COST-UTILITY ANALYSIS IN A UK SETTING OF SELF MONITORING OF BLOOD GLUCOSE IN PATIENTS WITH TYPE 2 DIABETES

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Background (1)
Burden of illness

- 200 million people are currently affected by diabetes around the world
- Diabetes is associated with a huge healthcare burden
  - Approximately 10% of global healthcare expenditure
  - Majority of costs due to complications
- Risk of complications can be reduced by improving control of blood glucose levels
Background (2)
Costs of diabetes are complication driven

- Annual cost per patient with type 2 diabetes is dependent on complication status

No diabetes | Diabetes, no complications | Diabetes, microvascular complications | Diabetes, macrovascular complications | Diabetes, micro- and macrovascular complications
---|---|---|---|---
€1,373 | €1,723 (1.3-fold increase) | €3,355 (2.4-fold increase) | €3,437 (2.5-fold increase) | €5,642 (4.1-fold increase)

Background (3)
SMBG is recommended for all type 2 diabetes patients

- IDC, WHO and the AADE global consensus conference on SMBG
  - Both measurement of HbA1c and SMBG are essential for assessing glycemic control
  - SMBG should be recommended to all people with diabetes as an integral part of an overall diabetes management program

- SMBG provides information on the actual blood glucose levels at the time of testing
  - Allows immediate action to be taken
  - Can differentiate between fasting and post-prandial hyperglycemia

- Consensus statement describes SMBG as an essential component of management for insulin-treated patients with diabetes
Background (4)

Effects of SMBG on glycemic control

• Karter et al. reported an observational study in over 17,500 type 2 diabetes patients from the Northern California Kaiser Permanente Diabetes Registry
  • Patients on oral medication or diet control had lower HbA1c levels with SMBG versus no SMBG
  • Follow up analysis showed that greater SMBG testing strip usage corresponded to greater improvements in HbA1c

• Recent meta-analysis of SMBG as part of a multi-component therapy in non-insulin requiring patients with type 2 diabetes (Sarol et al. 2005)
  • Eight RCTs
  • 1,307 adults treated over 3-10 months
  • SMBG following education was associated with 0.4%-points lower HbA1c levels versus no SMBG

• Another recent meta-analysis pooled the results of 6 RCTs (Welschen et al. 2005)
  • SMBG versus no SMBG in non-insulin treated patients with type 2 diabetes
  • Statistically significant decrease in HbA1c of -0.39%-points (95% confidence intervals -0.56 to -0.21) in patients using SMBG versus no SMBG
Study hypothesis

1. SMBG improves HbA1c
   - Decreased complication rates
   - Increased QALYs

2. Increased Costs of SMBG
   - Offset by lower complication costs

3. SMBG cost-effective
   - In type 2 diabetes
   - Non-insulin treated patients (OADs or diet+exercise)
   - Insulin treated patients
Key data sources

• Base-case cohort definition
  • Demographics, CVD risk factors, baseline co-morbidities
    • Karter *et al.* Kaiser Permanente database/publications

• SMBG effects on HbA1c
  • HbA1c effects only (no effect on hypo rates or other risk factors assumed)
    • Karter *et al.* Kaiser Permanente database/publications
    • Meta-analyses
      • Welschen *et al.* Diabetes Care 2005;28:1510-17
      • Cochrane Database Syst Rev 2005;18(2):CD005060
Summary effects of SMBG

• Diet and exercise - SMBG testing 1 x daily
  • HbA1c reduced by $-0.3\pm1.84\%$-points

• OHAs - SMBG testing 2 x daily
  • HbA1c reduced by $-0.4\pm1.84\%$-points

• Insulin - SMBG testing 3 x daily
  • HbA1c reduced by $-0.6\pm1.84\%$-points

SDs calculated from weighted average of SDs from SMBG arm of trials included in Welschen et al. meta-analysis
## Costs of SMBG

<table>
<thead>
<tr>
<th>Unit Cost</th>
<th>£0</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMBG monitor (machine) supplied for free in the UK</td>
<td></td>
</tr>
<tr>
<td>Assume in all 3 patient groups, in the first year, patients are trained for 1 hour by a diabetes nurse</td>
<td>£10.74</td>
</tr>
<tr>
<td>Cost per strip</td>
<td>£0.306</td>
</tr>
<tr>
<td>Cost per lancet</td>
<td>£0.0324</td>
</tr>
</tbody>
</table>
## Annual costs of SMBG

<table>
<thead>
<tr>
<th>Costs of SMBG, diet and exercise</th>
<th>Year 1:</th>
<th>£134.34</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Years 2+:</td>
<td>£123.60</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Costs of SMBG, OHAs</th>
<th>Year 1:</th>
<th>£257.94</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Years 2+:</td>
<td>£247.20</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Costs of SMBG, insulin</th>
<th>Year 1:</th>
<th>£381.54</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Years 2+:</td>
<td>£370.80</td>
</tr>
</tbody>
</table>

To account for other routine treatment costs (medications, education etc):

- +£469 / patient / year on SMBG (from intensive UKPDS costs)
- +£394 / patient / year not using SMBG (from conventional UKPDS costs)
Other assumptions and sensitivity analyses

