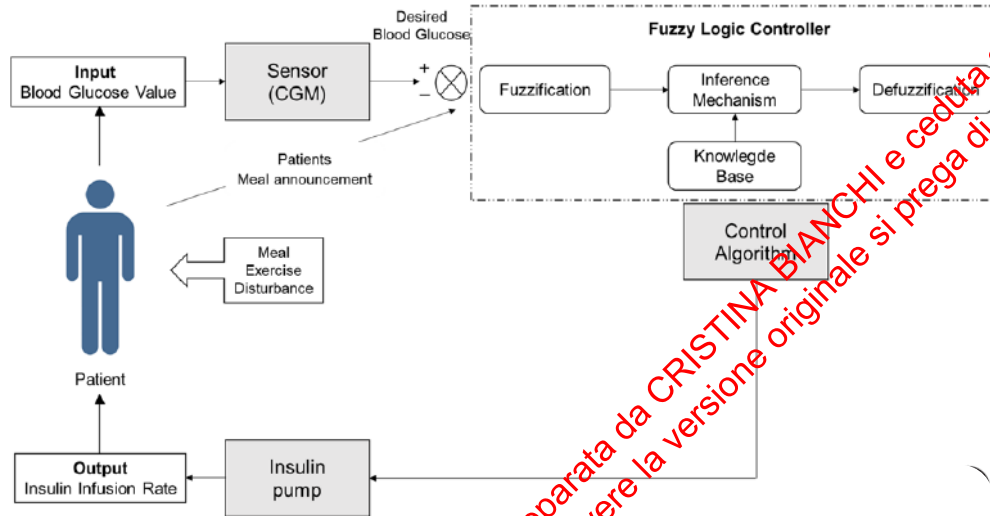
Control algorithms of artificial pancreas system: model predictive control (MPC) algorithm



MPC algorithms predict future glycaemic excursions and adjust insulin delivery based on inputs including:

- sensor glucose levels and
 - insulin boluses given,
- simultaneously considering:
- insulin absorption delays,
 - active insulin, and
 - diurnal and post-prandial variability in glucose levels

Control algorithms of artificial pancreas system: fuzzy logic algorithm



The fuzzy logic approach involves modulating insulin delivery based on rules which reflect the reasoning of experienced diabetes practitioners.

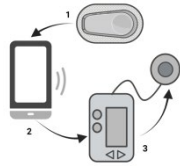
The fuzzy logic operates through supervised learning based on expert opinions to establish a specific decision

AID: comparison of algorithms

	Smart Guard	Control I-Q	DBLG1	CamAPS FX	SmartAdjust
Algorithm	PID with insulin feedback	Adaptive MPC	MPC with Machin Learning	Adaptive MPC	Adaptive MPC
Automatic basal rate modulation	✓	✓	✓	✓	✓
Correction insulin delivery	Automated correction boluses (up to 12 per hour)	Automated basal rate adjustment every 5 min and automated correction boluses (up to 1 per hour)	Automated correction boluses	Automated corrections via intensive basal rate adjustments	Automated corrections via intensive basal rate adjustments
Correction boluses	✓	✓	✓	✗	✗
Algorithm location	Pump integrated	Pump-integrated	Dedicated handset	App-based	Pod-integrated
Pre-set basal insulin rates influence AID	No	Yes (users can set multiple basal rates and different basal profiles)	No	No	No (informs AID for first 48 h)
Glucose target	100-120 mg/dl	112.5-160 mg/dl	100-130 mg/dl	80-200 mg/dl	110-150 mg/dl

Treating Hypoglycemia and Hyperglycemia with AID

How AID system functions



Hypoglycemia	Hyperglycemia
Reduces and/or suspend insulin delivery when the glucose is predicted to go below a certain value within a certain period time	Increases basal insulin delivery or administers a small bolus when the glucose is predicted to go above a certain value within a certain period time

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AID: strategies for addressing interplandial hyperglycemia

Control I-Q	DBLG1	CanAPS FX	SmartAdjust
Educate - Suggest considering the administration of a correction bolus through the in-built calculator of the pump - In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing an infusion set change - For meals with high fat and protein contents suggest adding carbohydrate equivalents for fat/proteins and splitting the bolus	Educate - Suggest considering the administration of a correction bolus through the in-built calculator of the pump - In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing an infusion set change - Suggest enabling the Sleep activity mode in the sleeping hours - For meals with high fat and protein contents suggest disabling the Sleep activity mode in the sleeping hours	Educate - Suggest enabling the "Boost" function to intensify algorithm driven insulin delivery - Suggest considering the administration of a correction bolus through the in-built calculator of the pump - In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing an infusion set change - For meals with high fat and protein contents suggest splitting the bolus and ticking 'slowly absorbed meal' in the "add meal" menu	Educate - Suggest considering the administration of a correction bolus through the in-built calculator of the pump - In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing an infusion set change - For dinner meals with high fat and protein contents - suggest adding carbohydrate equivalents for fat/proteins and splitting the bolus
Adjust - Reduce the AIT by 30-60 min - Lower the GT level by 10 mg/dl	Adjust - Increase the basal rate by 10-20% - Reduce the ISF by 10-20%	Adjust - Increase the HA by 10% when SG lies above the hyperglycemia threshold - Increase the NA by 10% when SG lies within the hyperglycemia threshold - Lower the GT level by 10 mg/dl	Adjust - Lower the GT level by 10 mg/dl - For hyperglycemic episodes persisting despite user-initiated correction boluses, consider lowering the "correct above" threshold or reducing the ISF and/or the AIT

