HHSC: Texas Diabetes Council
October 28, 2021

Texas Diabetes Council addresses issues affecting people with diabetes in Texas and advises the Texas Legislature on legislation that is needed to develop and maintain a statewide system of quality education services for all people with diabetes and health care professionals who offer diabetes treatment and education.

Governor Appointed Representatives

Name	Position	Term Expires*
Feyi Obamehinti, EdD – Chairperson	General public member with expertise or demonstrated commitment to diabetes issues	2023
Jason Ryan, JD – Secretary	Consumer member	2025
Aida "Letty" Moreno-Brown, RD, LD	General public member with expertise or demonstrated commitment to diabetes issues	2027
Ardis Reed, MPH, RD, LD, CDCES	Registered licensed dietitian with specialization in diabetes education	2023
Christine Wicke, PharmD	Consumer member	2025
Dirrell Jones, JD	General public member with expertise or demonstrated commitment to diabetes issues	2025
Felicia Fruia-Edge	Consumer member	2023
Gary Francis, MD, PhD	Licensed physician with specialization in diabetes treatment	2027
Maryanne Strobel, RN, MSN, CDCES	Registered nurse with specialization in diabetes education and training	2027
Ninfa Peña-Purcell, PhD	General public member with expertise or demonstrated commitment to diabetes issues	2027
Stephen Ponder, MD	Member with experience and training in public health policy	2025

Non-Voting State Agency Representatives

Name	Organization
Averi Mullins	Teacher Retirement System of Texas
Diana Kongevick	Employees Retirement System of Texas
Lisa Golden, MAEdHD	Texas Workforce Commission
Kelly Fegan-Bohm, MD, MPH, MA	Texas Department of State Health Services
Mitchel Abramsky, MD, MPH	Texas Health and Human Services Commission

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1. Welcome and Logistical Announcement. The quarterly meeting was convened by the Chair Feyi Obamehinti, EdD.

2. Introduction of New TDC Member. Averi Mullins was replaced by the Teacher Retirement System.

3. Roll Call. A quorum was present.

4. Consideration of July 22, 2021, Meeting Minutes The minutes were approved with one minor, nonsubstantive change.

5. 87th Texas Legislative Session Legislation Passed
We have one of the best times in Texas history for effective and targeted diabetes education as never before with the passing of some critical diabetes related bills by the 87th Legislature. A huge thank you to our Governor, Senators, Representatives, Doctors, Community Leaders that worked tirelessly to pass these bills. Here on the Council, I want to thank our Advocacy and Outreach Workgroup for their dedication and commitment to some of these bills: Jason Ryan, Veronica De La Garza, Dr. LaCivita (former Chair), and Dr. Sloan.

One of the ways to make our diabetes education here at the Council effective is sharing with everyone that could use this information. I have always felt that much of our work is not getting to the people that need them. Please take it upon yourself to share with local community organizations, places of worship, local clinics, medical entities- our physicians are doing their very best, yet there are lots of grounds to cover to ensure that everyone that needs the results of our work get them, know of the work and are able to utilize the work.

1. SB 827—Caps insulin copays. This bill caps insulin copays to $25 per prescription for a 30-day supply for those on state regulated plans and for state employee plans. Analysis of this bill: (a) Provides that this subchapter applies only to a health benefit plan (HBP) that provides benefits for medical or surgical expenses incurred as a result of a health condition, accident, or sickness, including an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or a small or large employer group contract or similar coverage document that is offered by certain organizations.(b) Provides that this subchapter applies to group health coverage made available by a school district in accordance with Section 22.004 (Group Health Benefits for School Employees), Education Code. (c) Provides that this subchapter, notwithstanding any provision in Chapter 1551 (Texas Employees Group Benefits Act), 1575 (Texas Public School

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Employees Group Benefits Program), 1579 (Texas School Employees Uniform Group Health Coverage), or 1601 (Uniform Insurance Benefits Act for Employees of The University of Texas System and The Texas A&M University System) or any other law, applies to certain coverage plans under those chapters. 1

2. HB 18—Prescription drug savings program. Establishes a program for Texans without health benefit plan coverage for a prescription drug benefit through which those individuals will be able to purchase prescription drugs at the post-rebate price.

3. HB 4—Tech-related health care services. Requires Medicaid and other public benefits programs recipients to have the option to receive services as telemedicine medical services, telehealth services, or otherwise using telecommunications or information technology (among other telehealth expansion efforts)

4. HB 133—Medicaid benefits postpartum. Continues postpartum coverage for pregnant women for 6 months.

5. HB 1935—Emergency insulin. Gives pharmacists the authority to dispense a 30-day emergency supply of insulin and insulin-related equipment and supplies if specific criteria are met.

6. HB 2509—Graduate medical education for podiatric medicine. Relates to measures to support or enhance graduate medical education for the practice of podiatric medicine in this state. UTRGV will house the first podiatry school in the state.

7. HB 3459—Prior authorization. Streamlines prior authorization requirements and removes barriers i.e. for certain services, if a physician earns insurer approval on 80% of preauthorization requests for the service in one calendar year, the doctor will be exempt from preauthorization for that service in the next calendar year. Secondly, the bill requires insurers' utilization reviews to be with a physician in the same or similar specialty as the patient's physician. This bill reduces health insurers red tape delays.

