Emerging Technologies in Diabetes

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Disclosures

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For successful completion, participants are required to be in attendance in the full activity, complete and submit the program evaluation at the conclusion of the educational event.

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Objectives:

• 1. State the scope and use of glucose monitoring devices
• 2. Describe the advancements associated with the creation of smart syringe insulin delivery and the impact on patients
Formalities

Valeritas: Vgo insulin delivery device

Insulet company: OmniPod insulin pump

Astra Zeneca: Panel on Farxiga and Renal Disease

I am not being paid for this event

Disclosures
Objective: Review Diabetes Technology Leaders

Discuss emerging technologies for Diabetes management outside traditional brick and mortar facilities.

Understand the resources available and how to utilize them to improve care.
Dramatic Changes in Diabetes Technology

Continuous Glucose Monitoring
- Freestyle Libre
- Dexcom G6
- Eversense

Insulin Pump Therapy
- Minimed
- Omni Pod
- Tandem
Mobile Applications

Diabetes Technology on the go!

Vgo a “smart syringe”
The next era of glucose monitoring
History of Testing

**Urine Glucose**

- **1500 B.C. Egyptians**
  - Observed ants were attracted to the urine of those with an emaciating disease

- **Middle Ages**
  - Physicians "water tasters" diagnosed diabetes by tasting urine for sweetness, hence diabetes mellitus

- **1900's**
  - Copper reagents used to test urine glucose levels
  - Urine color compared to a chart to determine level
  - First quantification based on level of renal glucose spill
1960’s
- Dextrostix – large drop of blood on a strip
- Washed off at 60 seconds, color compared to a chart
- Semi-quantitative assessment, not very accurate

1980’s
The Glucometer released. Same basic process as today
- Over time, smaller amounts and blood removal step eliminated
- Electrochemical strips developed
- Wider ranges of hematocrit were permitted
- Lancets became smaller and by 2010, “virtually” painless
2000’s
- Continuous glucose monitoring
- “Professional” equipment (patient blinded to glucose data)

Issues
- Time of data capture (3 days to several weeks)
- Accuracy (has been increasing)
- Calibration (correlation to fingerstick glucose)
- Cost (limited use to):
  - Pumps to increase their “AI”
  - Severe hypoglycemia and hypoglycemia unawareness
  - DMT1
2010’s
- First “real-time” CGM was the Glucowatch
- Wristwatch device stimulated the secretion of subcutaneous fluid
- Glucose was measured using an electrode
- Non-invasive but irritating, so not a commercial success

2018
- Freestyle Libre was the first “price equal” CGM to capillary blood monitoring systems
- Other companies / strategies developing / emerging
So, why is this important…
Most patients fail to achieve optimal control or adhere to testing guidelines.

- 67% do not adhere to recommended testing frequency
- 66% report skipping testing
- 66-80% fail to achieve HbA1c target of <7.0%


Courtesy of Freestyle Libre
Frequency of glucose monitoring is closely associated with improved HbA1c levels. ADA guidelines recommend testing 6-10 times per day for patients on mealtime insulin or pump therapy.

3. ADA Standards of Care in Diabetes 2017

Courtesy of Freestyle Libre
CGM provides a wealth of data to patients and can reveal patterns not seen in SMBG.

Of unrecognized hypoglycemia occurs at night.  

1. ADA Standards of Care in Diabetes 2017

Courtesy of Freestyle Libre
Profession

CGM’s
Easy for your patients to use\(^1\) to check glucose

**START**
- Apply sensor to back of upper arm
- Scan sensor to activate and wait 1 hour for first glucose reading

**SWIPE**
- Wear sensor for up to 14 days with painless\(^1\) glucose readings anytime

**ACCESS**
- View real-time glucose readings and trends on the reader

Courtesy of Freestyle Libre
Connect with your Patients using LibreView

**CONNECT**

Connect and log into LibreView.com
Follow on-screen instructions to upload data from reader

**VIEW**

Glucose data is stored securely in the cloud so members can view their reports, anytime, anywhere

**SHARE**

Patients can elect to share data with their care team

*LibreView is developed, distributed, and supported by NewYu, Inc. The LibreView data management software is intended for use by both patients and healthcare professionals to assist people with diabetes and their healthcare professionals in the review, analysis and evaluation of historical glucose meter data to support effective diabetes management. The LibreView software is not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice. Trademarks are the property of their respective owners. Images are for illustration purposes only. Not actual patient data.*
Patients can see their patterns and trends!

