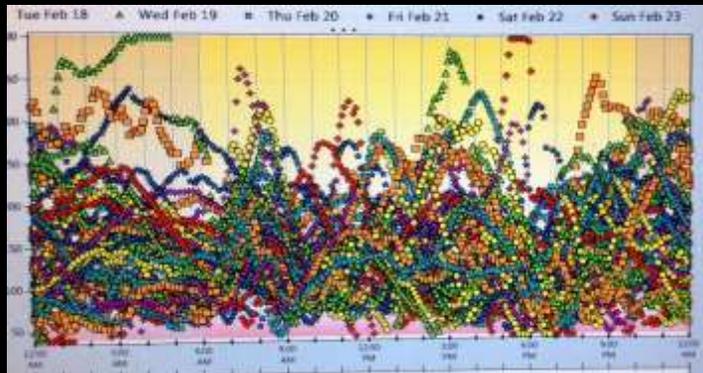


## Case Studies: Interpreting Pump and CGM Downloads



Irl B. Hirsch, MD  
Professor of Medicine  
University of Washington School of Medicine  
Seattle, Washington

## Disclosures

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- Consultant: Abbott Diabetes Care, Roche Diagnostics, Becton Dickinson

## Clinic Visits

- Downloads are *very* helpful (perhaps critical)
- My belief: the download should be part of the vital signs for anyone using insulin, and even more important for CSII and CGM users
- Unfortunately, some downloads are not very helpful
- Different options on where to download-clinic vs. home
  - T1D Exchange-few download at home; can this be changed?

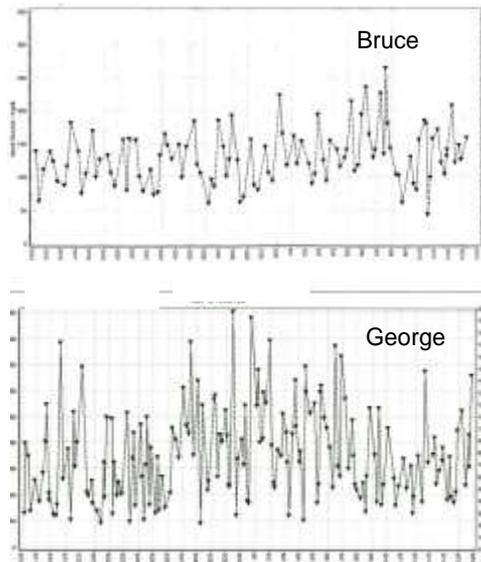
## Downloading is Important!



(Meters,  
pumps, and  
sensors)

Both patient's A1C = 7.6%. Who is doing better?

Teaching Point:  
although not perfect,  
downloading allows  
you to better  
understand and  
quantitate one's  
diabetes "fingerprint"



## Standard Deviation

- Our clinically available measurement of glycemic variability for both SMBG and CGM
  - Many other statistical analysis are available but correlation will be with CGM and outcomes, not SMBG (current studies using CV)
- Can determine both overall and time specific SD
- SMBG: Need sufficient data points
  - Minimum 5 but prefer 10

## Calculation To Determine SD Target SMBG

**SD X 3 < MEAN**

- SD X 2 < mean, may be difficult for some type 1 patients. Formulas only relevant for mean BG between 120-180

CGM

**SD X 3 < MEAN**

Need better metrics: CV, TIR, TBR, TAR all to be correlated with outcomes

## Example: George

Read "aggregate" mean/SD

Statistics	NIGHT	Breakfast	MID-AM	Lunch	MID-AFTERN	Dinner	MID-EVENIN	BED	
# of Readings	7 %	1421 %	468 %	1716 %	3517 %	3816 %	354 %	811 %	24100% 215
Avg # Readings /	0.47	1.53	0.57	1.17	1.20	1.17	0.27	0.80	7.17
Maximum (mg/dL)	339	248	225	245	277	205	207	281	339
Minimum (mg/dL)	88	57	54	51	58	55	82	75	57
Mean (mg/dL)	164	122	120	130	144	114	125	150	133
Std Dev (mg/dL)	62.03	47.37	43.74	48.54	53.02	31.81	41.07	52.95	50.44
Events									
Hypo (<60)	0	2	0	0	0	1	0	0	3
Hyper (>180)	4	5	3	7	9	1	1	8	8
Above Target	38 %	530 %	1424 %	434 %	1253 %	1914 %	525 %	258 %	1435 % 75
On Target	57 %	826 %	1241 %	726 %	822 %	848 %	1638 %	329 %	793 % 70
Below Target	7 %	143 %	2035 %	640 %	1425 %	940 %	1438 %	313 %	333 % 70

