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Foundations of Cardiometabolic Health Certification Course

Certified Cardiometabolic Health Professional (CCHP)

The Use of Pumps and AID Systems for Diabetes Management

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Disclosure of Potential Conflicts of Interest

Advisory Boards

- Abbott Diabetes Care
- Lilly
- Medscape
- Vertex

Research Funding

- Insulet
- Abbott

Stock Options

- Omada Health
- Livongo/Teladoc

Goals

- Discuss the types of insulin pumps and AID systems that are available
- Consider their use in people with type 1 and type 2 diabetes
- Review cases of people using these systems and develop a clinical strategy for their use in an office setting

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Pumps and AID Systems: Features & Patient Selection

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Why Prescribe Insulin Pumps?

- Insulin pumps are a tool for giving insulin and are a choice between patient and provider
- Pumps:
  - Use only one kind of insulin (usually a rapid acting insulin) and allow for varying basal rates and bolus doses
  - Reduce the need for injections (although require infusion set insertion every 2 – 3 days)
  - Provide a bolus calculator for insulin dosing
  - Allows for temporary adjustments in basal rates
- Clinical trials have shown only modest A1c improvement between stand-alone pumps compared to multiple-daily injections
- However, newer generation, CGM-integrated pumps (the “artificial pancreas” or Automated Insulin Devices [AID]) have been associated with less hypoglycemia, less glucose variability, and more time in range and are increasingly prescribed

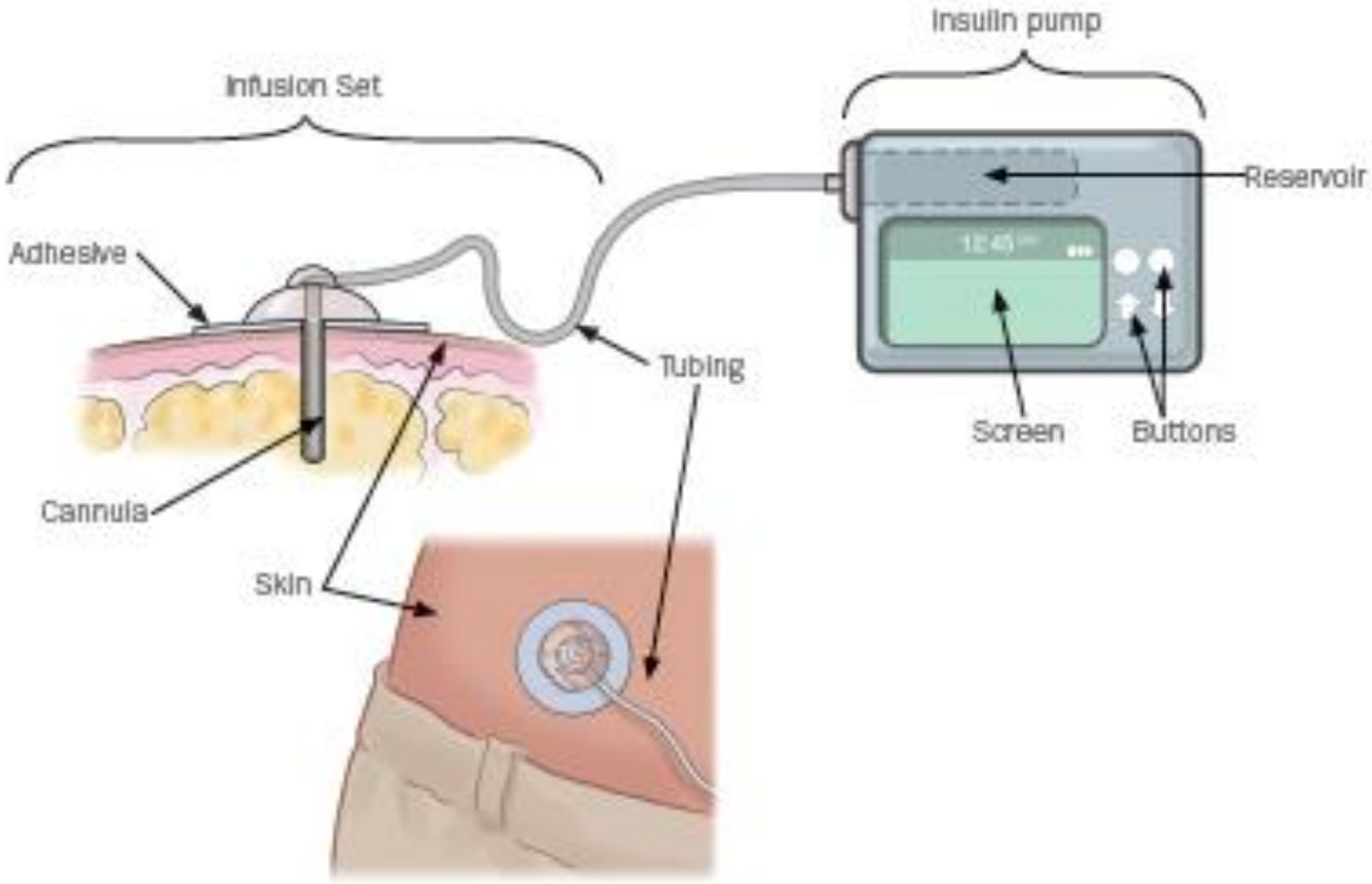
AACE/ACE. *Endocrine Practice*. 2014;20:463-489. ADA. *Diabetes Care*. 2019;42(Suppl. 1):S71–S80. Yeh H-C, et al. *Ann Intern Med*. 2012;157:336-347. Weaver KM, et al. *Diabetes Technol Ther*. 2018;20(suppl 2):16-23. Cordero TL, et al. *Diabetes Technol Ther*. 2017;19:749-752. Garg SK, et al. *Diabetes Technol Ther*. 2017;19:155-163.

Who Should Have an Insulin Pump?

- Anyone on multiple daily insulin therapy who is testing frequently and adherent to follow-up
  - Must be able to enter carbs/meals
  - Must be able to do all tasks to trouble shoot pump if an issue arises
  - Covered by Medicare and most insurances for T1DM. Medicare doesn't (yet) cover pumps for T2DM
  - Patient must want to use an insulin pump
- For people with Type 1 Diabetes AID systems are considered the treatment of choice
  - RCT data shows superiority over MDI/traditional pumps

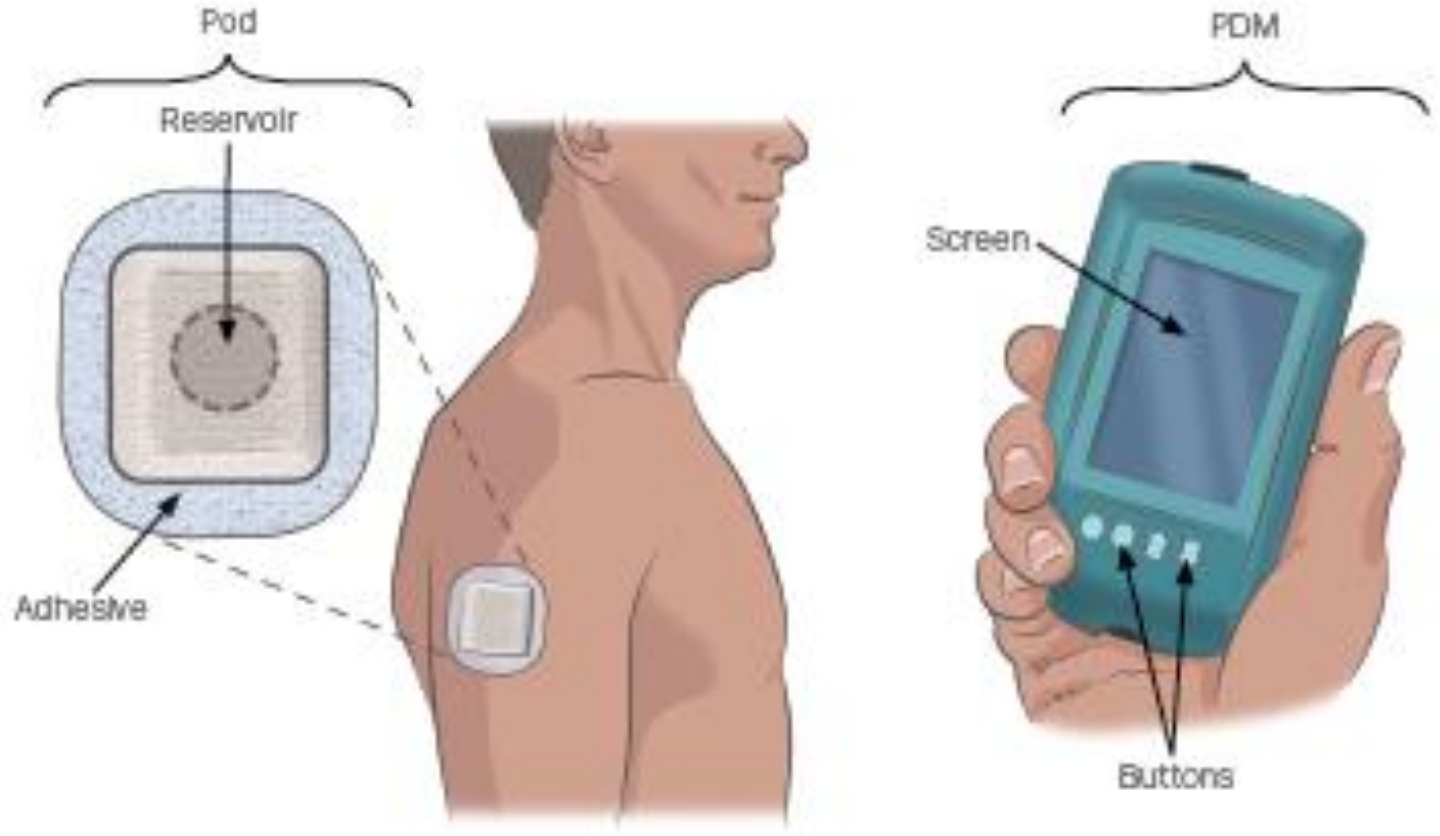
Diabetes Care. 2021 Jan;44(Suppl 1):S15-S33. doi: 10.2337/dc21-S002