How often in target?  How much variability?  Average by time?  How many lows?

Courtesy of Freestyle Libre
**Increased engagement**
Self-monitoring frequency met or exceeded ADA guidelines 6-10 times per day (for IIT)

1. ADA Standards of Care in Diabetes 2018
2. Bolinder et al., Lancet 2016; 388:2254-63

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**More control**
Significantly reduced time in hypoglycemia\(^1\)
Significantly more time in range\(^1\)

\(^1\) Aijan, R., Insights from Real World Use of Flash Continuous Glucose Monitoring (2018, June). Symposium conducted at the conference for American Diabetes Association 78th Scientific Sessions, Orlando, FL., USA
FreeStyle Libre 14 day system demonstrated similar outcomes in real world data

>470,000 readers
4.8B glucose measurements
4 years of data

FreeStyle Libre 14 day system users check glucose frequently¹

12 average scans per day

ZERO Fingersticks!

Welcome to the world of real-time CGM
The ALL NEW and Improved Dexcom G6

- G6 readings can be used to make diabetes treatment decisions when taking up to a maximum acetaminophen dose of 1,000 mg every 6 hours. Taking a higher dose may affect the G6 readings.


Dexcom G6 allows for remote monitoring of the patient’s glucose data, increasing their circle of support.
Enhancement to G6 Alerts – Urgent Low Soon

• Providing Alerts and Alarms that are Clinically Relevant (Urgent Low Soon)

• Urgent Low Soon Alert – Actionable AND Accurate
  • Future alert function
  • Provide earlier actionable alert without increasing nuisance factor (93% detection1)

Urgent Low Soon alert (will be at 55 within 20 minutes)
Hypo Alarm (55)
Quickly assess key metrics on one dashboard

• View relevant glucose patterns and trends to help with diabetes management decisions.
• Access all patient glucose data in an easy-to-use clinic portal.
• Invite patients to share their CGM data to keep appointments efficient.
• Supports all Dexcom devices, including G6.
• Free to use! Available at clarity.dexcom.com/professional

We found 2 patterns during this date range. The best day was June 6, 2018.

Anne had a pattern of nighttime highs
Anne had a pattern of significant highs between 5:00 AM and 6:45 AM. Nine high events contributed to this pattern. One of the contributing events was a rebound high.

Anne had a pattern of daytime highs
Anne had a pattern of significant highs between 11:10 AM and 3:10 PM. Twelve high events contributed to this pattern. One of the contributing events was a rebound high.

Anne's best glucose day
Anne's glucose data was in the target range about 63% of the day.
Senseonics, Inc.

The Unmet need for a Long-Term CGM sensor
Sensor
- Fully implanted
- Small size
- Up to 90 days

Smart Transmitter
- On-body vibe alerts
- Removable/Rechargeable
- Gentle adhesive

Mobile App
- Real-time readings every 5 mins
- No extra receiver
- Trends, alerts w/ predictive alerts

With fully implantable sensor
With a removable transmitter
Sensor that lasts up to 90 days
With on-body vibe alerts
How the Eversense CGM System Works
A Different Kind of Transmitter – Lifestyle Friendly.

- Powers sensor and calculates glucose readings
- Can be taken off and on without having to replace sensor
- Unique on-body vibe alerts for added safety
- Fresh, gentle-on-skin adhesive
- Lightweight and water-resistant
New developments in insulin delivery
Most Patients will Eventually Require Insulin Therapy

The UKPDS found that more than half of newly diagnosed people with type 2 diabetes (T2DM) will require insulin initiation within 6 years of starting other antidiabetic therapies.¹

Due to the progressive nature of T2DM, insulin secretion diminishes largely as a result of a deterioration of beta-cell function.²-⁴
Treat to Target Study
Basal-only Insulin Regimens Eventually Have Diminishing Returns
Non-adherence to insulin is associated with poor glycemic control\(^4\)

