Self-monitoring of blood glucose (SMBG) in patients with type 2 diabetes on oral anti-diabetes drugs: cost-effectiveness in France, Germany, Italy, and Spain

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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.

CRD summary
This study examined the cost-effectiveness of self-monitoring of blood glucose once, twice, or three times per day for patients with type 2 diabetes who were treated with oral antidiabetic drugs, in four European countries. Self-monitoring was cost-effective, over 40 years, with a cost-utility ratio that depended on the country-specific cost reimbursement levels, but remained acceptable. The analysis used a valid cost-effectiveness framework and the results were robust, but a more extensive reporting of the data sources would have been useful.

Type of economic evaluation
Cost-utility analysis

Study objective
This study examined the cost-effectiveness of self-monitoring of blood glucose once, twice, or three times per day for patients with type 2 diabetes, who were treated with oral antidiabetic drugs, in four European countries.

Interventions
The strategies were self-monitoring of blood glucose once, twice, or three times per day versus no self-monitoring.

Location/setting
France, Germany, Italy, and Spain/primary care.

Methods
Analytical approach:
The analysis was based on the published IMS Center for Outcomes Research (CORE) Diabetes Model, which projected the economic and clinical outcomes over a horizon of 40 years. The authors stated that the perspective of the national reimbursement system was adopted.

Effectiveness data:
The clinical evidence came from a variety of selected published sources. The baseline patients’ characteristics and the monitoring efficacy, which was the key clinical input, were from a published US observational study that included a large cohort of patients (Karter, et al. 2006, see ‘Other Publications of Related Interest’ below for bibliographic details). Country-specific epidemiological sources were used. The analysis also included country-specific data for patients taking part in specific screening programmes and other typical clinical patterns. The transition probabilities between health states were already incorporated in the model. Assumptions were needed for the long-term effects of self-monitoring.

Monetary benefit and utility valuations:
The utility values were from the UK Prospective Diabetes Study and other published studies.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary benefit measure and they were discounted at an annual rate of 6% for Spain, and 3% for France, Germany, and Italy.

Cost data:
The economic analysis included the costs of self-monitoring (meter, strips, lancets, and one hour of nursing time for
training) and the direct medical costs associated with diabetes-related complications (cardiovascular, renal, ulcer, amputation, neuropathy, and eye problems). The costs of self-monitoring were based on reimbursement values supplied by the manufacturers. The costs of complications were from a published study. All costs were in Euros (EUR) and the price year was 2007. An annual discount rate of 3% was used for France, Germany, and Italy, while a 6% rate was used for Spain.

Analysis of uncertainty:
A Monte Carlo simulation, based on nonparametric bootstrapping, was carried out to generate the mean costs and QALYs as well as cost-effectiveness acceptability curves. Univariate sensitivity analyses were also performed on the discount rate, time horizon, and disutility associated with self-monitoring (using data from a published study).

Results
In France, the total costs were EUR 40,978 without monitoring and ranged from EUR 41,937 to EUR 43,079 with increasing frequency of self-monitoring. In Germany, they were EUR 52,635 without monitoring and ranged from EUR 52,848 to EUR 54,196 with self-monitoring. In Italy, they were EUR 50,669 without monitoring and ranged from EUR 52,055 to EUR 55,328 with monitoring. In Spain they were EUR 19,802 without monitoring and ranged from EUR 20,128 to EUR 21,040 with monitoring.

In France, the expected QALYs were 4.609 without monitoring and ranged from 4.688 to 4.873 with self-monitoring. In Germany, they were 4.974 without monitoring and ranged from 5.104 to 5.284 with monitoring. In Italy, they were 4.721 without monitoring and ranged from 4.830 to 5.024 with monitoring. In Spain they were 4.048 without monitoring and ranged from 4.137 to 4.263 with monitoring.

In France, the incremental cost per QALY gained with monitoring over no monitoring was EUR 12,114 for once per day, EUR 6,282 for twice per day, and EUR 7,958 for three times per day. In Germany, it was EUR 1,633 for once per day, EUR 1,974 for twice per day, and EUR 5,045 for three times per day. In Italy, it was EUR 12,694 for once per day, EUR 11,934 for twice per day, and EUR 15,368 for three times per day. In Spain it was EUR 3,661 for once per day, EUR 3,101 for twice per day, and EUR 5,751 for three times per day.

The three monitoring strategies were likely to be cost-effective, when considering the standard threshold for cost-effectiveness for each country. Shorter time horizons led to higher cost-utility ratios, but monitoring remained the preferred strategy, in most cases.

Authors' conclusions
The authors concluded that self-monitoring was cost-effective, over 40 years, in all four countries, with an incremental cost-utility ratio that depended on the country-specific cost reimbursement levels, but was always below EUR 16,000 per QALY.

CRD commentary
Interventions:
The comparators were appropriately selected to represent all the possible monitoring strategies for the patient population.

Effectiveness/benefits:
The derivation of the clinical inputs and the utility values was only partly described. The monitoring efficacy was from a large US observational study, which had a non-randomised design and the results might not be transferable to European countries. The authors stated that several multivariate analyses were included in the observational study to reduce bias. Country-specific sources were appropriately used for the epidemiological data and clinical patterns, but these sources were not described. Limited information on the other data sources was provided, as they were already incorporated in the model. This makes it difficult to formally judge the data validity. Only the most uncertain inputs were considered in the sensitivity analysis. QALYs were appropriate given the impact of the disease on quality of life, which is a relevant dimension of health for diabetic patients. The methods used to elicit the preferences were not described.
Costs:
The categories of costs were consistent with the perspective. The costs were presented as total categories and the unit costs and resource quantities were not given. The methods used in the published study that provided the diabetes-related costs were not clearly described. These issues limit the transparency of the analysis. The cost estimates appear to have been treated deterministically and the impact of varying them was not assessed in the sensitivity analyses.

Analysis and results:
The results were extensively presented and the total costs, effects, and incremental values were reported for each country and each comparator. The authors acknowledged that self-monitoring was only compared with no monitoring and an incremental analysis of the monitoring options (once, twice, or thrice per day) would have been interesting. The uncertainty was assessed using valid approaches and the findings were clearly discussed. Good points of the analysis were the use of a widely validated decision model and the multi-country analysis.

Concluding remarks:
The analysis used a valid cost-effectiveness framework, and the results were robust, but a more extensive reporting of the data sources would have been useful.

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