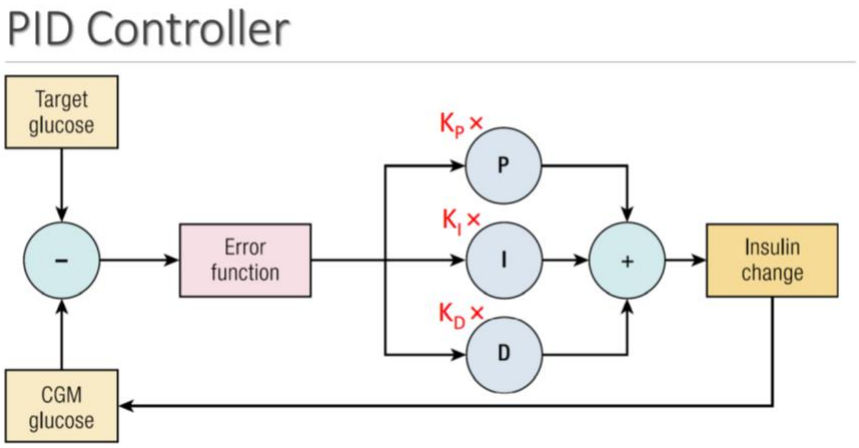
6. Advancements in Self-Directed Hybrid Closed Loop Insulin Pump Systems

(Automated Insulin Dosing) Rahan Lal

Rapid changes in diabetes technology have allowed for closed-loop control of insulin delivery. Every United States pump manufacturer now has an automated insulin dosing system available. Each

system relies on different rules (algorithms) to control the delivery of insulin. Some rely primarily on CGM while others use models to predict the future. The designers and/or regulators must balance the interests of glycemic control, safety, personalization, generalizability and adaptation.

Algorithm Basics

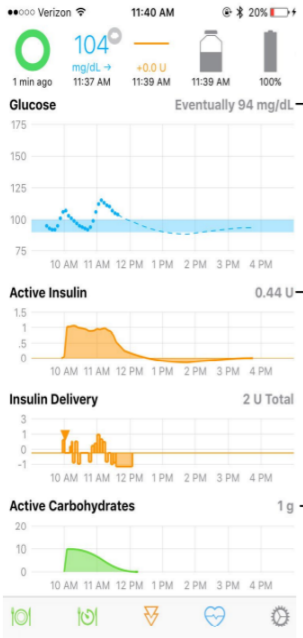


Fuzzy Logic (e.g. Mauseth 2013)

	BG Rate	VN			N			Z			P			VP		
	BG Acceleration	N	Z	P	N	Z	P	N	Z	P	N	Z	P	N	Z	P
BG Level	VVH	0.00	0.00	0.00	0.10	0.15	0.80	0.10	0.15	0.80	0.15	0.30	1.40	0.20	0.50	2.00
	VH	0.00	0.00	0.00	0.05	0.10	0.25	0.10	0.15	0.30	0.10	0.25	1.20	0.15	0.40	1.90
	H	0.00	0.00	0.00	0.00	0.05	0.10	0.05	0.10	0.25	0.10	0.15	1.00	0.10	0.35	1.80
	N	0.00	0.00	0.00	0.00	0.00	0.05	0.00	0.05	0.10	0.05	0.10	0.45	0.05	0.10	0.60
	L	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.05	0.00	0.00	0.05	0.05	0.05	0.10

FIG. 1. Insulin dosage calculation schemata (version 1.5). The fuzzy logic controller uses current glucose level, rate of change, and acceleration to calculate insulin dosage. This example shows that when the glucose level is normal (N) (red circle), the rate is zero (Z) (blue circle), and the acceleration is positive (P) (green circle), the dose is 0.10 units of insulin (black circle). All of the dosing rules are based on a 5-min glucose sample time. BG, blood glucose; H, high; L, low; N, negative (for rate and acceleration); VH, very high; VN, very negative; VVH, very, very high.

