Type 1 Diabetes

Winning with Bernstein Ages 5 to 18

Lester Hightower

LowCarbUSA Symposium for Metabolic Health Boca Raton, Florida, January 12, 2024



About Me

- Technology entrepreneur, mostly focused on freight transportation.
- Bachelor's degree in Economics from Florida State University.
- Founding board member of the nonprofit Rivere Foundation, that promotes low-carb and high-protein dieting for improved diabetes management (D.B.A. "Let Me Be 83").

"Let Me Be 83" is a plea for normal blood sugars (83 mg/dL).

About This Talk

In some ways, this talk is a "five year follow up" to a presentation that I gave in 2019 at the Children with Diabetes Friends for Life Conference in Orlando.

That 2019 presentation was similar but different, and it can be viewed at *https://lesterhightower.com/diabetes/CWDFFL_2019_Orlando*.







My Connection to Type 1 Diabetes is Andrew His diagnosis came in June of 2010, a few weeks after his 5th birthday.

Summer before kindergarten Height: 3' 6" Weight: 39 lbs



College freshman, academic scholarship Height: 6' 4.5" Weight: 190 lbs

Andrew's Journey with T1D and His A1c Values



Andrew's Glycemic Control vs USA Prevailing

Andrew had 43 HbA1c tests from Nov-2010 to Dec-2023.

Their average is **5%** ± 0.23 (4.77% - 5.23%).

Compare 5% to T1D prevailing outcomes in the USA, shown in the graph to the right that was published in February of 2019.

Andrew's average A1c of 5% would be about here



https://www.liebertpub.com/doi/full/10.1089/dia.2018.0384

Andrew's Glycemic Control vs USA Prevailing

	A1C Chart based on DCCT formula											
		1	Diabete	s Contre	ol and C	omplica	tions Tr	ial (DCC	T);			
			eA	G in mg	/dL = (3	5.6 x Hb	oA1c) - 7	7.3 or				
eAG in mmol/l = (1.98 x HbA1c) – 4.29.												
A1C	4.0	A 10	drouv?o	121.00				4.7	4.8	4.9	5.0	5.1
mg/dl	65	An	arews	13 ∓ ye	ar aver	age (± 1	std dev)	90	93	97	101	104
mmol/l	3.6	3.8	4.0	4.2	4.4	4.6	4.8	5.0	5.2	5.4	5.6	5.8
A1C	5.2	5.3	5.4	5.5	5.6	5.7	5.8	5.9	6.0	6.1	6.2	6.3
mg/dl	108	111	115	118	122	126	129	133	136	140	143	147
mmol/l	6.0	6.2	6.4	6.6	6.8	7.0	7.2	7.4	7.6	7.8	8.0	8.2
A1C	6.4	6.5	6.6	6.7	6.8	6.9	7.0	7.1	7.2	7.3	7.4	7.5
mg/dl	151	154	158	161	165	168	172	176	180	183	186	190
mmol/l	8.4	8.6	8.8	9.0	0.2	0.4	0.6	<mark>- 9</mark> 8	10.0	10.2	10.4	10.6
A1C	7.6	7.7	7.8	7.9	8.0	8.5	9.0	9 <mark>5</mark>	Broy	ailing	Outoo	maa
mg/dl	193	197	200	204	207	225	243	2 1	Prev	annig	Juico	mes
mmol/l	10.8	11.0	11.2	11.4	11.0	12.0	19.9	14. 5	15.5	17.5	19.5	21.5
Super Op	otimal	Opti	Optimal Normal Pre Diabetes Diabetes Dangerous				us					

The Repercussions of Poor Blood Glucose Control



Volume 43, Issue 4
Publications
April 2020

CARDIOVASCULAR AND METABOLIC RISK | FEBRUARY 13 2020

Impact of Glucose Level on Micro- and Macrovascular Disease in the General Population: A Mendelian Randomization Study

Hazard ratios for various diabetes complications for A1c levels above the comparator of 4.6%