## Example: George

Read "aggregate" mean/SD  
Read frequency of testing

Statistics	NIGHT	Breakfast	MID-AM	Lunch	MID-AFTERN	Dinner	MID-EVENIN	BEDT		
# of Readings	7 %	1421 %	468 %	1716 %	3517 %	3816 %	354 %	811 %	215	
Avg # Readings /	0.47	1.53	0.57	1.17	1.20	1.17	0.27	0.80	7.17	
Maximum (mg/dL)	339	248	225	245	277	205	207	281	339	
Minimum (mg/dL)	86	57	54	51	58	55	82	75	57	
Mean (mg/dL)	164	122	120	130	144	114	125	150	133	
Std Dev (mg/dL)	62.03	47.37	43.74	48.54	53.02	31.81	41.07	52.96	50.44	
Events										
Hypo (<60)	0	2	0	0	0	1	0	0	3	
Hyper (>180)	4	5	3	7	9	1	1	8	8	
Above Target	38 %	530 %	1424 %	434 %	1253 %	1914 %	525 %	258 %	1405 %	75
On Target	57 %	826 %	1241 %	726 %	922 %	848 %	1638 %	329 %	793 %	70
Below Target	7 %	143 %	2035 %	640 %	1425 %	940 %	1438 %	313 %	333 %	70

## Example: George

Read "aggregate" mean/SD  
Read frequency of testing  
Review time-specific

Statistics	NIGHT	Breakfast	MID-AM	Lunch	MID-AFTERN	Dinner	MID-EVENIN	BEDT		
# of Readings	7 %	1421 %	468 %	1716 %	3517 %	3816 %	354 %	811 %	24100% 215	
Avg # Readings /	0.47	1.53	0.57	1.17	1.20	1.17	0.27	0.80	7.17	
Maximum (mg/dL)	339	248	225	245	277	205	207	281	339	
Minimum (mg/dL)	86	57	54	51	58	55	82	75	57	
Mean (mg/dL)	164	122	120	130	144	114	125	150	133	
Std Dev (mg/dL)	62.03	47.37	43.74	48.54	53.02	31.81	41.07	52.96	50.44	
Events										
Hypo (<60)	0	2	0	0	0	1	0	0	3	
Hyper (>180)	4	5	3	7	9	1	1	8	8	
Above Target	38 %	530 %	1424 %	434 %	1253 %	1914 %	525 %	258 %	1405 %	75
On Target	57 %	826 %	1241 %	726 %	922 %	848 %	1638 %	329 %	793 %	70
Below Target	7 %	143 %	2035 %	640 %	1425 %	940 %	1438 %	313 %	333 %	70

## Case 1: Downloading 101: Understanding the Basics

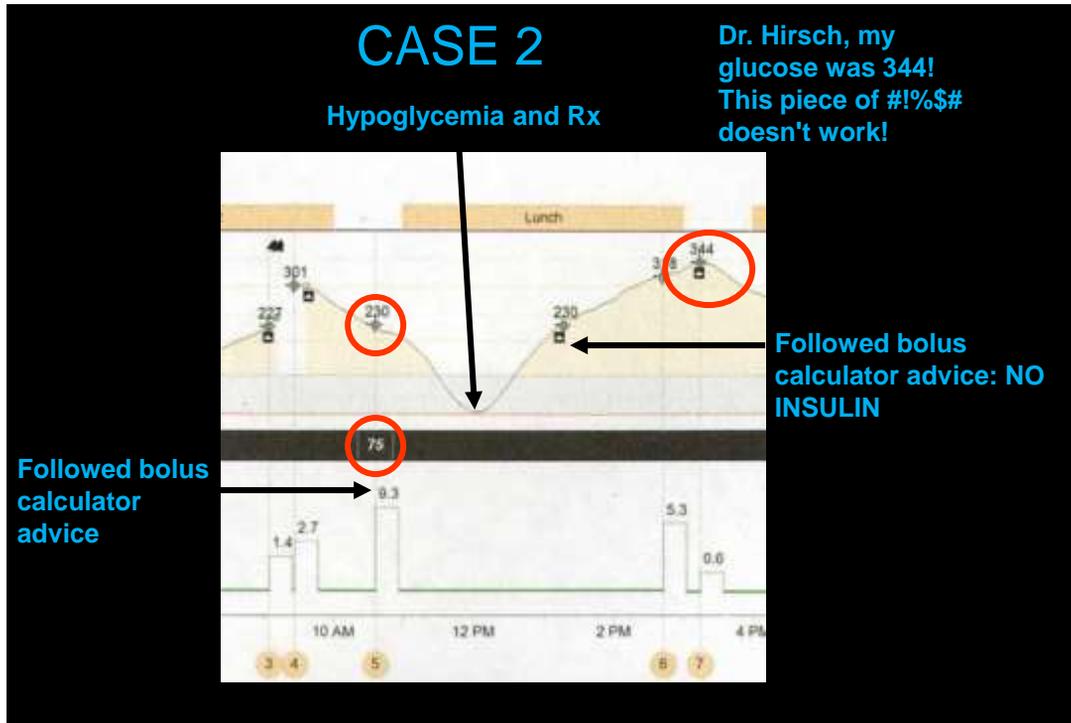


- Helen is a 50-year-old woman with type 1 diabetes for 35 years
- Pump therapy for 3 years; A1C 6.8%
- Last severe hypoglycemic episode 13 year ago during pregnancy
- Uses bolus calculator 100% of the time

