There are many emerging technologies that will change the practice of diabetes management. They are demonstrating improved patient and clinician outcomes and provide patients with less disease burden. The quest for noninvasive monitoring and more comprehensive glucose data collection and insulin delivery systems has provided new monitoring and insulin delivery technologies to assist patients, caregivers, and health care professionals to improve diabetes management. Reducing glycemic excursions, hypoglycemia, diabetes related complications, and hospitalizations can lead to improved paid-for-performance measures and reimbursement opportunities for health care organizations and health systems.

This presentation will review some of the newest emerging technologies in diabetes and identify several products that have recently launched, are FDA approved and launching, as well as a few that are coming down the pipeline. This presentation will review several new insulin delivery devices including new or innovative technologies being created by: Tandem Diabetes, Medtronic Diabetes, LifeScan and Companion Medical Inc. Some of the latest products for glucose monitoring devices and software will also be discussed. In addition, a few pipeline products will be reviewed including technologies centered on closed-loop insulin delivery systems and the potential for a glucose sensing contact lens.

References:

2. Abbott Laboratories (2019, October). Freestyle LibrePro: The more you can see, the more you can do. Retrieved from http://www.freestylelibrepro.us/
EMERGING TECHNOLOGIES IN DIABETES MANAGEMENT: THE WHO, WHAT & WHEN FOR IMPROVING CONTROL

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Objectives

- Discuss new diabetes technologies on the horizon, including recently launched, preparing to launch and products in the pipeline including:
- Identifying new insulin delivery devices,
- Reviewing new glucose monitoring devices & Software/Applications,
- Discussing who is appropriate candidates for such technologies based on ADA's Standards of Care in Diabetes—2017.

Breakdown of Discussion

**Insulin & Other Injectable Delivery Devices**
- Tandem's T:slim
- Medtronic's 670G
  - Pro Infusion Set
  - LifeScan's OneTouch Visa
  - Companion Medical's InPen
  - Intarcia's GLP-1 mini-pump
  - Omnipod Dash System
  - Future of Closed-Loop Insulin delivery systems

**Glucose Monitoring Devices & Software**
- Abbott's Libre Pro
- One Drop Premium
- mySugr/Roche integration
- Dexcom's Touchscreen receiver
- Sugar.IQ w/Watson
- Google's Contact Lens

Medtronic's 630G System

- SMARTGUARD™ TECHNOLOGY
- Takes action to reduce lows*, without ruling out highs* or clinical lows
- Suspend on low feature pauses insulin delivery for up to two hours—so glucose levels can recover
- Exclusive to MiniMed systems

**BOLUS WIZARD® CALCULATOR**
- Automatically calculates and recommends precise bolus doses
- Helps your patients avoid insulin stacking

**PREDICTIVE ALERTS**
- Prompts patients to take action sooner to prevent lows and keep them in range
- Can be set in 5 minute increments up to 30 minutes

**BUILT-IN CGM**
- Wirelessly sends glucose information to the pump every 5 minutes
- Gives you patients real-time trends for making good treatment decisions

ADA's Standard of Care 2017:

- This technology may be particularly useful in insulin-treated patients with hypoglycemia unawareness and/or frequent hypoglycemic episodes,
- Although studies have not shown consistent reductions in severe hypoglycemia.
- The Automation to Simulate Pancreatic Insulin Response (ASPIRE) trial of 247 patients with type 1 diabetes and documented nocturnal hypoglycemia showed that sensor-augmented insulin pump therapy with a low glucose suspend function significantly reduced nocturnal hypoglycemia over 3 months without increasing A1C levels.
**Medtronic MiniMed Pro Infusion Set with BD FlowSmart technology – 2016.**

- This infusion set has several key improvements:
  - **smaller catheter on the market**, made of soft polymer instead of stainless steel
  - **28 gauge thickness versus 25 gauge**, so a 6mm set would have a 30 gauge needle
  - **uses "inline infusion pressure"** – like low pressure in plumbing, reducing the tendency for blockage/bulbus
  - the tubing connection swivels, so it can attach in multiple directions and lock in at the angle that’s most comfortable
  - **Available in both Paradigm and Luer Lock versions** of the new set so it can be used with many different commercially available systems
  - and last not least, IT **HAS A SIDE PORT**, (or second side hole) that serves as an "ancillary path for fluid" – an alternate route for the insulin to flow in case the first path is blocked

**Companion Medical’s InPen – 2017**

The first insulin pen with built-in Bluetooth, enabling dose data to be sent to a phone app automatically. It also calculates & recommends optimal dosing; tracks history & timing of doses; Monitors insulin temperature; Displays last dose and insulin-on-board; and reports can be sent to the health care provider.