AID: strategies for addressing interprandial hypoglycemia

Control I-Q	DBLG1	OmAPS FX	SmartAdjust	
<i>Educate</i> • Suggest taking 5-10 grams of fast acting sugars	<i>Educate</i> • Suggest taking 5-10 grams of fast acting sugars	<i>Educate</i> • Suggest taking the recommended amount of rescue carbs	<i>Educate</i> • Suggest taking 5-10 grams of fast acting sugars and ticking “hypo treatment” in the “add meal” menu	<i>Educate</i> • Suggest taking 5-10 grams of fast acting sugars
<i>Adjust</i> • Raise the GT level by 10 mg/dl • Increase the AIT by 30-60 min	<i>Adjust</i> • Reduce the basal rate by 10-20% • Increase the ISF by 10-20%	<i>Adjust</i> • Reduce the HA by 10% • Reduce the NA by 10% • Raise the GT level by 10 mg/dl • Raise the hypoglycemia threshold by 5-10 mg/d	<i>Adjust</i> • Raise the GT level by 10 mg/dl	<i>Adjust</i> • Raise the GT level by 10 mg/dl • For hypoglycemic episodes following user-initiated correction boluses, consider raising the “correct above” threshold or increasing the ISF and/or the AIT

AID: strategies for addressing nocturnal hyperglycemia

Control I-Q	DBLG1	CanAPS FX	SmartAdjust
Educate - Suggest considering the administration of a correction bolus through the in-built calculator of the pump - In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing an infusion set change - For dinner meals with high fat and protein contents suggest adding carbohydrate equivalents for fat/proteins and splitting the bolus	Educate - Suggest considering the administration of a correction bolus through the in-built calculator of the pump - In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing an infusion set change - Suggest enabling the Sleep activity mode in the sleeping hours - For dinner meals with high fat and protein contents suggest disabling the Sleep activity mode in the sleeping hours	Educate - Suggest enabling the "Boost" function to intensify algorithm driven insulin delivery - Suggest considering the administration of a correction bolus through the in-built calculator of the pump - In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing an infusion set change - For dinner meals with high fat and protein contents suggest splitting the bolus and ticking 'slowly absorbed meal' in the "add meal" menu	Educate - Suggest considering the administration of a correction bolus through the in-built calculator of the pump - In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing an infusion set change - For dinner meals with high fat and protein contents - suggest adding carbohydrate equivalents for fat/proteins and splitting the bolus
Adjust - Reduce the AIT by 30-60 min - Lower the GT level by 10 mg/dl	Adjust - Increase the basal rate by 10-20% - Reduce the ISF by 10-20%	Adjust - Increase the HA by 10% when SG lies above the hyperglycemia threshold - Increase the NA by 10% when SG lies within the hyperglycemia threshold - Lower the GT level by 10 mg/dl	Adjust - Lower the GT level by 10 mg/dl - For hyperglycemic episodes persisting despite user-initiated correction boluses, consider lowering the "correct above" threshold or reducing the ISF and/or the AIT

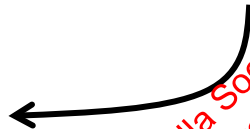
AID: strategies for addressing nocturnal hypoglycemia

Control I-Q	DBLG1	OmniAPS FX	SmartAdjust
Educate Suggest taking 5-10 grams of fast acting sugars	Educate Suggest taking the recommended amount of rescue carbs	Educate Suggest taking 5-10 grams of fast acting sugars and ticking "hypo treatment" in the "add meal" menu	Educate Suggest taking 5-10 grams of fast acting sugars
Adjust - Raise the GT level by 10 mg/dl - Increase the AIT by 30-60 min	Adjust - Reduce the basal rate by 10-20% - Increase the ISF by 10-20%	Adjust - Raise the NA by 10% - Raise the GT by 10 mg/dl - Raise the hypoglycemia threshold by 5-10 mg/dl	Adjust - Raise the GT level by 10 mg/dl - For hypoglycemic episodes following user-initiated correction boluses, consider raising the "correct above" threshold or increasing the ISF and/or the AIT

