Emerging Technologies in Diabetes Management: The Who, What and When for Improving Control
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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 Medical Care in Diabetes—2017.

Breakdown of Discussion

Insulin & Other Injectable Delivery Devices
- Tandem’s T:slim X2
- Medtronic’s 630G – Pro Infusion Set
- LifeScan’s OneTouch Via
- 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

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.

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, A limiting of dose. Monitors insulin temperature. Displays last dose and insulin-on-board, and reports can be sent to the health care provider.
**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 505.
- 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—injected 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 its delivery mechanism, the FDA may decide to seek opinions from an Advisory Committee prior to making its decision.

**MySugr Logbook /Accu-Chek Connect Integration – Fall 2016**

The MySugr mobile app benefits from multiple integration features, including the ability to sync data for export, and helps patients track their blood glucose over the course of the day. It engages patients through gamification mechanics, activities & rewards, and by using a ‘monster friend’ to show their progress.

The app helps estimate A1c scores based on daily measurements of SMBG, focusing primarily on patients using insulin for diabetes management.

**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., 25 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.
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**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: $89.95 ($20 off with new subscription)
- Unlimited Strips & Experts:
- Monthly: $39.95
- Annual Prepaid: $33.33

**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 uninterrupted, normal daily routines of their patients.
- Reduced equipment costs, maintenance and time.

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*Image credits: Intarcia, MySugr, Accu-Chek, Abbott Laboratories, Medtronic, and IBM.*
Dexcom’s Pipeline

Current Projects

A smaller transmitter and a new one-button applicator are currently under regulatory (FDA) review (US).

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 in early 2017. Meaning a confirmatory finger stick test is not required before giving insulin. FDA discussions continue following the positive Advisory Committee meeting in July.

Medicare coverage in 2018?

Dexcom/Verily Sensor Project

G6 Intro

Significant reduction in size of CGM on the body, looking at make 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 in the US use CGM).

Will use the G6 sensor and is expected to need no finger stick 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.

Google’s Role in the Diabetes Market

Google’s Glucose Sensing Contact Lenses

The system would likely contain 2 or 3 parts: (i) the contact lens; (ii) a “reader” device, which would communicate and power the lens; and (iii) 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.

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.

Medtronic MiniMed Pro Infusion Set with BD FlowSmart technology – 2016.

This infusion set has several key improvements:

- smallest catheter on the market, made of soft plunger instead of stainless steel
- 28 gauge thickness versus 25 gauge, so a 6mm set would have a 30 gauge needle
- uses “line infusion pressure” — like low pressure in plumbing, reducing the tendency for blockage/buildup
- 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
Closing the Loop (or at least the backpack!)
We’ve come along way...

This is a picture of the very first insulin pump from 1983 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
Not commercially available due to its size. of a Marine backpack.

The NIH is funding the new, International Diabetes Closed Loop (IDCL) Trial.

Medtronic’s Algorithms for a Closed Loop System

Medtronic’s 670G Semi-Closed Loop System

Medtronic’s 630G System

Tandem’s Closed Loop Potential

Tandem T: Slim’s X2 Insulin Delivery 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.
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 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 miniaturized and external insulin pumps

Advancements in the Artificial Pancreas (AP)

Biostator: The Artificial Pancreas 1977

The Artificial Pancreas 2010
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

Advancements in the Artificial Pancreas (AP)

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 developed a proprietary infusion set, which have two needles and dual-tubing but will require only a single insertion for both glucagon and insulin delivery.

Free Living Home Use of an Artificial Beta Cell

Adults (AP@home04) Poster 987, EASD 2015
Three European centers; UK, Germany, Austria
33 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

Children and adolescents (APCam08)
Three UK centers, Cambridge, London, Leeds
25 children and adolescents with T1DM aged 6 to 18 years with HbA1c below 10% on CSII
2-8 week run-in period and optimization
Overnight closed-loop for 3 months

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


We Still Have no CURE!!

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