Types of Insulin Pumps: A “Tubed” Pump



Source: Patient Guide. STEPP-UP Project. Ruelas VF, et al. Diabetes Care. 2018;67(Suppl 1).

Types of Insulin Pumps: A “Tubeless Pump”



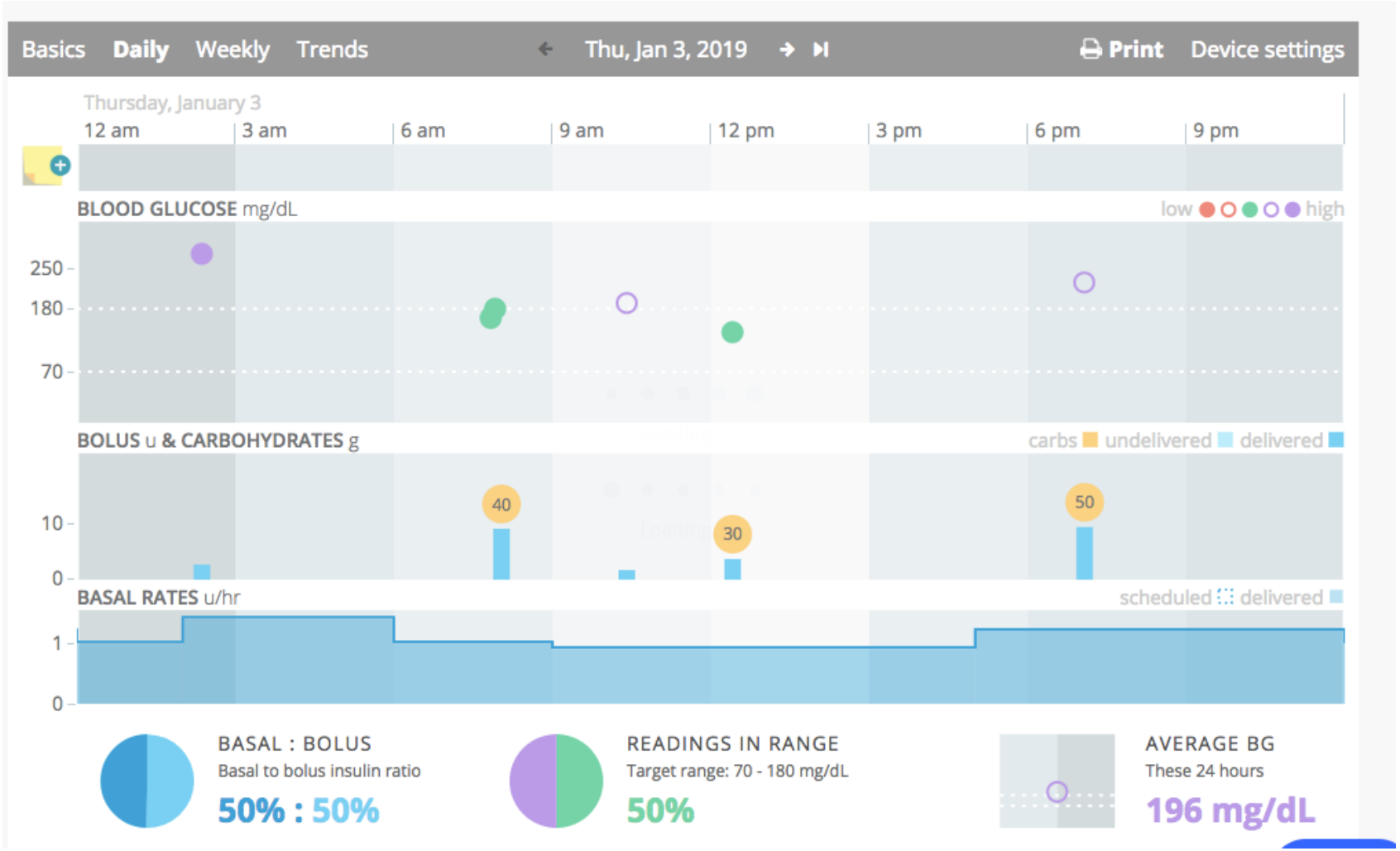
Source: Patient Guide. STEPP-UP Project. Ruelas VF, et al. Diabetes Care. 2018;67(Suppl 1).

Disposable Pumps: A Form of a Tubeless Pump

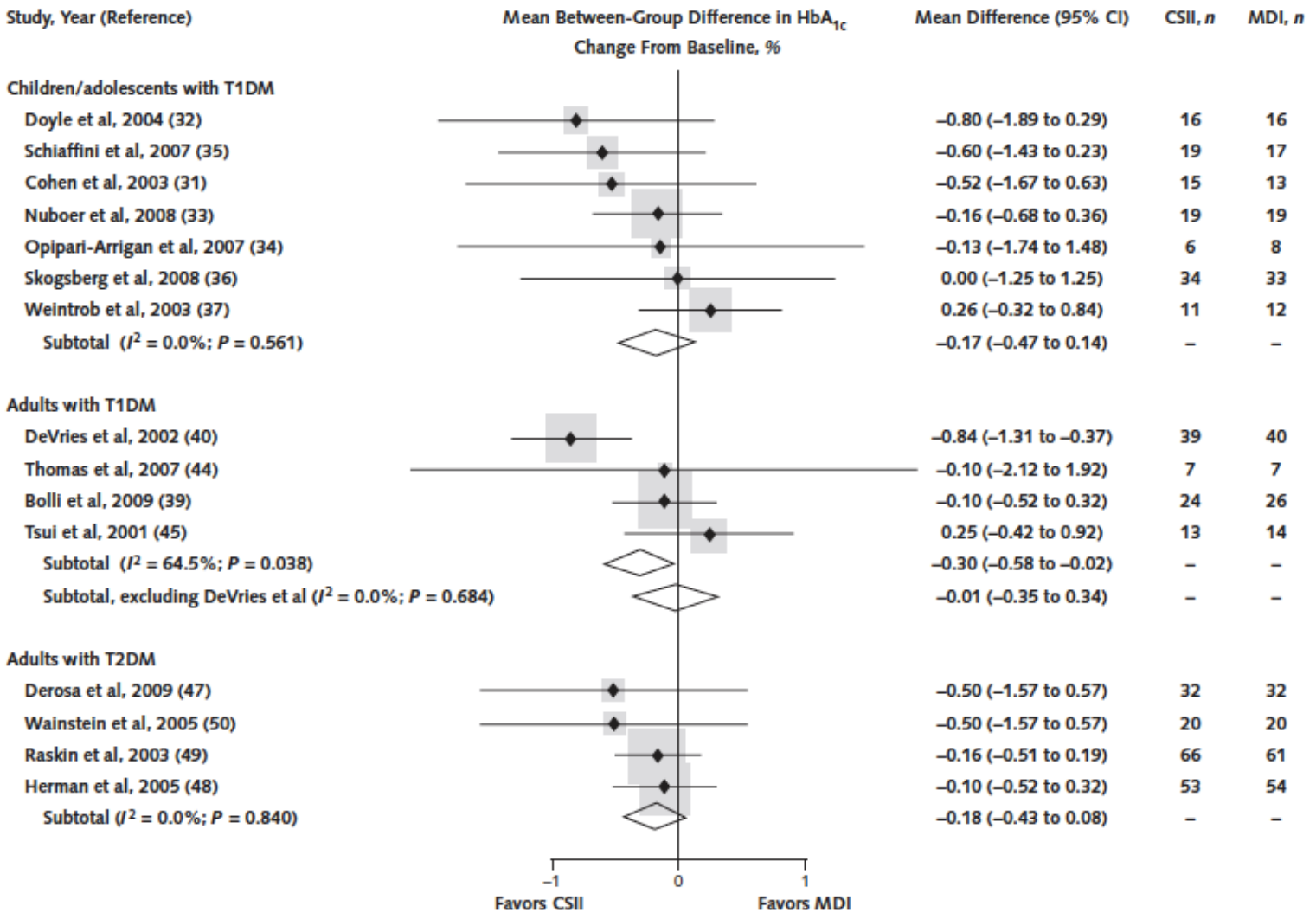
- Designed for people with type 2 diabetes
- Provides a set basal rate for 24 hours that is not altered by time of day
- Bolus insulin delivery is less granular (bolus in 2-unit increments)
- Pump needs to be replaced (from every 24 hours to every 3 days depending on pump)
- Provides some of the flexibility of pump therapy (no need for injections for each meal) but lacks some of the sophistication of other pump therapies