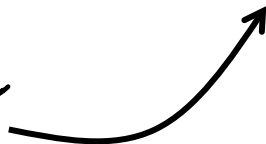
Advanced Hybrid Closed Loop



Meals



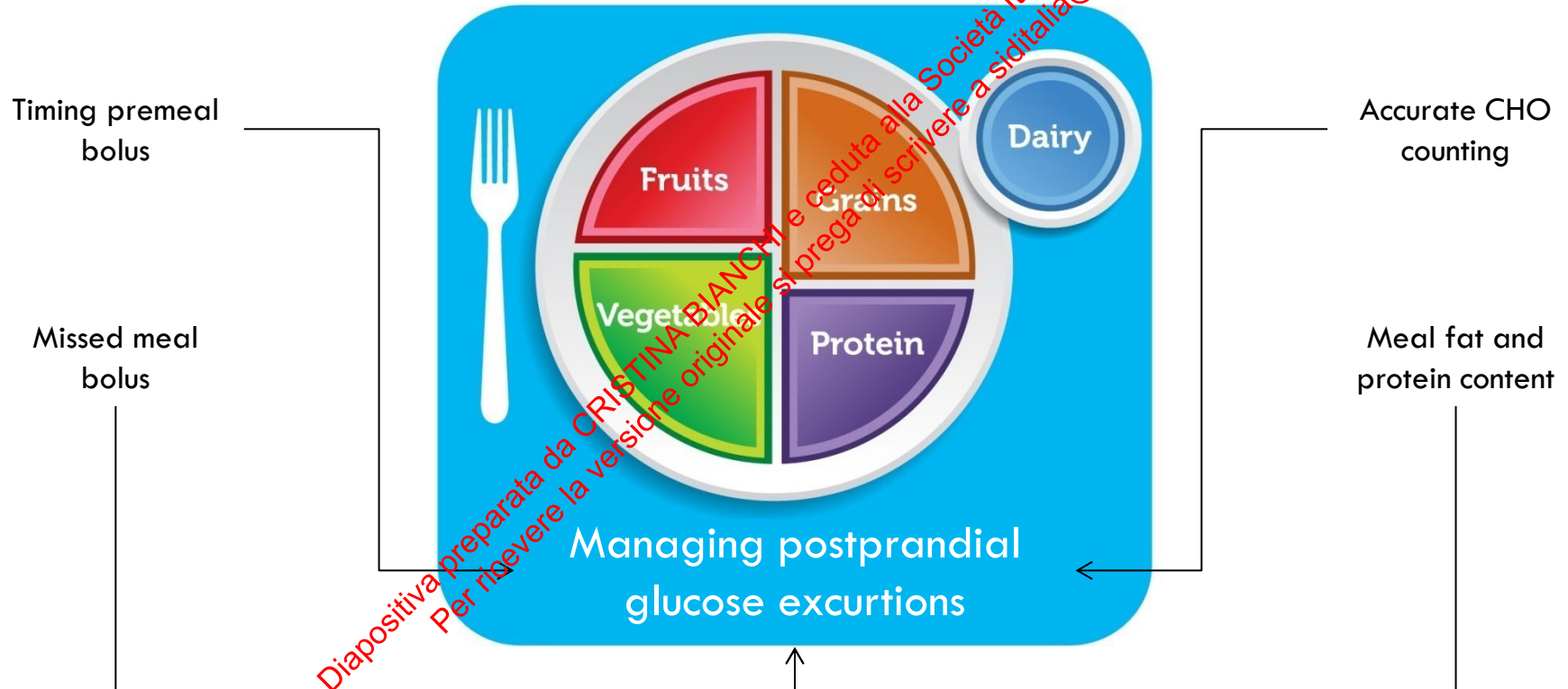
Physical
activity



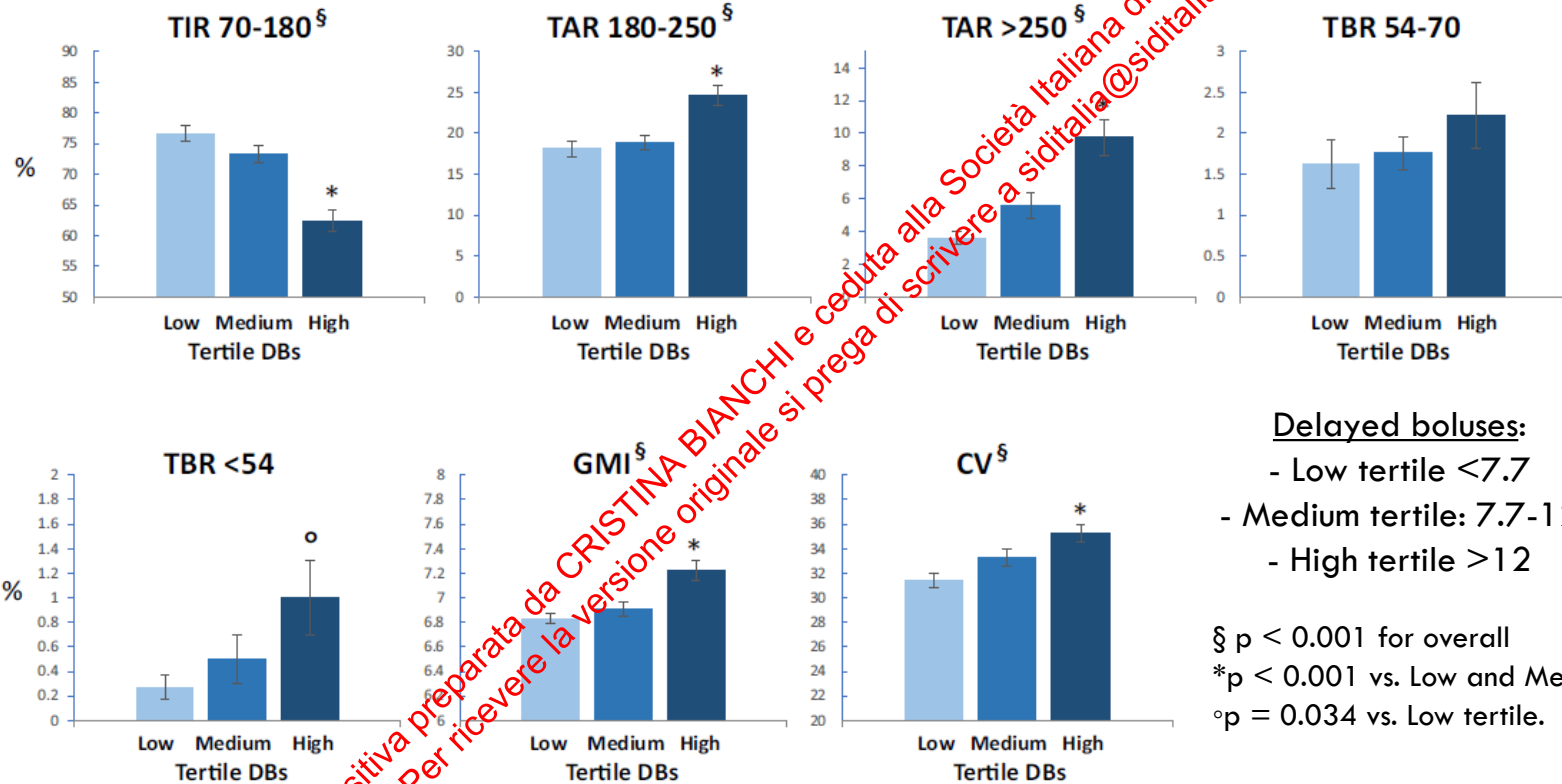
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Meals and Advanced Hybrid Closed Loop

Current automated AID systems are hybrid, requiring carbohydrate content to be “announced” for insulin dose calculation before a meal starts



Delayed prandial insulin boluses and glucose control



Delayed boluses:

- Low tertile <7.7
- Medium tertile: 7.7-12
- High tertile >12

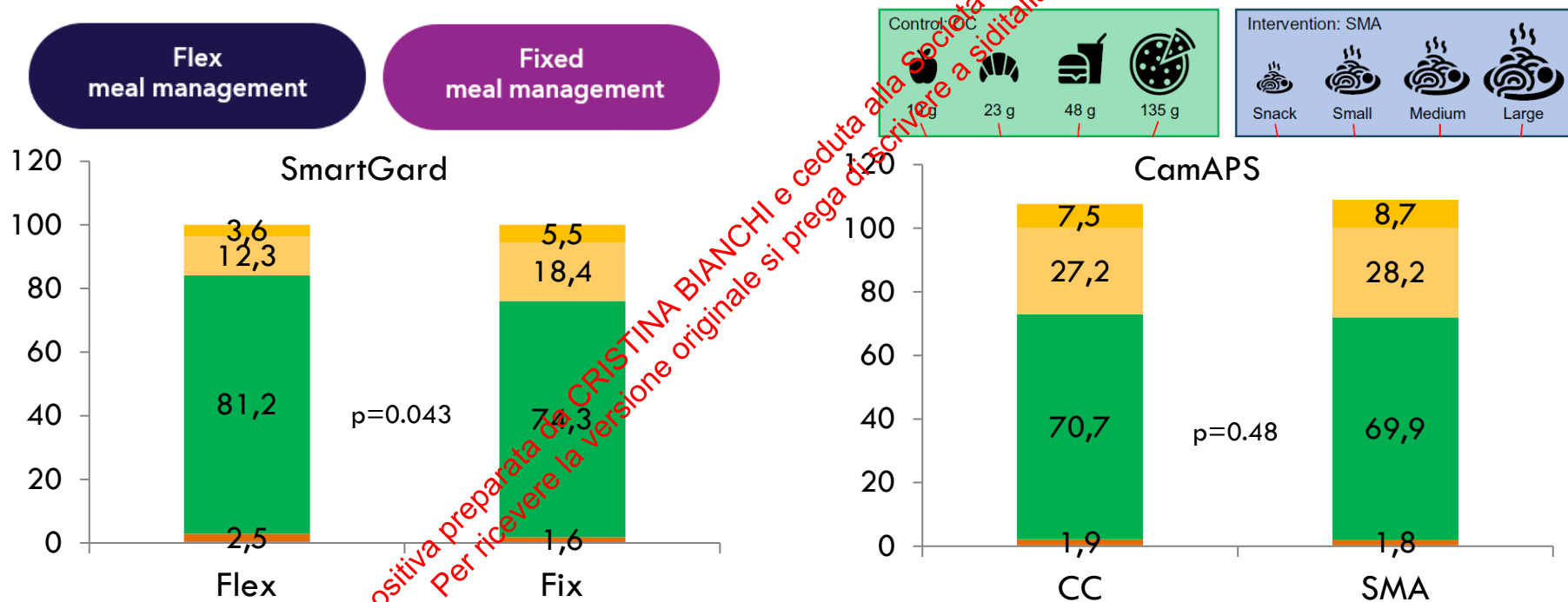
[§] p < 0.001 for overall

*p < 0.001 vs. Low and Medium tertiles

^op = 0.034 vs. Low tertile.

Strategies to improve post-prandial glucose control with AID

Using a qualitative estimate of carbohydrate content ("small," "medium," or "large") instead of accurate carbohydrate count requirement



AID: strategies for addressing postprandial hyperglycemia

Control I-Q	DBLG1	CamA FX	SmartAdjust
<i>Educate</i> - Suggest considering the administration of a correction bolus through the in-built calculator of the pump - Review and reinforce carbohydrate counting skills - Suggest increasing the time interval between the (insulin) bolus and the meal	<i>Educate</i> - Suggest considering the administration of a correction bolus through the in-built calculator of the pump - Review and reinforce carbohydrate counting skills - Suggest increasing the time interval between the (insulin) bolus and the meal	<i>Educate</i> - Suggest considering the administration of a correction bolus through the in-built calculator of the pump - Suggest enabling the "Boost" function to intensify algorithm driven insulin delivery - Review and reinforce carbohydrate counting skills - Suggest increasing the time interval between the (insulin)	<i>Educate</i> - Suggest considering the administration of a correction bolus through the in-built calculator of the pump - Review and reinforce carbohydrate counting skills - Suggest tapping "Use sensor" to use sensor glucose trend for bolus calculation - Suggest increasing the time interval between the (insulin) bolus and the meal
<i>Adjust</i> Reduce the ICR by 10-20%	<i>Adjust</i> Reduce the ICR by 10-20%	<i>Adjust</i> Increase aggressiveness for breakfast – lunch - dinner by 10-20%	<i>Adjust</i> - Reduce the ICR by 10-20% - Lower the GT level by 10 mg/dl - Switch to ultra-rapid acting insulin analogs (faster aspart, ultrarapid lispro)

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AID: strategies for addressing postprandial hypoglycemia

Control I-Q	DBLG1	ComAB/FX	SmartAdjust	
Educate • Suggest taking 10-15 grams of fast acting sugars • Review and reinforce carbohydrate counting skills • Suggest reducing the time interval between the (insulin) bolus and the meal • For slowly absorbed meals suggest splitting the bolus	Educate • Suggest taking 10-15 grams of fast acting sugars • Review and reinforce carbohydrate counting skills • Suggest reducing the time interval between the (insulin) bolus and the meal • For slowly absorbed meals suggest use of extended bolus feature (1-2h)	Educate • Suggest taking the recommended amount of rescue carbs • Review and reinforce carbohydrate counting skills • Suggest reducing the time interval between the (insulin) bolus and the meal • For slowly absorbed meals suggest splitting the bolus	Educate • Suggest taking 10-15 grams of fast acting sugars and ticking “hypo treatment” in the “add meal” menu • Review and reinforce carbohydrate counting skills • Suggest reducing the time interval between the (insulin) bolus and the meal • For slowly absorbed meals suggest splitting the bolus and ticking 'slowly absorbed meal' in the “add meal” menu	Educate • Suggest taking 10-15 grams of fast acting sugars • Review and reinforce carbohydrate counting skills • Suggest tapping “Use sensor” to use sensor glucose trend for bolus calculation • Suggest reducing the time interval between the (insulin) bolus and the meal • For slowly absorbed meals suggest splitting the bolus
Adjust • Increase the ICR by 10-20%	Adjust • Increase the ICR by 10-20% • Reduce the basal rate by 10-20% • Increase the ISF by 10-20%	Adjust • Reduce aggressiveness for breakfast – lunch - dinner by 10-20%	Adjust • Increase the ICR by 10-20% • Raise the GT level by 10 mg/dl	Adjust • Increase the ICR by 10-20% • Turn reverse correction ON • Raise the GT level by 10 mg/dl • Raise the “correct above” threshold as Appropriate