**LifeScan’s OneTouch Via—2017**

- The bolus-only, super slim wearable device holds 200 units of insulin and can be worn for three days.
- Squeezing two buttons (including through clothes) – will discreetly deliver a two-unit bolus.

**Intarcia’s GLP-1 mini-pump**

- Intarcia, recently submitted a New Drug Application to the US FDA for its implantable type 2 diabetes therapy, ITCA 650.
- The novel option continuously releases exenatide (a GLP-1 agonist) over the course of three to six months from a mini-pump – about the size of a matchstick – inserted just under the skin by a healthcare provider in a quick procedure (a matter of minutes).
- Many look forward to having a low hassle, needle-free GLP-1 agonist for type 2 diabetes treatment, since the options currently available involve daily or weekly injections.
- An FDA decision is expected by late 2017.
- However, given the first-of-its-kind innovation behind it’s delivery mechanism, the FDA may decide to seek opinions from an Advisory Committee prior to making its decision.

**Omnipod’s Dash Insulin Management System**

Omnipod’s Dash is expected to launch by the end of 2017 and will integrate Bluetooth into the body-worn, tubeless pod, and use a transformed, locked down Android smartphone for functions currently performed on the personal diabetes manager (PDM) handheld device.

**Abbott’s FreeStyle Libre Pro and FreeStyle Libre (potentially in early 2017).**

The FreeStyle Libre Pro system requires NO fingerstick calibration so patients do not need to be trained by their healthcare professional on calibration. After the sensor is applied to the arm, there is no requirement for the patient to interact with the system.

- Provides reliable glucose data.
- Healthcare professionals receive up to 14 days of continuous glucose data based on uninterrogated, normal daily routines of their patients.
- Reduces equipment costs, maintenance and time.
One Drop: Premium

- One Drop Premium (Oct 2016) is a service providing:
  - Unlimited test strips
  - Bluetooth-enabled meter (Chrome)
  - 24/7 in-app diabetes coaching, and
  - A personalized diabetes educational program.

Cost of subscription to the Premium Plan
- Meter: $99.95 ($20 off with new subscription)
- Unlimited Strips & Experts: $39.95
- Annual Prepaid: $33.33

Dexcom’s Pipeline

- A smaller transmitter and a new auto-applicator are currently under regulatory (FDA) review.
- An Android version of the G5 app is currently under FDA review, with launch expected early 2017.
- A new touchscreen receiver is currently under FDA review.
- An insulin-dosing label claim is hoped for following the positive Advisory Committee meeting in July.
- Medicare coverage is in 2018.

ADA Guidelines for pCGM

Use of pCGM in patients with Type 1 DM:
- 17,317 participants confirmed that more frequent CGM use is associated with lower A1C.
- Another study showed that children with 70% sensor use (i.e., ≥ 5 days per week) missed fewer school days.
- Small randomized controlled trials in adults and children with baseline A1C, 7.0–7.5% have confirmed favorable outcomes including a reduced frequency of hypoglycemia (defined as BG <70 mg/dL) and maintaining A1C <7% during the study period in groups using CGM, suggesting that CGM may provide further benefit for individuals with type 1 diabetes who already have good glycemic control.

Dexcom/Verily Sensor Project

- Significant reduction in size of CGM on the body, looking at making it less expensive, and will bring technology to far more people than are currently using it (only about 1-in-5 people with type 1 diabetes in the US use CGMs).
- Will use the G6 sensor and is expected to need no fingerstick calibration. Expected to be approved for making insulin-dosing decisions, and to communicate directly with smartphones via Bluetooth.
- A first-gen version (smaller than FreeStyle Libre) is expected in late 2018, while the smaller second-gen version is expected as early as 2020.

