Cost-utility analysis in a UK setting of self-monitoring of blood glucose in patients with type 2 diabetes


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The study examined the self-monitoring of blood glucose (SMBG) in patients with Type 2 diabetes.

Type of intervention
Diagnosis and treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised three different cohorts of hypothetical patients with Type 2 diabetes. The three cohorts were defined by the treatment received, namely a diet and exercise programme, OADs and insulin therapy.

Setting
The setting was primary care. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness data were derived from studies published between 1999 and 2005. Some resource use data and costs were derived from studies published between 1994 and 2005. The price year was 2004.

Source of effectiveness data
The effectiveness evidence was derived from a synthesis of published studies and authors' opinions.

Modelling
A published, Internet-based, interactive model was used to simulate the clinical and economic consequences of SMBG versus no SMBG in the three different cohorts of Type 2 diabetes patients. The CORE Diabetes model consisted of 15-interdependent sub-models that simulated the complications of diabetes. Such complications included angina, myocardial infarction (MI), congestive heart failure, stroke, peripheral vascular disease, diabetic retinopathy, macular oedema, cataract, hypoglycaemia, ketoacidosis, lactic acidosis, nephropathy, neuropathy, foot ulcer and amputation. The model also took mortality unrelated to diabetes into account. Each of the sub-models was a Markov model. Time-dependent transitional probabilities were used. The time horizon of the model was patient lifetime. The model had already been successfully validated.

Outcomes assessed in the review
The outcomes estimated from the literature were treatment effect, adherence to SMBG, and impact of SMBG on health
utility. The clinical and economic demographics of the three cohorts of patients were also estimated. All other data associated with the simulation, such as survival, transition probabilities, utility weights and death rates, appear to have been derived from the primary publications of the model and were not reported in this paper.

Study designs and other criteria for inclusion in the review
It was unclear whether the primary studies were identified through a systematic review of the literature or selectively, although it is likely that a systematic review was performed originally when the model was developed. The primary studies were published systematic reviews or meta-analyses, randomised clinical trials and retrospective cohort studies. Length of follow-up, interventions under examination and change in HbA1c level were reported for each study.

Sources searched to identify primary studies
Not reported.

Criteria used to ensure the validity of primary studies
The use of clinical trials and published meta-analyses represents a strength of the current study since these are valid sources of data. However, retrospective cohort studies are usually considered to be a weak source.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
Eleven primary studies (including the two primary publications of the decision model) provided the clinical data.

Methods of combining primary studies
Not reported.

Investigation of differences between primary studies
Not reported.

Results of the review
SMBG was associated with a reduction from baseline in HbA1c of 0.3% in the diet and exercise cohort, 0.4% in the OAD cohort, and 0.6% in the insulin cohort. The standard deviation of the change in HbA1c for each treatment cohort was 1.84%.

The rate of adherence to SMBG was 78%.

There was no impact of SMBG on health utility.

In terms of the baseline characteristics of the three cohorts:

the mean baseline HbA1c level was 7.9% (+/- 2.1) in the diet and exercise cohort, 8.6% (+/- 2.2) in the OAD cohort, and 8.5% (+/- 2.0) in the insulin cohort;

the mean age was 60.1 (+/- 12.3) years in the diet and exercise cohort (female 48%), 61.1 (+/- 11.5) years in the OAD cohort (female 46%), and 61.8 (+/- 10.7) years in the insulin cohort (female 52%); and

the duration of diabetes was 6.6 (+/- 8.7) years in the diet and exercise cohort, 7.2 (+/- 8.7) years in the OAD cohort, and 12.8 (+/- 9.3) years in the insulin cohort.
Methods used to derive estimates of effectiveness
The authors made some assumptions that were used in the decision model.

Estimates of effectiveness and key assumptions
The number of SMBG tests per day was assumed to be one for patients on diet and exercise, two for patients on oral agents, and three for patients on insulin.

It was assumed that differences in HbA1c due to the effect of SMBG would be maintained over the course of the simulation.

It was assumed that SMBG had no impact on hypoglycaemic event rates.

It was assumed that there would be no improvement in HbA1c in patients who did not adhere to SMBG.

Measure of benefits used in the economic analysis
The summary benefit measure used was the number of quality-adjusted life-years (QALYs). These were estimated using the decision model. Data on utility weights for each health state, required for the calculation of QALYs, were not presented but they may have been reported in the primary publication of the decision model. An annual discount rate of 3.5% was used. The expected survival and expected survival free of new complications were also reported as model outputs.

Direct costs
The analysis of the costs was carried out from the perspective of the NHS. It included the costs associated with SMBG, treatment of diabetes complications, outpatient consultations, education, medications and other investigations. The unit costs were not presented separately from the quantities of resources used. The costs were mainly derived from NHS official sources and published studies. Resource use was based on authors' opinions and some published information. Some conservative assumptions that did not favour the SMBG were also made. The price year was 2004. All costs that were not available in 2004 values were inflated using the composite NHS price inflation index. Discounting was relevant, as the long-term costs were estimated, and an annual rate of 3.5% was used to estimate the present value of future costs.

Statistical analysis of costs
The costs were presented as mean values with standard deviations.

Indirect Costs
The indirect costs were not considered.

Currency
UK pounds sterling (§).

Sensitivity analysis
Univariate sensitivity analyses were carried out to assess the robustness of the cost-utility ratios. The parameters varied were the discount rate (alternative values of 6% for costs and 1.5% for benefits), time horizon (10 and 20 years), effect of SMBG on HbA1c (duration of effect: only 5 years), adherence rate (52% rather than 78%), and utility (an equivalent decrement in utility to that of taking insulin due to SMBG in patients treated either with diet and exercise, or an OAD was assumed). Alternative values were mainly based on published evidence. A Monte Carlo simulation was also performed. The model was run 1,000 times and mean values with standard deviations were generated using a non-
parametric bootstrapping approach.