Physical activity and Advanced Hybrid Closed Loop

Exercise intensity and mode	  			 		  		
	Postprandial, continous, sustained, prolonged aerobic exercise (low stress hormon response)			Mixed activity; individual and team sports		Overnight fasted, burst, explosive, competitive anaerobic exercise (high stress hormon response)		
Avarage glucose response to exercise	 					 		
Exogenous insulin requirements around exercise	 					 		
Carbohydrate intake requirement around exercise	 					 		

Physical activity and Advanced Hybrid Closed Loop

CGM trend arrow

- Start an activity under stable glucose conditions

Glucose target

- Set a higher glucose target 1–2 h before PA

Insulin on board (IOB)

- Aim for low IOB at onset of PA

Carbohydrates (CHO)

- Consume CHO just before PA if needed

Time of day
and prandial status

- Adjust bolus insulin dose for meals consumed <2 h prior to PA according with PA intensity and duration

Placement of insulin pump
and CGM devices

- Consider location of the infusion set and CGM placement in areas less likely to fail, based on activity type

Blood glucose
and ketone monitoring

- Have a glucose meter readily available
- Have a ketone monitoring system available if the PA is prolonged or intense

Physical activity and AID

Planned physical activity

Before PA (1–2 h before)		During PA (every 20–30 min)	After PA ^a
Glucose level	Strategy		
>15.0 mmol/l or Previous history where increase in glucose expected during PA	- May not need higher glucose target - Usual prandial insulin dose before PA - If glucose >15.0 mmol/l (and symptoms of DKA exist), check infusion site for any noticeable causes of blockages, such as kinked tubing or pressure/discomfort at infusion site, and test for ketones	If glucose <7.0 mmol/l, consume 3–20 g CHO depending on CGM trend arrow	If glucose >15.0 mmol/l after PA, resume usual settings and continue to monitor ketones and glucose levels
5.0–15.0 mmol/l	Start higher glucose target^b If PA occurs <2 h after meal, perform 25–33% prandial bolus reduction		If glucose 5.0–15.0 mmol/l after PA, resume usual settings
<5.0 mmol/l or Previous history where decrease in glucose expected during PA	Start higher glucose target^b - If PA occurs <2 h after meal, perform 25–33% prandial bolus reduction - CHO (10–20 g) snack at PA onset with no prandial insulin	If glucose <5.0 mmol/l, consider 3–20 g CHO and maintain higher glucose target for up to 2 h post PA	

^aConsider 25–33% reduction in prandial bolus insulin with the following meal after PA. For unplanned PA, the frequency of CHO intake is generally expected to be higher and closer to the upper limit of CHO amount recommendations than that for planned PA

^bIf PA occurs after a meal where a prandial bolus dose is delivered, set the higher glucose target before performing the prandial bolus reduction

Unplanned physical activity

At PA onset		During PA (every 20–30 min)	After PA ^a
Glucose level	Strategy		
>15.0 mmol/l or Previous history where increase in glucose expected during PA	- May not need higher glucose target - If glucose >15.0 mmol/l (and symptoms of DKA exist), check infusion site for any noticeable causes of blockages, such as kinked tubing or pressure/discomfort at infusion site, and consider testing for ketones	If glucose <7.0 mmol/l, consume 3–20 g CHO depending on CGM trend arrow	If glucose >15.0 mmol/l after PA, resume usual settings and continue to monitor ketones and glucose levels
5.0–15.0 mmol/l	Start higher glucose target until end of PA^b May consider CHO (10–20 g) snack at PA onset with no prandial bolus insulin		If glucose 5.0–15.0 mmol/l after PA, resume usual settings
<5.0 mmol/l or Previous history where decrease in glucose expected during PA	Start higher glucose target until end of PA^b CHO (10–20 g) snack at PA onset with no prandial bolus insulin		If glucose <5.0 mmol/l, consider 3–20 g CHO and maintain higher glucose target for up to 2 h post PA