## Case 1: Interpreting a Downloaded Pump Logbook

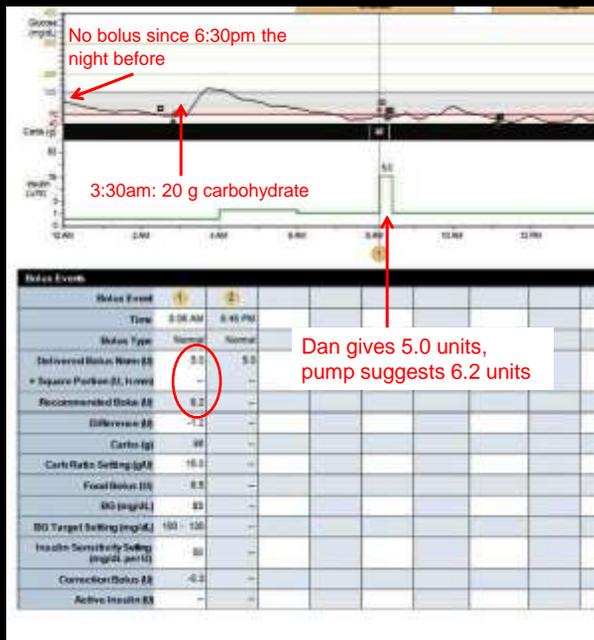
Pre-Breakfast	Post-Breakfast	Pre-Lunch	Post-Lunch	Pre-Dinner	Post-Dinner	Bed-time	3:00 a.m.
128 (4 + 0.5)	--	205 (5 + 2.2)	65	98 (5.5)	--	221 (0 + 2.2)	55
165 (3 + 1.5)	242 (0 + 1.8)	182 (4.5 + 1.1)	No test (Rx low)	195 (5 + 1.4)	--	133	--
121 (3 + 0)	207 (0 + 1.4)	144 (3.5 + 0.1)	No test (Rx low)	No test (4.5)	166 (0.4)	93	--
114 (3.5 + 0)	--	223 (3 + 2.4)	Low in clinic	--	--	--	--

1. Basal overnight OK
2. Needs more insulin at breakfast
3. Too much insulin at lunch (appears to be prandial, not correction dose)
4. Probably needs lower correction dose at bedtime



## Case 3: Dan, Who Has Normal Hearing But Does Not Listen

- 64-year-old construction worker, retiring in 3 months
- Type 1 diabetes for 58 years, averages 1-2 severe hypoglycemic episodes *per year*, despite using sensor-augmented pump therapy
- A1C for the past 20 years has averaged around 6% despite *strong* recommendations to raise targets
- He often will override his pump's bolus calculator despite his physician consistently reducing his insulin doses
- He frequently increases basal insulin and bolus calculator-derived doses on his own



### Case 3: Downloads

Thoughts:

- Too much hypoglycemia
- Basal doses clearly too high
- He appreciates his bolus calculator is too aggressive
- Difficult for him to rationalize his need to raise glycemic targets
- ADA targets\*: <7.5% or <8%, depending on interpretation of his current health status
- He needs threshold suspend function!

\*Chiang JL, Kirkman MS, Laffel LMB, Peters AL; on behalf of the Type 1 Diabetes Sourcebook Authors. *Diabetes Care*. 2014;37:2034-2054.

### CASE 4: CSII/CGM Download from AI

- 55-year-old man with type 1 diabetes for 35 years
- Using insulin pump therapy for 15 years
- Has always struggled to keep A1C <7.5%
- Mild nonproliferative diabetic retinopathy, stable microalbuminuria (albumin-to-creatinine ratio: 60), mild polyneuropathy, last severe hypoglycemia 10 years ago
- Hoping that continuous glucose monitoring (CGM) using a sensor-augmented pump will improve control
- After using CGM for 4 months, A1C is now 7.6% (down from 8.1% 3 months ago); BMI is 27 kg/m<sup>2</sup>