Predictive Control



Future Predicted Glucose =
Factors to improve prediction accuracy +

Active **Insulin** Effect on BG +

Active **Carbohydrate** Effect on BG +

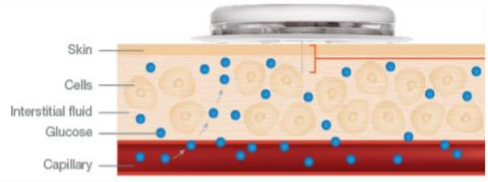
Commercial AID

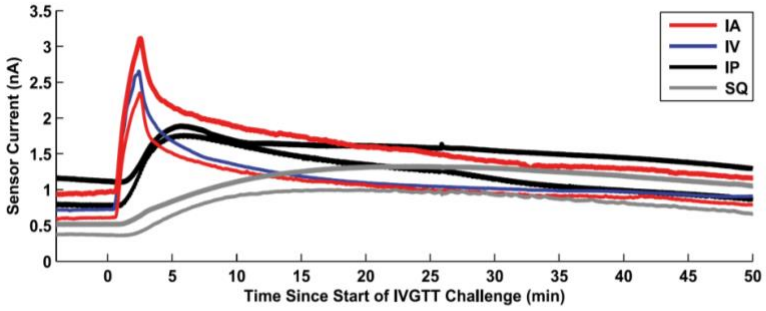
CGM

Available Sensors	Dexcom G6	Medtronic Guardian Connect	Abbott FreeStyle Libre 14 Day*	Senseonics Eversense*
How many parts does it have?	3: transmitter, sensor, and receiver	3: transmitter, sensor, and smartphone used as the receiver	2: sensor and receiver	3: transmitter, implantable sensor, and smartphone/ smartwatch used as the receiver
Does it offer alerts and alarms?	Yes, can be customized	Yes, can be customized	No	Yes, can be customized
How do I view data?	On a smartphone (Apple or Android), smartwatch, or the receiver	On an Apple smartphone	On a smartphone (Apple or Android) or on the receiver	On a smartphone (Apple or Android) or smartwatch
How do I share the data with family members?	Real-time data can be shared using an app	Real-time data can be shared using an app; family members can also receive text message alerts	Data from whenever you scan can be shared using an app	Real-time data can be shared using an app
How many fingersticks are needed to calibrate the sensor?	None	2 per day	None	2 per day
How long is the sensor used?	10 days	7 days	14 days	90 days
How does it attach to the body?	Sensor is inserted in 1 step, and integrated adhesive holds the sensor and transmitter in place	Sensor is inserted with the use of a Medtronic one-press insertion aid, then the sensor and transmitter are held in place by an outer adhesive	Sensor is inserted in 1 step, and integrated adhesive holds it in place	Sensor needs to be inserted by a doctor, nurse practitioner, or physician assistant, then the transmitter sits outside the body and is held in place by an adhesive

- Wire-based sensors rely on glucose oxidase
- Eliminating calibrations requires: (1) identical hardware manufacturing and (2) accurate data

Interstitial limits





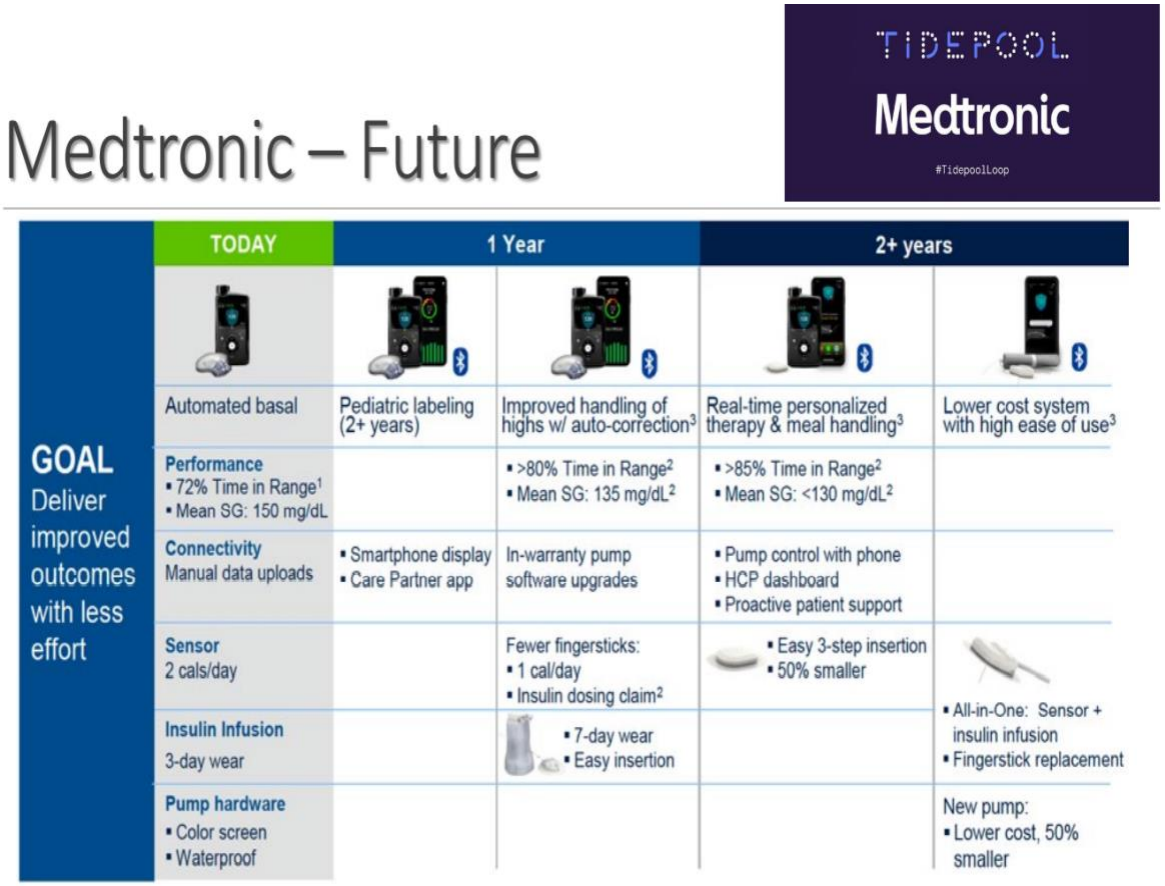
- Glucose sensing in the interstitial fluid smooths and delays the blood signal (Burnett 2014)
- More algorithms used to coerce the signal to make it look diabetes-like.

No Data = No Accuracy Penalty

USERS	REGULATORS	COMPANY
	• We want to make sure reported data is accurate. • But we do not enforce exactly how much needs to be reported.	• We are seeing data we do not trust. • If we report it we may adversely effect accuracy metrics.

Medtronic 670G/770G is a PID with an internal model of insulin-on-board received FDA approval in September 2016 ad is the first commercial “hybrid” closedloop device.

Medtronic 780G is a PID with an internal model of insulin-on-board some of the time is a licensed fuzzy logic from DreaMed but with mixed messages on how much it is used.



