SMBG Bolus Calculator Design

Steve Scott
Divisional Vice President Research and Development
Abbott Diabetes Care
Agenda

• Why include a Bolus Calculator?
• Design Process
• Risk Management
• Setup and Use of Meter Bolus calculator
• Dose Calculation
• Field Experience of Calculator
Need for a blood glucose meter that could assist patients with bolus insulin dosing

• People with Diabetes are not meeting glycemic targets or goals\textsuperscript{1-3}

• People with Type 2 are not advanced to insulin in a timely manner and insulin therapy is not advanced in a timely manner\textsuperscript{4-6}

• Health Care Providers use fixed dose or pre-mixed insulin because it is easier for patients to use, even though the doses might not match the food they eat or their blood glucose levels\textsuperscript{7,8}

1 Lasserson, D, Diabetologia 2009; 52: 1990-2000
2 Riddle, M, Diabetes Care 26:3080-3086, 2003
3 Koro, CE, Diabetes Care 27: 17-20, 2004
5 Karter, A, Diabetes Care 33:733-735, 2010
6 Peyrot, M, Diabetes Care 28:2673-2679, 2005
7 Fritsch, A, DM Obesity & Metab 12:115-123, 2010
Recommended new carb ratio

Breakfast 1:12
Lunch 1:12
Dinner 1:10
dose before the meal!

L. Kurt Midyett, MD
Insulin dose adjustment can be challenging to teach & learn

Teaching insulin dosing is very difficult & time consuming

Numeracy challenges knowledge, skill & time
Low Numeracy Skills

Calculating insulin doses relies on the ability of the patient to quickly make complex calculations in their head, so it’s not surprising that many people get it wrong.

In a published study, only 41% of diabetic patients could calculate an insulin dose that required adjustment for both carbohydrate intake and blood glucose level.

Do Bolus Calculators Help?

- People have difficulty with the calculations required for dose adjustment, resulting in dosing errors or suboptimal doses\(^9,10\)

- Bolus calculators facilitate adjustable dose calculations, which can result in better glycemic control\(^11-13\)

10 Marden S, Diabetic Medicine 27: 730-31, 2010
Creating a Bolus Calculator

• Build a calculator into a SMBG meter that will perform the math for the patient

• Calculator does what a patient would otherwise have to do manually.

• What does the patient have to think about?
  • How much insulin do I need to cover my meal?
  • Do I need to adjust my insulin for my glucose level?
  • I took insulin some time ago – is it still active?
  • Do I need to adjust my insulin for anything? (e.g. exercise?)

• Having established the need and what needs to be included, how do we design a SMBG bolus calculator?
Designing a SMBG Bolus Calculator
Product concept & prototype research:
Input from over 5,500 patients and 1,500 HCPs (Endos, DNs, GPs, Dietitians) in 11 countries

2009

- **Preliminary Concept Research**
  - 12 HCPs at IDF. Canada, US, Austria, Australia, UK, Israel

- **Ipsos Vantis Forecast - Preliminary**
  - 600 insulin patients and HCPs. US, UK

2010

- **Round 1 Interface and Design Research**
  - 94 insulin patients and HCPs. US, Germany, France, UK
  - OCT

- **Round 2 Interface and Design Research**
  - 48 insulin patients and HCPs. US, Germany, France, UK
  - NOV

- **Japan KOL Interviews**
  - 6 Endos
  - DEC

- **Japan Patient and HCP Interviews**
  - 5 endos, 5 patients.
  - FEB

- **Ipsos Vantis Forecast - Expanded**
  - 5,000 insulin patients and 1,200 HCPs. US, UK, France, Germany, Japan, Australia
  - MAR

- **Human Factors Prework Research**
  - 48 HCPs and patients. US, Germany, France, UK
  - SEPT

- **Italy KOL Interviews**
  - 3 Endos
  - FEB

Product Development Research

Market Assessment Research

The product has not been cleared by the Food and Drug Administration (FDA) and is not available for sale in the United States.
## Product Research

### 2011

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Formative Human Factors</strong></td>
<td>6 HCPs, 19 Fixed Patients, 25 Adjustable dose Patients, Chicago</td>
</tr>
<tr>
<td><strong>Human Factors Research</strong></td>
<td>25 HCPs, 25 Fixed dose Patients, 25 Adjustable dose Patients, Chicago &amp; San Francisco</td>
</tr>
<tr>
<td><strong>Numeracy Study</strong></td>
<td>100 Fixed dose Patients, 100 Adjustable dose Patients, Walham, MA &amp; Renton, WA</td>
</tr>
</tbody>
</table>

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Designing the Insulin Calculator - Dealing with Potential Hazards through Design Mitigations
Design and Human Factors Conclusions

An SMBG Bolus Calculator has some unique design features

• Setup
  − 2 setup options required
    • Easy – Fixed meal dose
    • Advanced – For carb counters
  − Option for variable meal (time of day) correction factor
  − Manual insulin logging
  − Set up of calculator needs to be completed by HCP

• Use
  − Patients liked the idea of a suggested dose calculated based on HCP instructions and settings