# CASE 4: Where to Start?

## 1. Review insulin doses

Standard (active)	
24-Hour Total	28.40 U

TIME	U/hr
0:00	1.10
2:00	1.10
7:00	1.10
<b>NEW</b> 18:00	1.15
22:00	1.10

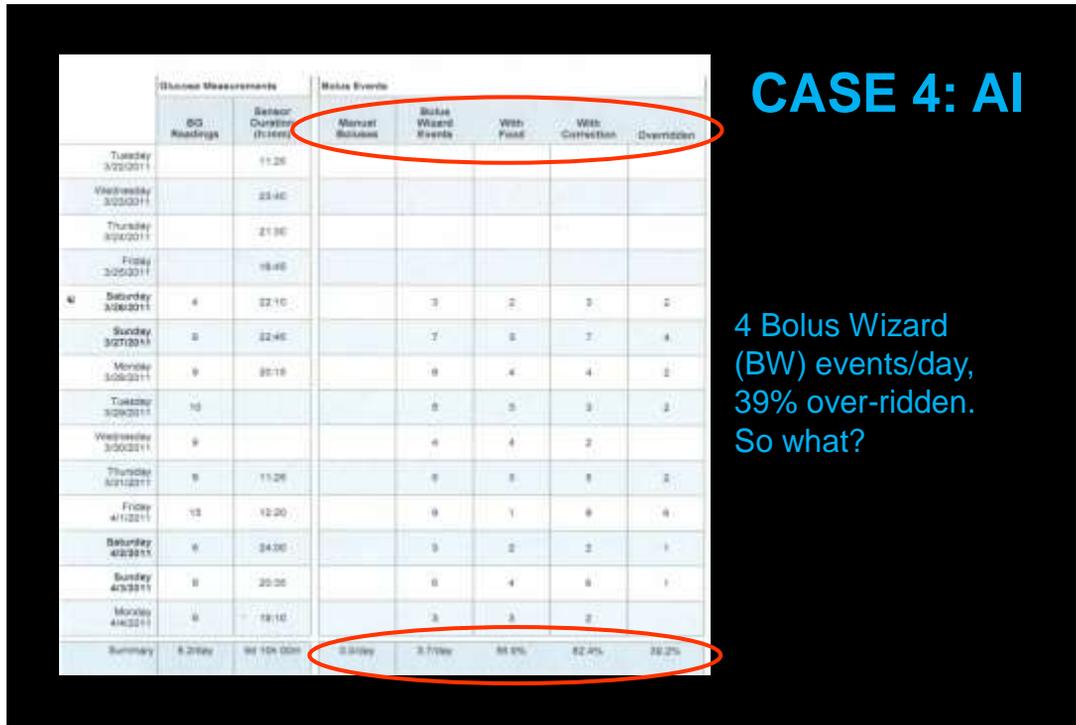
Bolus Wizard		(h:mm)	(h:mm)
Bolus Wizard	On	--	--
Units	g, mg/dL		
Active Insulin Time	4.00		
Insulin Concentration	--		

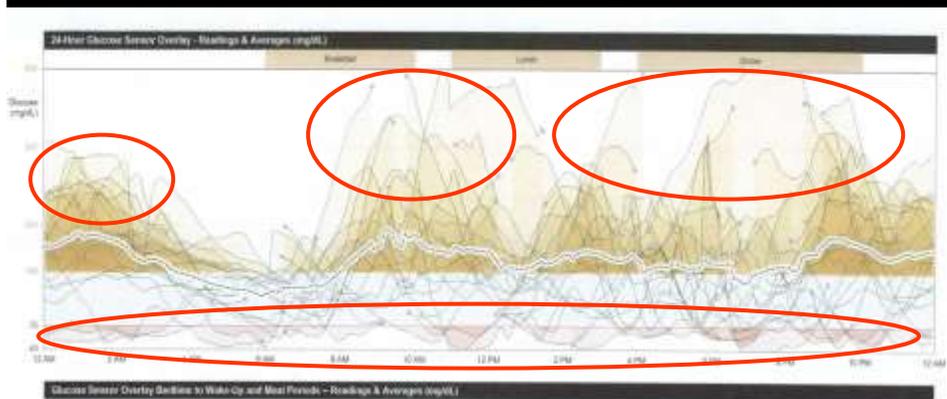
Carbohydrate Ratio (g/U)		Insulin Sensitivity (mg/dL per U)		Blood Glucose Target (mg/dL)		
TIME	Ratio	TIME	Sensitivity	TIME	Low	High
0:00	8.0	0:00	35	0:00	90	120
7:00	6.0	2:00	35	5:00	90	120
18:00	8.0	7:00	35			
		18:00	35			
		20:00	35			

Statistics	3/22 - 4/18	
Avg BG (mg/dL)	167	± 79
BG Readings	221	8.2/day
Readings Above Target	136	62%
Readings Below Target	26	12%
Sensor Avg (mg/dL)	156	± 72
Avg AUC > 140 (mg/dL)	35.9	18d 23h
Avg AUC < 70 (mg/dL)	1.4	18d 23h
Avg Daily Carbs (g)	170	± 56
Carbs/Bolus Insulin (g/U)	8.7	
Avg Total Daily Insulin (U)	35.5	± 4.0
Avg Daily Basal (U)	15.9	45%
Avg Daily Bolus (U)	19.6	55%

