Patient-centred and professional-directed implementation strategies for diabetes guidelines: a cluster-randomized trial-based cost-effectiveness analysis

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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.

Health technology
Two strategies for the management of patients suffering from Type 2 diabetes were examined. One was a patient-centred programme, while the other was a professional-directed implementation programme.

With the professional-directed programme (PRO), educational meetings were organised for physicians and diabetes-specialist nurses (DSNs) to discuss current guidelines on the prevention and treatment of diabetes complications. In addition, a desktop reminder card with key guideline statements was distributed and, after 6 months, each physician received personal benchmarked feedback on medical performance, based on additional patient questionnaires.

With the patient-centred programme (PAT), educational meetings were also organised for physicians and DSNs to discuss the key guidelines described in a patient-held booklet called the "diabetes passport", which aimed to educate and to record the results of medical examinations. Also, educational meetings were organised for patients with diabetes, and information leaflets and waiting room posters were designed.

Type of intervention
Secondary prevention.

Economic study type
Cost-utility analysis.

Study population
The study population comprised patients with Type 2 diabetes.

Setting
The setting was secondary care. The economic study was carried out in the Netherlands.

Dates to which data relate
The effectiveness data were derived from studies published between 1997 and 2005. The data on resource consumption were derived from a study published in 2005. The price year was 2001.

Source of effectiveness data
The effectiveness evidence was derived from a synthesis of published studies.

Modelling
A published probabilistic Markov model, which described the epidemiology of Dutch Type 2 diabetic patients, was modified and used to predict the lifetime costs and benefits of the two strategies for the management of disease. The
model accounted for ageing of patients, the increase in glycated haemoglobin (HbA1c) level, and the age-related increase in the risk of complications. Further, it computed the occurrence of mild and severe long-term diabetic complications and excess mortality due to diabetes. The time horizon of the model was the patient’s lifetime. No other details were given and no graphical representation of the model was provided.

**Outcomes assessed in the review**
The outcomes estimated from the literature were the effectiveness of the two programmes, utility adjustments for minor and major complications, and the relationship between HbA1c level and progression towards diabetic complications. The effectiveness of the programmes was assessed in terms of HbA1c and hazard reduction in cardiovascular mortality.

**Study designs and other criteria for inclusion in the review**
The primary studies appear to have been identified selectively. The effectiveness data were derived from a 1-year clinical trial carried out in 13 hospitals in the Netherlands, the main details of which were reported. There were 276 patients in the control group, 248 in the PRO group and 240 in PAT group (45.9% men in all groups). Mortality came from national figures. Information on the other studies was not provided.

**Sources searched to identify primary studies**
Not relevant.

**Criteria used to ensure the validity of primary studies**
The use of a clinical trial ensured the internal validity of the effectiveness data. The validity of other clinical inputs was unclear.

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

**Number of primary studies included**
Five primary studies provided the clinical evidence.

**Methods of combining primary studies**
Not relevant.

**Investigation of differences between primary studies**
Not reported.

**Results of the review**
The 1-year clinical trial data showed that HbA1c values changed from 7.9% (+/- 1.1) to 8.1% (+/- 1.25) in the control group, from 8.0% (+/- 1.2) to 7.9% (+/- 1.1) in the PRO group, and from 8.1% (+/- 1.2) to 7.8% (+/- 1.2) in the PAT group. These differences between groups were statistically significant, (p<0.0001).

The proportion of patients with HbA1c values of less than 7.0% was 0.161 in the control group, 0.188 in the PRO group and 0.242 in the PAT group.

The proportion of patients with HbA1c values between 7.0 and 8.5% was 0.540 in the control group, 0.608 in the PRO group and 0.560 in the PAT group.
The proportion of patients with HbA1c values in excess of 8.5% was 0.299 in the control group, 0.204 in the PRO group and 0.198 in the PAT group.

The utility adjustment for minor complications was 0.75.

For severe complications, the utility adjustment was 0.69 for blindness or low vision, 0.61 for end-stage renal disease and 0.59 for lower extremity amputation.

The coefficients for the estimation of the relationship between HbA1c level and progression towards diabetic complications were also reported.

**Measure of benefits used in the economic analysis**

The summary benefit measure used was the expected quality-adjusted life-years (QALYs). These were estimated by combining data on survival and quality of life that were derived from the literature. Details of the utility weights were reported. A discount rate of 3% was applied, although undiscounted results were also reported. Life-years were also reported, but were not combined with the costs.

**Direct costs**

The perspective adopted in the study was unclear. The categories of costs included were medications for glucose control (mainly insulin), management of complications, and resources related to the interventions. The latter included preparation meetings, educational meetings, coordination of intervention, medical audit, feedback report, diabetes passports, waiting room posters, instruction leaflets and desktop reminder cards. The unit costs were not presented separately from the quantities of resources used. The resource use data were collected alongside the clinical trial published in 2005 using pre- and post-intervention questionnaires. The sources of the costs were not stated clearly. The costs of treatment for complications, amputation, follow-up after amputation, end-stage renal disease and blindness were assumed to be the same in all three groups and were taken from guideline evaluation studies. The price year was 2001 and costs estimated in previous years were updated to 2001 values using health care-specific deflators. The reason for not discounting the future costs was unclear. In fact, while some costs were incurred over a 1-year timeframe, others are likely to be incurred over the patient's lifetime.

