



Diabetes Technology

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Declaration

- ◉ I do not have any financial interest, arrangement or affiliation with any of the organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation

Objectives


- Discuss the growing role of technology in diabetes management
- Identify candidates for diabetes technology
- List what is new to the market



Diabetes

- Type 1 Diabetes is the 3rd most common chronic disease of childhood
- In the US, 170,000 youth have Type 1 diabetes
 - Increasing incidence of type 2 diabetes in children and adolescents
 - Increasing incidence of type 1 diabetes in adults
- CDC Morbidity & Mortality weekly report 3/30/2018
 - 91% -Type 2 of diagnosed diabetes in 2016
 - 6% -Type 1
 - 3% -“other”

Current Diabetes Management

- Insulin: injected
 - Basal
 - Lantus / Basaglar (Glargine)
 - Levemir (Detemir)
 - Tresiba (Degludec)
 - 200u/ml or 100u/ml
 - Bolus
 - **N**  sliding scale
 - Correct Blood Glucose & for carbohydrates coverage
 - Correction Factor
 - Carb Ratio
 - Novolog (Aspart)
 - Humalog (Lispro)
 - Apidra (Glulisine)



Current Diabetes Management - NOT for Peds

- “Faster” fast acting insulin: injected
 - Fiasp
 - Onset 2 -3 minutes
 - FDA approval 2017
- Inhaled insulin
 - Afrezza
 - Not studied for younger than 18yo
- FDA approval 2014
- Spirometry
- Premeasured doses inhaled prior to meals
 - Onset 12 minutes – peak 1 ½ - 3 hours
 - Dose dependent
- Not for DKA treatment



<https://www.fiaspro.com>



www.afrezza.com

Current T2 Diabetes Management

- Type 2 is reversible!
- Baseline information
 - What's their norm day?
 - A1c in clinic & diagnostic labs
 - Measure abdominal girth
- Education
 - What "is" Type 2 DM?
- Lifestyle changes
 - Not a "diet"....
 - Decrease Carbohydrates
 - Increase activity
 - Better choices
- Sometimes may need
 - Oral hypoglycemic medication
 - Glucophage – Metformin
 - Sulfonylurea
 - Insulin



Technology



1963

Technology

- Insulin Pump Therapy (CSII)
 - Tube system
 - Tubeless system
- Hybrid Closed Loop System - Pump
 - Artificial Pancreas
 - Insulin pump and CGMS integration
- Low Glucose Suspend - Pump
 - Predicts helps to prevent lows
 - Insulin pump and CGMs integration
- Continuous Glucose Monitoring (CGM)
 - Continuous reading of glucose levels
 - Shows the trend of glucose levels
- Flash Glucose Monitor

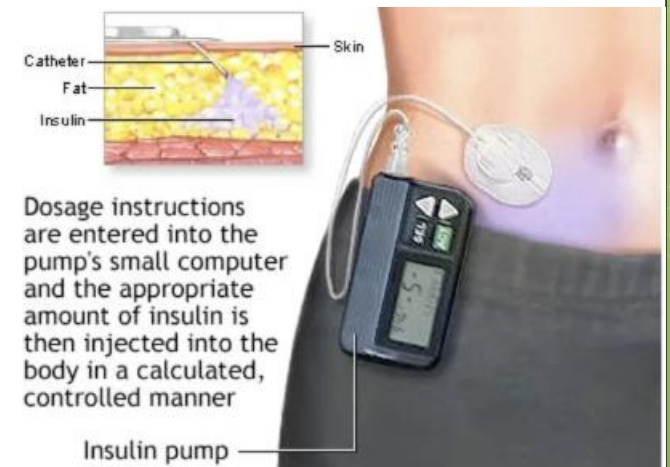
Insulin Pump Therapy

- The following pumps are available in Hawaii with representatives & customer service that are available to assist the families

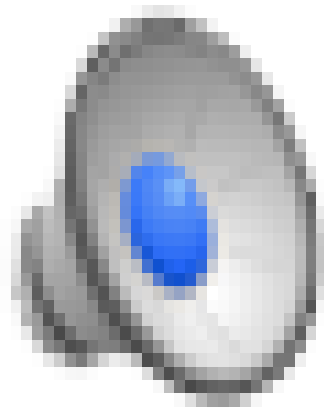


Pumps

- Adhesive
 - Try without assistance of products first
- Reservoir with fast acting insulin
- Change site every 3 days
- Administers insulin based on regimen entered
 - Basal – calculation of rate
 - Like a leaky faucet
 - Bolus – carbohydrate ratio and correction factor
 - Insulin on board – how long it lasts in body
 - Minus from dosing
- Target blood glucose
 - ADA recommendations
 - 90-130 mg/dl
 - Individualizing care per patient