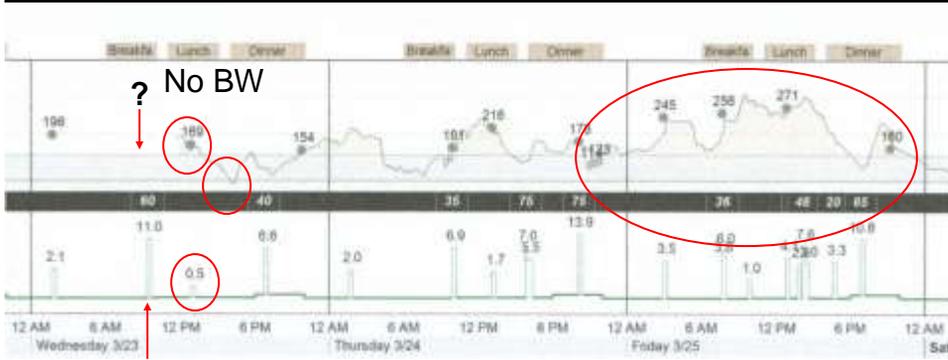
## CASE 4: AI



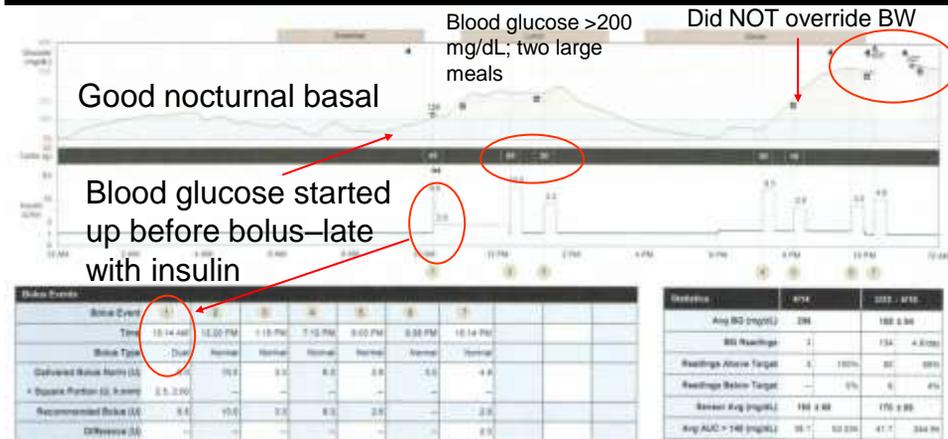
## AI: Message from Dashboard: HELP!



# Overview for AI ("Looking from the plane")

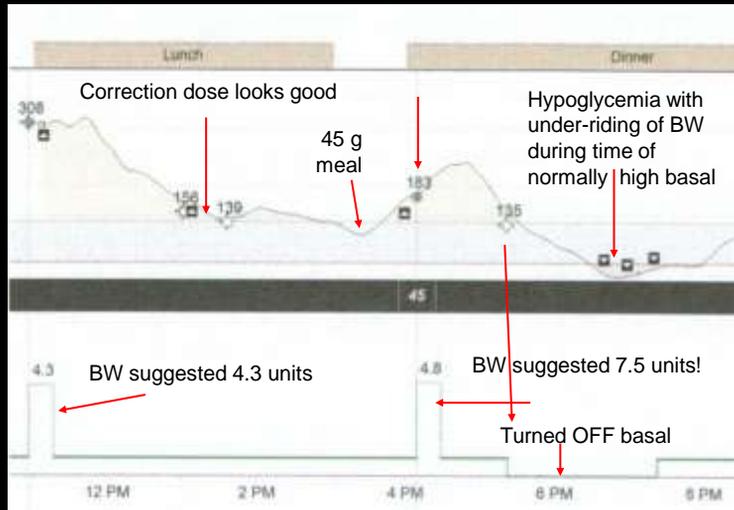


# Details, Details . . .



Followed BW for dose, did not acknowledge trend, used dual-wave bolus (despite being late with bolus!)

## Why AI Has Always Struggled with His Diabetes



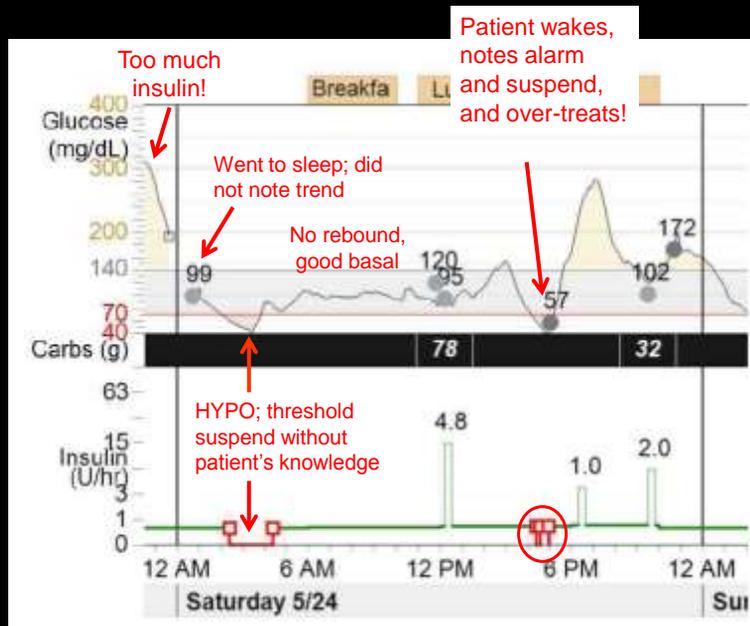
## What Can We Conclude About AI?

- Nocturnal basal doses and insulin sensitivity factor look appropriate
- Timing of boluses remains a challenge
- Daytime basal doses probably too high, especially at 6:00 pm; daytime insulin-to-carbohydrate (I:C) ratio most likely too aggressive
- Suggest:
  - – Daytime basal testing
  - – “Increase” I:C ratio (less insulin)
  - – Emphasize timing!