Micro- and Macrovascular Disease	5.1%	5.7%	6.5%	9.0%
Retinopathy	1.92x	5.02x	12.73x	75.4x
Peripheral neuropathy	1.19x	1.40x	2.48x	5.41x
Diabetic nephropathy	1.92x	5.19x	11.57x	47.7x
Peripheral artery disease	1.03x	1.11x	1.33x	2.23x
Myocardial infarction	1.06x	1.21x	1.40x	1.87x
Andrew —			l	

1. <u>https://lesterhightower.com/diabetes/HazardRatios_202004_ADA_paper.html</u>

2. <u>https://diabetesjournals.org/care/article/43/4/894/35826/Impact-of-Glucose-Level-on-Micro-and-Macrovascular</u>

Prevailing outcomes

Andrew is not constantly fixated on blood sugars...

FORTEGRA CSI

ORTEGRA CSI



ANDREW HIGHTOWER FINISHED 18TH IN NORTHEAST FLORIDA IN REBOUNDING WITH 8.5 REBOUNDS PER GAME. *ACCORDING TO THE TIMES UNION



2023 All Academic Team

At college, he plays 3-4 hours of basketball, 5-6 days per week.

FORTEGE

GRA' CSI

Florida State University

FACA ACADEMIC

ALL-STATE 2A

ANDREW

5 PARTANUI



Andrew Hightower Major: Sports Management

Andrew's day-to-day diabetes management tools





Notice that technology is not key to Andrew's success...

Diabetes technology is not improving outcomes...





The Key to Success: Dr. B's Diabetes Solution Easily, "the best \$20 I have ever spent!"



Takeaways

T1D prevailing outcomes are bad and they are getting worse, despite diabetes related technology advances and uptake.

• Vastly better outcomes are possible.

A low-carb & high-protein diet is the key.

A Summary of Dr. Bernstein's Diabetes Management Regimen

and

How We Apply It Day-to-Day

High-Level Overview of Dr. Bernstein's Regimen

The Laws of Small Numbers

"Big inputs make big mistakes; small inputs make small mistakes."





Low-carb, high-protein diet

- Carbohydrate has a limit.
- Protein has a goal.
- Fat is along for the ride.

Properly using insulins

- Using the correct insulins.
- Proper dosing and timing.

Precisely correcting lows

- Using measured glucose doses.
- Not over-correcting.

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An Example of Daily Carbohydrate & Protein Intake

Two random November 2018 days for Andrew averaged as follows:

Grams
30.5
258



This slide is directly from my 2019 CWD FFL presentation. In November of 2018, Andrew was 13 years old and in the 7th grade.

How Much Protein?

Dr. Bernstein Recommends (daily):

- A minimum of 1.2 g/kg of body weight for sedentary adults.
- Two to five times that amount (2-6 g/kg) for active, growing children.

Andrew's hunger guides his protein consumption

When younger and living at home, Andrew would ask to adjust his protein portions up and down as his hunger guided. Living on his own now, he does that himself.

Andrew exercises a lot (mostly basketball) and he burns a lot of calories, and therefore usually eats large meals (a lot of protein and calories). If his exercise is limited for a few days, he will shrink the size of his meals.

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Properly Using Insulins

Using the correct insulins - for a low-carb, high-protein diet, Regular has the best profile of action. **Proper dosing and timing** - experimentally determine correct dose and timing, per meal, per time of day.





Richard K. Bernstein, MD

On the right bolus insulin for low carb meals

"If you are on a low carb diet, the timing of Regular (e.g. Humulin-R) insulin is just the timing you need."

(1) R insulin matches the glucose load of low carb, protein meals.
(2) Ultrarapid insulin peak is too fast and too sharp to match low carb,



High-Level Overview of Dr. Bernstein's Regimen

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Precisely Correcting Low Blood Sugars

Glucose does not need to be digested or converted by the liver into anything else. It is absorbed directly through the mucous membranes of the stomach and gut.

Measured amounts of *pure glucose* to raise blood sugar *rapidly* and *precisely*.