OmniPod



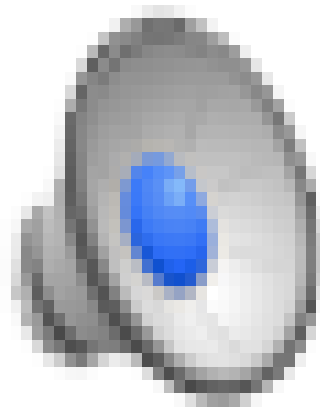
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OmniPod

- Pod and PDM – Personal Diabetes Manager
- Tubeless
- Pod = waterproof, no tubing, easy to load and to start.
- Easy to maneuver
- Set reminders
- Data can be downloaded via Glooko for physicians
- Preset Carbohydrate Menu
- 2018 – Medicare coverage via pharmacy. Only pump to be covered via pharmacy, not only DME
- Widely used in pediatric population
- FDA approval from 2 years old



Medtronic 670g



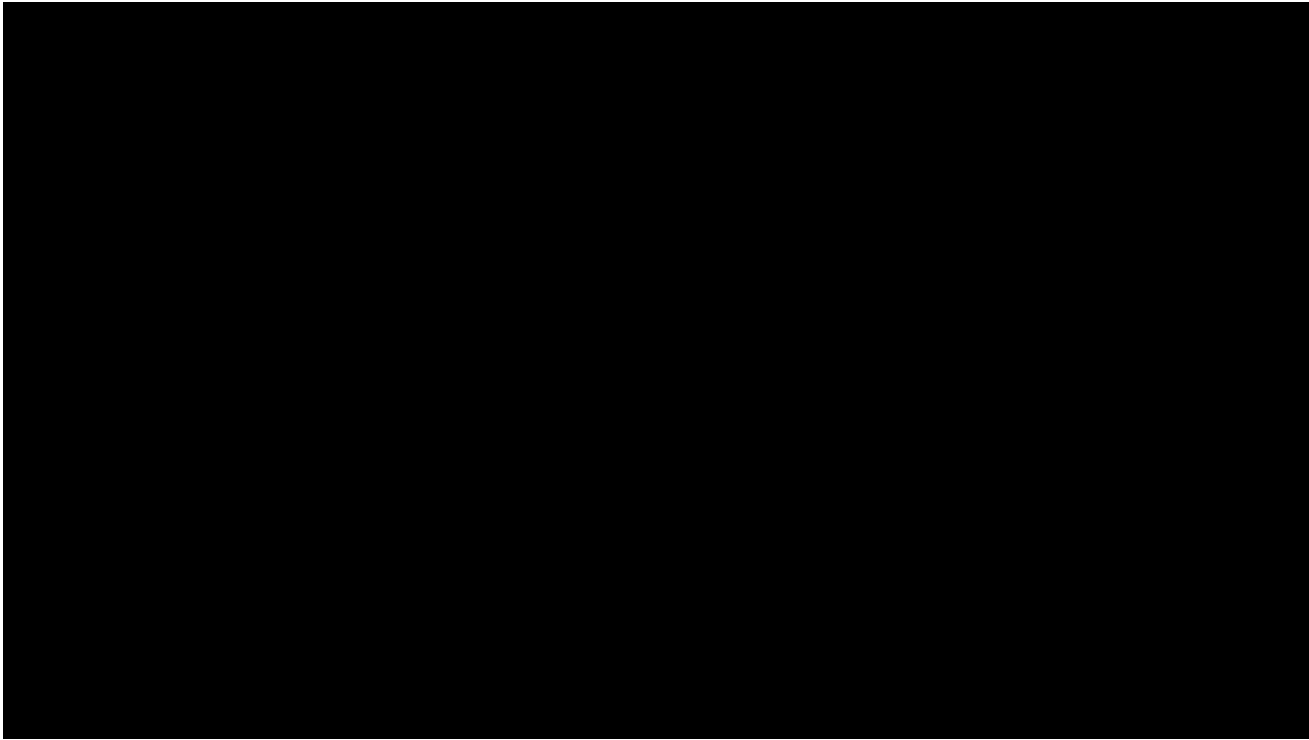
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Medtronic 670g

