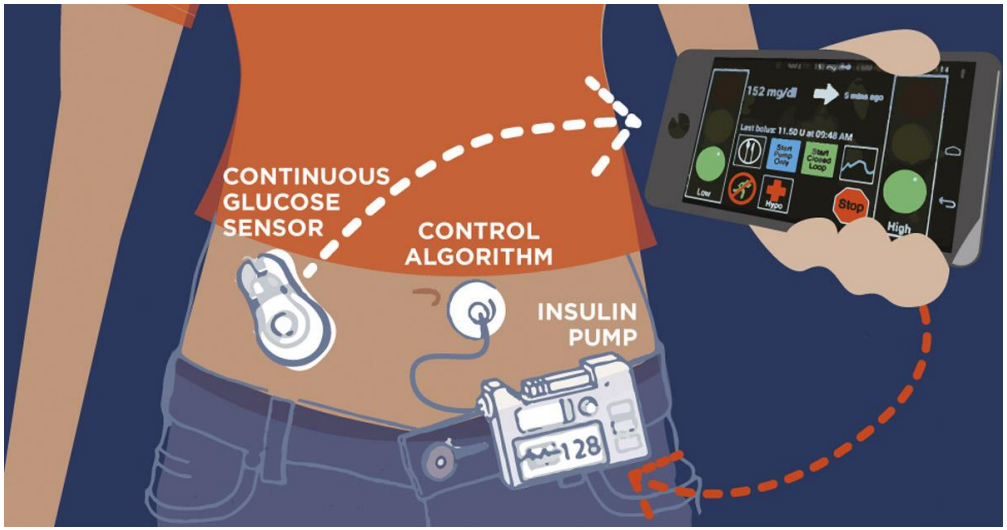
Insulin Pump therapy from basics to hybrid technology



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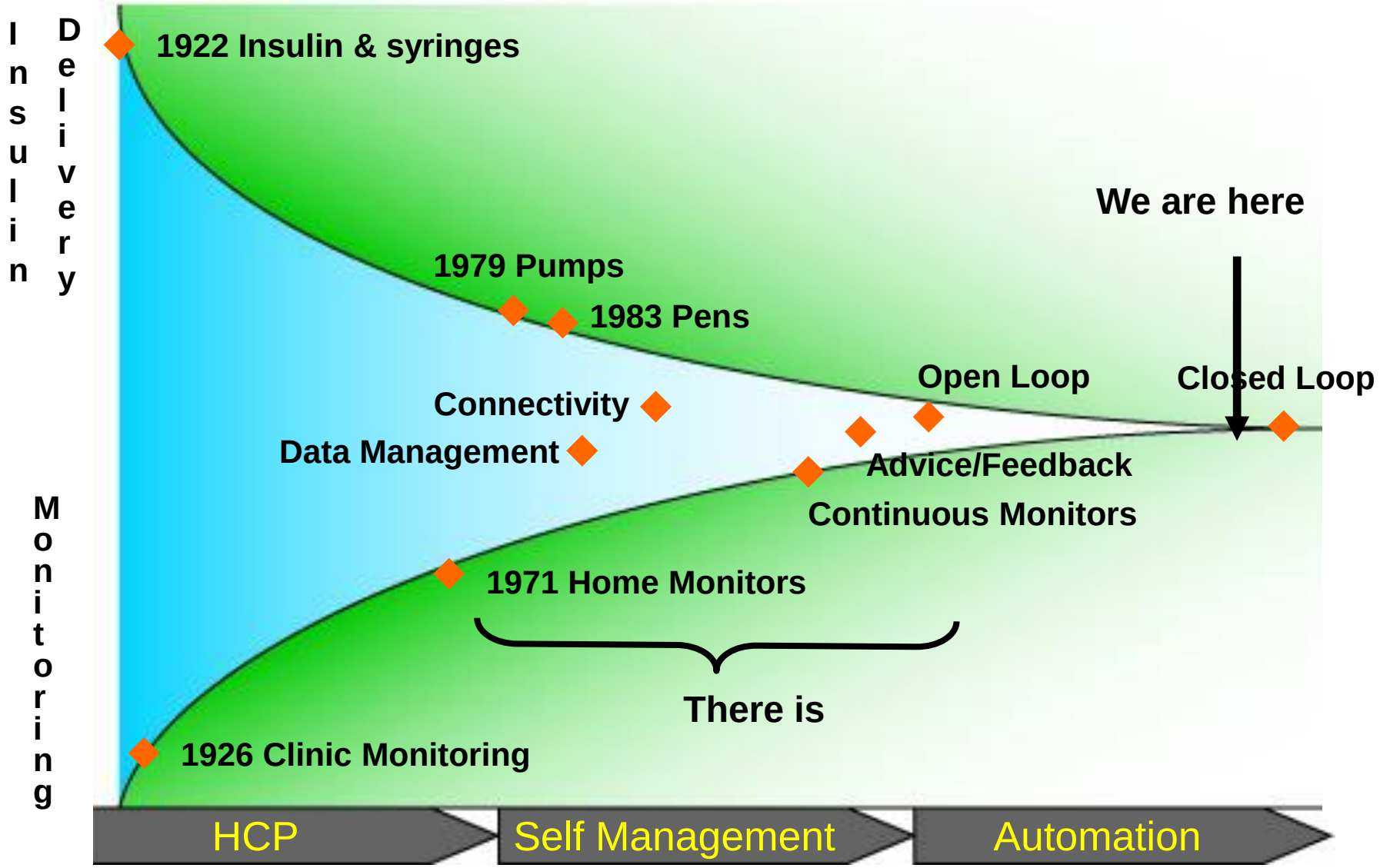
Highlights

- Diabetes development towards closed loop insulin delivery.
- Who is a pump candidate?
- Advantages of insulin pump.
- Glucose exposure & glucose variability.
- Glycemic Goals.
- Carbohydrate counting is essential prior of thinking to start insulin pump.
- Insulin pump therapy started from classic pumps into smart pump and currently hybrid closed loop pump using IQ technology.
- Basic terminology we need to know prior of making pump settings.
- Calculation of insulin pump settings.
- Disadvantages of insulin pumps.
- Questions & Answers.

Diabetes Development Toward Automation



Insulin Pump Therapy

Who Is A Pump Candidate?

- Type 1 and insulin-requiring type 2 patients who are unable to achieve acceptable glycaemic control, including those with:
- Elevated A1C.
- Glycemic variability.
- Recurrent hypoglycemia, nocturnal hypoglycemia, activity-induced hypoglycemia, and hypoglycemia unawareness.
- Pregnancy/Pre-pregnancy.
- Recurrent diabetic ketoacidosis (DKA)/recurrent hospitalizations.
- Dawn phenomenon.
- Gastroparesis.
- Patient preference, meal-timing flexibility, and normalization of lifestyle.
- Low insulin requirements (not easily measured via syringe).
- Inability to self-administer insulin (pre-school/grade school).
- Inability to predict food or meal intake (infant/toddler).
- Insulin resistance, Type 2 diabetes.