https://www.go-vgo.com
https://www.myceqursimplicity.com

Pump Printout



Meta-analysis CSII vs MDI



Soupal J et al. Diab Tech Ther 18:532-538, 2016
Yeh HC et al. Ann Int Med 157:336-347, 2012

Automated Insulin Delivery Systems (AID): Combining Pumps and Sensors

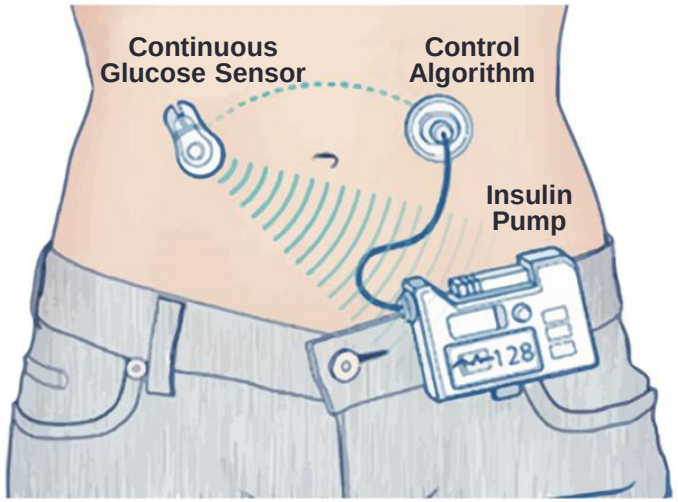
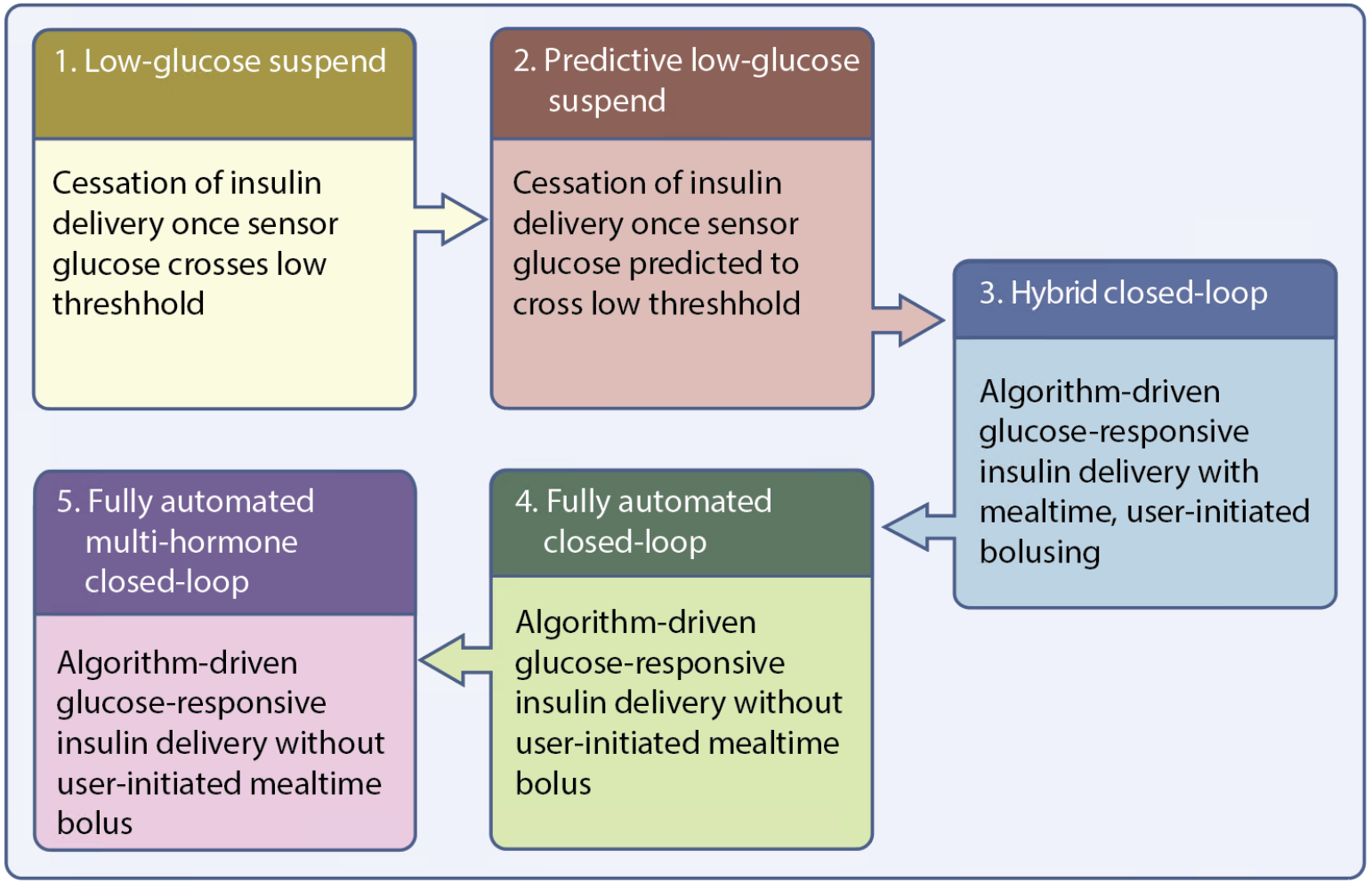


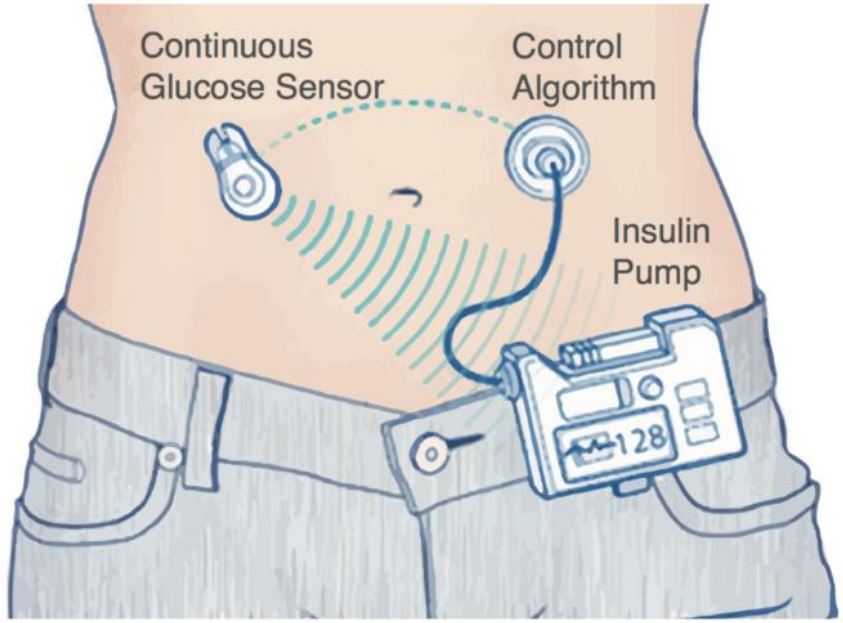
Image used with permission from A. Peters

Key developmental milestones towards a truly artificial pancreas



Boughton and Hovorka (2021) Diabetologia DOI 10.1007/s00125-021-05391-w

AID Systems: Combining Pumps and Sensors



Adapted from: Aathira R, et al. World J Diabetes. 2014:689-696.