- Integrated system – closed loop
- Tube system
- Pump Water resistant 12 ft. / 24 hours
 - Sensor 8 ft. / 30 minutes
- Auto correct glucose readings
- Auto mode vs. manual mode
 - “Safe basal” 90 minutes
- Low glucose suspend/ Suspend before low
 - Reactive vs. preventative
 - Stops insulin up to 30 minutes before preset low limit
 - Automatically restarts insulin when levels recover
 - without bothersome alerts.
- At least 4 blood glucose checks a day
- Lowers A1C and reduces hypoglycemia from baseline no controlled studies published in peer reviewed journals.
- FDA approval from 7 years old



T-Slim



<https://youtu.be/84vPQLVSpTI>

T-Slim

- Tube system
- Touch face
- Easy to maneuver for settings
- Updates system via USB to computer
- No batteries – charge via USB
- 2018: Predictive Glucose Threshold Suspend combined with Dexcom G6
 - Low glucose suspend
 - Predicts lows – suspends insulin
- T:connect Diabetes Management Software for clinicians and patients
- Also connects via diaSend and Tidepool
- T:Flex pump – holds up to 480 units of insulin, largest capacity
- Water resistant 3 ft. / 30 minutes
- FDA approved from 6 years old



Pump comparisons

**HAWAII
PACIFIC
HEALTH**

KAPI'OLANI
PALI MOMI
STRAUB
WILCOX

Insulin Pumps currently available in the United States

Insulin Pump	FDA approved age	Minimum Insulin Increment	Reservoir capacity	Sensor data option on pump screen	Waterproof	Unique features
Insulet Omnipod	Age 2	0.05 units	200 units	No	25 feet for 60 minutes	<ul style="list-style-type: none">• Tubeless• Easy insertion and change process• Lowest startup cost
Medtronic Minimed 630G	Age 14	0.025 units	300 units	Yes	12 feet for 24 hours	<ul style="list-style-type: none">• Basal suspend on low BG• Can bolus insulin from ContourNext linked meter
Medtronic Minimed 670G	Age 7	0.025 units	300 units	Yes	12 feet for 24 hours	<ul style="list-style-type: none">• Hybrid closed loop system<ul style="list-style-type: none">- Basal suspends on low or predicted low BG- Auto mode adjust basal every 5min based on CGM data
Tandem T:slim X2	Age 6	0.01 bolus 0.001 basal	300 units	Yes, Dexcom G5 or G6	3 feet for 30 minutes	<ul style="list-style-type: none">• Basal-IQ predictive low BG suspend• Remote software updates – no need to buy a new pump to get updated features• Rechargeable

Source: All information obtained from company websites, accessed 08/28/2018
(www.dexcom.com, www.freestylelibre.us, www.medtronicdiabetes.com, www.myomnipod.com, www.tandemdiabetes.com)

Continuous Glucose Monitors (CGM)



www.dexcom.com



www.medtronic.com

CGM

- Drove 18% of overall Diabetes Industry growth for 2017
- Grew 46% year over year, a record high
 - Abbott Libre – estimated 50% growth
 - Dexcom – 27% growth
 - Medtronic – 22% growth
- 2018 Growth
 - Dexcom G6 – first integrated CGM (iCGM), indicated and designed to be used with other diabetes devices, for patients on intensive insulin therapy
 - Guardian Connect
 - Senseonics – first surgically implanted CGM “Eversense”
 - Libre – intermittent scan CGM

Dexcom G6



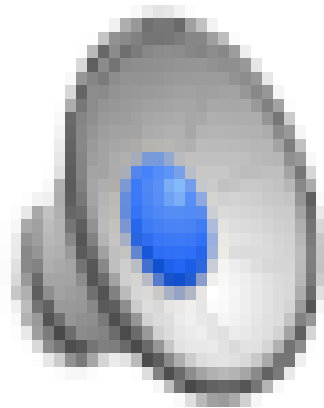
<https://www.youtube.com/watch?v=2lIQKe2-r7Q>