Candidate Requirements

- Realistic expectations.
- Psychologically stable patient /caregivers.
- Educated, caring & trustable person/ caregivers.
- Counts carbs very precisely.
- Willing to solve problems using diabetes management skills.
- Regular follow-up to the clinic.

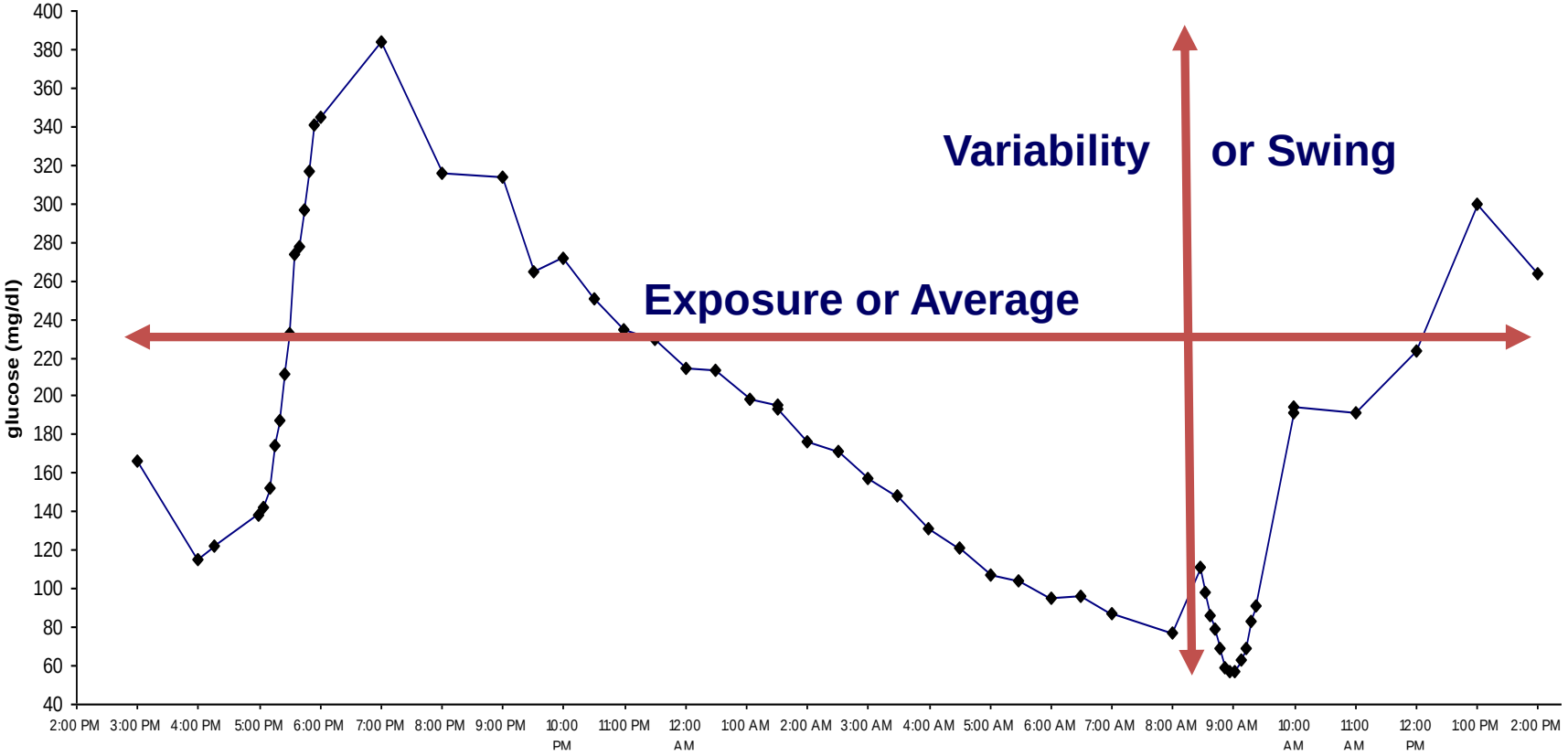
Benefits of Insulin Pump Therapy

- Improved glycemic control
- Less frequent / severe hypoglycemia
- Enhanced quality of life
- Improved patient satisfaction
- Ease of management
- Reduced glucose toxicity, which may also result in improved β-cell function

Currently, Available Intelligent Insulin Pump could improve Glucose toxicity & Variability

Glucose Exposure & Variability

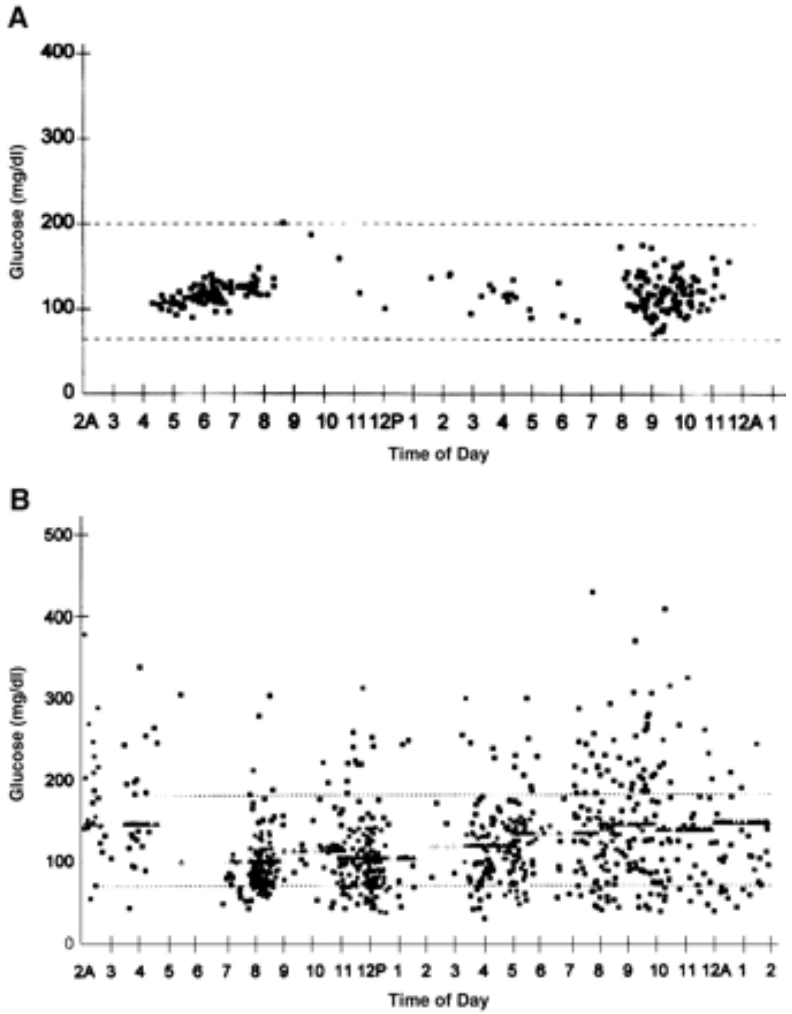
One day's tests every 30-60 min with usual meals and insulin