ADA’s Standards of Medical Care in Diabetes—2016: Summary of Revisions

Because of the growing number of older adults with insulin-dependent diabetes, the ADA added the recommendation that people who use continuous glucose monitoring and insulin pumps should have continued access after they turn 65 years of age.
Sugar.IQ Medtronic/Watson – Late 2016.

Sugar.IQ, uses CGM and insulin information from Medtronic integrated pumps & sensors along with IBM Watson’s cognitive computing power, combined with Medtronic’s expertise in diabetes, to find hidden patterns in diabetes data.

The app provides immediate personalized awareness on a single platform that brings together important data, perspectives & insights.


Google’s Role in the Diabetes Market

Google’s Glucose Sensing Contact Lenses

The system would likely contain 2 or 3 parts: (1) the contact lens; (2) a “reader” device, which would communicate and power the lens; and (3) a user display, to see and review the data.

The patent specifically mentions the possibility of eyeglasses, jewelry (e.g., earrings, necklace), or clothing (e.g., a scarf, hat, headband) functioning as the reader. The device however must be close enough to the lens to make sure that the lens can communicate with the reader.

The device could be a smart phone or wearable computer. One example given is a display worn on the head or in front of the eyes, such as Google Glass (another project in the Google[x] division).

Google’s Contact Lens Cont’d…

- The patent describes how high and low alarms might work and how continuous data could be displayed, suggesting that Google’s ultimate goal may be a CGM-like technology.
- The smart contact lens could be the same size as standard contact lenses and could be made of the same (or similar) material. In theory, they might not feel any different to wear than a normal contact lens.


Closing the Loop in Insulin Delivery Systems: No artificial physiology about it!

- The development of an artificial pancreas for the treatment of insulin-dependent diabetes has been a highly anticipated endeavor for patients, health care providers, scientists, and engineers alike.
- Recent progress in research and algorithm technology, together with aspects of β-cell physiology are leading to normal glucose homeostasis. Algorithms continue to be evaluated for their ability to deliver insulin, to recreate, as closely as possible, glucose and insulin profiles observed in healthy individuals.
- Emphasis is placed upon how the algorithms compare to the β-cell’s secretory response, specifically first-phase and second-phase insulin secretion and glucagon response.
- Experimental closed-loop data employing intravenous and subcutaneous glucose sensors and implanted and external insulin pumps


Closing the Loop (or at least the backpack!)—We’ve come along way…

- This is a picture of the very first insulin pump from 1963 by Dr. Arnold Kadish.
- It was worn on the back and was roughly the size of a Marine backpack.
- Not commercially available due to its size.
- First wearable pump=1976

Advancements in the Artificial Pancreas (AP)

- Biostator: The Artificial Pancreas 1977
- The Artificial Pancreas 2010

Closing the Loop (or at least the backpack!)—We’ve come along way…

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Advancements in the Artificial Pancreas (AP)
AP Summer Camp Study

- 5-day experiments in adolescents with Type 1 Diabetes
- Randomized cross-over design
- 5 days on bionic pancreas
- 5 days usual care
- Study and camp staff provide 24-hour coverage to monitor glycemia

Animas Hypoglycemia-Hyperglycemia Minimizer

- Timing: A launch is expected in late 2018/early 2019. Animas is still working with the FDA to plan a pivotal trial.
- What it looks like: It is a control algorithm built into an Animas pump that talks to a Dexcom CGM. Animas showed the following picture at a business update in May, though the product may have changed since that time.
- What the system promises to do: It will adjust insulin delivery to minimize both highs and lows.
- Notable features: The pivotal trial is expected to include children as young as two years old.