## Case 5: Carol, Who Shows Why Threshold Suspend Is Such an Important Advance

- 54-year-old woman with hypoglycemia unawareness and frequent severe hypoglycemia, yet who continues to be too aggressive with insulin
- Husband often travels

### Case 5: Download

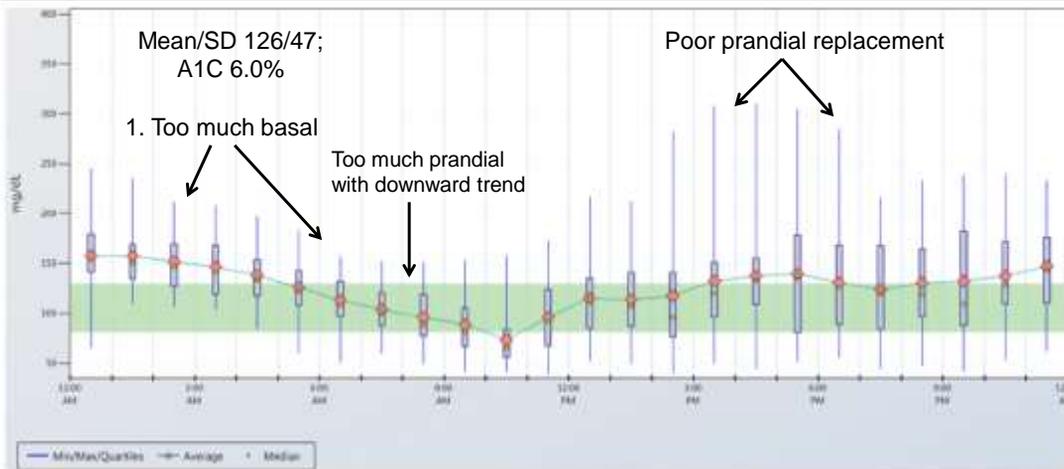


## Case 5: Conclusions About Carol

- Needs to be more conservative with insulin at bedtime and pay more attention to trend
- Threshold suspend works well and does not result in “rebound”
- Over-treatment of hypoglycemia remains a long-term problem

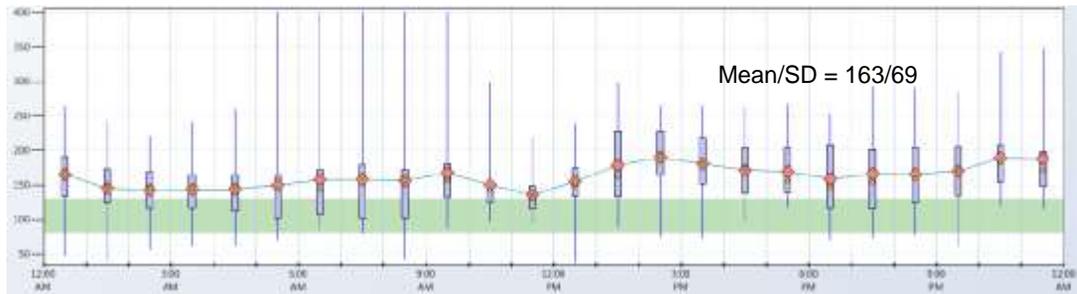
## CASE 6: Christie

- 32 y/o woman on 8 units glargine BID with pre-meal lispro 1:15, ISF 50 day, 60 at HS; jogs at 7am 5X's/week; b'fast at 8a, lunch at 1p, dinner at 7p

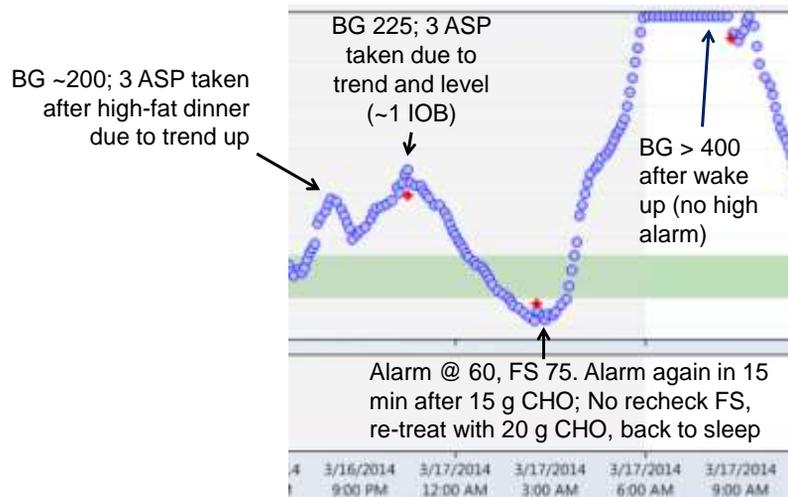


## Case 7: A Happy But Frustrated 54 y/o Woman Starting CGM

- 22 years T1DM, last SH 2 years ago, A1C starting CGM = 8.1%
- After 3 months A1C = 7.2% (MDI GLA/ASP, ISF 40)
- Low alarm 60 with 15 min repeat. Refuses high alarm
- What is the differential diagnosis?