Glucose Exposure & Glucose Variability

Like weight cycling, variable blood glucose may be more damaging than consistently high blood glucose

Exposure & Variability Are Different

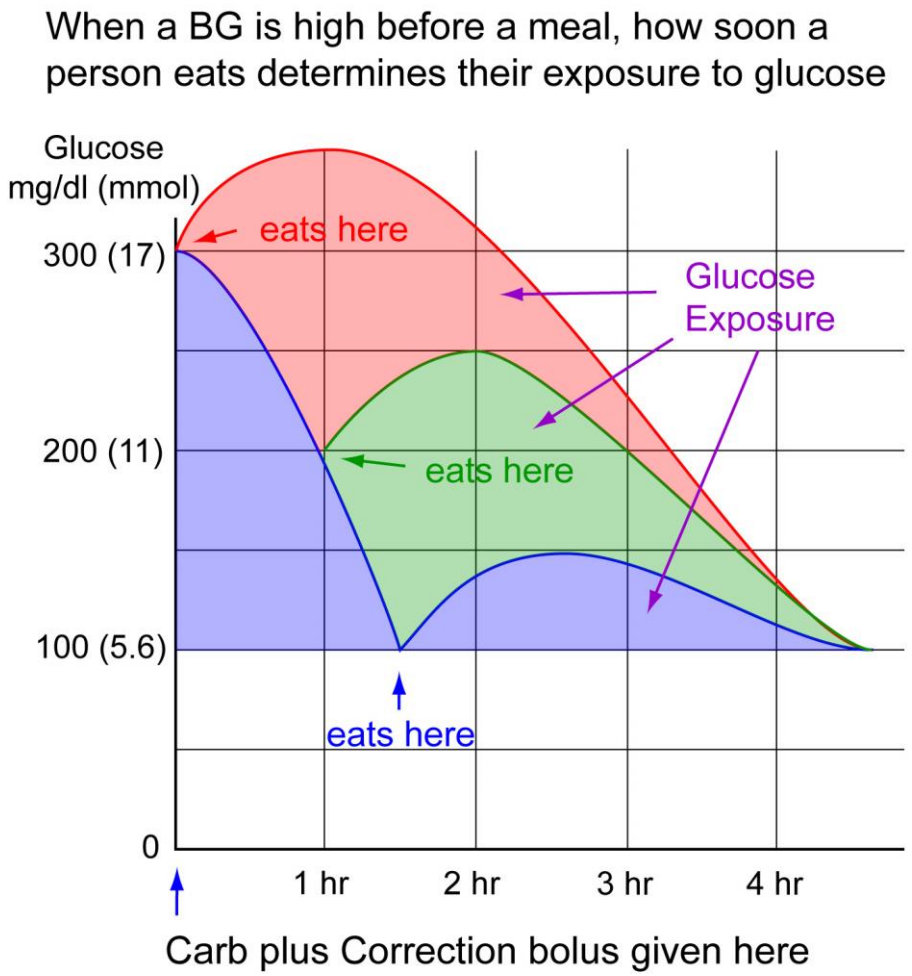


- Glucose variability (SD) and A1cs in two individuals:
  - Top: A1c = 6.6% SD = 20 mg/dl (1.1 mmol)
  - Bottom: A1c = 6.7% SD = 61 mg/dl (3.4 mmol).

Glucose Exposure & Glucose Variability

- Both damage health
- Both need to be lowered
- Devices help

Reduce Glucose Exposure



A lower glucose at the start of a meal reduces glucose exposure.

Rules:

Test early

Bolus early

Don't forget to eat on time

Don't forget you've already bolused

Glycemic Goals

- An A1C goal for many nonpregnant adults of <7% (53 mmol/mol) without significant hypoglycemia is appropriate.
- If using ambulatory glucose profile/glucose management indicator to assess glycemia, a parallel goal is a time in the range of >70% with a time below the range of <4%.
- Based on provider judgment and patient preference, achievement of lower A1C levels than the goal of 7% may be acceptable, and even beneficial, if it can be achieved safely without significant hypoglycemia or other adverse effects of treatment.

CGMS, AGP & TIR are of great help!!

- Standardized reports from continuous glucose monitoring devices with visual cues, such as the ambulatory glucose profile (AGP), should be considered as a standard printout for all CGM devices.
- Lower “Time in range (TIR)” is associated with a higher risk of microvascular complications and can be used for assessment of glycemic control.
- Additionally, time below target (<70) and time above target (>180mg/dL) are useful parameters for reevaluation of the treatment regimen.

AGP Report

Name

MRN

GLUCOSE STATISTICS AND TARGETS

Glucose Ranges	Targets [% of Readings (Time/Day)]	14 days % Sensor Time
Target Range 70–180 mg/dL	Greater than 70% (16h 48min)	
Below 70 mg/dL	Less than 4% (58min)	
Below 54 mg/dL	Less than 1% (14min)	
Above 180 mg/dL	Less than 25% (6h)	
Above 250 mg/dL	Less than 5% (1h 12min)	

Each 5% increase in time in range (70–180 mg/dL) is clinically beneficial.

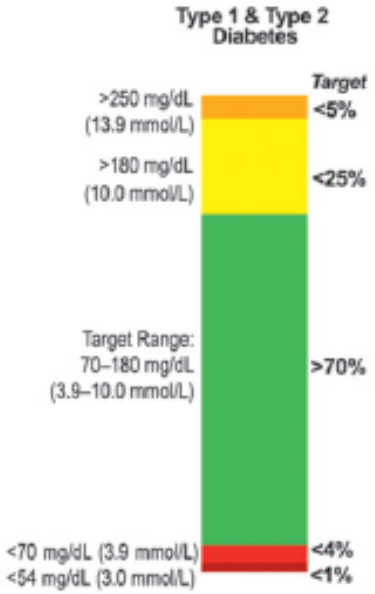
Average Glucose

Glucose Management Indicator (GMI)