TABLE 20-1Just a starting point. Individuals will vary.EFFECT OF 1 GRAM GLUCOSE UPON LOW BLOOD SUGAR

Body wei	ght	1 gram glucos	se will raise low blood sugar	
35 pounds	16 kilograms	20 mg/dl	1.11 mmol/l	
70	32	10	0.56	
105	48	7	0.39	NATIONAL BESTSELLER "Dr. Rennem is a true pioneer in developing practical approaches to controlling a devastating disease that is growing as epidemic proportions in this country."
140	64	5	0.28	Dr. Bernstein's
175	80	4	0.22	DIABETES
210	95	3.3	0.18	SOLUTION
245	111	3	0.17	A COMPLETE GUIDE TO ACHIEVING NORMAL
280	128	2.5	0.14	BLOOD SUGARS
315	143	2.2	0.12	NEWLY REVISED
				Richard K. Bernstein, MD

Q: Why Manage T1D This Way?

A: ✓ Safety, ✓ Quality of Life, and ✓ There is No Deprivation.

Why Manage T1D This Way?

Short-Term Safety

- High-carb foods require large doses of highly potent, ultra-rapid insulins.
- It is impossible to dependably match high-carb foods and ultra-rapid insulins.
- Instead, Andrew has "slower lows" and "lower highs" which are much safer.

Long-Term Safety

- Dr. Bernstein's dehydrating illness protocol (chapter 21) leads to dramatically fewer diabetes-related hospitalizations. Typical rates are high. <u>http://wrap.warwick.ac.uk/49876/</u>
- The commonly occuring, long-term complications of diabetes come from chronic, abnormally high blood sugar levels.

Why Manage T1D This Way?

Quality of Life

- Far less fear of diabetes due to the enhanced safety.
- Having "slower lows" and "lower highs" means that diabetes igodolcommands less constant attention.
- Becoming the "captain of your own ship" through the mastery of diabetes management is hugely rewarding.

There is No Deprivation

- Most foods that we eat are from the outer perimeters of grocery stores, and we eat phenomenally well.
- We gladly trade highly processed convenience foods for enhanced safety and quality of life.







Growing Kids, Protein, and Insulin and the

Related Tragedy of Novo Nordisk's Decision to Discontinue Levemir

Growing kids need a lot of protein



Between two endo visits (12/10/2018 and 02/13/2019), Andrew grew 2 cm (0.8 in) in 65 days.

Growing kids need insulin, an anabolic hormone

- Weekly average total daily doses (TDD) of insulin and A1c, since T1D dx.
- Andrew's TDD peaks exceed 160 IU per day and 1.8 IU/kg of body weight.



Insulin and Glucose/Glycogen Metabolism

Insulin causes glucose to go to one of three places:

- 1. to cells for immediate energy needs,
- 2. to the liver or muscles to restock any depleted glycogen reserves, or
- 3. to fat cells for long term storage.

Glucose is stored in the liver and muscles in a form called glycogen, an energy reserve that can be quickly mobilized for sudden glucose needs.

Muscle glycogen is converted into glucose by muscle cells, for their own use during strenuous exercise.

The liver converts its glycogen to glucose for use throughout the body.

Insulin and Glucose/Glycogen Metabolism

The liver should convert its stored glycogen to glucose only as the body needs.

Unfortunately for type 1 diabetics, this is how that process works:

- 1. The pancreas monitors blood glucose and releases insulin when high, and
- 2. the liver monitors insulin levels and converts glycogen to glucose when low.

And so, the inability to produce insulin is a double whammy:

- 1. Glucose from ingested carbohydrates cannot be taken up by the body, and
- 2. the liver constantly adds glucose from glycogen to the body, due to insulin levels constantly being at or near zero.

The purpose of basal insulin is to prevent the liver from constantly adding glucose to the body from glycogen, with the goal of holding blood sugar flat.

Multiple Daily Injection (MDI) Insulin Regimen

Common medical thinking assumes an essentially flat, 24-hour basal need, as shown in this diagram that is highly representative of the literature on the topic.

This depiction shows a 5-shot per day MDI regimen consisting of two basal doses and three meal boluses.

Depiction of a flat basal need.



Multiple Daily Injection (MDI) Insulin Regimen

The reality of basal needs is often very different than flat, particularly for growing kids. The green in this depiction shows Andrew's basal insulin requirements: Three doses of Levemir given at 7:00am, 9:45pm, and 2:00am each day.