**Estimated benefits used in the economic analysis**
In the diet and exercise cohort, the expected QALYs were 6.342 (+/- 1.864) with SMBG and 6.177 (+/- 1.753) with no SMBG (difference 0.165). The undiscounted life expectancy was 12.302 years with SMBG and 11.931 years with no SMBG (difference 0.371).

In the OAD cohort, the expected QALYs were 6.158 (+/- 1.839) with SMBG and 5.933 (+/- 1.708) with no SMBG (difference 0.225). The undiscounted life expectancy was 11.807 years with SMBG and 11.318 years with no SMBG (difference 0.489).

In the insulin cohort, the expected QALYs were 5.269 (+/- 1.665) with SMBG and 5.014 (+/- 1.577) with no SMBG (difference 0.255). The undiscounted life expectancy was 10.339 years with SMBG and 9.818 years with no SMBG (difference 0.521).

**Cost results**
In the diet and exercise cohort, the expected costs were 20,668 (+/- 7,469) with SMBG and 18,105 (+/- 6,724) with no SMBG (difference 2,564).

In the OAD cohort, the expected costs were 21,650 (+/- 7,019) with SMBG and 20,636 (+/- 6,807) with no SMBG (difference 1,013).

In the insulin cohort, the expected costs were 23,712 (+/- 7,276) with SMBG and 22,541 (+/- 6,617) with no SMBG (difference 1,171).

**Synthesis of costs and benefits**
Incremental cost-utility ratios were calculated in order to combine the costs and QALYs of the SMBG strategy over no SMBG.

The incremental cost per QALY was 15,515 in the diet and exercise cohort, 4,508 in the OAD cohort, and 4,593 in the insulin cohort.

The probabilistic sensitivity analysis showed that when using a threshold of 30,000 per QALY gained, the probability of SMBG being cost-effective over no SMBG was 51% in the diet and exercise cohort, 51% in the OAD cohort, and 55% in the insulin cohort.

The results of the univariate sensitivity analysis suggested that only when short-term time horizons were considered was the SMBG intervention less efficient. For example, with a 10-year time horizon, the incremental cost per QALY gained with SMBG was well above the threshold of 30,000 in the diet and exercise cohort, slightly above this threshold in the OAD cohort, and still cost-effective in the insulin cohort. Under the other scenarios, SMBG remained generally cost-effective, especially in the OAD and insulin cohorts.

**Authors’ conclusions**
From the perspective of the National Health Service (NHS), self-monitoring of blood glucose (SMBG) in patients with Type 2 diabetes, in the UK, was a cost-effective strategy on account of better glucose control. The extra cost of treatment was partially offset by a reduction in diabetes-related complications.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparators was clear in that no SMBG represents conventional care for patients with Type 2 diabetes, while SMBG was the proposed new strategy. The authors stated that urine monitoring of blood glucose was not considered as a relevant comparison, as it is currently not recommended as an alternative to SMBG.
You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a synthesis of published studies. The authors did not report the details of a systematic review of the literature. Most of the evidence, however, was already incorporated in the published decision model. The authors merely added data relating to SMBG. Several details of the studies were provided in order to assess their validity. The sources of the data used in the study differed, especially with respect to their quality. This was because the evidence came not only from clinical trials and meta-analyses, which are usually good sources of data, but also from retrospective cohort studies. The authors stated that the level of evidence could only be considered "moderate". Further, the poor quality of some clinical trials included in the reviews casts some doubt on the reliability of some clinical inputs. A narrative approach appears to have been used to combine the primary estimates. Some assumptions were also made. The impact of using alternative clinical values was satisfactorily investigated in the sensitivity analysis.

Validity of estimate of measure of benefit
The summary benefit measure was appropriate as QALYs incorporate the impact of the intervention on two relevant dimensions of health (survival and quality of life) for patients with diabetes. QALYs have the further advantage of being comparable with the benefits of other health care interventions. Discounting was applied, as recommended by UK guidelines. The impact of using an alternative discount rate was considered.

Validity of estimate of costs
The costs included were consistent with the perspective adopted in the study. The authors stated that the potential inclusion of indirect costs, as well as direct non-medical costs, would presumably represent an advantage for the SMBG strategy given the lower rate of diabetes-related complications. Typical NHS sources were used to derive the unit costs, which were reported for some items. However, the majority of the costs were expressed as macro-categories and a detailed breakdown of the items was not reported. This limits the possibility of replicating the analysis in other settings. Resource use data were mainly derived from published evidence or authors’ opinions. The cost estimates were specific to the study setting and sensitivity analyses were not performed on economic items. The price year was reported, which will facilitate reflation exercises in other time periods.

Other issues
The authors did not make extensive comparisons of their findings with those from other studies. They stated that their study was the first long-term evaluation of the cost-effectiveness of SMBG. The issue of the generalisability of the study results to other settings was not explicitly addressed, but numerous sensitivity analyses were carried out to increase the external validity of the study. The analysis referred to patients with Type 2 diabetes and this was reflected in the authors’ conclusions. The authors noted some potential limitations of their study, which have been highlighted in previous fields.

Implications of the study
The results of this preliminary study support the use of SMBG in patients with Type 2 diabetes. However, the authors stated that more rigorous studies should be carried out in order to provide an accurate estimate of the cost-effectiveness of SMBG.

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