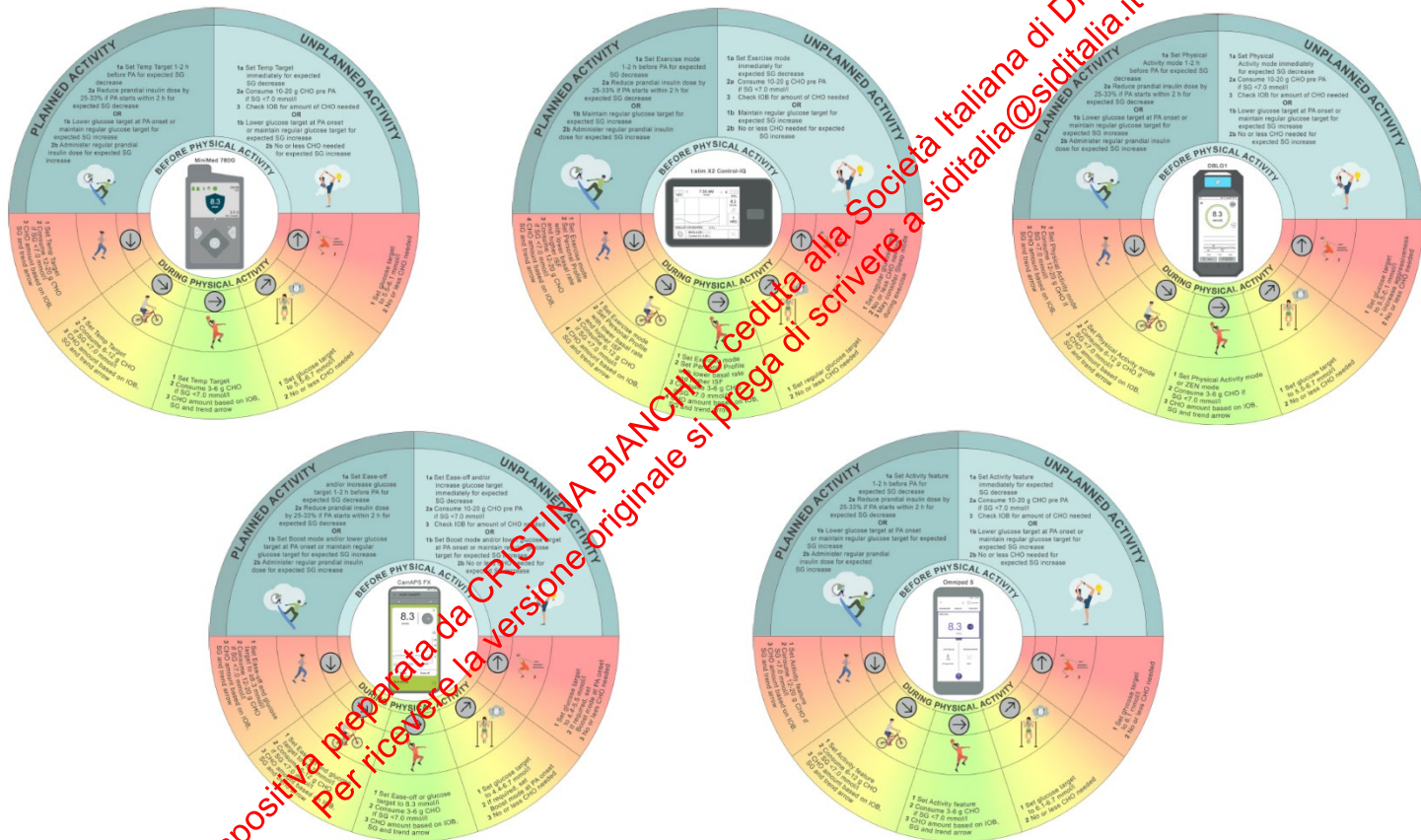
^aConsider 25–33% reduction in prandial bolus insulin with the following meal after PA. For unplanned PA, the frequency of CHO intake is generally expected to be higher and closer to the upper limit of CHO amount recommendations than that for planned PA

^bIf PA occurs after a meal where a prandial bolus dose is delivered, set the higher glucose target before performing the prandial bolus reduction

AID: comparison of algorithms

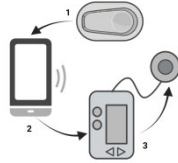
	Smart Guard	Control I-Q	DBLG1	CamAPS FX	SmartAdjust
Calibration	Optional	✗	✗	✗	✗
Glucose target	100-120 mg/dl	112.5-160 mg/dl	100-130 mg/dl	80-200 mg/dl	110-150 mg/dl
Other modes	Activity mode: target of 150 mg/dl and no autocorrections	Exercise activity: target 140-160 mg/dl Sleep Activity: target 112.5-120 mg/dl basal rate modulation only	Activity mode: target +68 mg/dl and less aggressive algorithm Zen mode: target +9-40 mg/dl and less aggressive algorithm	Ease-off mode: target 126 mg/dl, less insulin delivery (-35%) Boost mode: insulin delivery (+35%), more responsive algorithm	Activity mode: target 150 mg/dl restricted insulin delivery
Approved in pregnancy	✓	✗	✗	✓	✗

Physical activity and Advanced Hybrid Closed Loop



Reverting to open loop/manual mode

How AID system functions



Augmented insulin delivery may not be able to respond quickly to rapid increases in insulin resistance that occur during illness, stress, steroid use

Generates alerts.