• HF studies demonstrated
  − HCPs were able to setup calculator correctly
  − Patients were able to obtain and understand the suggested bolus dose

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Basics – Understanding and Comprehension

• Overcome any lack of understanding of calculator settings e.g. correction factor, carbohydrate ratio and insulin duration.
  – Offer different modes of usage to suit patient/HCP needs:
  – Mode of calculator ( “Easy” vs “Advanced”)
  – Meal marking vs Carbohydrate counting (“Carbohydrates” and “Servings”)
  – Settings by time of day vs one setting for 24 hrs

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General labeling mitigations to allow better understanding of insulin calculator – Patient facing

Provide detailed instructions for use of calculator
• in labeling
• in device user interface

Using the Rapid-Acting Insulin Calculator

This optional feature requires an understanding of the use of insulin. Misuse or misunderstanding of this feature and the suggested dose may lead to inappropriate insulin dosing. The calculator suggests doses for rapid-acting insulin only. The calculator is only for use with fingerstick blood glucose results from the built-in meter. You cannot use the insulin calculator with Sensor glucose readings.

An access code is required to set up or change the rapid-acting insulin calculator settings. This access code is available only to your health care professional. Work with your health care professional to set up or change the calculator for you.

If you are not sure about the calculator’s suggested dose, you can adjust it based on instructions from your health care professional.

CAUTION: The rapid-acting insulin calculator cannot account for all the factors that may affect your insulin dose. These include incorrectly entered data, incorrectly set date or time, un-logged insulin, smaller or larger meals, sickness, exercise, etc. It is important that you review your suggested dose and account for these factors before taking insulin.

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General labeling mitigations to allow better understanding of insulin calculator – HCP facing

This setup has two parts:
1. Enter your patient’s meal-time insulin settings.
2. Enter your patient’s correction settings.

Setting up the Insulin Calculator
The insulin calculator can help your patients calculate their rapid-acting insulin doses based on meal and fingerstick blood glucose level information. From the Professional Options screen, select Insulin Calculator.

CAUTION: This feature requires an understanding of the use of insulin. Misuse or misunderstanding of this feature and the suggested dose may lead to inappropriate insulin dosing. The calculator suggests doses for rapid-acting insulin only.

Complete the setup to store your patient’s individual insulin settings in the Reader. The calculator uses the fingerstick blood glucose results, meal information and the stored settings to calculate a suggested insulin dose based on this formula:

\[
\text{Blood glucose correction (if needed)} + \text{Meal | Carbohydrate Intake} - \text{Active Insulin (if present)} = \text{Total suggested dose}
\]

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Ensure correct dose logging

- Errors could happen during any of the following activities:
  - Carbohydrate counting errors directly influence the suggested dose
  - Incorrect logging such as meal selection directly influence the suggested dose
  - Double logging can result in multiple dose recommendations

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Design mitigations to ensure correct dose logging

Meal entry on-screen instructions

Enter Carbs

Carbohydrates
Food contains carbohydrates (carbs), which break down into glucose. Carbs may affect the amount of insulin you need to take. Ask your health care professional how to estimate the grams of carbs in food so you can use the Reader’s insulin calculator.

Servings
1 serving = x grams of carbs
Food contains carbohydrates (carbs), which break down into glucose. Carbs may affect the amount of insulin you need to take. Ask your health care professional how to estimate the servings of food so you can use the Reader’s insulin calculator.

Prevent double logging

Breakfast
Lunch
Dinner
No meal

Double Check
You have already logged rapid-acting insulin for dinner today.
Do you want to log more rapid-acting insulin for dinner?

User adjustment and dose details summary

Suggested Dose
Adjust if needed

12 U
User change: +2

Dose Details
For 30 g carbs  9
For 143 mg/dL  +2
Active insulin  -1
User change  +2

Total 12 U

The suggested dose covers the carbs in your meal, corrects for your current glucose level, and accounts for rapid-acting insulin that was previously logged.

Dose Details
For breakfast  9
For 143 mg/dL  +2
Active insulin  -1
User change  +2

Total 12 U

Insulin to cover your meal
Insulin to correct for your current glucose level
Insulin remaining in your body
A change you have made to the suggested insulin dose
Your total suggested dose

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Prevent erroneous dose recommendation due to incorrect insulin logging

- Rapid-acting insulin is not logged consistently enough (user forgets to log)

- Incorrect dose amounts logged (compared to what was administered)
Design Mitigations to ensure proper insulin logging

Provide a ability for the user to log any forgotten dose

Appropriate cautions in labeling

**CAUTION:** It is important to log all your rapid-acting insulin doses so your Reader can account for active insulin when calculating your suggested doses. Failure to log all your rapid-acting insulin doses may result in a suggested dose that is too high.

Allow appropriate dose resolution

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Prevent erroneous dose recommendation due to incorrect Calculator setup

• If key HCP settings such as correction factor, carbohydrate ratio, insulin duration are not set appropriately, insulin dose recommendations will be incorrect.
Design Mitigations to ensure proper calculator setup

Restrict access to settings

- Enter Code to Unlock
  - A
  - B
  - C
  - done

Professional Options can only be used by a healthcare professional.