Bifurcation of AM and PM Basal Insulin Doses

It is common for growing children to have highly bifurcated basal needs during the daytime versus overnight, likely due to overnight growth hormone release.

Daytime	Levemir Doses	09/30/2017 (12 yo)	09/26/2019 (14yo)	10/02/2021 (16yo)	09/16/2023 (18yo)
L	07:00 AM	6.5 IU	14.5 IU	20 IU	19 IU
night ∫	09:45 PM	36.5 IU	49 IU	6 IU	31 IU
Over	02:00 AM	7 IU	15.5 IU	36 IU	13 IU
	TDD of Levemir	50 IU	79 IU	62 IU	63 IU
	Overnight %	87%	82%	67%	70%

Examples of Andrew's basal dose bifurcation from ages 12 to 18

Novo Nordisk's Discontinuation of Levemir

Insulin detemir is sold exclusively by Novo Nordisk and under the brand name Levemir.

Discontinuation Notice

Please be aware that Novo Nordisk will be discontinuing Levemir® in the U.S.

- Supply disruptions of Levemir[®] FlexPen[®] are expected in mid-January 2024
- Levemir® FlexPen® will be discontinued on April 1, 2024
- Levemir[®] vial will be discontinued on December 31, 2024



Please speak with your healthcare provider about treatment options to determine the best course of action.

If you have any questions, please contact your healthcare provider or call the Novo Nordisk Customer Care Center at 800-727-6500.



https://www.mynovoinsulin.com/insulin-products/levemir/home.html

https://www.change.org/p/urge-novo-nordisk-to-continue-producing-and-supplying-insulin-detemir-levemir

November 8, 2023



Novo Nordisk's Discontinuation of Levemir A Big Problem for Children with Type 1 Diabetes

Basal insulin choices today:

- Glargine (Lantus/Sanofi, Basaglar+Rezvoglar/Eli Lilly, Semglee/Mylan Pharmaceuticals)
- Detemir (Levemir/Novo Nordisk) ← being discontinued
- Degludec (Tresiba/Novo Nordisk)

Insulin	Action Time	Half-life	
Glargine	12 - 24 hours	24 hours	
Detemir	8 - 16 hours	7 hours	← being discontinued
Degludec	up to 42 hours	25 hours	

Only detemir (Levemir) can accommodate the extreme daytime versus nighttime bifurcation of basal insulin needs that growing children commonly have.

Levemir is the only basal insulin that can be diluted for infants and toddlers.

- These action-times differ somewhat from those published by the manufacturers, but they are far more accurate based-on real-world, patient experiences.
- https://my.clevelandclinic.org/health/drugs/13902-injectable-insulin-medications
- <u>https://www.drugs.com/compare/levemir-vs-tresiba</u>
 <u>https://www.drugs.com/compare/levemir-vs-lantus</u>

Novo Nordisk's Discontinuation of Levemir A Problem for All People with Type 1 Diabetes

To achieve their long-action times:

- Glargine crystallizes under the skin when injected.
- Detemir and Degludec remain in solution and bind to albumin.

Due to its method of action, Glargine has an acidic pH and stings when injected.

If Glargine is accidentally injected into a vein or capillary instead of fatty tissue, it does not crystallize as designed and instead delivers a highly dangerous rapid-acting insulin effect. The powers that be play down this problem, but patients know it all too well. Internet search for terms like "Lantus low" and "Lantus ambulance" to see for yourself.

Detemir and Degludec do not pose a danger similar to the Lantus low.

Novo Nordisk's Discontinuation of Levemir The "Lantus low" is described by Sanofi themselves!

From page 45 of Sanofi's Lantus Product Monograph, ATC code A10AE04.

Hypoglycemia can result from injection directly into a blood vessel ... followed by hyperglycemia since there was no Lantus deposition for long-term absorption.

And another problem...

The Glargine/Lantus coefficient of variation is inferior to Levemir's, which is yet another problem with the discontinuation of detemir.