## Case 7: A 54 y/o Woman Starting CGM



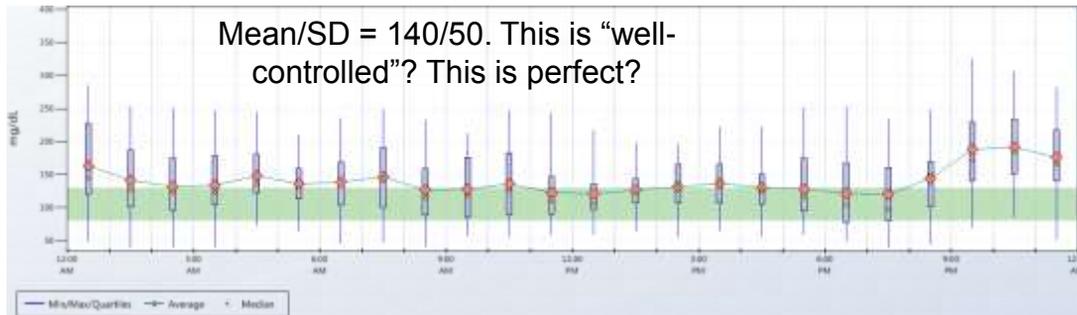
## Case 7: The Learning Curve

- Bacon cheeseburgers are difficult to cover!
- IOB has to be factored
- The ISF is too aggressive for bedtime
- A high alarm is needed no matter how much the alarms are not wanted to protect from this type of problem at night (after negotiation she agreed to a high alarm of 240 mg/dL)

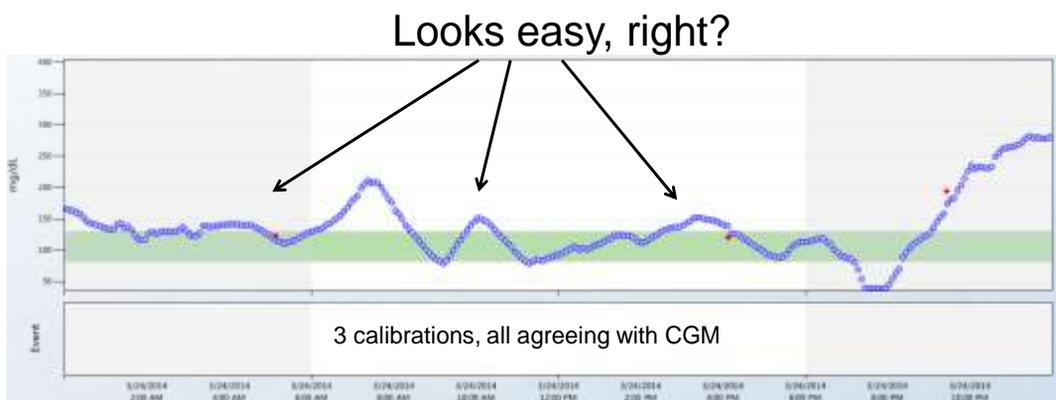
## Case 8: A 61 y/o Man Using CGM X 4 Years

- 52 years T1DM, last severe hypoglycemia 6 years ago
- A1C = 6.7% but *his* goal is < 6.5% (what is his actual target?)
- Glargine/Lispro
- PDR Rx'ed 35 years ago, microalbuminuria resolved, no known CVD
- Other meds = ACEI, statin, ASA