Reinforce settings confirmation

- Setup Complete
  - When checking glucose, the insulin calculator will now be available.

- Calculator Settings
- Reader Basics
- Professional Options
  - done

Provide step by step instructions

- Choose Setup Option
  - Easy
    - For patients who start with a fixed dose of rapid-acting insulin at meals.
    - back
    - done

- Choose Setup Option
  - Advanced
    - For patients who count carbs (in grams or servings) to adjust their rapid-acting insulin dose at meals.
    - back
    - done

This setup has two parts:
1. Enter your patient's meal-time insulin settings.
2. Enter your patient's correction settings.

Provide contextual help screens

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Other potential hazards that are controlled by mitigations “under the hood”

- If time is set incorrectly or changed due to daylight savings
  - For IOB calculations use relative time so there is no impact

- Final insulin output calculations
  - To be safe always round down insulin totals.
  - Within 2 hours of another dose do not calculate correction insulin
  - Below 60mg/dL glucose levels do not calculate insulin
  - If user actively changes recommended dose, provide warning as necessary

- Old BG readings could be used for calculation.
  - Enforce calculator lockout i.e. Calculator cannot be used with a reading that is more than 15 min old.
Bolus Calculator Setup

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Insulin calculator inputs

HCP settings
- Blood Glucose target
- Correction factor
- Carbohydrate ratio*
- Insulin duration*

Meter
- current BG result

User
- carbohydrate amount*
- user change

* Advanced mode only
Setup of Meter Bolus calculator

Choose Setup Option

For patients who count carbs (in grams or servings) to adjust their rapid-acting insulin dose at meals.

Enter food by:

- Grams of carbs
- Servings

Carbohydrate Ratio

1 u insulin for 15 grams carbs

Midday: 10am to 4pm

Carbohydrate ratio 1 unit insulin for:

- 15 g morning
- 15 g night
- 15 g midday
- 15 g evening

Carbohydrate Ratio

1 u insulin for 15 grams carbs

Midday: 10am to 4pm

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Setup of Meter Bolus calculator

How does your patient correct their glucose?
- To a single target
- To a target range

Correction Target
- 100 to 140 mg/dL
Optional: by time of day

Correction Target
- 100 to 140 mg/dL
Optional: by time of day

Correction Target
- 100 to 140 mg/dL
- Evening: 16:00 to 22:00

Correction Factor
- 1 u insulin for 50 mg/dL
Optional: by time of day

Correction Factor
- 50 mg/dL morning
- 50 mg/dL night
- 50 mg/dL midday

Correction Factor
- 50 mg/dL evening

Correction Factor
- 1 u insulin for 50 mg/dL

Insulin Duration
- 4:30 hrs:min

Do you want the Active Insulin symbol to be displayed on the Home screen?
- Yes
- No

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## Operation of Calculator

**Advanced mode**

**Suggested Bolus =**

**Meal Bolus + Correction Bolus – Active Insulin + User Change**

<table>
<thead>
<tr>
<th>Component</th>
<th>Input Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meal Bolus:</td>
<td>Input = Carbs and uses Carbohydrate ratio</td>
</tr>
<tr>
<td>Correction Bolus:</td>
<td>Input = Glucose Reading and uses Correction Target and Correction Ratio</td>
</tr>
<tr>
<td>Active Insulin:</td>
<td>Input = Insulin logged and insulin duration</td>
</tr>
<tr>
<td>User Change:</td>
<td>User selected change to suggested dose</td>
</tr>
</tbody>
</table>
Example: carb / meal with correction insulin & active insulin

<table>
<thead>
<tr>
<th>Setting Numbers</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Carb Ratio</td>
<td>1 u : 10 g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction Factor</td>
<td>1 u : 50 mg/dL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target BG</td>
<td>100 mg/dL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin Duration</td>
<td>6 hours</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **BG reading** 204 mg/dL
- **Target BG** 100 mg/dL
- **Correction Factor** 1 u : 50 mg/dL

**Entered Carbs** 20 g

**Carb Ratio** 1 u : 10 g

**Meal Insulin** 2 units

**Correction Insulin** 2 units

**Total Insulin** 4 units

**Total Suggested Dose** 2 units

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Current Usage Statistics and Field Experience

• Usage Statistics
  − Abbott Diabetes Care has been shipping meters with a Bolus Calculator outside the United States since 2011
  − We estimates there are > 600,000 users worldwide with meters containing a bolus calculator
  − ADC analysis has estimated that 60% of these meters have the Bolus Calculator switched on
  − Worldwide users of the Bolus Calculator is >400,000

• User Study
  − Study of 409 insulin using patients showed 63% made errors when manually calculating insulin\textsuperscript{14}.
    • Error rate with calculator was 6% but all errors deviations from instructions in test protocol
  − 83% expressed confidence in calculator and 87% stated they preferred calculator to manual

• Complaint summary
  − ADC has not seen any serious adverse event in use of calculator since 2011.