Dexcom G6

- Visually follow blood glucose trends
 - Receiver
 - iPhone and Android apps
- No finger sticks – No calibrations
- Indicated for treatment / decisions / dosing
 - Helps to make treatment decisions based on arrows
- High/ low alerts
 - Urgent low soon 20 minutes @ 55 mg/dl
- 5 minute increment glucose readings
- 10 day sensor change – 2 hour warm up
- Simple, one-touch sensor insertion “Peel it, stick it, click it”
- Approval for buttocks and abdomen sites
- Slimmer wearable profile (30% slimmer than G5)
- CLARITY software downloads, remote access for clinician
- Dexcom Share – virtual sharing
- Available in pharmacy and DME, Medicare approved
- FDA approval:
 - 2016: Use CGM data to dose insulin
 - 2018: No finger sticks and links with other pumps
 - Unrivaled accuracy meeting new FDA accuracy requirements
 - Approval from 2 years old



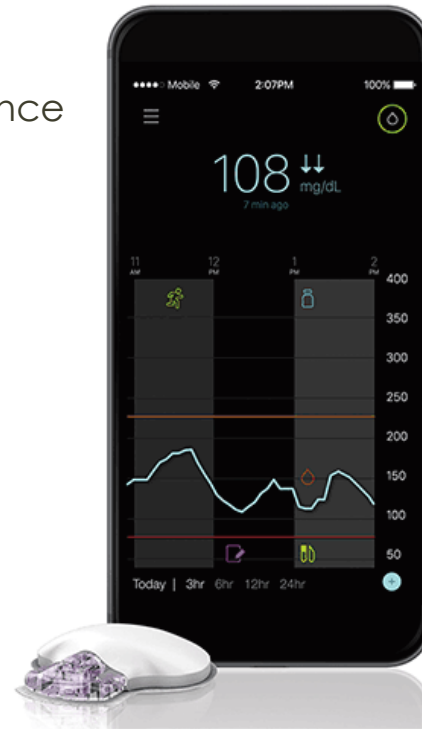
Medtronic Guardian Connect



<https://youtu.be/mOiBGdme1jM>

Medtronic Guardian Connect

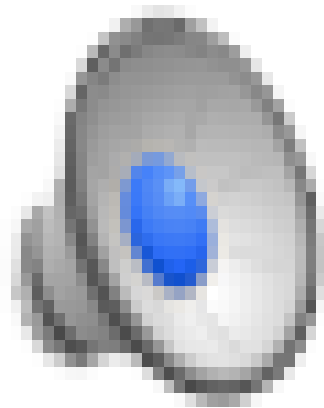
- FDA Approval from 14-75 years of age
- Use with smart phone app
 - Guardian Connect
 - Hi/lo alert
 - Predictive hi/lo 10 – 60 minutes in advance
 - Sugar IQ
 - Has a carb log of pics
 - Send text for trends
 - Foods, BG rates, good /bad
- False highs with acetaminophen
- Lightweight, low profile transmitter
 - taped to arm or abdomen
- Transmitter is recharged, reused
- 7 day sensor use
 - 2 hour warm up
- At least 2 finger sticks – 4 is best
- 5 minute increment readings
- Shows trend of glucose levels
- “Manage Care Partners” virtual sharing
- No Medicare coverage, no pediatric indication at time of launch



Flash Glucose Monitor



Freestyle Libre



<https://youtu.be/VCmCWnn-qwA>

Freestyle Libre

- FDA approval for 18 years old +
- Wear sensor on upper arm – 14 day use
- Reduction in hypoglycemia, no A1C lowering in published trials
- Small Sensor & Transmitter in one - disposable
- Water resistant 3 ft. /30 minutes
- Scanned to pull data upon request, with reader
- No alerts or alarms
- Data may be downloaded by healthcare provider, if patient scans at least every 8 hours
- No finger sticks – No calibrations
 - Finger sticks only when prompted
- May experience inaccurate results
 - with elevated levels of ascorbic acid (Vitamin C)
 - salicylic acid (used in Aspirin)
 - severe dehydration or excessive water loss
- Does not connect to pumps or any devices including phones
- Available in pharmacy with prescription
- Medicare approved via DME suppliers, no pediatric indication