## Case 8: 61 y/o Man with T1D, A1C 6.7%

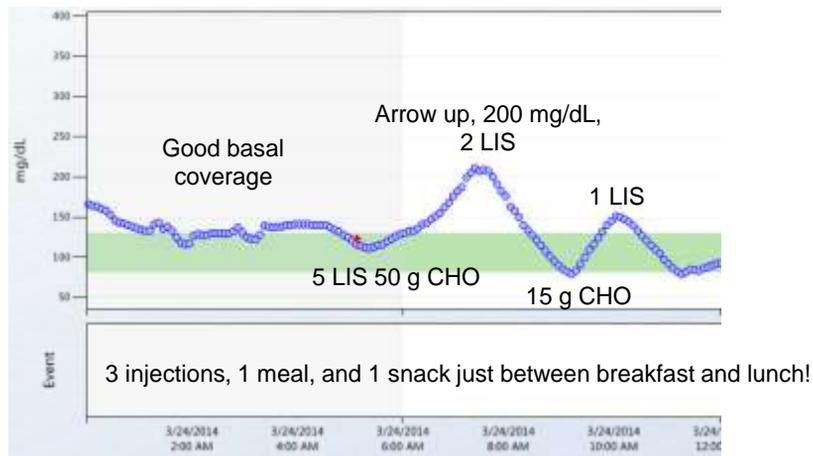


## Case 8: 61 y/o Man With T1D X 52 Years



ALARMS: 70 and 200

## Case 8: 61 y/o Man, T1D X 52 Years



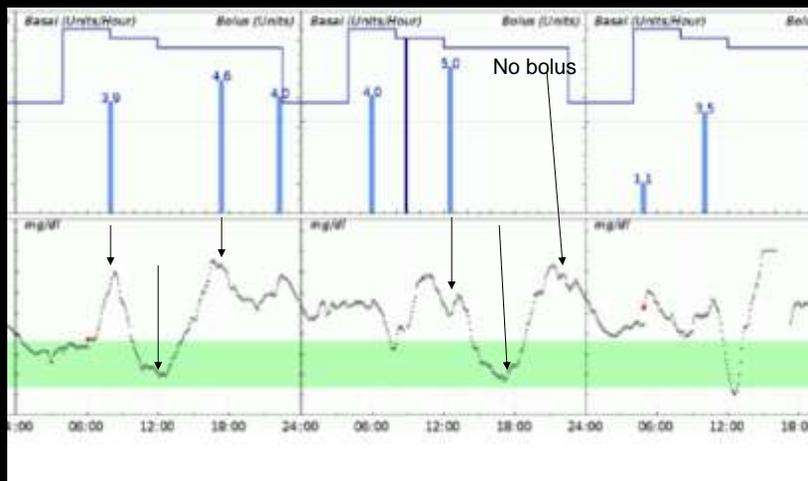
## CASE 9

- 60 y/o woman, 41 years T1D using Animas Vibe
- Past history significant for PDR s/p PRP, DAN with gastroparesis
- After many years of no diagnosis, found in 2010 to have stiff-person's syndrome
- HbA1c prior to SPS Dx usually in the 7-8% range, after Dx most in 9-11% range.
- 75-80% of total daily insulin is basal insulin
- What's going on?

## Case 9: AGP from 60 y/o Woman with SPS Feb 2016, HbA1c 10.1%

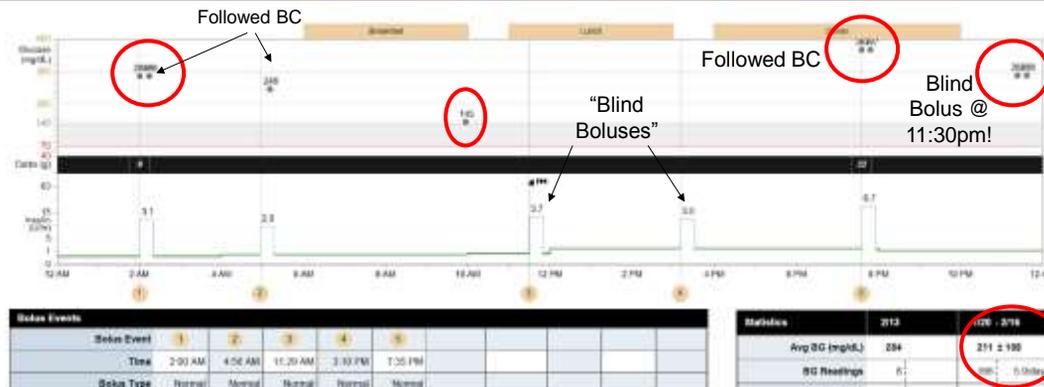


## CASE 9: The Answer to the Problem



## CASE 10

- 66 y/o woman with T1D X 44 years using CSII, Medicare only, 62 y/o husband with T2D on insulin high deductible (\$6K)
- Woman with A1C historically in mid 7's, for past year in 9's, first DKA in 40+ years 1 month prior to this clinic visit
- What is going on?



## CASE 10 Conclusions

- Need to be careful with interpreting some Carelink downloads for frequency of SMBG
- Patient needs to use her own strips
- Blind boluses a huge problem
- SDs > 100: major problems usually with timing of insulin
- Would like this patient to use CGM!

## Bonus Case: Animas Download

What's going on here?

2/23/08	BG	183	454	139	122	85	287	57	122	208
	BOL	2.90	457			8.86	0.00	3.86	3.30	17.80
	BAS			1.700	1.900					36.900
	CHO					28	28		18	83
	EVT									
2/24/08	BG	166	294		228	88		48	120	146
	BOL	3.66	297			1.31				
	BAS		12.40	1.700	1.900	1.70	0.00	0.00	5.80	23.43
	CHO									36.900
	EVT					40			28	102

Blind bolus

## What I Want To See in A Download

- Basic statistics
  - Overall and time specific means/SD
    - SMBG: minimum:  $SD \times 2 < \text{mean}$  (better if  $SD \times 3 < \text{mean}$ ) if mean 120-180
    - CGM:  $SD \times 3 < \text{mean}$
  - CSII: Basic insulin stats
    - TDD, % basal, over-ride % for bolus calculator
    - Daily summary to better understand ICR, ISF, basal rates, and if appropriate over-under-rides for trends or anticipated exercise
  - CGM: basic BG stats
    - Overall patterns and daily decision making to best understand how patient thinks through each challenge

## Most Common Patient Mistakes

- Over-calibrate/under-calibrate
- Don't look at sensor often-only react (if then) to alarms
- Over-react to alarms not taking into account "lag times"-results in insulin stacking
- Not using enough SMBG to make decisions!



## Conclusions

- **Although this may not be the case for all clinicians, we have found developing a specific infrastructure for meter, pump, and CGM use in our clinic to be worthwhile**
- **While there are many similarities with CGM use and CSII (new technology, early adapters, etc.), one fundamental difference is the ability to download the data allowing the clinicians to see how the patients act, react, and even think about their diabetes management**

## My Thoughts

- There are two reasons why endocrinologists don't download the technology (which is critical to understanding how to best assist patients)
  - No infrastructure in the office leading to poor inefficiency and perception of not time or cost effective
  - They were never taught how to do this!  
Resources for how to do this are scarce, is still relatively new, and is changing rapidly

**Thank You**