The WHO Lists Detemir as an Essential Medicine

WHO Model List of Essential Medicines – 23rd List (2023) 18.5 Medicines for diabetes 18.5.1 Insulins insulin injection (soluble)* Injection: 40 IU/mL in 10 mL vial; 100 IU/mL in 10 mL vial; 100 IU/mL in 3 mL cartridge or pre-filled pen. *including quality-assured biosimilars Injection: 40 IU/mL in 10 mL vial; 100 IU/mL in 10 mL vial; intermediate-acting insulin* 100 IU/mL in 3 mL cartridge or pre-filled pen (as compound *including quality-assured biosimilars insulin zinc suspension or isophane insulin). The selection and use of essential medicines □ long-acting insulin analogues* World Health Organization Therapeutic alternatives: Model List of Essential Medicines Injection: 100 IU/mL in 3 mL cartridge or pre-filled pen. - insulin degludec - insulin detemir - insulin glargine *including quality-assured biosimilars

From page 47

https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.02 https://iris.who.int/bitstream/handle/10665/371090/WHO-MHP-HPS-EML-2023.02-eng.pdf

Web Annex A

23rd list

World Health Organization

Please Help Change Novo Nordisk's Decision

- Alison Smart is leading a campaign to try to change Novo Nordisk's decision to discontinue Levemir.
- Alison is in the audience today and has some flyers available with details.
- You can contact Alison at <u>insulinoptions@gmail.com</u>.
- You can sign a petition at <u>https://chng.it/XNqsFZVZVR</u>.
- Please take a flyer and then reach out to your political representatives and mail or email letters to tell them why Levemir (detemir) is important to you and/or to the diabetes community at large.



Middle Schooler



In 2018, Andrew spoke to a N.Y. Times reporter...

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The New York Times

How a Low-Carb Diet Might Aid People With Type 1 Diabetes

By Anahad O'Connor May 7, 2018

Like many children, Andrew Hightower, 13, likes pizza, sandwiches and dessert.

But Andrew has Type 1 diabetes, and six years ago, in order to control his blood sugar levels, his parents put him on a low-carbohydrate, high-protein diet. His mother makes him recipes with diabetic-friendly ingredients that won't spike his blood sugar, like pizza with a low-carb, almond-flour crust; homemade bread with walnut flour instead of white flour; and yogurt topped with blueberries, raspberries and nuts.



"I do this so that I can be healthy," Andrew, who lives with his parents in Jacksonville, Fla., said of his diet. "When I eventually move out and go to college, I'm going to keep up what I'm doing because I'm on the right path."

https://www.nytimes.com/2018/05/07/well/live/low-carb-diet-type-1-diabetes.html



Management of Type 1 Diabetes With a Very Low-Carbohydrate Diet Belinda S. Lennerz, Anna Barton, Richard K. Bernstein, R. David Dikeman, Carrie Diulus, Sarah Hallberg, Erinn T. Rhodes, Cara B. Ebbeling, Eric C. Westman, William S. Yancy Jr and David S. Ludwig Pediatrics 2018;141;



Andrew was in 7th grade.

In 2019, at CWD FFL, I addressed these questions

What if Andrew hates you...? What if he rebels...?

- 1. The DCCT showed benefit from tight glucose control, even decades after the study ended.
- 2. If he rebels, he wasn't harmed on my watch.
- 3. He'll leave my care knowing the consequences of poor glucose control and how to avoid them.

In short, this is really just parenting with higher stakes, at least where Andrew's physical wellbeing is concerned, and I have faith in Proverbs 22:6 -*"Train up a child in the way he should go and even when he is old he will not depart from it."*



In 2024, here with all of you, I share an update...

...on Andrew's first semester away at college.



Breakfasts

Andrew sometimes texts photos to me ... of meals that he prepares for himself in his apartment.



Dinners

Andrew sometimes texts photos to me ... of meals that he prepares for himself in his apartment.



And he had a few challenges... Like this ankle injury that occurred while playing basketball:



But overall, Andrew did really well for his first time living away from home, he made good grades, and his mom and I are proud of him.

Andrew's endocrinologist's perception...