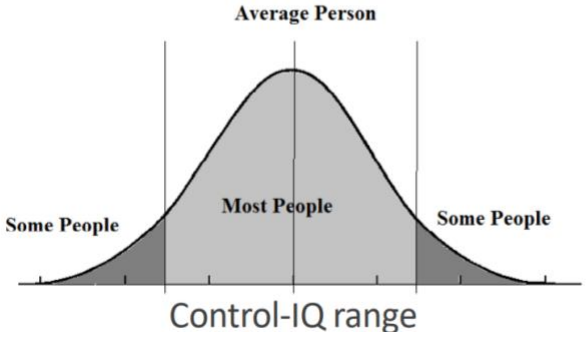
Medtronic Algorithm Questions

- Over what time frame do you perform derivative, integral? Longer could reduce error but also reduces responsiveness.
- How frequently do the KP, KI , KD get tuned (effects rate of adaptation)?
- When and how much fuzzy logic gets used for 780G? What is the basis for the logic?

Tandem Control-IQ™ received FDA approval in December 2019 and estimates glucose and insulin in the body using available pump data and compares it to an internal model.

Tandem Control-IQ™

- Basal modulation: The internal model uses parameters for basal, ICR and ISF that are derived from your total daily dose and **not** your profile settings.



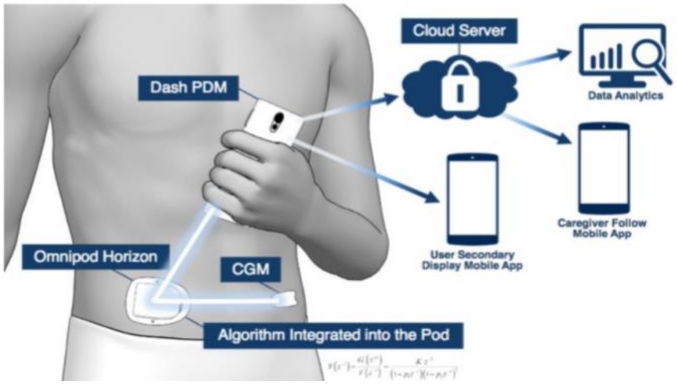
Who are "Some People"
Low/High Carb
*Honeymoon
Outside insulin/Afrezza
Very young/old
Organ dysfunction
Cystic Fibrosis
Other forms of diabetes (e.g. *T2DM, gestational)

Tandem Algorithm Questions

- What is the rate of adaptation?
- What equations govern inferred settings?
- Auto boluses are based on programmed ISF, but basal modulation based on inferred settings and capped by set basal. For most users is the bulk of automated insulin given by basal modulation or auto boluses?

Insulet

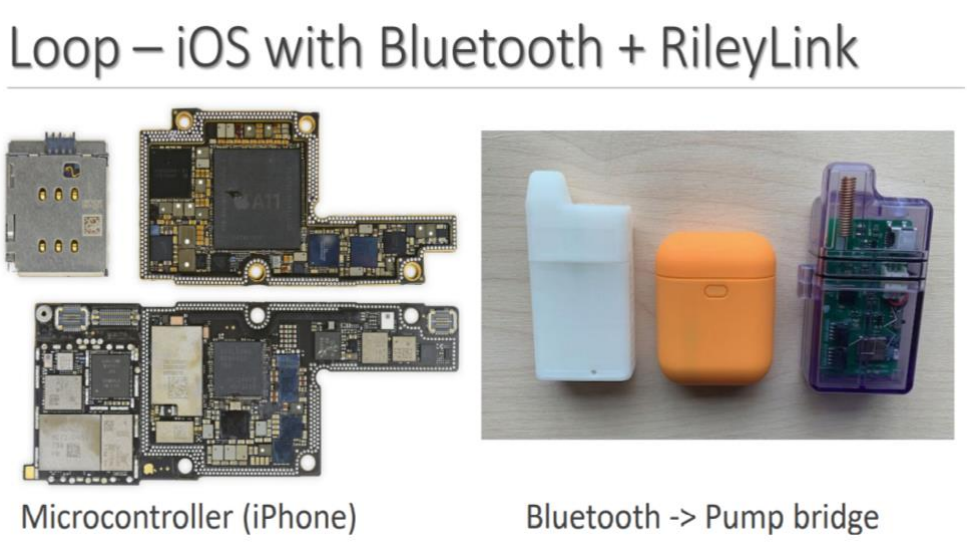
- Loop compatibility over 433MHz
- OmniPod 5 (submitted)
- First pump to support Tidepool Loop



Horizon Algorithm Questions

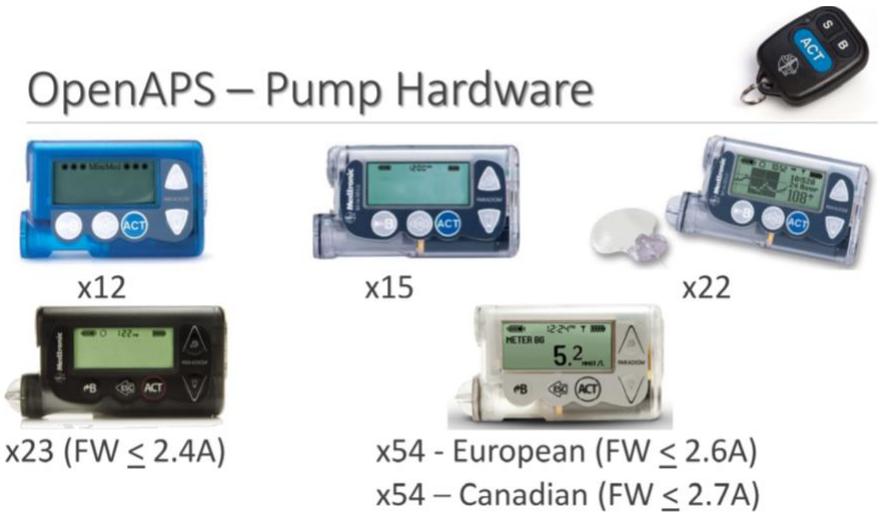
- What is the rate of adaptation?
- What equations govern inferred settings? What happens if initialized basal settings are way off?
- When to use Horizon algorithm versus Tidepool Loop?

