Background

Type 2 diabetes mellitus (T2DM) is associated with a significant economic burden. In 2010-2011, the total annual cost of T2DM was estimated to be €21.8 billion in the UK (direct costs, €3.6 billion; indirect costs, €13.0 billion), and treating and managing complications of the disease amounted to 80% of the total direct costs.

Healthcare expenditure for the management of T2DM is escalating with the increasing prevalence of the disease. In addition, use of insulin to treat T2DM is associated with higher costs compared with oral medication; a German prospective study (n = 2561) found a 66% increase in resource use related to diabetes in the 6 months after initiation of insulin therapy.

The FreeStyle Libre™ system is a novel, sensor-based, factory-calibrated flash glucose monitoring system that continuously measures glucose levels in a patient’s interstitial fluid. Data are wirelessly transferred from the sensor (which lasts for up to 14 days) to a handheld reader.

The REPLACE trial was a 6-month, multicentre, randomized trial of the flash glucose monitoring system versus self-monitoring of blood glucose (SMBG) in adults with poorly controlled T2DM using intensive insulin therapy (Table 1).

In the REPLACE trial, substantial decreases in all-cause healthcare resource use were observed for people using the flash glucose monitoring system compared with people using SMBG.

By reducing healthcare resource use, the flash glucose monitoring system can potentially reduce healthcare costs for people with T2DM using intensive insulin therapy.

Objective

A model was developed to assess the budget impact of the flash glucose monitoring system compared with SMBG from the German healthcare payer’s perspective.

Methods

Glucose monitoring

Costs of glucose monitoring included the acquisition costs of the flash glucose monitoring system reader and sensors, and the costs of lancets and test strips (Table 2).

Costs were based on unit costs in Germany.

People using SMBG alone were assumed to carry out an average of three SMBG tests per day, as observed in the REPLACE trial.

According to the product labelling, people using the flash glucose monitoring system need to use SMBG to check flash glucose monitoring system readings: 1) during times of rapidly changing glucose levels; 2) in order to confirm hypoglycaemia or impending hypoglycaemia; and 3) if symptoms do not match the flash glucose monitoring system reading. As observed in the REPLACE trial, flash glucose monitoring system users were assumed to conduct an average of 0.3 SMBG tests per day.

Healthcare resource use

Patients with high levels of glycated haemoglobin (HbA1c) and a long duration of diabetes, such as those included in the REPLACE trial, have a high risk of developing complications which may lead to increased use of healthcare resources.

All-cause resource use is widely used in economic evaluations as disease-specific resource use is difficult to assess objectively, particularly for people with diseases such as T2DM, who are likely to have comorbidities.

All-cause healthcare resource use data observed in the REPLACE trial were incorporated in the model, and included resource use resulting from emergency room visits, ambulance call-outs and hospital admissions.

Costs were based on estimated costs for Germany.

People using the flash glucose monitoring system in the REPLACE trial used fewer healthcare resources than those using SMBG alone (Table 3).

Results

Glucose monitoring

The total costs of glucose monitoring are estimated to be €897 higher per patient per year (PPPY) for people using the flash glucose monitoring system compared with using SMBG alone (Table 2).

Table 2. Baseline patient characteristics in the REPLACE trial

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Flash glucose monitoring system (n = 148)</th>
<th>SMBG (n = 75)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male, %</td>
<td>54.0</td>
<td>45.3</td>
</tr>
<tr>
<td>Age, years (SD)</td>
<td>58.9 ± 11.0</td>
<td>58.9 ± 11.0</td>
</tr>
<tr>
<td>HbA1c (% SD)</td>
<td>6.65 ± 1.0</td>
<td>6.75 ± 0.8</td>
</tr>
<tr>
<td>Duration of diabetes, years (SD)</td>
<td>19 ± 8</td>
<td>19 ± 8</td>
</tr>
<tr>
<td>Duration of insulin, years (SD)</td>
<td>9 ± 6</td>
<td>10 ± 7</td>
</tr>
<tr>
<td>Frequency of SMBG tests per day (SD)</td>
<td>3.6 ± 1.3</td>
<td>3.9 ± 1.3</td>
</tr>
</tbody>
</table>

All-cause healthcare resource use data observed in the REPLACE trial were incorporated in the model, and included resource use resulting from emergency room visits, ambulance call-outs and hospital admissions.

Healthcare resource use

For people with T2DM using intensive insulin therapy, the flash glucose monitoring system system resulted in a reduction in all-cause healthcare resource use in the REPLACE trial (Figure 1), which is estimated to amount to a €1282 reduction in healthcare resource use costs PPPY compared with SMBG (Table 3).

Table 3. All-cause healthcare resource use costs calculated from data observed in the REPLACE trial

<table>
<thead>
<tr>
<th>Resource</th>
<th>Costs (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital admissions</td>
<td>293.73</td>
</tr>
<tr>
<td>ER visits</td>
<td>127.72</td>
</tr>
<tr>
<td>ER visits, SMBG</td>
<td>132.64</td>
</tr>
<tr>
<td>ER visits, Flash glucose monitoring system</td>
<td>163.14</td>
</tr>
<tr>
<td>ER visits, Flash glucose monitoring system vs SMBG</td>
<td>252.00</td>
</tr>
<tr>
<td>Ambulance call-outs</td>
<td>744.00</td>
</tr>
<tr>
<td>Ambulance call-outs, SMBG</td>
<td>569.67</td>
</tr>
<tr>
<td>Ambulance call-outs, Flash glucose monitoring system</td>
<td>129.75</td>
</tr>
<tr>
<td>Ambulance call-outs, Flash glucose monitoring system vs SMBG</td>
<td>736.91</td>
</tr>
</tbody>
</table>

Conclusions

The budget impact model calculations show that when considering aggregate costs of glucose monitoring and all-cause healthcare resource use in people with T2DM using intensive insulin therapy, the use of a flash glucose monitoring system is estimated to provide a 15.4% reduction in costs compared with SMBG, on a PPPY basis.

These results suggest that, compared with SMBG, a flash glucose monitoring system can be considered to be more affordable and provide a potential cost-saving benefit to the German healthcare system.

At sensor prices lower than the one used in this model, the flash glucose monitoring system would be even more affordable.

To achieve optimal glycaemic control, some people with T2DM using multiple daily injections may require more than the three SMBG tests per day observed in the REPLACE trial. By contrast, there is no incremental cost of additional scans using the flash glucose monitoring system.

The budget impact of the flash glucose monitoring system can also be assessed using low glucose events (for example < 45 mg/dL) as a proxy for severe hypoglycaemia. This approach is most suitable for populations in which the costs of hypoglycaemia are likely to outweigh the costs related to long-term complications of diabetes, such as people with well-controlled type 1 diabetes mellitus (T1DM).

This model will be presented in a future publication.

References

3. Haak et al. Presented at the 9th International Conference on Advanced Technologies and Treatments for Diabetes (ATTD), 3–6 February, Milan, Italy.
11. GKM-Spitzenverband, Berlin 2014, InEK 2014a (Fallpauschalen), InEK 2014b (Fallzahlen).