- Andrew's endocrinologist is a nice man and a good doctor who is supportive, but he equates success with effort and he therefore perceives that insanely hard work is being done for Andrew to obtain near-to-normal blood sugars.
- Knowing the prevailing outcomes that he sees every day, it is easy to understand how this doctor would assume that we have a constant fixation on blood glucose management, despite that not being true.
- Leading up to college, this doctor pressed hard for Andrew to move to a closed loop insulin pump system because "he can't do for himself what you do as his parents." Now, he pitches closed loop insulin pumps to "reduce the burden on Andrew."
- The truth is that managing type 1 diabetes is hard, no matter the management regimen that is followed, but Andrew's "hard" avoids most of the chaos that typical T1D management entails and has the tremendous upside of truly winning!

I am here today because...



- Andrew's style of T1D management is unconventional, and we have almost always faced pushback from his medical teams.
- But it works and he is not alone!
- At some point, practical evidence of success should overcome dogma, and thus I share Andrew's story.

Conventional T1D Management

A parent/caregiver quide

Carbohydrate Counting for Children with Diabetes

Answers That Matter

Sponsored by...

How Many Carbs Does Your Child Need to Eat?

Your registered dietitian (RD) can help you decide how many carbs your child needs. The amount depends on your child's age, gender and activity level. Each child has different needs. The carb amounts in the table below are general examples. If your child is physically active, he or she may need more carbs.

Boys	<5 years	5-12 years	Teens
	30 to 45 grams of	45 to 60 grams of carbs at	60 to 75+ grams of carbs at
	carbs at each meal	each meal	each meal
Girls	30 to 45 grams of carbs at each meal	45 to 60 grams of carbs at each meal	45 to 75 grams of carbs at each meal

Snacks, if needed, are usually 15 to 30 grams of carbs.

Talk to your RD or healthcare provider to help you decide on the amount of carbs that is right for your child at each meal and snack.

Sample of an approximate 45 gram carb meal:

1/2 cup mashed potatoes

1/2 cup canned peaches

- 1 cup skim milk†
- + Children younger than 2 years old should drink whole milk.

Add these to complete the meal: 2–3 ounces of chicken

1 green salad

1-2 tablespoons of dressing

Teen Boys Need 225g+ Carbs/Day!

Diabetes, care and Education (DCE), a dietetic practice group of the Academy of Nutrition and Dietetics, promotes quality diabetes care ind education. DCE is comprised of members of the Academy of Utrition and Dietetics who are leaders in the field of medical prirition therapy (MNT) and care of people with diabetes. Their expertise is widely recognized throughout the diabetes community. We are pleased to have had the opportunity to collaborate with this group of professionals on the creation of Lilly's Carbohydrate Counting for Children with Diabetes.

We hope you find it a valuable resource.



https://drive.google.com/file/d/1pQYcrMUm-3cP18L3cXx6lytrmpViXfVi/view?usp=sharing

Conventional T1D Management Needs to Change

• Prevailing outcomes show that conventional T1D management does not work.



- Prevailing outcomes are getting worse over time.
- Technology worship is rampant in T1D, but tech is not improving things.
- Harm is being done, including to children, and we can do much better.
- The tiny minority who find and follow Dr. Bernstein's approach are often unsupported (at best) and are frequently frightened, threatened, or worse.

Some Lost Wisdom of the Past



"Successful treatment of diabetes with insulin depends on the utilization of all those measures that have proved of the greatest value in the treatment of diabetes without insulin. These are: adherence to a diet which will keep the urine sugar-free; avoidance of over nutrition or extreme undernutrition, and a method of life compatible with the strength such a diet affords."

"Insulin does not cure diabetes. Insulin does not allow a diabetic to eat anything he desires. It is cruel for prominent individuals to make such statements and arouse false hopes."

June 2, 1923, in the Journal of the American Medical Association Elliott P. Joslin, M.D., founder of the Joslin Diabetes Center

- <u>https://jamanetwork.com/journals/jama/article-abstract/234300</u>
- https://www.joslin.org/about/elliot_p_joslin_md.html

Written one year after Eli Lilly first made insulin commercially available.

Perfection is not attainable, but if we chase perfection we can catch excellence.

— Vince Lombardi —









The End

I hope this talk was helpful. *Thank you for listening.*