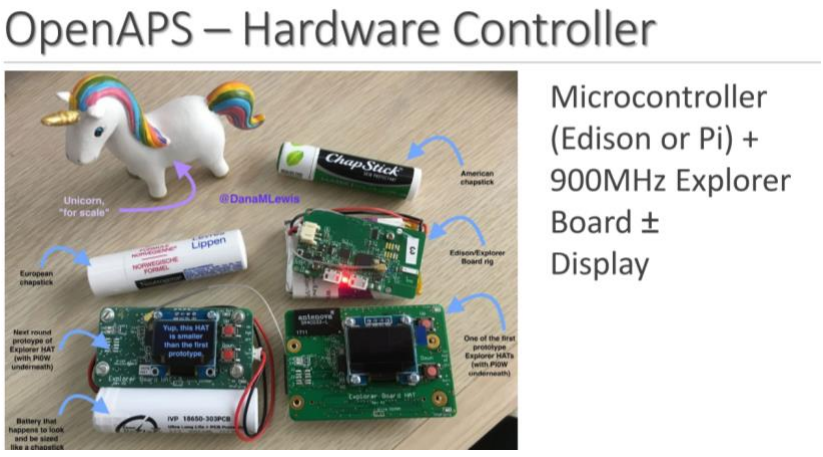
Open-Source AID



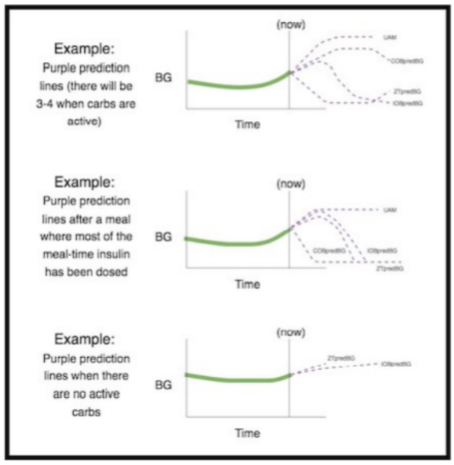
Loop – Where to go for help?

- https://loopkit.github.io/loopdocs/
- https://loop.zulipchat.com
- https://www.facebook.com/groups/TheLoopedGroup
- https://github.com/LoopKit/Loop
- https://getrileylink.org/





OpenAPS – Algorithm

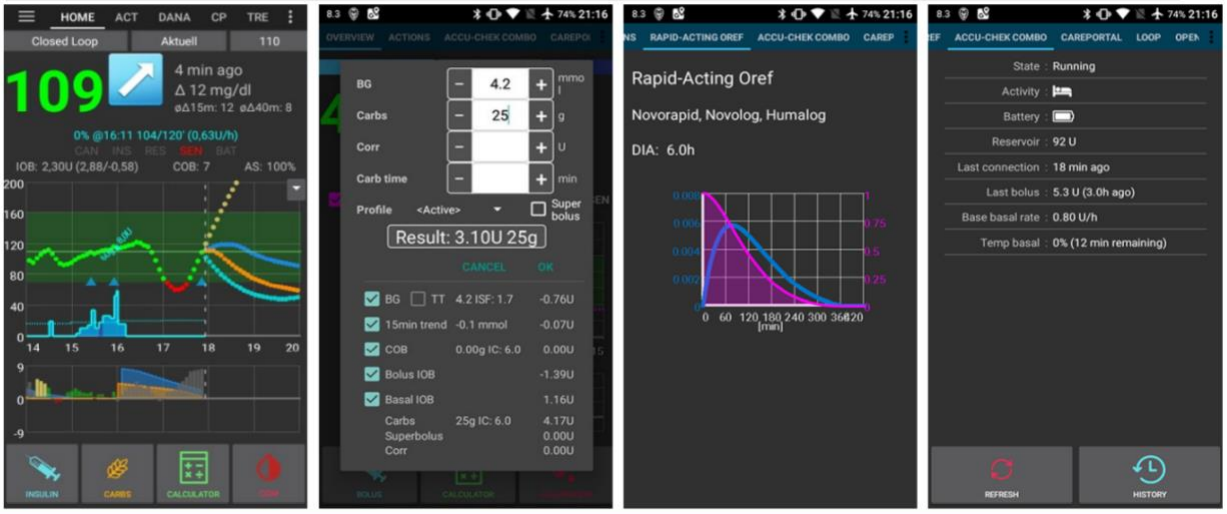


- Issue increasing/decreasing boluses every 5 minutes based on CGM data if glucose stable or rising. Once glucose falling IOB drops quickly, due to 0 basal, until BG stable or more insulin warranted.