72.5% of physicians report patients not administering insulin as prescribed\(^1\)

Common barriers contributing to non-adherence\(^2\)
- Impact to daily living
- Injection embarrassment & pain
- Number of injections

As injections adherence\(^3,4\)

How V-Go® Works

1. Start Button
   Inserts the 4.6 mm, 30 gauge needle and begins the 24-hour preset basal rate

2. Needle Release Button
   Slide and push to retract needle after 24 hours

3. Bolus Ready Button
   Activates bolus delivery button

*Fill with U-100 rapid-acting insulin

On-demand bolus is manually activated using 2 buttons
Press start button to insert needle and start a continuous 24-hour preset basal rate of insulin.

On-demand insulin for mealtime coverage in 2 units/click.
ENABLE Study

Achievement of A1C Targets with V-Go®

% Achievement of A1C Targets

- Baseline
- On V-Go (7 months)

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High Risk (A1C > 9%)

- 76% (Baseline)
- 24% (On V-Go)

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<7.0%<8.0%≤9.0%>9.0%

- 23 (Baseline)
- 24 (On V-Go)
- 52 (Baseline)
- 54 (On V-Go)
- 46 (Baseline)
- 24 (On V-Go)

N=283

*P<0.001 compared to baseline
Achievement percentages for <7, <8 and ≤9% are cumulative and represent the total % of patients achieving each target threshold independently

V-Go® Initiation Dosing Guidance+

<table>
<thead>
<tr>
<th>Weight Range</th>
<th>Basal Rate</th>
<th>Start Bolus Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;200 lbs</td>
<td>V-Go 20 U/24 hours</td>
<td>3 clicks/meal</td>
</tr>
<tr>
<td>200-250 lbs</td>
<td>V-Go 30 U/24 hours</td>
<td>4 clicks/meal</td>
</tr>
<tr>
<td>&gt;250 lbs</td>
<td>V-Go 40 U/24 hours</td>
<td>5 clicks/meal</td>
</tr>
</tbody>
</table>

Consider 1 click with snack. 1 click = 2 Units of insulin.

*Individual dosing needs may vary

Understand the total daily dose of insulin your patient is actually taking with their current insulin regimen versus what is being prescribed. Selecting the correct V-Go option may lessen the risk of hypoglycemia (low blood sugar).

It is common practice to reduce the total daily insulin dose when starting a patient on continuous subcutaneous insulin infusion therapy and this reduction should be considered when starting a patient on V-Go.

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1Data on file – Valeritas 2017, Inc.
MOTIV Study

Simple Bolus Titration Algorithm for V-Go®

**V-Go Titration based on SMBG**

- **Maintain current CLICKS at each meal if achieving 2 hour post-meal blood sugar target**

- **If your blood sugar reading is < 100 mg 2 hrs after meal**
  - Decrease By 1 CLICK
  - 1 click = 2 units for the same meal tomorrow

- **If your blood sugar reading is > 170 mg 2 hrs after meal**
  - Increase By 1 CLICK
  - 1 click = 2 units for the same meal tomorrow

Repeat until 2 hour post meal blood sugar reading is between 100 and 170 mg/dl consistently for 3 days

SMBG=Self monitored blood glucose

Insulin Pumps
The Road to a Closed Loop
Intuitive and simple to use color touchscreen interface and graphical displays

- User-centric, modern, and sleek design
- Secure, locked down smartphone
- Bluetooth® Wireless Technology communication to Pod and meter
- Integrated CalorieKing® food library
- Zero basal rate
- Can set insulin to carb ratio in 0.1 increments
- English and Spanish

*Available in the English language only
USA-40969-ENG AW R3 01/19
Step by step instructions allow for easy system set-up

Real-time graphical representation of user settings
On-screen instructions for Pod activation

1. Fill new Pod with U-100 insulin (leave blue Pod needle cap on)
2. Listen for 2 beeps, then tap NEXT
3. Prepare infusion site
4. Remove blue Pod needle cap and check cannula. Then remove paper backing.
5. Check Pod and then apply to site.
6. Tap START to insert cannula and begin your basal delivery.
An alternative to carb counting

Program customizable bolus presets
Omnipod DISPLAY™ App

Allows patients to monitor their diabetes from their own smartphone

- More interaction with smartphone
- Receive notifications and alarms
- Find My PDM – easy access
- Invite friends and family to view data
Omnipod DISPLAY™ Widget

Allows patients to see their insulin data simultaneously with their CGM data

- Combined view of insulin data with blood glucose data

![Diagram of Omnipod DISPLAY™ Widget showing collapsed and expanded views, with labels for Insulin on Board, Amount of insulin in Pod, and Blood glucose data from CGM Widget.]