Glucose Variability

Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES

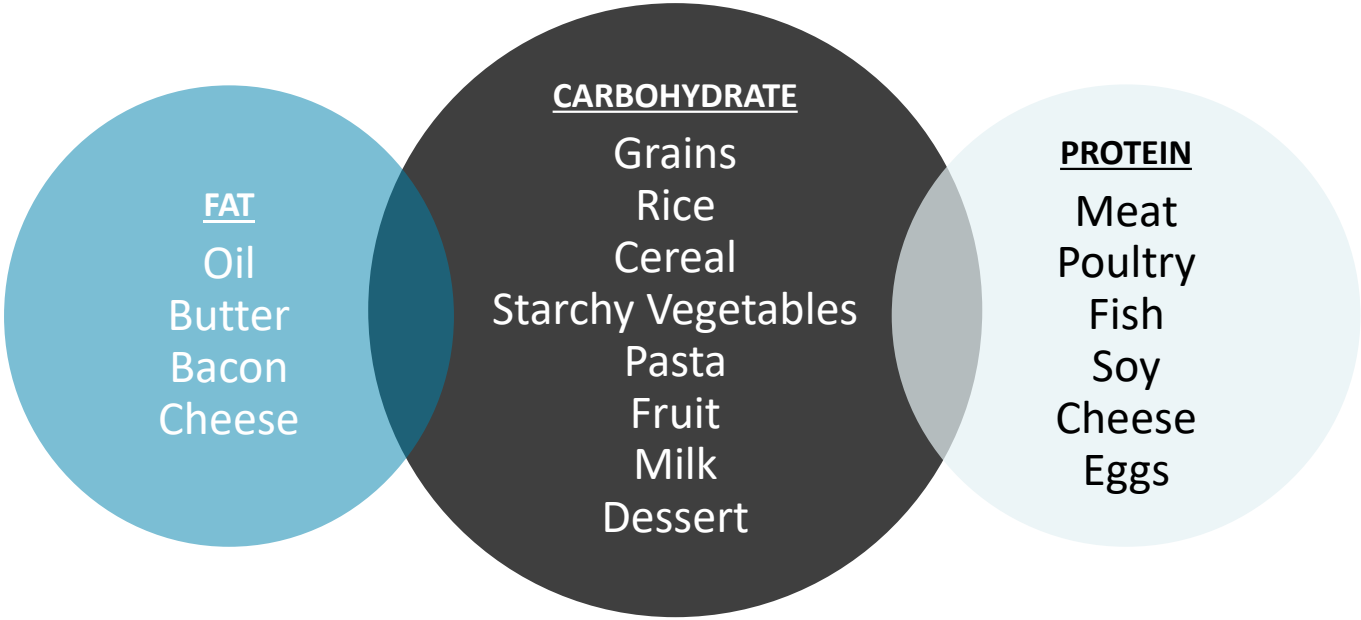


Glycemic Targets:
Standards of Medical Care in Diabetes - 2021. *Diabetes Care* 2021;44(Suppl. 1):S73-S84

Carb Counting

Carb Counting

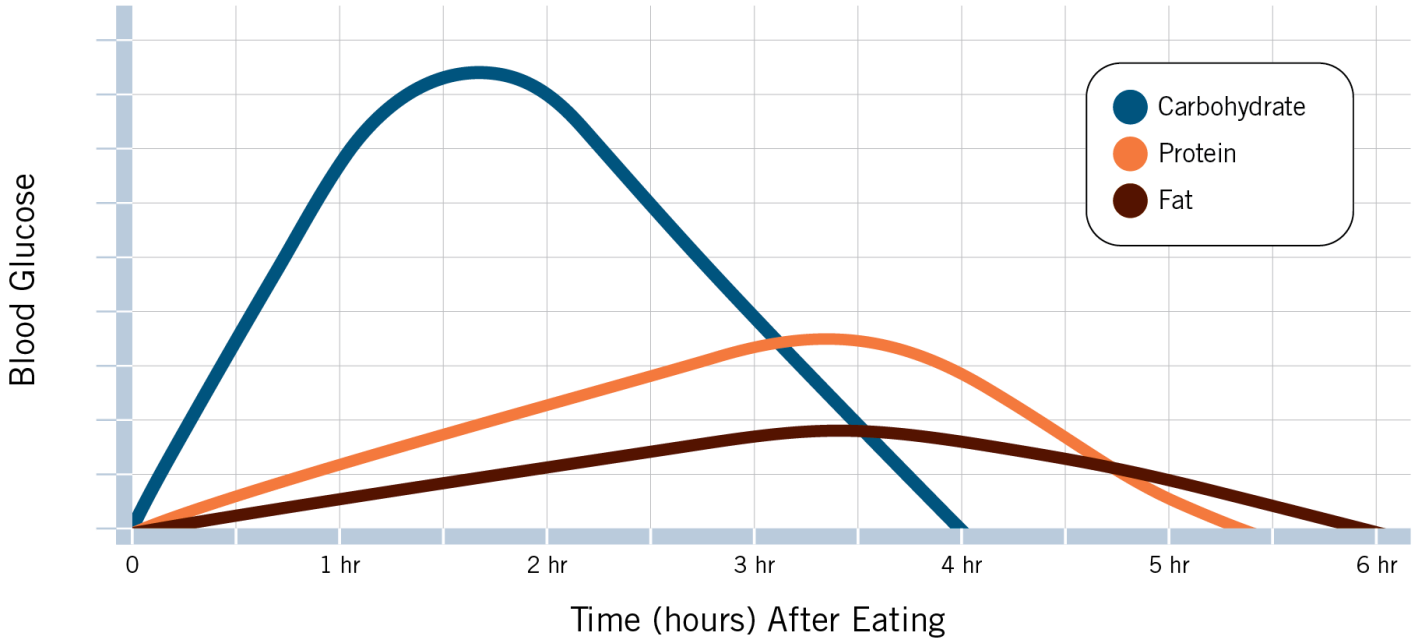
Food Glycemic index and carbohydrate counting play an instrumental role in balancing blood glucose



Carb Counting

Patients should be aware of which foods contain low/high glycemic index carbohydrates.

Carb Counting

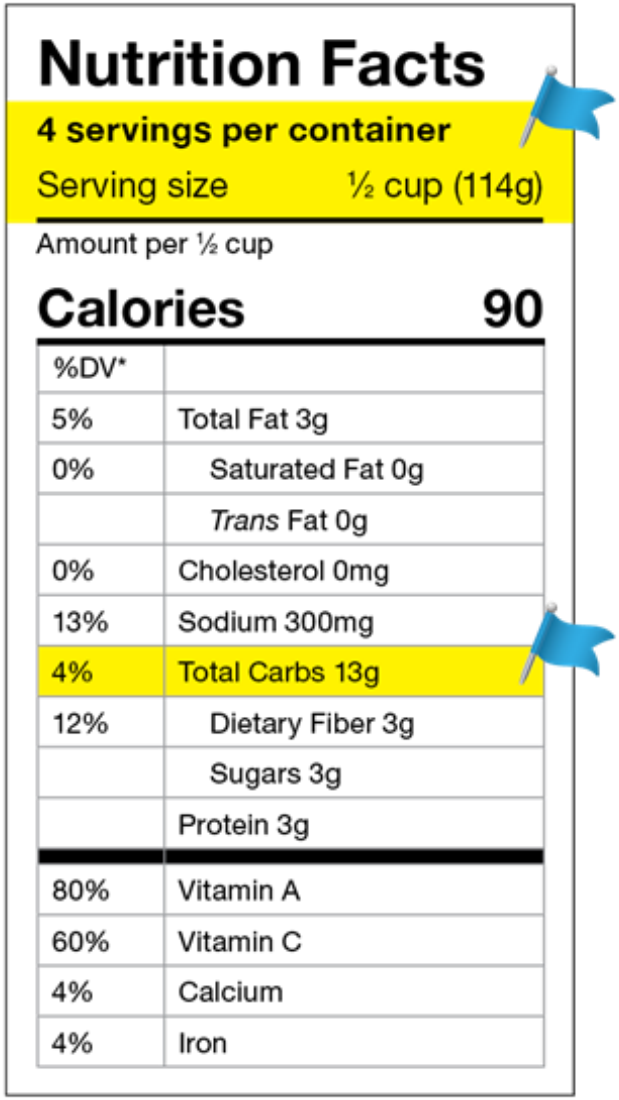


Carb Counting

- Carbohydrate counting is not an exact science
- Requires a variety of tools for making an educated guess