OpenAPS – Where to go for help?

- https://openaps.readthedocs.io/en/latest/
- https://gitter.im/nightscout/intend-to-bolus
- https://gitter.im/openaps/autotune
- https://www.facebook.com/groups/TheLoopedGroup

AndroidAPS



AndroidAPS – Where to go for help?

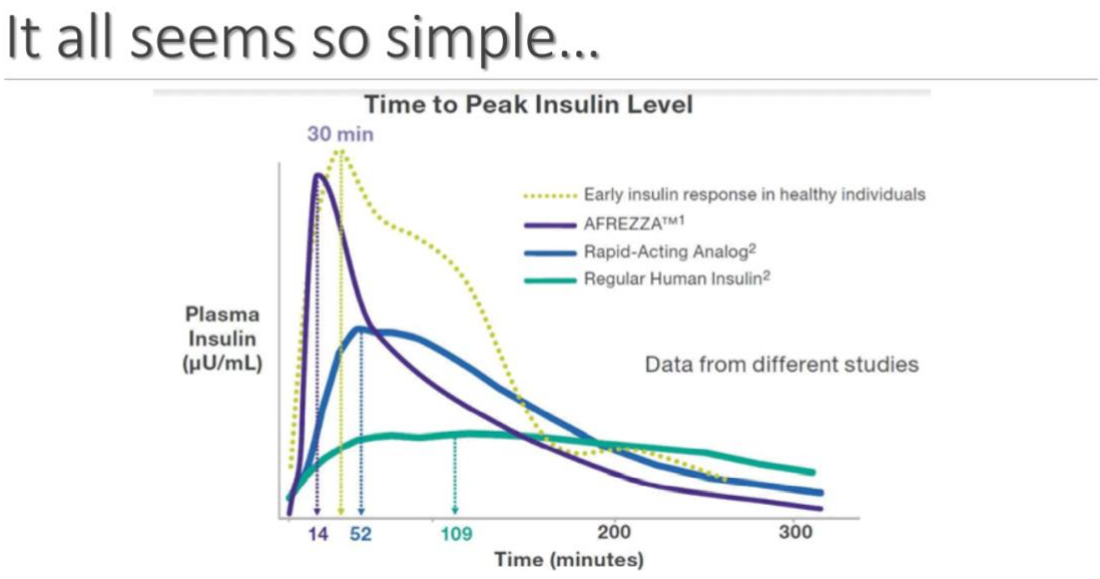
- https://androidaps.readthedocs.io/en/latest/EN/
- https://www.facebook.com/groups/1900195340201874/
- https://gitter.im/MilosKozak/AndroidAPS
- https://github.com/MilosKozak/AndroidAPS/issues
- developers@androidaps.org

When predictions are tough

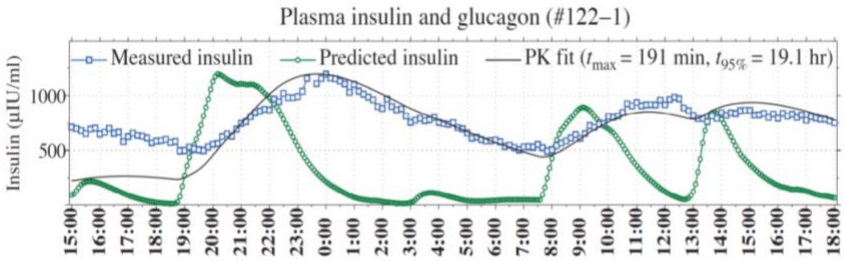
- Vicious circle: Initial β cell loss ◊ ↑ glucose ◊ oxidative stress ◊ Glucose toxicity ◊ ↓ β cell function ◊ 0 insulin state ◊ DKA
- When we start treatment with insulin, we remove the glucose toxicity and whatever β cells remain start producing some insulin again
- The amount of insulin produced is a function of the residual beta cell mass and secretory capacity (itself glucose dependent).

Endogenous insulin secretion

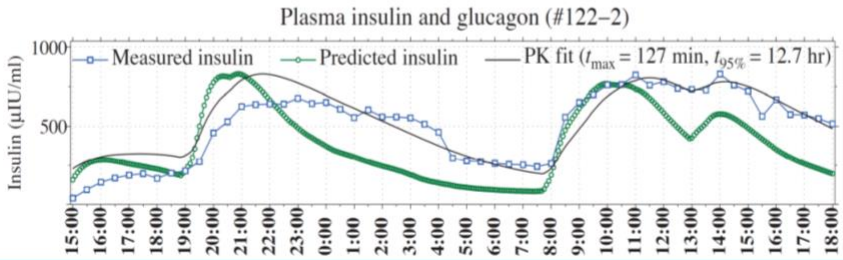
- Because the number of beta cells and their ability to secrete is in constant flux, it becomes challenging to model and treat.
- There is often adequate insulin secretion overnight when there is no food intake and low levels of counter regulatory hormones that increase glucose.
- Hard to compensate when you don't know about insulin.