Medtronic 670G Pump: First HCL System 9/2016

Observational Data

Research Letter

FREE

October 4, 2016

Safety of a Hybrid Closed-Loop Insulin Delivery System in Patients With Type 1 Diabetes

Richard M. Bergenstal, MD[1]; Satish Garg, MD[2]; Stuart A. Weinzimer, MD[3]; et al

» Author Affiliations | Article Information

JAMA. 2016;316(13):1407-1408. doi:10.1001/jama.2016.11708

Parameter	Run-in Period	Study Period
Sensor glucose, mean (SD) [median], mg/dL	150.2 (22.7) [150.1]	150.8 (13.7) [149.9]
Percentage of time with glucose level in range, mean (SD); median (IQR)		
Sensor glucose values		
>300 mg/dL	2.3 (4.2); 1.3 (0.2-2.6)	1.7 (1.9); 0.9 (0.5-2.1)
>180 mg/dL	27.4 (13.7); 26.7 (16.0-37.2)	24.5 (9.2); 24.1 (17.3-29.8)
71-180 mg/dL	66.7 (12.2); 67.8 (59.0-75.1)	72.2 (8.8); 73.4 (67.7-78.4)
≤70 mg/dL	5.9 (4.1); 5.2 (3.0-7.6)	3.3 (2.6); 2.9 (1.7-4.3)
≤50 mg/dL	1.0 (1.1); 0.6 (0.2-1.3)	0.6 (0.6); 0.4 (0.2-0.8)
Sensor glucose values at night time only[a]		
>180 mg/dL	26.8 (15.2); 26.4 (15.3-35.8)	21.6 (9.9); 20.6 (13.6-28.5)
71-180 mg/dL	66.8 (14.0); 67.0 (57.6-75.2)	75.3 (9.8); 76.4 (69.0-83.1)
≤70 mg/dL	6.4 (5.3); 5.4 (2.3-8.5)	3.1 (2.2); 2.6 (1.7-4.2)
Within-day SD of glucose, mean (SD); median (IQR), mg/dL[b]	50.1 (9.9); 48.9 (43.7-56.2)	46.7 (7.3); 45.6 (41.7-50.4)
Within-day coefficient of variation of glucose, mean (SD); median (IQR), %[b]	33.5 (4.3); 33.1 (30.3-36.4)	30.8 (3.3); 30.7 (28.2-33.0)
Glycated hemoglobin, mean (SD) [median], %	7.4 (0.9) [7.3]	6.9 (0.6) [6.8]

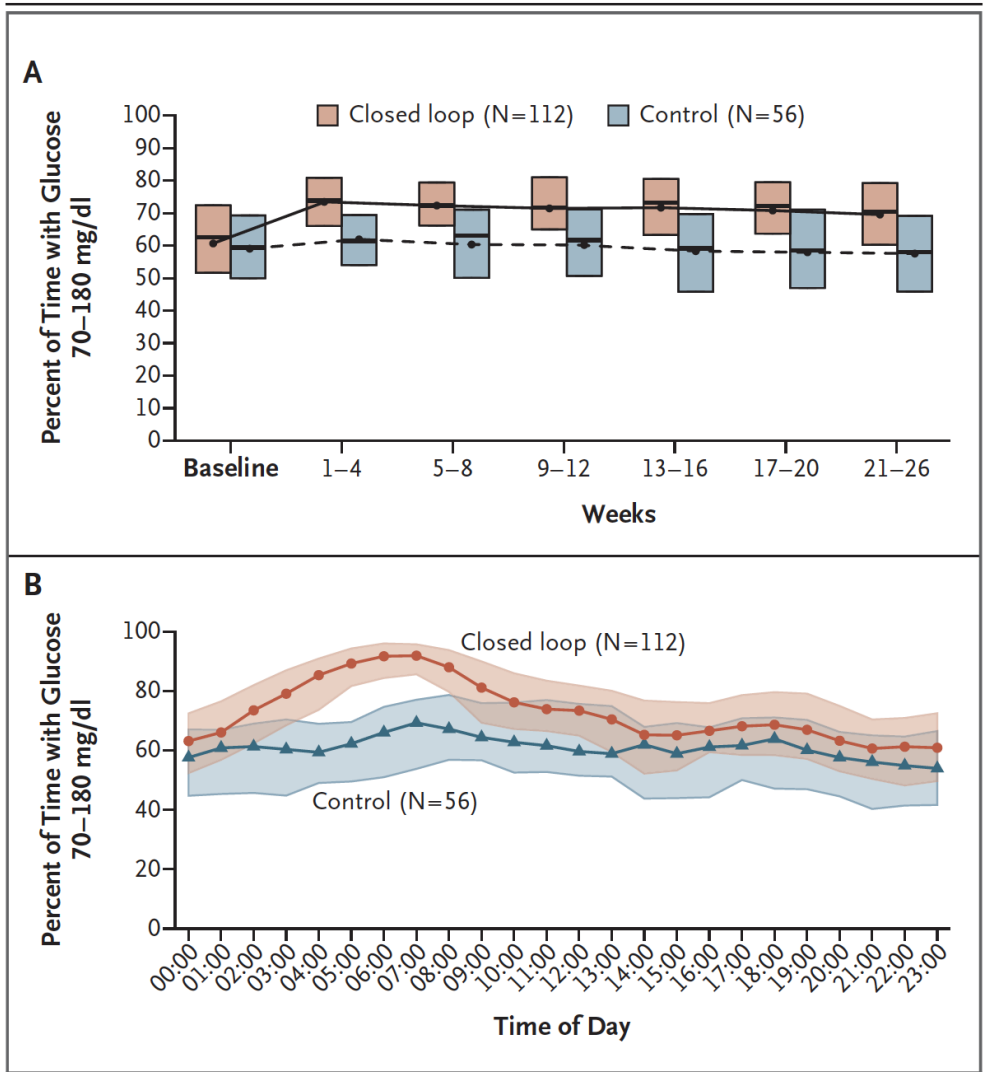
Medtronic 780G

New Features:

1. Guardian 4 sensor which does not require calibration in automode
2. Seven-day infusion set
3. Can set target as low as 100 mg/dl
4. Gives correction bolus doses every 5 minutes
5. On the market for 3 years in Europe—strong data to support its use

