Do You REALLY Know When and How Much Insulin Your Patients are Taking?

Smart Dosing Monitors Can Help.

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- Notice of Requirements For Successful Completion
  - Please refer to learning goals and objectives
  - Learners must attend the full activity and complete the evaluation in order to claim continuing education credit/hours

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  - Advisory Board: Capillary Bio, Companion Medical, Glooko, Eli Lilly
  - Consultant: Adocia, Byram Healthcare, MySugr

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- Companion Medical has provided an honorarium for delivery of this program
Objectives

✓ Delineate the clinical challenges among insulin pen users and their providers
✓ Describe the features of the various “smart” insulin pen devices
✓ Detail the clinical utility and limitations associated with “smart” pen devices

Insulin Use in the United States

• Approx. 8 Million Insulin Users
  – 1.6M type-1
  – 6.1M type-2
    • 1.6M taking rapid insulin
  – 3.2M take insulin multiple times daily
  – 80% take insulin by INJECTION (pen/syringe)

Source: Centers for Disease Control and Prevention

Management challenges faced by people who inject insulin

• Data logging
• Missed doses
• Meal dose calculations
• Stacking
• Double-Dosing
• Spoilage
• Complexity of add-ons
Management challenges faced by people who inject insulin

- Missed / Forgotten Doses by Adults

<table>
<thead>
<tr>
<th>Basal Insulin</th>
<th>Rapid Insulin</th>
</tr>
</thead>
<tbody>
<tr>
<td>36%</td>
<td>24%</td>
</tr>
</tbody>
</table>


- Impact of missed meal doses in youth

<table>
<thead>
<tr>
<th>A1c</th>
<th>&lt; 1 miss/wk</th>
<th>1 or more miss/wk</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.0%</td>
<td>8.0%</td>
<td>8.8%</td>
</tr>
</tbody>
</table>


- Management challenges faced by people who inject insulin (computer-modeled study for people w/T1D)

- ~ 2 missed bolus doses/week: $\Delta$ A1c .3-.4%
- ~ 2 missed basal doses/week: $\Delta$ A1c .2-.3%
- ~ 38% missed bolus doses/week: $\Delta$ A1c 1.8%

Management challenges faced by people who inject insulin

• Numeracy Issues
  – 25% unable to identify their BG targets
  – 56% unable to count carbohydrate grams using a food label
  – 59% unable to calculate insulin dose based on grams of carbohydrate and BG


Management challenges faced by people who inject insulin

Use of dosing Advisor software by people w/T1
  – A1c reduction of 0.6% after 12 months
  – 19% increase in time in-range (70-150)
  – No change in nocturnal hypoglycemia
  – No change in total daily insulin or weight


Challenges faced by CLINICIANS of people who inject insulin

• Insufficient Information
  – Lack of dosage logs
  – Lack of other data
• Inaccurate Information
  – Accidental
  – Intentional
• Time Limits for Training, Data Integration
Challenges faced by CLINICIANS of people who inject insulin

Time required to teach dosage adjustments

<table>
<thead>
<tr>
<th>Using Written Instructions</th>
<th>Using “Slide Rule” Aid</th>
</tr>
</thead>
<tbody>
<tr>
<td>43 Min</td>
<td>18 Min</td>
</tr>
</tbody>
</table>

Kaufman et al., Diabetes Care, Vol 22, No 8, August 1999

Smart Pen Technologies: Timesulin (Bigfoot Biomedical)

- Tracks time since last dose was delivered
- Based on removal/replacement of device from pen
- Fits most disposable pens
- Not yet cleared by FDA
Smart Pen Technologies: Timesulin

**Issues Addressed:**
- ✗ Missed Doses
- ✓ Double Dosing
- ✗ Dose Calculations
- ✗ Bolus Stacking
- ✗ Spoilage
- ✗ Logging Accuracy
- ✗ Logging Detail
- ✗ Training Time
- ✓ Complexity

Smart Pen Technologies: Clipsulin (Diabnext)

**Issues Addressed:**
- ✗ Missed Doses
- ✓ Double Dosing
- ✗ Dose Calculations
- ✗ Bolus Stacking
- ✗ Spoilage
- ✓ Logging Accuracy
- ✗ Logging Detail
- ✓ Training Time
- ✓ Complexity

- Counts audible clicks, displays last dose
- Works with most commercially-available pens
- ½- or 1-unit settings; +/- buttons for manual adjustment
- Automatic bluetooth transmission of doses to smartphone app
- HCP platform for viewing data
- Not yet FDA-cleared
Smart Pen Technologies:

GoCap (Common Sensing)
- Attaches to Lantus and Apidra disposable pens
- Tracks doses and units left in pen
- Missed dose alerts
- Temperature alerts
- Wireless upload to smartphone app; user can enter BG & carbs
- Commercial version available in US mid-2020

Smart Pen Technologies:

GoCap (Common Sensing)

Issues Addressed:
✓ Missed Doses
✓ Double Dosing
◆ Dose Calculations
◆ Bolus Stacking
✓ Spoilage
✓ Logging Accuracy
?? Logging Detail
◆ Training Time
◆ Complexity

Smart Pen Technologies:

NovoPen Echo (Novo Nordisk)
- Durable pen
- Takes 3.0 ml cartridges of Novolog
- Doses in ½-unit increments
- Displays last dose, time since last dose
- FDA-cleared
Smart Pen Technologies: NovoPen Echo/Plus (Novo Nordisk)

- Durable pen
- Takes 3.0 ml cartridges of Toujeo, Tresiba, Novolog, Fiasp
- Doses in ½-units
- Displays last dose, time since last dose, IOB
- 800-dose memory
- Near Field Communication (scan) for downloading
- Not yet FDA-cleared; Launched in Europe 2019

Smart Pen Technologies: NovoPen Echo / Plus

- Issues Addressed:
  - Missed Doses
  - Double Dosing
  - Dose Calculations
  - Bolus Stacking
  - Spoilage
  - Logging Accuracy
  - Logging Detail
  - Training Time
  - Complexity

Smart Pen Technologies: InPen (Companion Medical)

- Prescription item
- Durable pen, takes Humalog or Novolog 3ml cartridges (different pens)
- Doses in ½-units
- Temperature monitor
- Bluetooth connection to smartphone app; "prime" doses factored out
- Customizable dose calculator
- Displays & adjusts for IOB
- Generates detailed PDF log reports
- Missed bolus and basal dose reminders
- FDA-cleared, prescription required
Smart Pen Technologies: InPen

Issues Addressed:
- Missed Doses
- Double Dosing
- Dose Calculations
- Bolus Stacking
- Spoilage
- Logging Accuracy
- Logging Detail
- Training Time
  - Complexity

Other Devices In Development
- Novo Nordisk Bluetooth FlexTouch Pen Attachment
- BioCorp “Easylog” smart pen cap
- Lilly integrated smartpen/Dexcom/smartphone app
- Pendiq Digital Pens

Insights to derive from smart dose monitor data
- Were doses actually taken?
- When were they taken?
- How much was taken?
- Were dosage calculations correct?
- Are the current dosing formulas working?