Carb Counting Resources

- Food Labels
- 15-gram Carbohydrate Reference Guide
- Books, Pamphlets, Apps
- Restaurant Guides



Nutrition Facts

4 servings per container

Serving size ½ cup (114g)

Amount per ½ cup

Calories 90

%DV*	
5%	Total Fat 3g
0%	Saturated Fat 0g
	Trans Fat 0g
0%	Cholesterol 0mg
13%	Sodium 300mg
4%	Total Carbs 13g
12%	Dietary Fiber 3g
	Sugars 3g
	Protein 3g
80%	Vitamin A
60%	Vitamin C
4%	Calcium
4%	Iron

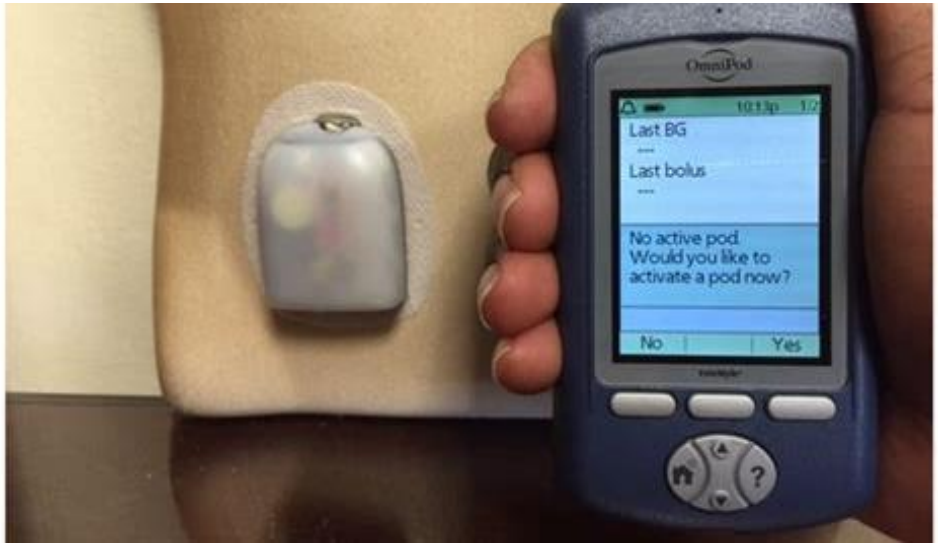
Insulin Pump Origins

- The first insulin pumps appeared in 1979 when large portable chemotherapy pumps were converted to deliver insulin
- Autosyringe AS2C and Harvard Apparatus Mill Hill Infuser were early models
- Used a large 50 ml syringe that required users to dilute insulin to U-36 or U-18
- Had only one basal rate and no memory

1976 Biostator (top) and 1978 Autosyringe AS2C –>

Insulin Pumps : Past

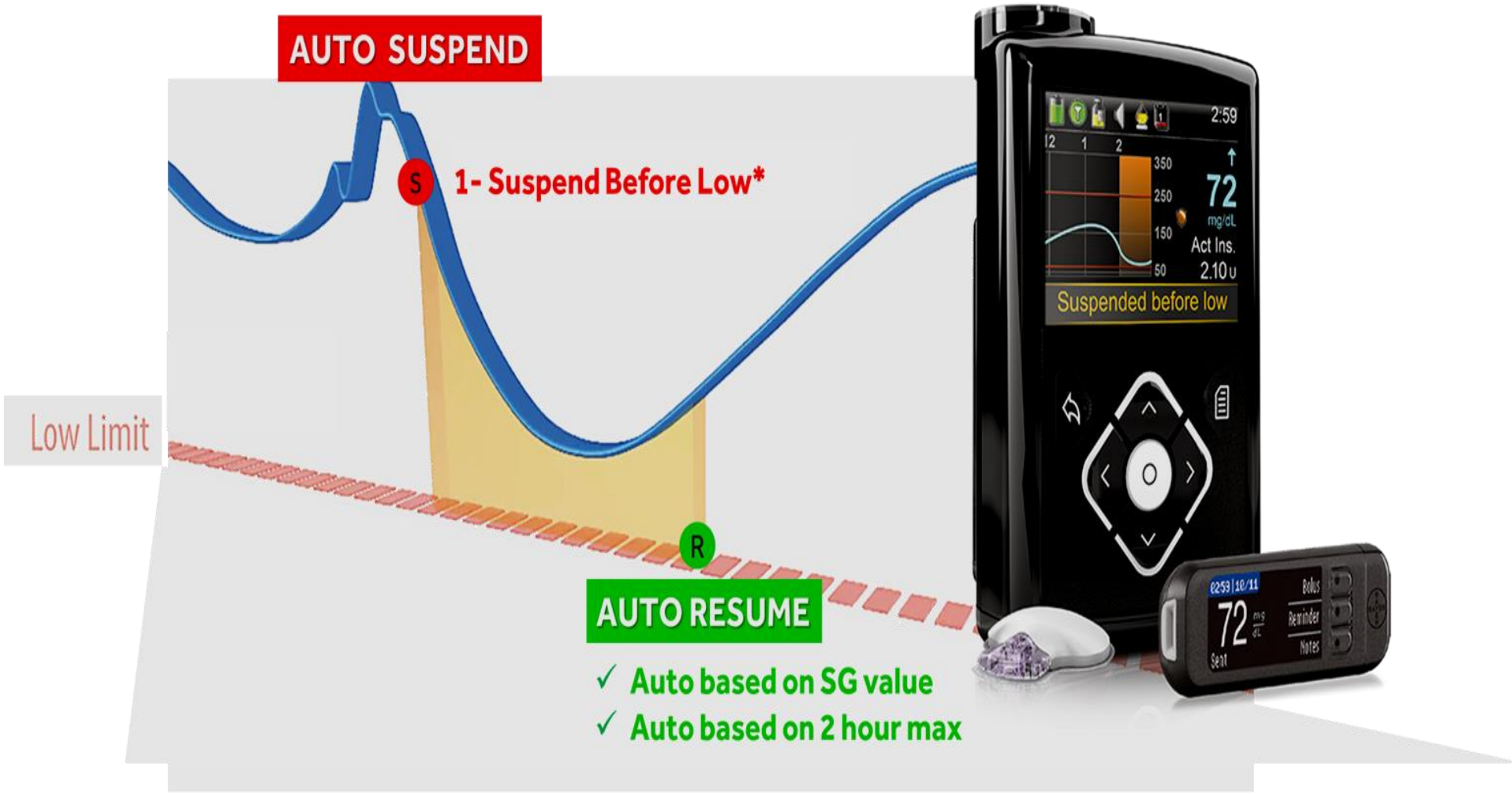
Various insulin pumps available



Sensor Augmented Smart Insulin Pumps

- The combination of continuous glucose sensors with insulin pumps has enabled the development of automated insulin delivery systems.
- A controller algorithm adjusts insulin delivery rates based on a continuous stream of glucose sensor data.
- Suspending basal insulin delivery for low sensor glucose levels has been shown to markedly reduce hypoglycemia without worsening glycaemia.
- Sensor-augmented pumps that preemptively suspend insulin delivery when sensor glucose levels are predicted to be low show promise in minimizing hypoglycemia.