Users responsibilities



Guidelines should be in place for managing insulin during illness, stress and medications that raise glucose

Respond to AID and CGM alerts. Use blood glucose meter when symptoms don't match CGM reading.

Tips and best practices



Consider switching to manual mode during increased insulin needs such as illness, stress or steroid use.

Ensure users understanding when and how to use a back-up plan.

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: settings and adaptations in Pregnancy

	Smart Guard	Control I-Q	DBLG1	CamAPS FX	SmartAdjust
Set up requirements	Glucose Target AIT CHO/INS	Basal Rates CHO/INS ISF Body weight	Glucose Target Mean CHO consumed Body Weight	Glucose Target Body Weight TDDI CHO/INS	Glucose Target CHO/INS
Glucose target	100 mg/dl (also available from 110-120) <i>Adjustable</i>	112.5-120 Sleep mode in 24 hours (no automatic correction boluses) Non-Adjustable	100* mg/dl (from 100 to 130 mg/dl) <i>Adjustable</i>	99 mg/dl up to the 16th week 81 mg/dL overnight 90 during the day from the 16th week <i>Adjustable</i>	110 mg/dl (from 110 to 150 mg/dl) <i>Adjustable</i>
Active Insulin Time (AIT)	2 hrs <i>Adjustable</i>	5 hrs Non-Adjustable	Adaptive learning <i>Automatically adjusted</i>	Adaptive learning <i>Automatically adjusted</i>	2 hrs <i>Adjustable</i>
CHO/INS	↑ 1st trimester ↓ 2nd and 3rd trimesters	↑ 1st trimester ↓ 2nd and 3rd trimesters (up to 400/TDD units/g)	Non-adjustable, bolus aggressiveness can be increased from the 2nd trimester	↑ 1st trimester ↓ 2nd and 3rd trimesters	↑ 1st trimester ↓ 2nd and 3rd trimesters
Insulin Sensitivity Factor (ISF)	-	Adaptable (up to 1620/TDD)	-	-	Adaptable (affects TDD)

AID: strategies for addressing hyper- and hypoglycemia in pregnancy

	Postprandial Hyperglycemia		Hypoglycemic trend
	Settings	Strategies	
Smart Guard	Evaluate correction bolus through the CHO/INS Add a “fake” quantity of CHO at meal bolus Increase max bolus if needed	Anticipate bolus (10-15' in 1st trimester, 30'-45' in 2nd-3rd)	Temp Target 150 mg/dL
Control-IQ	Does not accept reduction of bolus <110 mg/dl Increase max bolus if needed Extended boluses (15 min-2 hrs)	Manual correction bolus e.g. 1-5 units no more than one every 2-3 hours with noCHO/INS, especially post-dinner and bedtime Anticipate bolus (10-15' in 1st trimester, 30'-45' in 2nd-3rd)	Exercise mode Target 140–160 mg/dL
DBLG1	Manual correction bolus with no CHO/INS	Anticipate bolus (10-15' in 1st trimester, 30'-45' in 2nd-3rd)	Emergency carbohydrates Sport mode, Zen mode Raised target for 1–8 hrs)
CamAPS Fx	Boost function (+35% algorithm-driven insulin delivery) if post-prandial blood glucose > 140 mg/dl after 1 h Evaluate correction bolus through the CHO/INS if blood glucose > 180 mg/dl	Use minimum glucose threshold and evaluate if not to enter glucose value to deliver bolus without reverse correction Anticipate bolus (10-15' in 1st trimester, 30'-45' in 2nd-3rd)	Ease-off mode (increases glucose target by +45 mg/dL)
SmartAdjust	Evaluate correction bolus through the CHO/INS Turn “Reverse Correction” OFF	Anticipate bolus (10-15' in 1st trimester, 30'-45' in 2nd-3rd) The lowest “Correct Above” threshold	Exercise mode Target 150 mg/dL

Conclusions: the aid of AID

- ✓ Advances in technology are transforming type 1 diabetes management, also in pregnancy.
- ✓ The landscape of AID has evolved rapidly over the past few decades into a range of refined algorithms and compact hardware options.
- ✓ 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.
- ✓ However, AID systems are not fully automated in that they still require basic diabetes management skills, including carbohydrate counting, and require the users to announce meals and exercise.

Therefore, for optimal use of diabetes technology, it is essential to improve the knowledge and skills of both healthcare professionals and users.





Team
"Diabete-Gravidanza e
Tecnologia"
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**Thanks
for listening!**

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