T:slim X2 with Control-IQ Technology

AID vs Sensor Augmented Pump: RCT Data



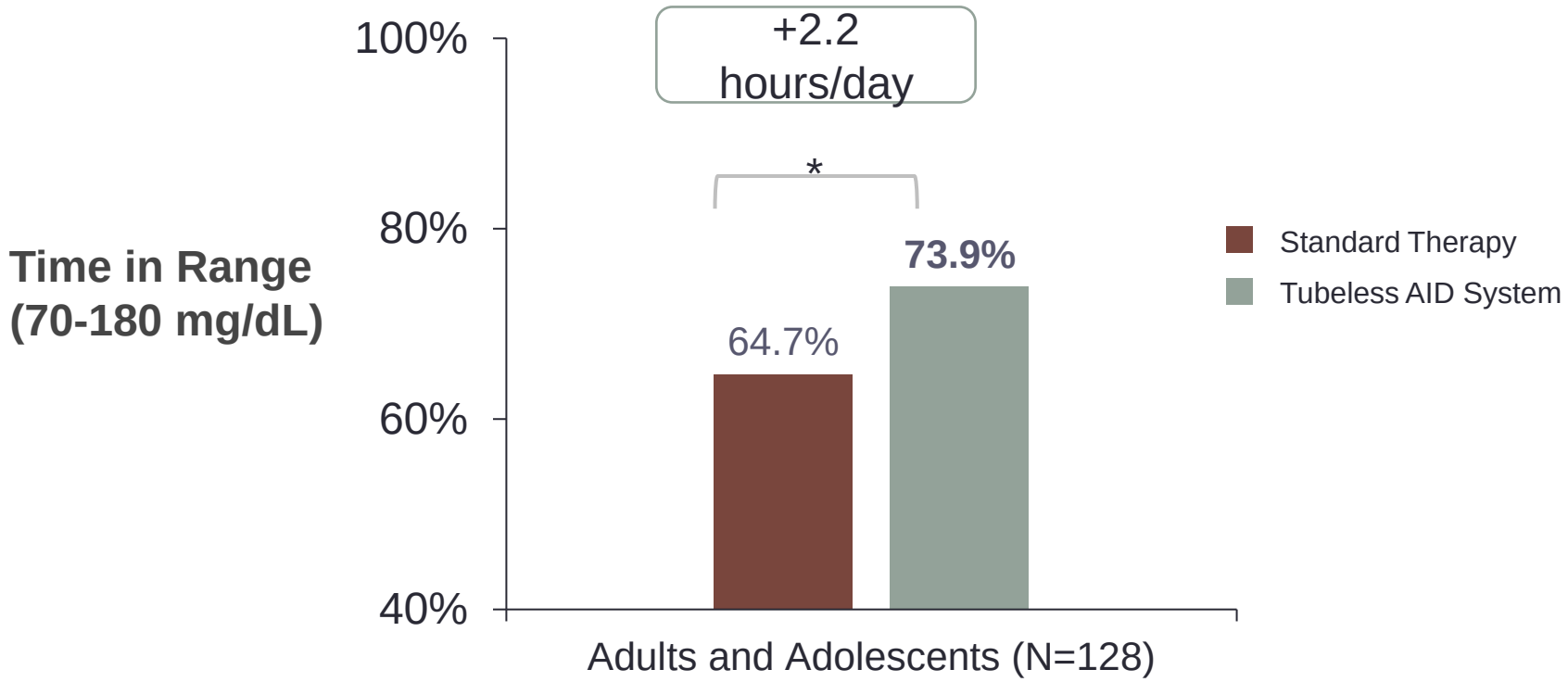
A1C reduced from ~7.4 to ~7.0% p=0.001

N Engl J Med 2019; 381:1707-1717 DOI: 10.1056/NEJMoa1907863

Tubeless Automated Insulin Delivery System: Omnipod 5

Brown S et al;. Safety Evaluation of the Omnipod 5 Automated Insulin Delivery System over 3 Months of Use in Adults and Adolescents with Type 1 Diabetes. Presented at Virtual Endocrine Society Annual Meeting; 2021

Primary Outcome: TIR During 3 Months of AID

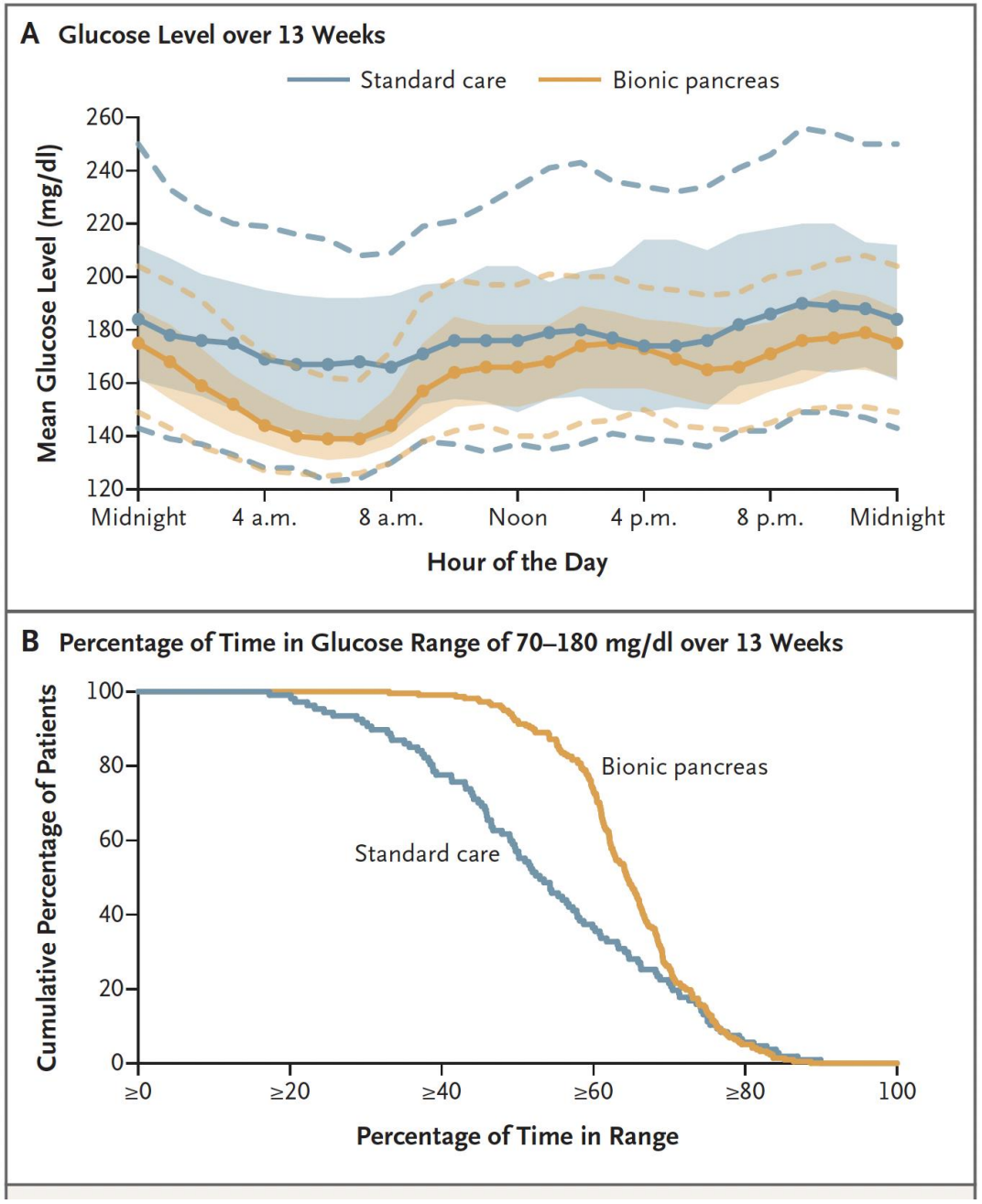


*p<0.001; Data shown as mean

Diabetes Care. 2021 Jun 7:dc210172. doi: 10.2337/dc21-0172

Beta Bionics Pump System

Beta Bionics Pump System



N Engl J Med 2022;387:1161-72.
DOI: 10.1056/NEJMoa2205225

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Insulin Pumps: Practical Considerations

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Patient and Provider Expectations

- **To use a pump, *a patient must be*:**
  - Knowledgeable and actively doing active self management (adequate SMBG/use of CGM, insulin injections, follow-up in clinic)
  - Able to do at least basic carbohydrate counting
  - Willing to learn a new system
  - Willing to trust a device
  - Able to trouble shoot, test ketones, revert to injection therapy
  - Able to call the pump manufacturer for technical help
- **To start a pump, *a provider must*:**
  - Give your patients a choice of pumps
  - Create initial pump settings
  - Know how to download pump data, analyze and adjust settings
  - Know how to help patients troubleshoot
  - Know how to prescribe/get authorization for the pump
  - Ensure that patients have 24/7 access to diabetes clinical care

AACE/ACE. Endocrine Practice. 2014;20:463-489.
AADE Practice Paper. 2018. www.diabeteseducator.org.
Shubrook JH, et al. Primary Care Reports. 2014;20:101-112.

Initiating Pump Therapy Process

- Start paperwork—patient and physician must sign their respective forms
- Patient discusses out-of-pocket cost with pump company and decides whether or not to move forward
- Provide additional paperwork/chart notes for pump company/distributor as requested
- Set up training
  - Company pump trainer
  - Office staff trainer
- Complete initial pump settings page (worksheets available)
- Order vials of rapid acting insulin for the patient

AACE/ACE. Endocrine Practice. 2014;20:463-489.
AADE Practice Paper. 2018. www.diabeteseducator.org.
Shubrook JH, et al. Primary Care Reports. 2014;20:101-112.