The reality (El-Khatib 2010)



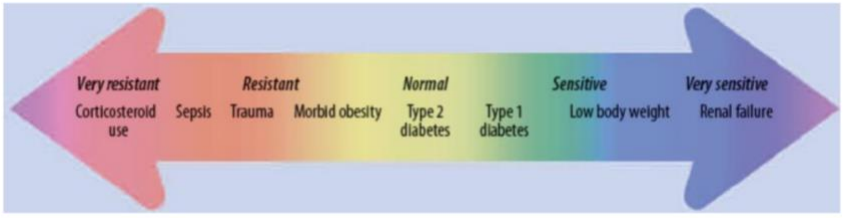
Fast Insulin Model



Slow Insulin Model

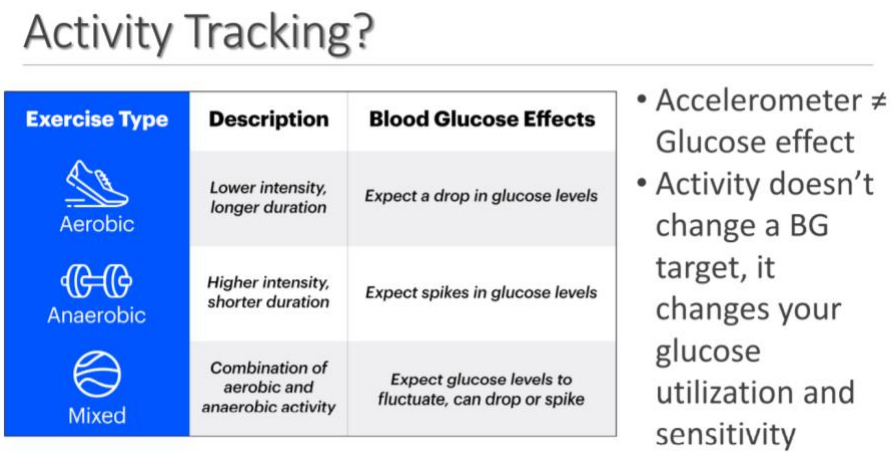
Insulin Sensitivity Factor (ISF)

$$\frac{1500}{TDD} \leftarrow \frac{1700}{TDD} \rightarrow \frac{1900}{TDD}$$



What can change your ISF?

- Age/Puberty
- Cortisol, Epinephrine, Growth Hormone, Testosterone, Estrogen, Glucagon
- Body composition
- Blood sugar
- Illness/Stress
- Medications
- Exercise



Goals

What are your goals?

- Setting the high score vs living your life without complications so you can do what you want
- The best controlled participant in DCCT was mid-70% time-in-range. The average TIR for people who did not develop retinopathy or microalbuminuria was 44 ± 15%.
- Tighter control when consuming a normal carbohydrate diet can come with weight gain, which can cause more cardiovascular risk than your blood sugars.

Conclusions

- More choices than ever
- Until we get the "perfect" system knowing how it functions is important
- Commercial systems often require difficult decisions by designers and regulators
- Open source systems offer unparalleled transparency and personalization

Questions/Answers/Comments

Time and Range statement how was the 44% reached? Also, there are so many options… do you have any opinion of how to prescribe these? Dosing for meals is still a problem. The speaker stated that the 44% time and range was an outcome measure and went back to the DCCT and during the trial people were doing 7-point glucose checks. They converted those checks back to time and ranges. There are only 4 or 5 independent values. Regarding the meal issue, the newer systems are still meeting time and range goals even if people do not enter their meals. We will get to the place where meal announcements are a thing the past. We must know how much the device contributes to the quality of life.

We have heard some things in the news about safety and the hacking of the Bluetooth technology in some devices. The speaker stated that the challenge is there was no security in place initially. The FDA has raised the issue of cyber security. It is unclear why they are concerned about the security issue. Bluetooth has an encryption component. The open source movement faces cyber security issues for sure.

7. Legislative Activities Overview and Guidance

TDC has two primary mechanisms for informing the legislature on designated topics — advising the legislature and the State Plan. It is recommended that TDC consult the DSHS staff assigned to support the council if it intends to use other avenues to advocate, educate, or advise the legislature or other governing entities. DSHS staff can then bring the issue to the DSHS program attorney to ensure the topic and activity is within the scope of statute. DSHS staff will also make sure that DSHS leadership and Government Affairs are updated on planned TDC legislative activities.

1. Advising the Legislature Statute allows the TDC to advise the legislature on legislation to further develop and maintain a statewide system of quality education services for persons with diabetes. Council members can comment or provide testimony on legislation; but it is recommended that when doing so Council members explain how the legislation affects persons with diabetes. When advising the legislature, it is important that members stay within the scope of Council duties under HSC, Chapter 103. Before TDC members engage in activities advising the legislature, the action should receive a favorable vote by TDC in a public meeting. Because DSHS, other state agencies, and their staff cannot lobby the legislature, a TDC member comment or testimony for or against proposed legislation cannot be presented as the official position of DSHS. Other than the required assistance in developing the TDC's legislative reports, DSHS staff cannot assist TDC with drafting materials that take a position on or propose legislation. The following table provides general guidance for TDC members' actions. Volunteer workgroup members cannot participate in these actions on behalf of TDC.

After an approving vote by the TDC, TDC members can do the following…

TDC Member Action	Allowed per DSHS Legal
Initiate contact with a legislator verbally or in writing	Yes
Provide testimony in a hearing for or against a bill	Yes, notify DSHS first
Advise a legislator to vote a certain way on a bill	Yes, notify DSHS first
Propose legislation	Yes, notify DSHS first
Send a letter from TDC to non-legislative elected officials (e.g. Governor, Attorney General)	Yes, consult with DSHS first

Relevant Statute: The TDC powers and duties under HEALTH AND SAFETY CODE CHAPTER 103. TEXAS DIABETES COUNCIL include:
(a) The council shall address contemporary issues affecting health promotion services in the state, including:
(1) professional and patient education;
(2) evidence-based diabetes self-management education strategies;
(3) evidence-based strategies to achieve the council's mission;
(4) state expenditures for the prevention, detection, management, and treatment of diabetes and obesity; and
(5) public awareness of the specific risks and benefits of prevention, detection, management, and treatment of diabetes, including obesity-dependent diabetes.