‘SMARTGUARD™ TECHNOLOGY PROVIDES ADVANCED PROTECTION AGAINST HYPOGLYCEMIA (AUTO SUSPENSION & AUTO-RESUME OF INSULIN)



Intelligent Pumps

Minimed 780 -Automatically adjusts insulin delivery and corrects highs 24/7, every 5 minutes, as needed

Intelligent Pump Features

- Automatic TDD adjustment
  - Average blood sugar and standard deviation
  - % TDD used for corrections
  - Basal/bolus balance
- Automatic basal testing
  - Overnight
  - Daytime, when meal is skipped
- Automatic carb factor testing
  - Premeal, 2 hr postmeal peak, normal in 4-5 hrs?
- Automatic correction factor testing
  - High-to-normal in 4-5 hours?

Practical issues of the pump

Terminology

- Basal –background insulin released slowly through the day.
- Bolus – a quick release of insulin:
  - Carb bolus – covers carbs.
  - Correction bolus – lowers high readings.
- Insulin On Board (IOB) –insulin still active from recent boluses.
- TDD – total daily dose of insulin (all basal and bolus).

Insulin Pump Therapy

- Rapid-acting Insulin
- Basal
- Bolus

- Insulin Pump Settings
- Infusion Set
- CGM

Insulin Pump Therapy

A Personal Profile contains the following key insulin dose settings:

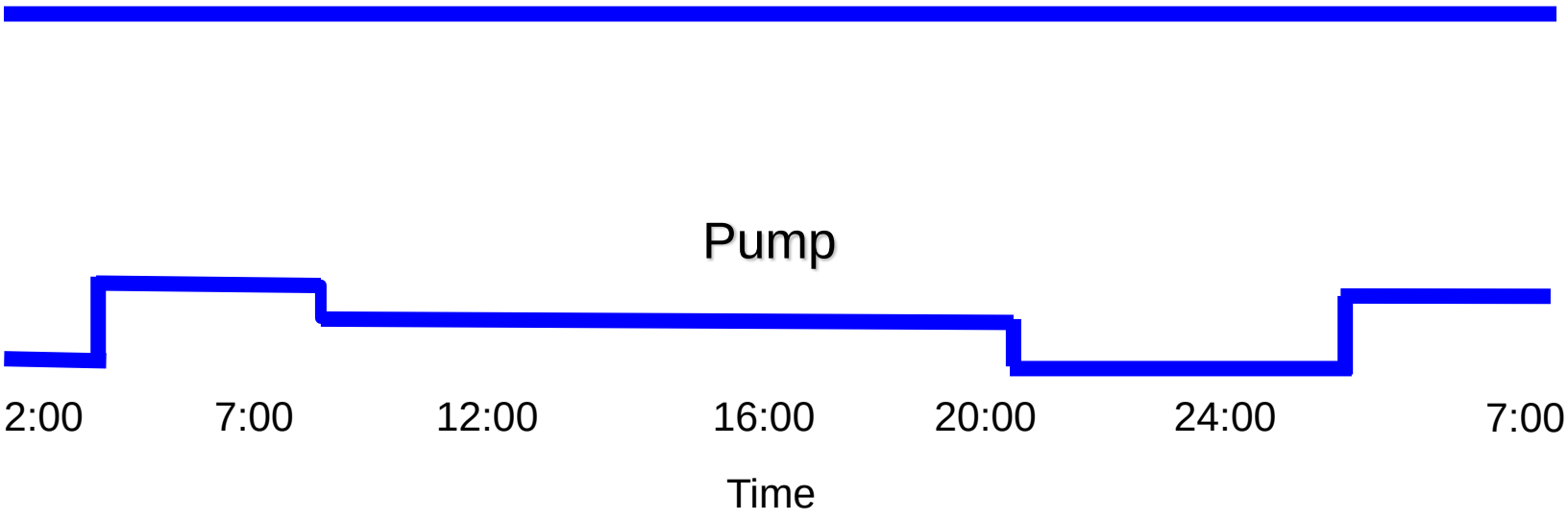
Five Key Insulin Dose Settings:

- Basal Rate
- Carbohydrate Ratio
- Correction Factor
- Target Glucose
- Insulin Duration

Insulin pump dose settings are determined and evaluated by a healthcare professional.

Basal: MDI versus Pump

- Basal insulin in MDI



Basal insulin delivery from a pump provides a better and faster match for life's needs

Insulin Pump Therapy

Rapid-acting U-100 Humalog and Novolog insulins are FDA approved and indicated for use in Tandem pumps.

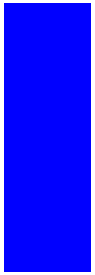
- Most similar to insulin produced by the body
- Strongest peak action within 1-1.5 hours
- Clears the body in 3-5 hours

A food bolus is calculated using:

- Carbohydrate grams
- Carb ratio

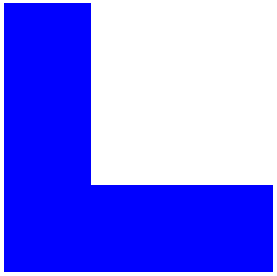
Note: Some may prefer to deliver a food bolus by entering units of insulin directly into the pump in place of using the bolus calculator. Confirm guidelines are in place in the student's 504 plan or contact their parents/guardian/healthcare provider.

Carb Bolus Varieties



- Normal carb bolus
  - Bolus taken immediately – most meals

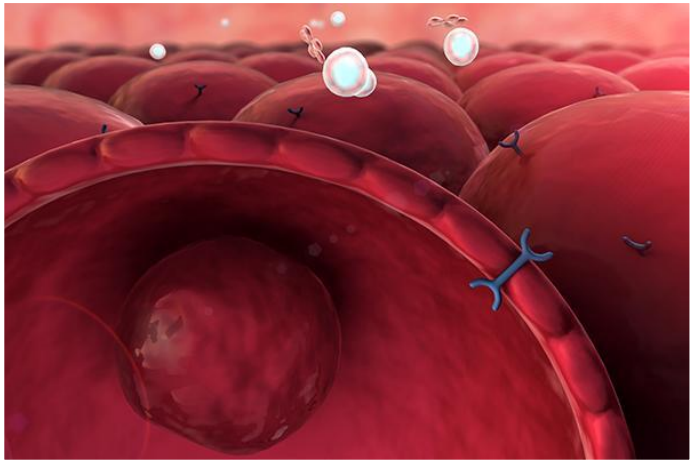
- Extended or square wave bolus
  - Bolus extended over time – gastroparesis



- Combo or dual wave bolus
  - Some now, some later – bean burrito, some pastas and pizzas.