- **Adherence rates**
  - 78% annual adherence rates base case analysis
  - 52% sensitivity analysis
  - Assume if not adherent, same costs and effects as “no SMBG”

- **Duration of effect on HbA1c**
  - Lifetime in base case
  - 5 years in sensitivity analysis

- **Time horizon**
  - Lifetime in base case
  - 10 years and 20 years in sensitivity analysis

- **Discounting**
  - 3.5% for costs and QALYs in base case
  - 6.0% for costs and 1.5% for QALYs in sensitivity analysis

- **Disutility associated with SMBG**
  - No disutility in base case
  - -0.034 (same as disutility of “insulin therapy” in type 2 diabetes) in sensitivity analysis
  - Break even analysis of disutility
CORE Diabetes Model
Structure (1)

- 15 inter-dependent sub-models
- Markov Model – standard modelling approach in progressive diseases
- First and second order Monte Carlo simulation
- Variable time horizon (1 to 100 years)
- Validated against published data from clinical and epidemiological studies
CORE Diabetes Model
Structure (2)
CORE Diabetes Model

Validation

- First order (internal)
- Second order (internal)
- Third order (external)
CORE Diabetes Model
Mortality, third order validation

# Results

**Base case – diet and exercise cohort (1)**

<table>
<thead>
<tr>
<th></th>
<th>SMBG</th>
<th>No SMBG</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undiscounted life expectancy (years)</td>
<td>12.302</td>
<td>11.931</td>
<td>0.371</td>
</tr>
<tr>
<td></td>
<td>(2.481)</td>
<td>(2.397)</td>
<td></td>
</tr>
<tr>
<td>Quality-adjusted life expectancy (QALYs)</td>
<td>6.342</td>
<td>6.177</td>
<td>0.165</td>
</tr>
<tr>
<td></td>
<td>(1.864)</td>
<td>(1.753)</td>
<td></td>
</tr>
<tr>
<td>Total lifetime costs (£)</td>
<td>20,668</td>
<td>18,105</td>
<td>2,564</td>
</tr>
<tr>
<td></td>
<td>(7,469)</td>
<td>(6,724)</td>
<td></td>
</tr>
</tbody>
</table>

**ICER**

£15,515 per QALY gained
## Results

### Base case – OAD and insulin cohorts

<table>
<thead>
<tr>
<th>Metric</th>
<th>OADs</th>
<th>Insulin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undiscounted life expectancy (years)</td>
<td>0.489</td>
<td>0.521</td>
</tr>
<tr>
<td>Quality-adjusted life expectancy (QALYs)</td>
<td>0.225</td>
<td>0.255</td>
</tr>
<tr>
<td>Total lifetime costs (£)</td>
<td>1,013</td>
<td>1,171</td>
</tr>
</tbody>
</table>

**ICER for patients on OADs**  
£4,508 per QALY gained

**ICER for patients on insulin**  
£4,593 per QALY gained
Results
Base case – diet and exercise cohort (2)

- Scatter plot of incremental costs versus quality-adjusted life years
Results

Base case – diet and exercise cohort (3)

- Acceptability curve

![Graph showing acceptability curve for SMBG in Type 2 Diabetes patients](image)
## Results

### Sensitivity analysis – diet and exercise cohort

<table>
<thead>
<tr>
<th>Scenario</th>
<th>QALE (QALYs)</th>
<th>Costs (£)</th>
<th>ICER (£/QALY)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Base case</strong></td>
<td>0.165</td>
<td>2,564</td>
<td>15,515</td>
</tr>
<tr>
<td>Discount rates 6% costs / 1.5% QALYs</td>
<td>0.224</td>
<td>2,192</td>
<td>9,772</td>
</tr>
<tr>
<td>Time horizon 10 years</td>
<td>0.030</td>
<td>2,266</td>
<td>74,528</td>
</tr>
<tr>
<td>Effect on HbA1c for only 5 years</td>
<td>0.118</td>
<td>3,052</td>
<td>25,802</td>
</tr>
<tr>
<td>52% annual adherence rate</td>
<td>0.135</td>
<td>1,221</td>
<td>9,020</td>
</tr>
<tr>
<td>Assuming disutility equivalent to taking insulin</td>
<td>0.077</td>
<td>2,623</td>
<td>34,259</td>
</tr>
</tbody>
</table>
Break-even analysis

SMBG disutility

![Graph showing the disutility associated with SMBG and the discounted quality-adjusted life expectancy (QALYs). The graph compares SMBG and no SMBG, with a likely range indicated.](image-url)
Conclusions (1)

- HbA1c improvements lead to better patient outcomes
  - Lower complication rates
  - Higher projected life expectancy
  - Higher QALYs

- Additional costs of SMBG partially offset by reduction in costs of complications

- Results are sensitive to assumptions about disutility associated with SMBG
  - SMBG still cost-effective when disutility value varied within plausible range
Conclusions (2)

• Based on the moderate levels of clinical evidence available to date:
  • SMGB should be considered “good value for money” in a UK setting
  • These are PRELIMINARY health economic results, and should be regarded as hypothesis generating rather than providing a definitive answer
  • Well designed, long-term, randomized comparative studies of SMBG are needed
  • Utility changes associated with SMBG must be more fully investigated