(b) The council shall advise the legislature on legislation that is needed to develop further and maintain a statewide system of quality education services for all persons with diabetes. The council may develop and submit legislation to the legislature or comment on pending legislation that affects persons with diabetes.

(c) The council may establish priorities and make recommendations for program expenditures that align with the council's mission.

(d) The council may engage in studies that it determines are necessary or suitable under the state plan as provided by this chapter.

2. State Plan Statute requires that the TDC submit a state plan for diabetes and obesity treatment and education to the Texas Legislature by November 1, each odd-numbered year.

Relevant statute: As required by HEALTH AND SAFETY CODE CHAPTER 103. TEXAS DIABETES COUNCIL103.013:
(a) The council shall develop and implement a state plan for diabetes treatment, education, and training to ensure that:
(1) this chapter is properly implemented by the agencies affected;
(2) incentives are offered for private sources to maintain present commitments and to assist in developing new programs; and
(3) a procedure for review of individual complaints about services provided under this chapter is implemented.

(b) The state plan may include provisions to ensure that:

(1) individual and family needs are assessed statewide, and all available resources are coordinated to meet those needs; and

(2) health care provider needs are assessed statewide, and strategies are developed to meet those needs.

(c)(b-1) The state plan may include provisions to address obesity treatment, education, and training related to:

(1) obesity-dependent diabetes; and

(2) the health impacts of obesity on a person with diabetes.

(d) The council shall make written recommendations for performing its duties under this chapter to the executive commissioner and the legislature. If the council considers a recommendation that will affect an agency not represented on the council, the council shall seek the advice and assistance of the agency before taking action on the recommendation. The council's recommendations shall be implemented by the agencies affected by the recommendations.

Questions/Answers/Comments

We cannot advise when we make contacts with legislators, is that correct. Every contact should be run through DSHS legal before contact is made. The actions on behalf of the Council would have to

be voted on by the Council in advance. You can still reach out to the legislators in an individual / personal capacity is allowed.

The chair stated that each council member is a professional and can advocate personally but not on the council as a whole unless authorized by the council.

8. Updates from State Agency Representatives.

DSHS—2021 Assessment of Programs and State Plan are routing internally for sending to the Legislature December 1.

ERS—State employee activities have become fairly robust. The wellness program is contemporary using walk and talk podcasts. There was a state employment wellness fair.

HHSC—New benefits for glucose monitoring benefit went into effect and the draft policy had been posted in May. The response to the public comments is under review.

TRS—a new member is present from the agency. Type 2 Diabetes Reversal Treatment - Virta Health, a diabetes health and management program. The goal is to reverse diabetes effect through Keto Diet. They take over the prescription authority of the physician, reducing the amount of insulin needed. There have been positive results from the program including a 27% medication reduction.

A question was asked about the metrics used. The primary tool of measurement is reduction in pharmacy utilization. The program looks at A1C reduction. There has been a 6.9% reduction which is higher than the Virta target goal. An estimate is used and not a lab test. To be part of the program you have to be ready to make changes.

Of the people recruited, were they free range people with diabetes? Diabetes is a progressive condition so ”reversal” can be confusing and what is really occurring is glucose management. TRS stated it was a hodge podge of people. There was no cherry picking other than they had to be on insulin.

With the Keto diet, do the people get their own food? TRS answered in the affirmative. The food must be purchased.

The Chair asked how public awareness was being managed. TRS stated that only individuals who were within the target group know about the program (10,000 members). The goal is to have 200 people enrolled in the program.

TWC—The biggest thing has been a restructuring of the independent living program who are visually impaired (including vision loss resulting from diabetes). We are reaching out to providers and individuals to make them aware of this service. Making technology available for people with visual problems should be included in the diabetes devices.

9. Announcements. There are two workgroups that are the legs of the council. The workgroup meetings are on hold pending the new meeting format.

10.Public Comment.

Dr. Fernard Pattel, Abbott Diabetes Care commented on CGM devices and that these improve glycemic control and save money for the Medicaid program. There are inequities in use of the devices especially with the African American community and this was exacerbated by the COVID 19 pandemic. Coverage and patient choice are issues impacting disparities. A shared decision making approach is essential for device selection. He asked for the ability to address the council on these issues.

Deb Keller, Mother of a type one diabetic stated the council's work saved the life of her son. She related her personal story. She stated that there is a need for a 90 day supply being distributed by the 28th of the month. Some devices are not available timely. Use of nasal Glucagon would be appreciated. (See Glucagon (medication) - Wikipedia)

11. Date and Topics for Next Meeting. Because of limited meeting space, alternative dates had to be explored. Hybrid format will be continued:

- Thursday, January 13, 2022
- Thursday, April 14, 2022
- Thursday, July 14, 2022
- Thursday, October 13, 2022

The proposed dates were approved

The Topic for the next meeting will be disparities on CGM devices and diabetes outcomes.

November is National Diabetes Month and activities
HB4 Tech Related Healthcare Services speaker/discussion (Telehealth in particular)

12. Adjourn. There being no further business the meeting was adjourned.

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