A correction bolus is calculated using:

- Current glucose
- Correction factor
- Target glucose
- Insulin on Board (IOB)



Target glucose (blood glucose) setting:
A specific blood glucose goal used to calculate a correction bolus

Insulin Pump Therapy

- **The Insulin Duration** setting helps prevent insulin stacking from too many boluses by identifying how long insulin from previous food or correction boluses will lower glucose

- **Insulin on Board (IOB)** represents the amount of insulin remaining in the body from previous boluses that may continue to lower blood glucose

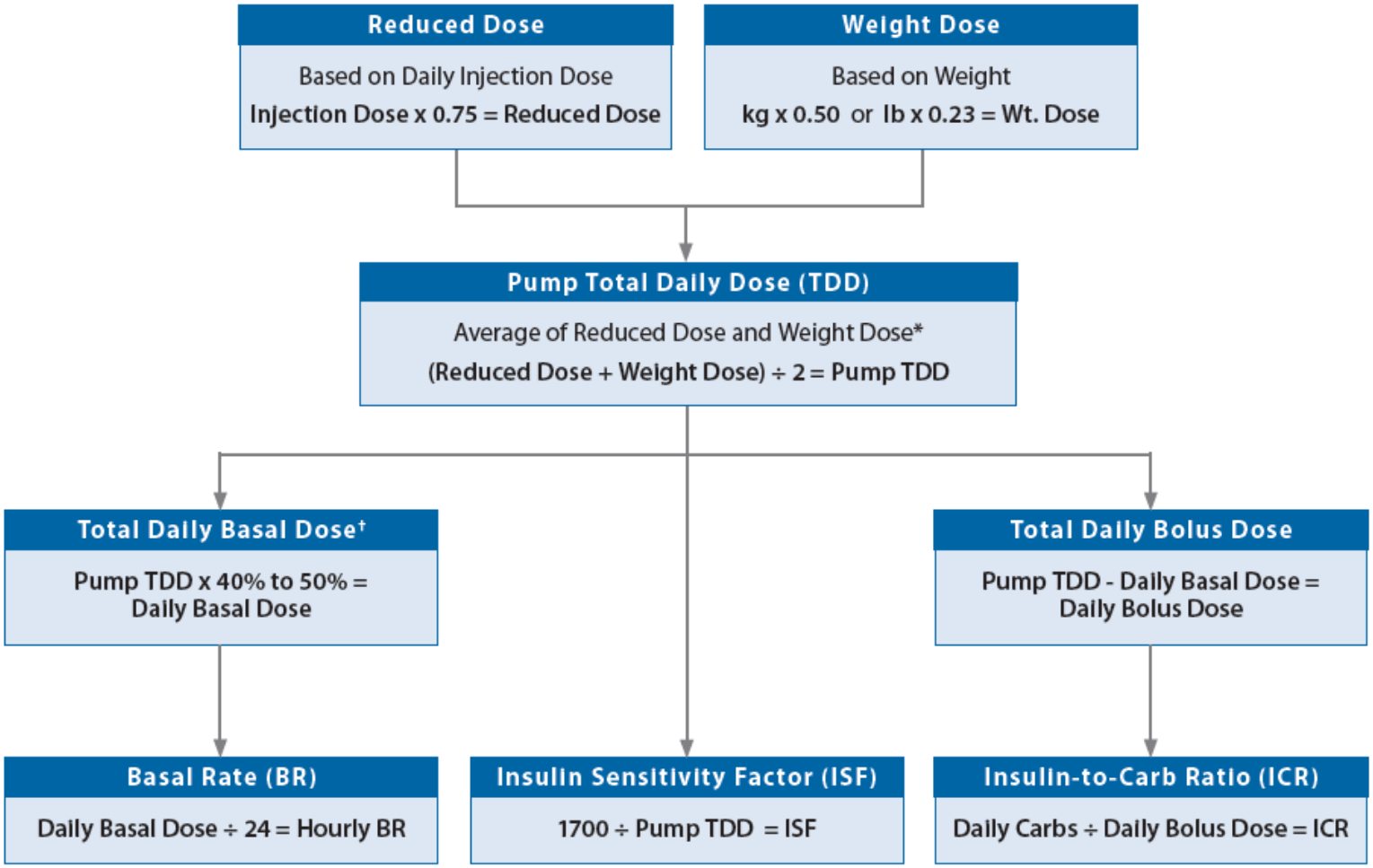
Calculations of the pump

Transition from MDI to pump

- Best time to insert the pump is in the morning, not during travel.
- Outpatient setting okay.
- Wean person off injections:
  - NPH, hold am dose
  - Glargine, detemir- take day before, if evening hold is best.
  - Degludec – take ½ usual dose day before if am, if evening, omit.

Guidelines for Initial Pump Settings

Insulin pump therapy uses rapid-acting insulin for both basal and bolus insulin requirements.



* Hypoglycemic unawareness or other concerns, use the lower dose.
† The percentage split for total daily basal and total daily bolus varies, especially in pediatric populations.

EXAMPLE PATIENT

Type 1 Male Weight: 70 kg (154 lb)

Current Daily Insulin Regimen	Rapid-acting: 11 units pre-meal x 3		33 u/day
	Long-acting: 20 units (Bedtime)	+	20 u/day
	Total Daily Injection Dose	=	**53 u/day**

Reduced Dose

53 u/day x 0.75 = **40 u/day**

Weight Dose

70 kg x 0.5 u = **35 u/day**

or

154 lb x 0.23 u = **35 u/day**

Initial Pump TDD

(40 u/day + 35 u/day) ÷ 2 = **37.5 u/day**

(Reduced Dose) (Weight Dose) (Pump TDD)

Clinical Considerations for Pump TDD

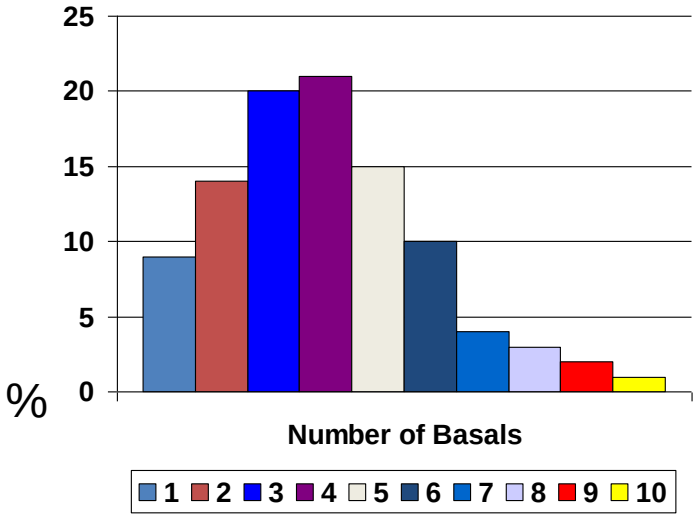
- Use less than a 25% reduction if daily injection dose is more than 70% rapid-acting insulin.
- Pediatric patients who have good control on injections may require as little as a 5% reduction.
- For children & teens, TDD is variable. May require as much as 1.0 u/kg to calculate weight dose.
- Hypoglycemia or hypoglycemia unawareness, use the lower of the two values.
- Persistent hyperglycemia, elevated A1C or pregnancy, use the higher value.
- Erratic glucose control, starting therapy at diagnosis or from oral medications, use weight method.