Starting a Pump

- Each pump company has their own pump trainers
  - These individuals can help you determine the patient's starting pump settings
  - The trainer will take 2-3 hours to teach your patient how to use the pump and should follow them initially to be sure there are no issues
  - This can be done in your office (if willing)
  - Sometimes done in steps (eg., saline first)
- Ideally patients would be seen in the office after 1-2 weeks on the pump to make any needed pump adjustments
- Working with a CDE can be extremely helpful
  - Completing pump settings (people on pumps typically need less insulin)
  - Help with carb counting education, problem solving, and setting patient expectations

AADE Practice Paper. 2018. www.diabeteseducator.org.
Shubrook JH, et al. Primary Care Reports. 2014;20:101-112.

Advancing to Integrated Pump/Sensor Systems

- Called “artificial pancreas”, hybrid closed loop system, automated insulin delivery (AID) system
- Patient wears a pump and a sensor, which communicate with each other through a controller
  - The controller increases/decreases the basal rate based on glucose levels
  - Patient still enters meal doses/exercise
- Benefits:
  - Associated with less hypoglycemia, less glucose variability, and more time in range compared to injections
- Barriers:
  - Two devices to wear each of which can have problems
  - Need to troubleshoot, understand and adjust automated system

Weaver KM, et al. Diabetes Technol Ther. 2018;20(suppl 2):16-23. Cordero TL, et al. Diabetes Technol Ther. 2017;19:749-752.
Garg SK, et al. Diabetes Technol Ther. 2017;19:155-163. Peters AL, et al. J Endocr Soc. 2018;2:1214-1225.

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Patient Cases: Insulin Pumps and AIDs

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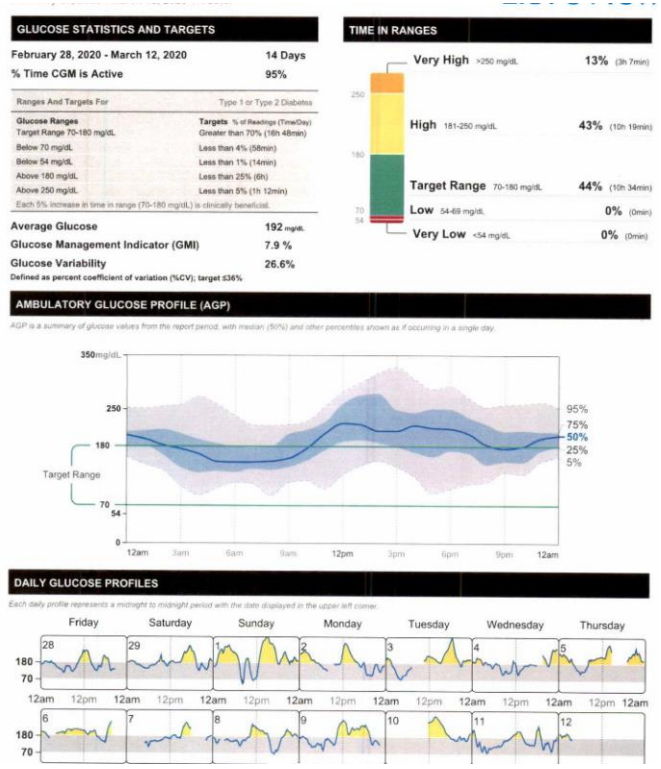
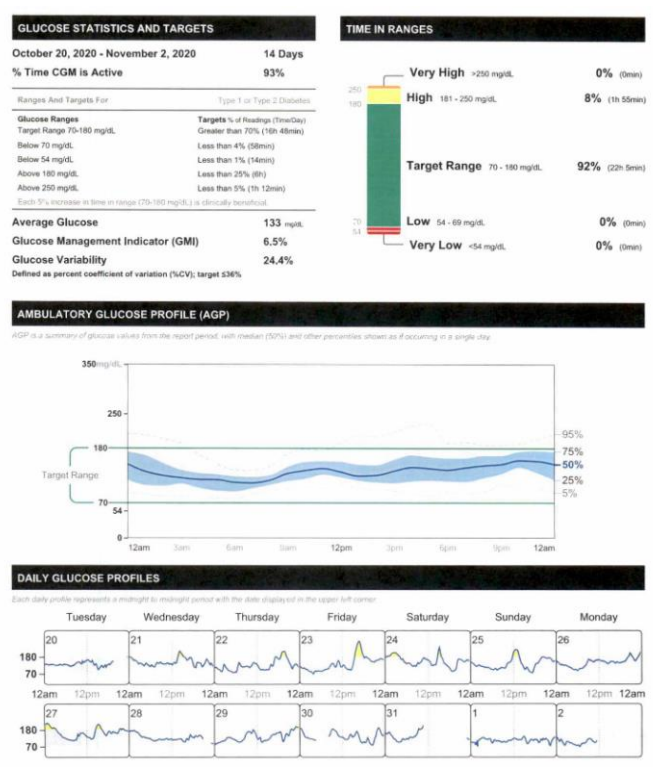
Case: Person with T2DM on MDI

- The patient is a 68 yo male
- On MDI with CGM
- Busy at work, often unable to dose before meals
- Says he can’t “figure out” how much insulin to give before he eats
- Tends to over-correct when high and stack his insulin
- A1C = 7.9%
- Started on a tubeless pump

Case: T2DM on MDI with Poor Control
Switched to Tubeless Pump



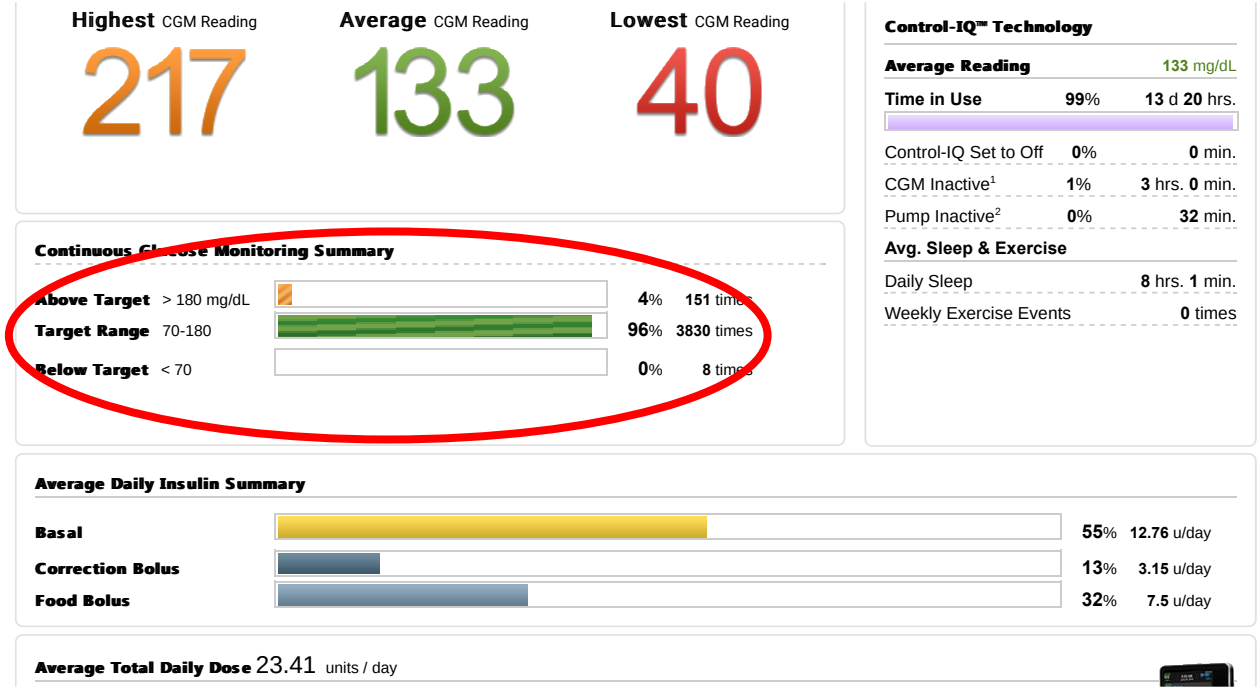


Tracing used with permission from A. Peters

Case: Person with Longstanding T1DM

- 73 yo male with a history of T1DM since age 2.
- When diagnosed, in the 1940's, BGM, pumps, insulin analogs and even disposable syringes not available.
- His parents were told that he wouldn't live to be 30.
- However, he grew up, became a teacher, a father and a grandfather.
- He lives in remote mountains in California but has an avid interest in his own healthcare.
- In spite of having all diabetic retinopathy, CVD, a colostomy due to a toxic megacolon he has lead a full and active life.
- He was started on an AID system.