Omnipod DISPLAY™, Omnipod VIEW™, and Omnipod DEMO™ apps coming soon
The Dexcom System does not have integrated functionality with the Omnipod DASH™ System

USA-40969-ENG AW R3 01/19
Medtronic is committed to deliver superior clinical outcomes with less work.

* System has CE Mark; System not approved in the US
† Investigational program not approved by the FDA; not commercially available
**Development programs not approved by the FDA; not commercially available
MINIMED™ 770G HYBRID CLOSED LOOP SYSTEM

Designed to:
- Stay up to date with upgradable pump software
- Provide discretion with smartphone display

ACTUAL 72%

TIR GOAL 80%

MINIMED™ 780G ADVANCED HYBRID CLOSED LOOP

Designed to:
- Deliver 100% of correction to meet target
- Deliver a correction every 5 mins, as needed
- Allow setpoint of 100 or 120 mg/dL

PERSONALIZED CLOSED LOOP

Designed to:
- Provide optional carb counting
- Adapt to behavior and physiology
- Improve connectivity through Smartphone control

TIR GOAL 85%

2 Investigational. Not approved by the FDA for any use and not commercially available in the US.
3 Investigational. Not approved by the FDA for any use and not commercially available in the US. Data based on feasibility studies.
4 In development. Not approved by the FDA for any use and not available for research or commercial use in the US. Data based on simulation modeling.
GATEWAY TO FUTURE INNOVATIONS

MiniMed™ 770G System

Design Goals

Future upgrades to latest technology

Care partner app keeps your loved ones in the loop

Discreet sugar checks on your phone

Automatic glucose data uploads
**SIMPLIFYING THERAPY MANAGEMENT**

<table>
<thead>
<tr>
<th>Algorithm</th>
<th>Sensor &amp; Key Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adapts to physiology &amp; behavior&lt;br&gt;Personalized for all patient types</td>
<td>50% smaller disposable CGM&lt;br&gt;Compared to current CGM for improved comfort</td>
</tr>
<tr>
<td>Automated Meal Handling&lt;br&gt;Reduced Carb counting</td>
<td>10 sec sensor insertion&lt;br&gt;Seamless and quick</td>
</tr>
<tr>
<td>100% Auto Mode Capable&lt;br&gt;TIR goal of &gt;85%</td>
<td>Smartphone Control&lt;br&gt;Keeps the pump tasks discreet</td>
</tr>
</tbody>
</table>

**With FDA Breakthrough Designation**

Development programs not approved by the FDA; not investigational nor commercially available.

Now with Basal-IQ™ Technology

Predicts and helps prevent lows with zero fingersticks*

*If glucose alerts and CGM readings do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions.
How does Basal-IQ™ Technology work?

Basal-IQ Technology uses CGM readings to predict glucose levels 30 minutes ahead. If the glucose level is predicted to be less than 80 mg/dL, or if a CGM reading falls below 70 mg/dL, insulin delivery is suspended. Insulin delivery resumes as soon as sensor glucose values begin to rise.
Technology you expect in a modern device

• Large color touchscreen
• Rechargeable battery
• Remote feature updates*
• Watertight construction†
• Micro-USB port

* New feature updates are subject to future FDA approvals. A prescription and additional training may be required to access certain future software updates. Charges may apply.
† Tested to three feet for 30 minutes (IPX7)
Conclusions

- This is an exciting time to be involved with helping people with diabetes successfully manage their disease
- Technology is dynamic and rapidly progressing
- Technology is allowing Diabetes management to occur outside the traditional brick and mortar facility
- Technology is better allowing patients to manage their disease and become their best selves.