CGM comparisons

Continuous Glucose Monitors (CGM) currently available in the United States

CGM	FDA approved age	Length of wear	Receiver options	Sensor data share option	Fingerstick Calibration	High/Low BG Alarms	Warm up period	Unique features
Dexcom G6	Age 2	10 days	<ul style="list-style-type: none"> • Smart Phone • Smart Watch • Pump Screen • Dedicated Receiver 	Yes	Not required	Yes	2 hours	<ul style="list-style-type: none"> • Approved for insulin dosing without SMBG • Greatest accuracy • No acetaminophen interaction • Not yet covered by Medicare
Dexcom G5	Age 2	7 days	<ul style="list-style-type: none"> • Smart Phone • Smart Watch • Pump Screen • Dedicated Receiver 	Yes	Every 12 hours	Yes	2 hours	<ul style="list-style-type: none"> • Approved for insulin dosing without SMBG • Accuracy influenced by acetaminophen
Medtronic Guardian Sensor 3	Age 14	Up to 7 days	<ul style="list-style-type: none"> • iPhone • iWatch • Pump screen • No dedicated receiver option 	Yes	3-4x/day	Yes	2 hours	<ul style="list-style-type: none"> • Customizable predictive high and low alerts (up to 60min prior) • Sugar.IQ app
Medtronic Guardian Connect	Age 14	Up to 7 days	<ul style="list-style-type: none"> • iPhone • iWatch • Pump screen • No dedicated receiver option 		3-4x/day	Yes	2 hours	<ul style="list-style-type: none"> • Designed for patients on insulin injections only • Customizable predictive high and low alerts (up to 60min prior) • Sugar.IQ app
Abbot Freestyle Libre	Age 18 and not in pregnancy	14 days	Standalone receiver	No	Not required	Yes, only when scanned by reader	1 hour	<ul style="list-style-type: none"> • Must scan over device with reader to get data • Lowest cost without insurance • Lowest accuracy • Lowest profile on body • Accuracy influenced by Vitamin C and salicylic acid

Source: All information obtained from company websites, accessed 08/28/2018

(www.dexcom.com, www.freestylelibre.us, www.medtronicdiabetes.com, www.myomnipod.com, www.tandemdiabetes.com)

Advance technology....

For Who?!

- ◉ Good baseline of regimen
- ◉ Checks glucose levels
- ◉ Gives insulin
- ◉ Knows what to do if in trouble
- ◉ Ketones!!
 - ◉ uses urine or blood strips
 - ◉ Rest, water and insulin

On The Horizon

Inhaled Glucagon

- Inhaled Glucagon
 - Dosing - weight dependent
 - Absorbed by mucosa
 - Awaiting FDA approval
- Less steps than injectable Glucagon



<http://clinidiabet.com/es/infodiabetes/noticias/2016/img/03.jpg>

<https://primarydailylo.wordpress.com/2017/11/22/>

Shelf Stable Glucagon

- Xeris G Pen
- Two- step use process
- No reconstitution
- New drug application
 - Completed phase 3 clinical studies

Another Fast Acting Insulin

- Insulin Lispro
 - Admelog (ad-mah-log)
 - FDA- December 11, 2017
 - Not less than 3 yo
 - Not for peds Type 2



Technology

- Ever happening so fast
- Bluetooth integration
- Hybrid Closed Loop
 - Hourly bolus corrections



Senseonics – Eversense

Implanted Sensor

- FDA panel vote positive 8 – 0 recommending approval
- Pending FDA Approval, could launch in 2018 in US,
 - currently available in Europe
- No receiver required, data is transmitted to phone
- Sensor is surgically implanted and removed every 90 days
- Transmitter is recharged every 24 hours
 - for at least 7 minutes
 - taped to arm over surgically implanted sensor
- 2 calibrations per day required
- Adjunctive use, all dosing decisions must be confirmed with SMBG
- Will not communicate with any other devices or pumps
- Transmitter vibrates on arm for high or low alerts
- App on phone will make audible alerts for highs or lows
- Data will be read via third party software: Glooko, Diasend, or Tidepool
- Adult use only at time of launch
- Does not meet “therapeutic CGM” requirements in current form, no Medicare coverage

Introducing the Eversense Continuous Glucose Monitoring System



90-Day Implantable
Sensor



Removable / rechargeable
Smart Transmitter



Clear, concise
Mobile App

Bigfoot Technology

- Has a vision for Automated Insulin Delivery (AID)
- Utilizes Abbott Libre, and defunct Asante SNAP pump
- Leverage existing smartphone technology
- Simple, tight integration between components
- Secure communication = connected ecosystem
- Automate decisions about insulin delivery in real time
- Leverage cloud-connectivity technologies
- Accessed with single prescription and reimbursed as a service for a monthly fee



- Created by a dad (Wall St. Trader) when his 5 year old son was diagnosed with Type 1 Diabetes .
- Timeline: 2020 Anticipated Launch

Thank you for your attention...

**My body produces
insulin like a cow
produces rainbows.
It just doesn't
happen.**