73 yo with T1DM since age 2



Highest CGM Reading 217

Average CGM Reading 133

Lowest CGM Reading 40

Continuous Glucose Monitoring Summary

Above Target	> 180 mg/dL	4%	151 times
Target Range	70-180	96%	3830 times
Below Target	< 70	0%	8 times

Control-IQ™ Technology

Average Reading	133 mg/dL	
Time in Use	99%	13 d 20 hrs.
Control-IQ Set to Off	0%	0 min.
CGM Inactive[1]	1%	3 hrs. 0 min.
Pump Inactive[2]	0%	32 min.

Avg. Sleep & Exercise

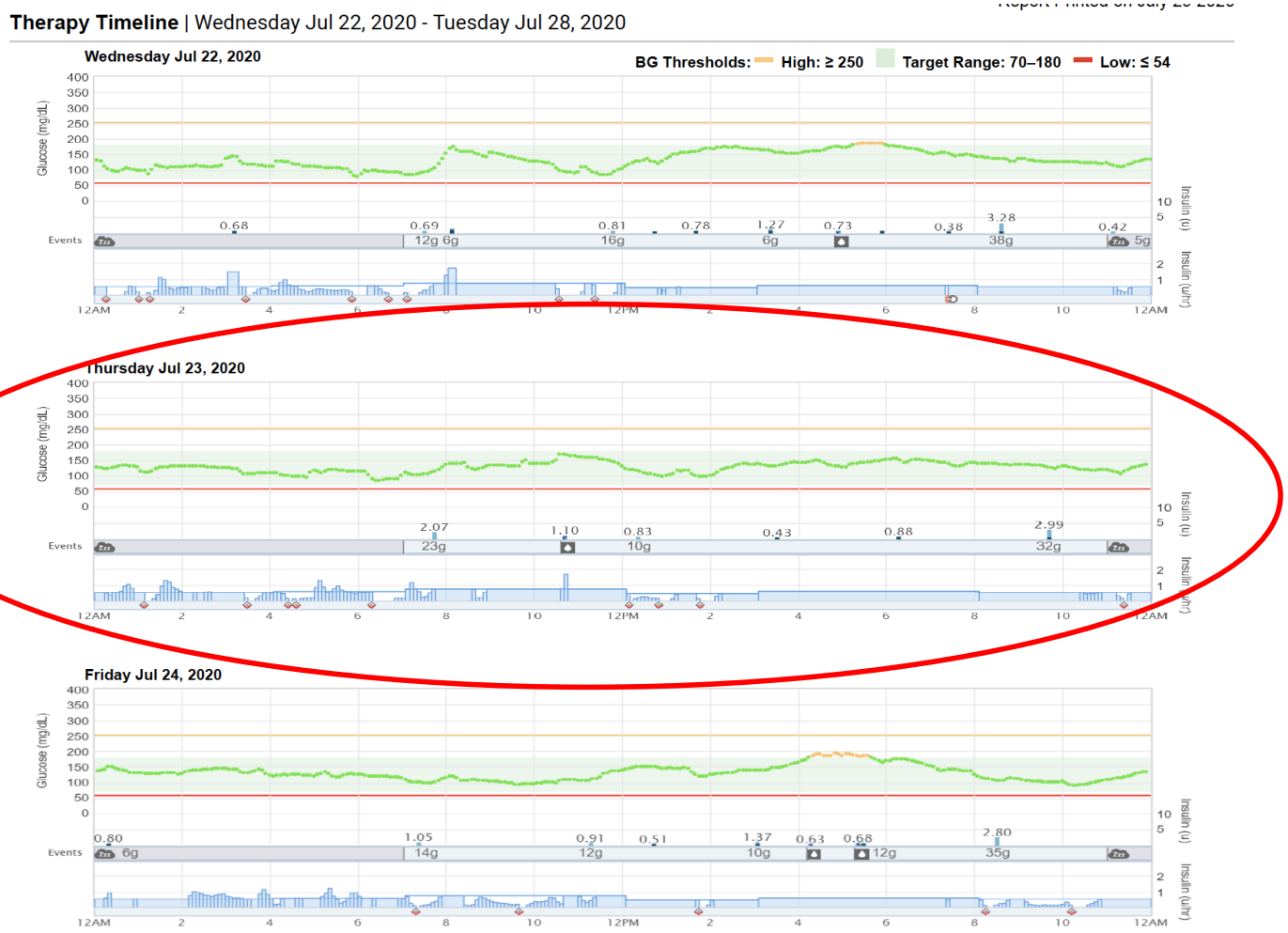
Daily Sleep	8 hrs. 1 min.
Weekly Exercise Events	0 times

Average Daily Insulin Summary

Basal	55%	12.76 u/day
Correction Bolus	13%	3.15 u/day
Food Bolus	32%	7.5 u/day

Average Total Daily Dose 23.41 units / day

73 yo with T1DM since age 2



Common Problems with Pumps

- Infusion set blockage
  - Usually related to insertion technique or location
  - Seen as a no delivery of insulin
- Patient runs out of insulin
- Batteries die on pump
- Relying on basal to cover everything
- Micromanaging
  - Not letting one action play out
- Settings not quite right

AACE/ACE. Endocrine Practice. 2014;20:463-489.
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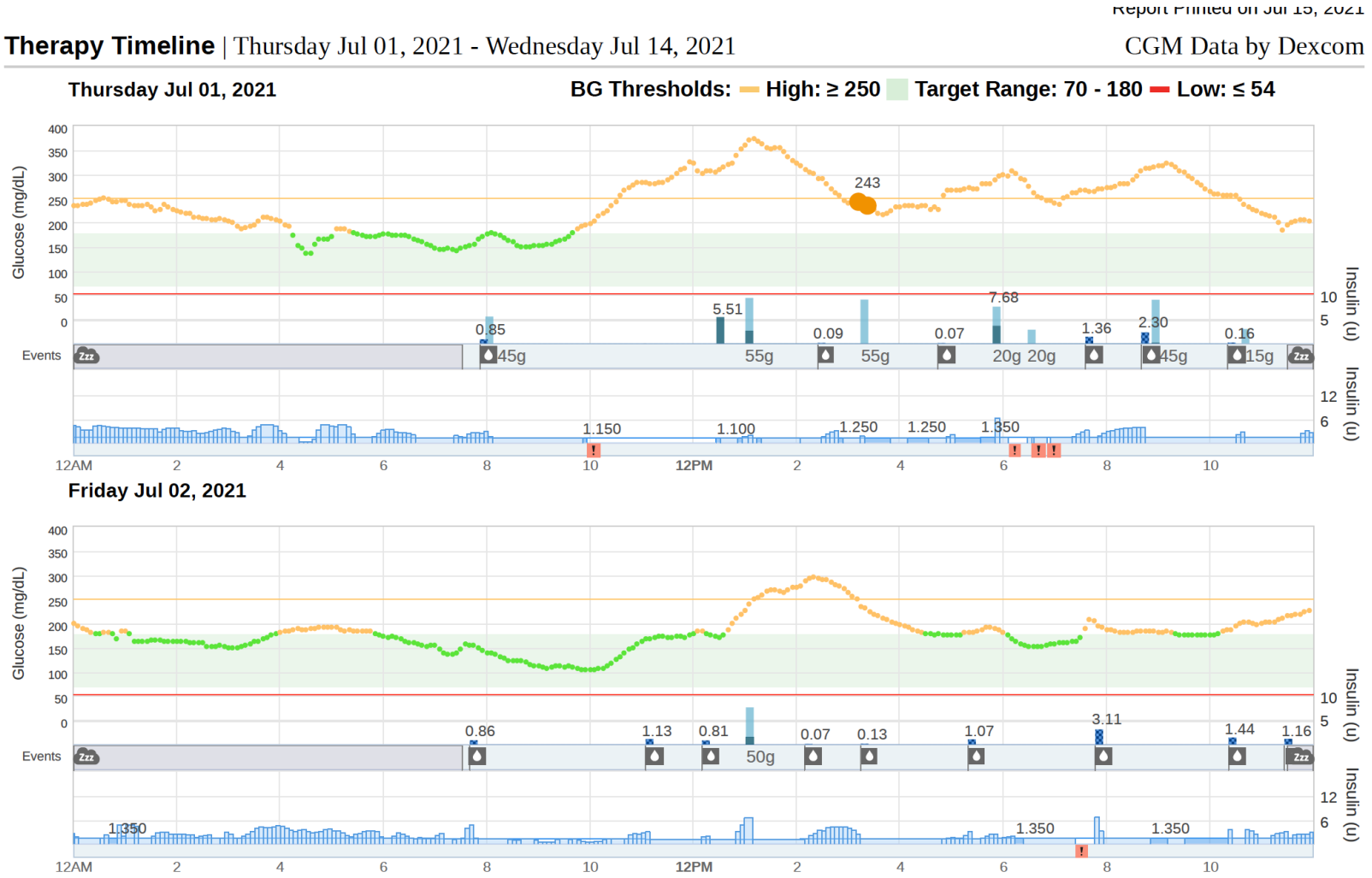
Busy Mom Forgets/Delays PreMeal Bolus Doses