Guidelines for Transitioning to Pump Therapy

Goal: Eliminate as much intermediate/long-acting insulin as possible before starting pump.

- Stop intermediate-acting insulin 12 hours before and long-acting insulin 24 hours before initiating pump therapy.
- Have patient give injections using small amounts of rapid-acting insulin as needed (every 3 to 4 hours) to keep BGs acceptable until pump therapy is initiated.
- In situations where intermediate or long-acting insulin is not discontinued, program a temporary basal rate to deliver a reduced basal amount (50% to 90% less than calculated starting rate) for the first 12 to 24 hours of therapy.

How Many Basal Rates?



- Percentage of pumpers who use 1 to 10 basals per day from self reports of several hundred pumpers at insulin-pumpers.org

One basal rate may work in children, while the complex metabolism of puberty often requires multiple rates

Total Daily Basal and Total Daily Bolus

First, determine the percent of TDD to be delivered as basal insulin and then multiply TDD by that percent. This will give you the Total Daily Basal amount. To calculate Total Daily Bolus subtract the Total Daily Basal amount from the TDD.

BASAL

Pump TDD x % Basal = Total Daily Basal

BOLUS

Pump TDD - Total Daily Basal = Total Daily Bolus

EXAMPLE PATIENT

50% of TDD as Total Daily Basal

Total Daily Basal

37.5 u/day x 0.5 = 18.75 u/day
(Pump TDD) (Total Daily Basal)

Total Daily Bolus

37.5 u/day – 18.75 u/day = 18.75 u/day
(Pump TDD) (Daily Basal Amount) (Total Daily Bolus)

Clinical Guidelines for Total Daily Basal and Bolus Percentages

	Total Daily Basal	Total Daily Bolus
Adults:	40% to 50%	50% to 60%
Puberty to Adult:	30% to 40%	60% to 70%
Pre-Puberty to Puberty:	20% to 40%	60% to 80%

Insulin-to-Carbohydrate Ratio (ICR)

If a patient on multiple daily injections has established an ICR that provides reasonable post-prandial control, start pump therapy using that ICR. Or, use one of the methods below to calculate the initial ICR. If a patient is not yet carb counting or does not have an accurate food log, use the 450 Rule.

METHOD 1	OR	METHOD 2
Estimated Daily Carb Intake		450 Rule
Carb Grams ÷ Total Daily Bolus = ICR		*450 ÷ Pump TDD = ICR*

EXAMPLE PATIENT		
Estimated Daily Carbs: 225 grams	Total Daily Bolus: 18.75 u/day	Pump TDD: 37.5 u/day
Method 1	OR	**Method 2**
225 grams ÷ 18.75 u/day = 12 grams/unit		**450 ÷ 37.5 u/day = 12 grams/unit**
1 unit covers ~ 12 grams of carbohydrate		1 unit covers ~ 12 grams of carbohydrate
ICR = 12 grams		**ICR = 12 grams**

Insulin Sensitivity – Correction Factor

- Amount that 1 unit of insulin is expected to lower glucose
- Based on average Total Daily Insulin (TDI) Dose (basal + bolus)
- The more insulin used, the lower the sensitivity
- Sensitivity varies by day
- Determined by dividing TDI into:
  - 1500 – aggressive or regular insulin
  - 1700 – common approach for analogs
  - 2000 – conservative approach

Insulin Sensitivity Factor (ISF)

If a patient on multiple daily injections has an established ISF that currently provides reasonable correction doses, you can start pump therapy using that ISF. Or, use one of the methods below to calculate the initial ISF. For patients who have frequent hypoglycemia or hypoglycemia unawareness, use the 2000 Rule.

METHOD 1	OR	METHOD 2
1700 Rule		**2000 Rule**
1700 ÷ Pump TDD = ISF		*2000 ÷ Pump TDD = ISF*

EXAMPLE PATIENT		
Pump TDD: 37.5 u/day		
Method 1	OR	**Method 2**
1700 ÷ 37.5 = 45.3 mg/dL		**2000 ÷ 37.5 = 53.3 mg/dL**
One unit decreases BG ~ 45 mg/dL		One unit decreases BG ~ 53 mg/dL
ISF = 45 mg/dL		**ISF = 53 mg/dL**

ISF CORRECTION FORMULA

(Current BG – BG Target) ÷ ISF = Correction Dose

EXAMPLE PATIENT
BG Target = 100 mg/dL ISF = 45 mg/dL
IF BG IS ABOVE TARGET (160 mg/dL): A positive correction dose is calculated. (160 – 100) ÷ 45 = 1.3 units
IF BG IS AT TARGET: No correction amount is calculated.
IF BG IS BELOW TARGET (60 mg/dL): A negative correction dose is calculated and subtracted from the food bolus. (60 – 100) ÷ 45 = –0.9 units

Clinical Considerations for Setting Initial Bolus Wizard Target Ranges*

	Daytime	Nighttime
• Adults and Adolescents (13+ yrs)	90 – 100 mg/dL	100 – 110 mg/dL
• School Age (6 – 12 yrs)	90 – 110 mg/dL	100 – 120 mg/dL
• Toddler to Pre-school (0 – 6 yrs)	100 – 120 mg/dL	110 – 130 mg/dL
• Hypoglycemia Unawareness	100 – 120 mg/dL	110 – 130 mg/dL
• Pregnancy	80 – 90 mg/dL	90 – 90 mg/dL

*Modifications to Bolus Wizard Target Ranges should be based on each patient's clinical history.

Clinical Considerations for Setting the Active Insulin Time

Adults: 4 to 5 hours • Children: 3 to 4 hours • Pregnancy: 3 to 4 hours

Active Insulin time - IOB

- How much “insulin on board” IOB to prevent stacking and hypoglycemia
- Typical time is 4 hours
- Typical active insulin time is 3-5 hours.
- Action time shorter in leaner, young, active individuals in hot climates (children 3 hours).
- Set at 6-8 hours for those with renal disease or using regular insulin.

Disadvantages of insulin pump

- Cost / Insurances refusal.
- Skin infections /Allergy.
- Changing infusion sets every 2-3 days!
- Tubing block / needle kink.
- Risk of DKA.

Questions & Answers