**Statistical analysis of costs**

The costs were treated deterministically in the base-case.

**Indirect Costs**

The indirect costs were not included in the economic evaluation.

**Currency**

Euros (EUR).

**Sensitivity analysis**

A probabilistic sensitivity analysis was carried out to address the issue of uncertainty in the model results. Clinical inputs were assigned normal distributions, while costs were given lognormal distributions and were varied in a Monte Carlo simulation of 10,000 iterations. The key areas of uncertainty were general mortality risk, the broad distribution of HbA1c levels, and the risk of developing a severe complication.

**Estimated benefits used in the economic analysis**

The estimated life-years were 14.11 (+/- 7.9) in the control group, 14.45 (+/- 7.9) in the PRO group and 14.64 (+/- 7.9) in the PAT group.
The total QALYs were 10.21 (+/- 5.8) in the control group, 10.50 (+/- 5.9) in the PRO group and 10.80 (+/- 5.9) in the PAT group.

Cost results
The annual cost per patient of the implementation strategies was EUR 2.00 for PRO and EUR 3.50 for PAT.

The total lifetime medical costs were EUR 23,250 (+/- 15,938) in the control group, EUR 32,648 (+/- 14,872) in the PRO group and EUR 32,870 (+/- 16,020) in the PAT group. The higher costs for PRO and PAT were mainly due to improved care and longer life expectancy.

Synthesis of costs and benefits
An incremental cost-utility ratio was calculated to combine the costs and benefits of the alternative strategies.

In comparison with no intervention, the incremental cost per QALY gained was EUR 70,630 (undiscounted QALYs: EUR 32,218) with PRO and EUR 34,808 (undiscounted QALYs: EUR 16,353) with PAT.

In comparison with PRO, the incremental cost per QALY gained with PAT was EUR 1,824 (undiscounted QALYs: EUR 881).

The probabilistic analysis of uncertainty showed that the diabetes control programmes cannot be introduced at less than an additional EUR 60.00 per patient per year. In particular, the PRO strategy has the highest likelihood of being the most cost-effective strategy at budget ranges between EUR 60.00 and EUR 65.00 per patient per year. If budgets higher than EUR 65.00 per patient per year were available, the PAT strategy would most likely be the best choice.

Authors' conclusions
Both the professional-directed programme (PRO) and the patient-centred programme (PAT) for Type 2 diabetes care were cost-effective, in comparison with standard care, for glucose control in the Netherlands. The authors pointed out that emphasis on cardiovascular risk might further improve the cost-effectiveness of the two programmes.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear since two new programmes were compared with the standard approach for the management of patients with Type 2 diabetes. Each approach was accurately described. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from published sources. However, it was unclear whether the studies were identified from a review of the literature; no information on the conduct and method of a review was provided. The clinical trial used to derive the effectiveness data was extensively described and this should ensure high internal validity. However, details and characteristics of the other primary studies were not described. The issue of uncertainty in the clinical data was investigated in the probabilistic sensitivity analysis.

Validity of estimate of measure of benefit
QALYs were the most appropriate benefit measure because they capture the impact of the intervention on both quality of life and survival, which are relevant dimensions of health for patients with Type 2 diabetes. The use of QALYs enables comparisons with the benefits of other health care interventions. Discounting was applied, as recommended in guidelines for economic evaluations, and the impact of undiscounted QALYs on the cost-utility ratios was investigated.

Validity of estimate of costs
The perspective of the study was unclear and a detailed breakdown of the cost items included in the analysis was not given. The unit costs were not presented and information on resource consumption was not provided. This limits the possibility of replicating the analysis in other settings. The sources of the costs were not explicitly reported, whereas the resource use data reflected actual health care consumption by patients enrolled in a clinical trial. It was not clear why a discount rate was not applied, given that some of the costs included in the analysis might occur over a long-term horizon. The price year was reported, which will assist with reflation exercises in other time periods. Statistical analyses of the costs were not performed but probabilistic distributions were assigned to cost items in the sensitivity analysis.

Other issues
The authors did not compare their findings with those from other studies. They also did not explicitly address the issue of the generalisability of the study results to other settings. However, it was pointed out that the estimated costs of the two programmes should be similar across European countries. This, to some extent, improves the external validity of the analysis. The issue of uncertainty around the mean values was addressed satisfactorily using a probabilistic sensitivity analysis. The study referred to patients with Type 2 diabetes and this was reflected in the authors’ conclusions.

Implications of the study
The study results support the implementation of programmes similar to the PRO and PAT interventions for the control of Type 2 diabetes.

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None stated.

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Other publications of related interest


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