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Pumps & AIDs: Conclusions

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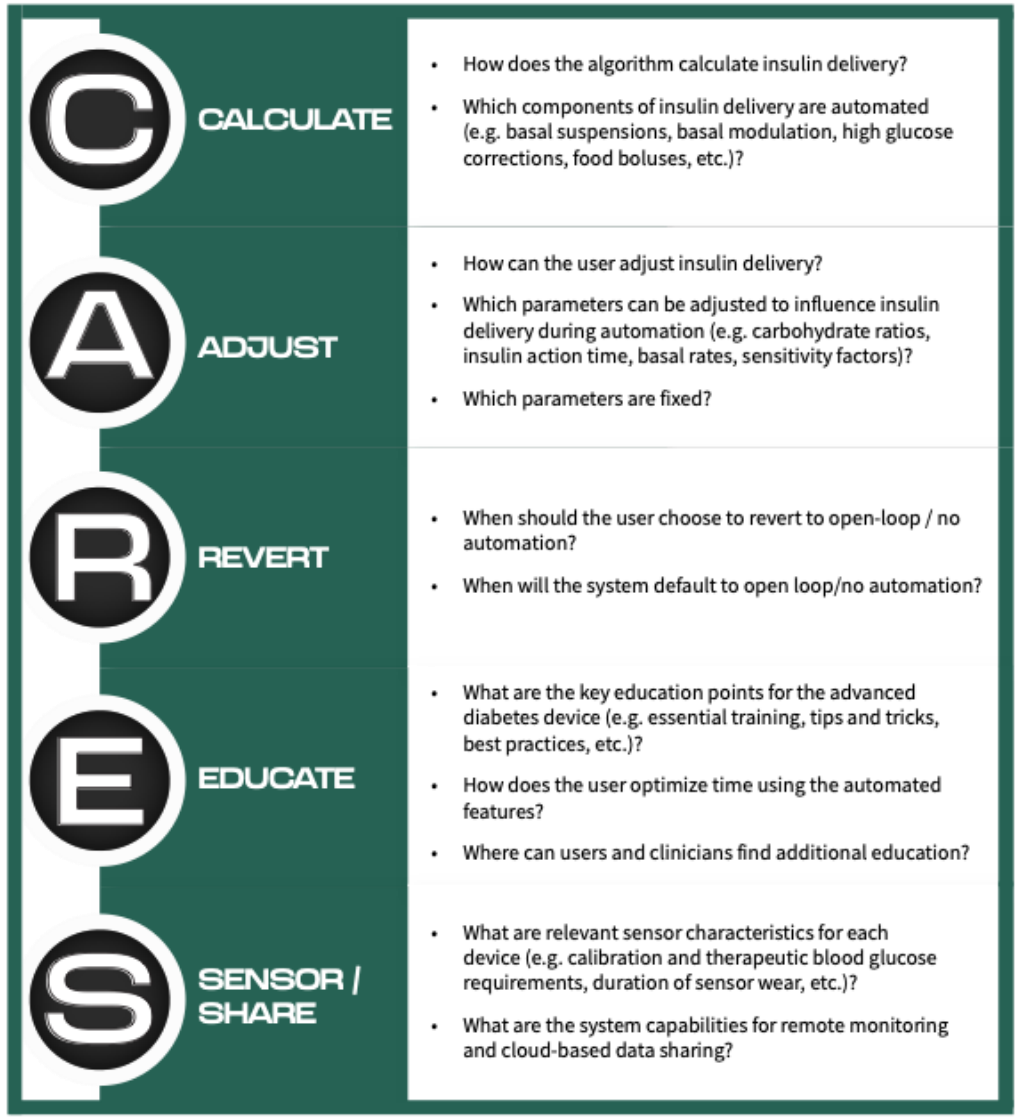
PANTHER PROGRAM

C.A.R.E.S. FRAMEWORK FOR ADVANCED DIABETES DEVICES



Messer, L.H. et al 2019 DTT https://doi.org/10.1089/dia.2019.0105
Laurel.Messer@cuanschutz.edu
BDCPantherDiabetes.org

Know Each AID System

	MiniMed 670G / 770G	MiniMed 780G	t:slim X2 Control-IQ	Omnipod 5
				
CALCULATE				
What is automation called?	Auto Mode	SmartGuard	Control-IQ	Automated Mode
Basal automation?	Automated basal insulin delivery calculated based on total daily insulin from past 2-6 days ("auto basal")	Automated basal insulin delivery calculated based on total daily insulin from past 2-6 days ("auto basal")	Automated basal insulin delivery that increases or decreases programmed basal rates	Automated basal insulin delivery calculated from total daily insulin, which is updated with each pod change
Bolus automation?	No (auto basal only to respond to hyperglycemia)	Auto-correction bolus if glucose > 120 mg/dL and at maximum "auto basal" delivery	Auto-correction bolus (max 1/hour) if glucose predicted to be >180 mg/dL, delivers 60% of calculated dose	No (adaptive basal only to respond to hyperglycemia)
Algorithm target glucose / range?	120 mg/dL	"BG Target" 100, 110, 120 mg/dL	112.5-160 mg/dL (range)	"Target Glucose" in pump menus or "BG Target Range" on glooko reports 110, 120, 130, 140, 150 mg/dL

https://www.bdcpantherdiabetes.org/device-comparison

Conclusions

- Insulin pump and AID systems can be very helpful in people on MDI
- However, it is a lifestyle choice and patients must be able to use the devices and trouble shoot if problems occur
- With current systems patients must still be able to enter in their meals and exercise for optimal benefit
- Downloading the pumps for analysis is vital in order to manage patients adequately

Thank You

Detailed Requirements for Prescribing a Pump

- Eligible patients must:
  - Show that they can understand how to use a pump and be psychologically able to adopt new technology
  - Have documented BG testing 4 times per day or use of CGM
  - Completed diabetes education, including carb counting
  - Chart documentation of all above (for Medicare must be giving injections 3 or more times daily)
- Providers must complete a certificate of medical necessity, order the pump from the pump manufacturer, provide chart notes, and fill out forms from the distributor as requested
- The pump company will:
  - Have specific forms to be completed
  - Communicate with the patient's insurer and determine how much the patient will need to pay out of pocket
- Once ordered, the pump will be shipped to the patient from a distributor or the pump company directly and training will need to be arranged

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AADE Practice Paper. 2018. www.diabeteseducator.org.

At Pump Training

- Review summary of training and goals with trainer and patient
  - Initial settings are simple
  - Will need adjustments
  - Insulin dose requirements typically drop
  - Sometimes saline starts
- Review the expectations of pump therapy with the patient
- Discuss plan for follow up, provide emergency back up support
- Schedule first pump start visit—ideally 2 to 4 weeks later
- Set up download station or plan to get a download

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AADE Practice Paper. 2018. www.diabeteseducator.org.
Shubrook JH, et al. Primary Care Reports. 2014;20:101-112.

Major Pump Issues that Require Assistance

- High glucose levels due to infusion set/site issues
  - See next slide for trouble shooting
- Catheter site inflammation/infection
  - May require antibiotics and/or incision and drainage
- Positive serum/urine ketones
  - Check for infusion set issues
- Pump failure (error message or black screen)
  - Have patient contact pump manufacturer help line for new pump

ALL PATIENTS MUST HAVE A BACKUP PLAN FOR POTENTIAL PUMP FAILURE. WHEN IN DOUBT, ADVISE REVERTING BACK TO INJECTION THERAPY.

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Shubrook JH, et al. Primary Care Reports. 2014;20:101-112.