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

https://www.diabetesselfmanagement.com
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
    - NØ 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.fiasppro.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

http://saukhyaconsultancy.com/service/diabetes/
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

https://youtu.be/0I5748rl0k
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

https://youtu.be/d75-BM9CbsU
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

www.medtronicdiabetes.com
T-Slim

https://youtu.be/84vPQLVSpTl
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
### Insulin Pumps currently available in the United States

<table>
<thead>
<tr>
<th>Insulin Pump</th>
<th>FDA approved age</th>
<th>Minimum Insulin Increment</th>
<th>Reservoir capacity</th>
<th>Sensor data on pump screen</th>
<th>Waterproof</th>
<th>Unique features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulet Omnipod</td>
<td>Age 2</td>
<td>0.05 units</td>
<td>200 units</td>
<td>No</td>
<td>25 feet for 60 minutes</td>
<td>Tubeless, Easy insertion and change process, Lowest startup cost</td>
</tr>
<tr>
<td>Medtronic Minimed 630G</td>
<td>Age 14</td>
<td>0.025 units</td>
<td>300 units</td>
<td>Yes</td>
<td>12 feet for 24 hours</td>
<td>Basal suspend on low BG, Can bolus insulin from ContourNext linked meter</td>
</tr>
<tr>
<td>Medtronic Minimed 670G</td>
<td>Age 7</td>
<td>0.025 units</td>
<td>300 units</td>
<td>Yes</td>
<td>12 feet for 24 hours</td>
<td>Hybrid closed loop system, Basal suspends on low or predicted low BG, Auto mode adjust basal every 5min based on CGM data</td>
</tr>
<tr>
<td>Tandem T:slim X2</td>
<td>Age 6</td>
<td>0.01 bolus 0.001 basal</td>
<td>300 units</td>
<td>Yes, Dexcom G5 or G6</td>
<td>3 feet for 30 minutes</td>
<td>Basal-IQ predictive low BG suspend, Remote software updates - no need to buy a new pump to get updated features, Rechargeable</td>
</tr>
</tbody>
</table>

Source: All information obtained from company websites, accessed 08/28/2018
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=2llQKe2-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**

<table>
<thead>
<tr>
<th>CGM</th>
<th>FDA approved age</th>
<th>Length of wear</th>
<th>Receiver options</th>
<th>Sensor data share option</th>
<th>Fingerstick Calibration</th>
<th>High/Low BG Alarms</th>
<th>Warm up period</th>
<th>Unique features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexcom G6</td>
<td>Age 2</td>
<td>10 days</td>
<td>• Smart Phone • Smart Watch • Pump Screen • Dedicated Receiver</td>
<td>Yes</td>
<td>Not required</td>
<td>Yes</td>
<td>2 hours</td>
<td>• Approved for insulin dosing without SMBG • Greatest accuracy • No acetaminophen interaction • Not yet covered by Medicare</td>
</tr>
<tr>
<td>Dexcom G5</td>
<td>Age 2</td>
<td>7 days</td>
<td>• Smart Phone • Smart Watch • Pump Screen • Dedicated Receiver</td>
<td>Yes</td>
<td>Every 12 hours</td>
<td>Yes</td>
<td>2 hours</td>
<td>• Approved for insulin dosing without SMBG • Accuracy influenced by acetaminophen</td>
</tr>
<tr>
<td>Medtronic Guardian Sensor 3</td>
<td>Age 14</td>
<td>Up to 7 days</td>
<td>• iPhone • iWatch • Pump screen • No dedicated receiver option</td>
<td>Yes</td>
<td>3-4x/day</td>
<td>Yes</td>
<td>2 hours</td>
<td>• Customizable predictive high and low alerts (up to 60min prior) • Sugar.iQ app</td>
</tr>
<tr>
<td>Medtronic Guardian Connect</td>
<td>Age 14</td>
<td>Up to 7 days</td>
<td>• iPhone • iWatch • Pump screen • No dedicated receiver option</td>
<td>3-4x/day</td>
<td>Yes</td>
<td>2 hours</td>
<td>• Designed for patients on insulin injections only • Customizable predictive high and low alerts (up to 60min prior) • Sugar.iQ app</td>
<td></td>
</tr>
<tr>
<td>Abbot Freestyle Libre</td>
<td>Age 18 and not in pregnancy</td>
<td>14 days</td>
<td>Standalone receiver</td>
<td>No</td>
<td>Not required</td>
<td>Yes, only when scanned by reader</td>
<td>1 hour</td>
<td>• 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</td>
</tr>
</tbody>
</table>

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

https://beyondtype1.org/ready-to-use-glucagon-rescue-pen/
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.