Medtronic’s 670G Semi-Closed Loop System

- First automated basal insulin delivery system that is FDA approved and will automatically increase/decrease basal insulin delivery in response to CGM information. It’s particularly effective overnight
- U.S. Launch March/April 2017

Medtronic’s Algorithms for a Closed Loop System

- Threshold suspend/suspend on low
- Predictive suspend
- Advanced hybrid closed-loop
- Path to reduced burden
- Towards personalized closed-loop

Omnipod’s Hybrid Closed-Loop Hopeful

- Launch is expected in late 2019.
- It includes an Omnipod™ patch pump, an integrated control algorithm, or Dexcom CGM, and a Bluetooth enabled wireless Dash handheld PDM (a locked down Android phone with cellular turned off).
- The handhold will also talk to a smartphone app to display key data and allow caregivers to remotely monitor.
- The system prevents to mediate basal insulin delivery. Users will need to give correction boluses and meal boluses.
- The hybrid closed-loop algorithm will be extended in the pod itself, meaning users can stay in closed loop when the handheld is out of range.
- Pediatric approval is a major priority for Insulet.

Tandem’s Closed Loop Potential

- The NIH is funding the new, International Diabetes Closed Loop (IDCL) Trial.
- This trial will combine Tandem’s t:slim X2 insulin pump, Dexcom’s G5 Bluetooth-enabled transmitter and software, and Type Zero’s inControl algorithm, into one device, controlled by a smartphone.
- It will control users’ insulin by monitoring and adjusting basal rates, giving insulin based on predicted highs, and stepping back on insulin delivery if the user is predicted to go low. The user however will need to manually bolus for meals.

Dexcom Inc. (January 13, 2017). From primary source, Ed Damiano, Boston University. Used with permission from Tomas C. Walker, DNP, APRN, BC-ADM, CDE, Director, Clinical Projects, Dexcom Inc.

Animas Hypoglycemia-Hyperglycemia Minimizer


DiaTribe (2016, June 28). Medtronic MiniMed 670G Trial Results: 44% Reduction in Hypoglycemia, 0.5% A1c Improvement. Retrieved from https://diatribe.org/medtronic-minimed-670g-trial-results-44-reduction-hypoglycemia-05-a1c-improvement


Medtronic Diabetes (2017, January 8). Medtronic data on file used with permission from Medtronic Sr. Global Medical Affairs Specialist, Linda Burkett

Omnipod’s Hybrid Closed-Loop Hopeful


Tandem’s Closed Loop Potential


The latest design is thinner and with a much lower power display, closer to what is planned to eventually launch. It has a 3.2-inch screen with higher resolution, with a black and white LED display. It will also have the Dexcom G5 CGM integrated inside.

Also working on a proprietary Dual Chambered Pump. The lasted design is thinner and both glucagon and insulin require only a single insertion for needles and dual-tubing but will require only one single insertion for both glucagon and insulin delivery.

The Artificial Beta Cell

- Three European centers; UK, Germany, Austria
- 23 Adults with T1DM with HbA1c between 7.5% and 10% on CSII
- Dedicated 4 week optimization period prior to randomization
- Day and night hybrid closed-loop for 3 months
- Overweight closed-loop for 3 months

- 25 children and adolescents with T1DH aged 6 to 18 years with HbA1c below 10% on CSII

References

We Still Have no CURE!!

Thank You!

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Who, What & When do we owe?

“We are privileged to serve individuals living with diabetes and are eager to collaborate with the technology community to help us meet our goal of improving the lives of those affected by the disease. By convening this influential group of like-minded innovators, our goal is to advance technology solutions that go beyond this event and create true impact for individuals living with diabetes.”

Jane Chiang, MD, executive vice president, medical innovation for the American Diabetes Association.


Beta Bionics:


Free Living Home Use of an Artificial Beta Cell

Adults (APCam08)

- Post 992: EASD 2015

- Three European centers; UK, Germany, Austria
- 23 Adults with T1DM with HbA1c between 7.5% and 10% on CSII
- Dedicated 4 week optimization period prior to randomization
- Day and night hybrid closed-loop for 3 months

- 25 children and adolescents with T1DH aged 6 to 18 years with HbA1c below 10% on CSII
- 2-8 week run-in period and optimization

- Overweight closed-loop for 3 months

But Remember

We Still Have no CURE!!

Thank You!