

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

Smart Dosing Monitors Can Help.

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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

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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

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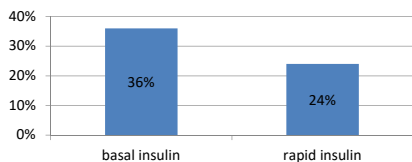
Management challenges faced by people who inject insulin

- 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



Source: Munshi, et al. Diabetes Care, 3/12/19. <https://doi.org/10.2337/dc18-1631>.

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Management challenges faced by people who inject insulin

- Impact of missed meal doses in youth



Source: Burdick, et al. Pediatrics, vol 113 No 3, March 2004.

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Management challenges faced by people who inject insulin

(computer-modeled study for people w/T1D)

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

Rendelov et al, Journal of Diabetes Science & Technology, Vol 2, Issue 2, March 2008

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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

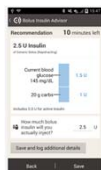
Marden et al. Diabetes Med 29:662-669, 2011; Osborn et al. J Health Comm 15:146-158, 2010; Cavanaugh et al. Diabetes Care 32:2149-2155, 2009.



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



Garg et al. Diabetes Technology & Therapeutics, Vol 10, No 5, 2008.



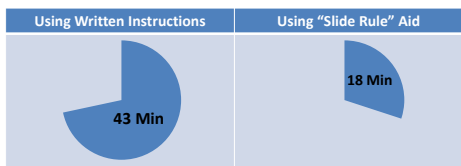
Challenges faced by CLINICIANS of people who inject insulin

- 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



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

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Smart Pen Technologies TO THE RESCUE!



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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



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Smart Pen Technologies: Timesulin



Issues Addressed:

- ✘ Missed Doses
- ✔ Double Dosing
- ✘ Dose Calculations
- ✘ Bolus Stacking
- ✘ Spoilage
- ✘ Logging Accuracy
- ✘ Logging Detail
- ✘ Training Time
- ✔ Complexity

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Smart Pen Technologies: Clipsulin (Diabnext)

- Counts audible clicks, displays last dose
- Works with most commercially-available pens
- 1/2- 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



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Smart Pen Technologies: Clipsulin



Issues Addressed:

- ✘ Missed Doses
- ✔ Double Dosing
- ✘ Dose Calculations
- ✘ Bolus Stacking
- ✘ Spoilage
- ✔ Logging Accuracy
- ✘ Logging Detail
- ✘ Training Time
- ✔ Complexity

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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



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Smart Pen Technologies:
GoCap



Issues Addressed:

- ✓ Missed Doses
- ✓ Double Dosing
- ✗ Dose Calculations
- ✗ Bolus Stacking
- ✓ Spoilage
- ✓ Logging Accuracy
- ?? Logging Detail
- ✗ Training Time
- ✗ Complexity

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Smart Pen Technologies:

NovoPen Echo (Novo Nordisk)

- Durable pen
- Takes 3.0 ml cartridges of Novolog
- Doses in 1/2-unit increments
- Displays last dose, time since last dose
- FDA-cleared



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**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



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**Smart Pen Technologies:
NovoPen Echo / Plus**



Issues Addressed:

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

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**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



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Smart Pen Technologies: InPen



Issues Addressed:

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

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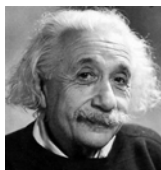
Other Devices In Development

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

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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?



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GET THE POINT!



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Questions?

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