The impact of initiatives in education, self-management training, and computer-assisted self-care on outcomes in diabetes disease management

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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
Three diabetes disease management initiatives for patients in a managed care setting were examined:

- education alone (E-alone);
- education with self-management training (E+SMT); and
- education with computer-assisted self-care (E+caSC).

Under E-alone, patients continued to receive standardised diabetes education and the interventions were mainly predetermined. The E+SMT protocol provided patients with one-on-one diabetes education (approximately 15 hours) by full-time patient education nurses with facilitated referral to clinical diabetes educators. E+caSC provided standardised care, but the patients were also instructed (for 15 to 30 minutes) on how to report outcomes daily to an automated, micro call centre located in the endocrinologist’s office using a touch-tone telephone. In this case, computer algorithms substituting for the monitoring provider analysed all inputs and calculated an adjustment in medication dosages while the patient was completing the call.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised diabetic patients enrolled in an HMO.

Setting
The setting was managed care. The economic study was conducted in the USA.

Dates to which data relate
The dates during which the effectiveness and resource use data were collected were not reported. Some of the evidence came from a study, the results of which were published in 1993 and 1996. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study and a further completed study, the main details of which had been published.
Link between effectiveness and cost data
The costing was conducted, in part prospectively, on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations were not reported. The first 978 eligible patients were identified from a total of 8,000 patients with diabetes who had been enrolled in the HMO-sponsored disease management programmes. There were 151 patients in the E-alone group, 589 patients in the E+SMT group and 238 patients in the E+caSC group. About 51% of the participants were male and the mean age was 58 years (age range: 19 - 81). The body weight at baseline ranged from 63 to 136 kg in men and from 56 to 131 kg in women. A total of 641 responsible physicians (including primary and/or subspecialty care physicians) took care of the patients participating in the study. There were also 45 care providers.

Study design
This was a quasi-experimental, longitudinal observational study that was conducted in several centres (the details were not provided). During the one-year study period, the outcomes were assessed at the following frequencies: 4/365 (quarterly office visits) for E-alone patients, 1/7 to 1/30 for E+SMT, and 365/365 (almost every day) for E+caSC. The patients appear to have been followed for one year. No information on the loss to follow-up was reported.

Analysis of effectiveness
All of the patients included in the initial study sample were considered in the analysis of effectiveness. The primary outcome measures used were changes in HbA1c percentage (assessed at baseline, 3 months and one year) and changes in mean body weight (estimated at baseline and after one year). The comparability of the study groups was not discussed.

Effectiveness results
The HbA1c values were:

8.8% (+/- 1.5) at baseline, 8.7% (+/- 1.4) at 3 months and 8.9% (+/- 1.8) after one year in the E-alone group (no statistically significant difference between baseline and follow-up results);

8.5% (+/- 1.9) at baseline, 7.4% (+/- 1.3) at 3 months, (p<0.01 versus baseline), and 7.4% (+/- 1.2) after one year, (p<0.01 versus baseline) in the E+SMT group; and

9.5% (+/- 1.7) at baseline, 8.6% (+/- 1.6) at 3 months, (p<0.01 versus baseline), and 8.4% (+/- 1.6) after one year, (p<0.01 versus baseline) in the E+caSC group.

The mean body weight changed:

from 80 (+/- 19) kg at baseline to 81 (+/- 18) kg after one year in the E-alone group,

from 77 (+/- 18) kg to 78 (+/- 19) kg in the E+caSC group, and

from 82 (+/- 15.9) kg to 94 (+/- 18.2) kg in the E+SMT group, (p<0.01).

Clinical conclusions
The effectiveness study showed that both E+caSC and E+SMT led to improvements in HbA1c values, while standard care did not result in any change from baseline values. Body weight increased significantly only in the E+SMT group.

Modelling
A mathematical model (not a decision tree) was used to assess the clinical and economic outcomes associated with the three strategies under evaluation. The model was adapted to the peculiar characteristics of diabetes care over a one-year
timeframe. It was populated with data observed in the effectiveness study. The model was used to link outcomes to desired normal values and to predict the dependency of the outcomes to provider and patient characteristics. A diagrammatic representation of the chronic disease management systems model, as well as other analytic details, was provided in the article.

Outcomes assessed in the review
In the DCCT group, the primary outcome measures used in the analysis were changes in HbA1c percentage and changes in body weight.

Study designs and other criteria for inclusion in the review
The only published study considered was a clinical trial with 101 patients. This group of patients had ongoing, self-management training and practised intensified therapy.

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not explicitly reported.

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

Number of primary studies included
Only one study provided the reference effectiveness evidence.

Methods of combining primary studies
Not relevant.

Investigation of differences between primary studies
Not relevant.

Results of the review
The HbA1c values were 9.2% (+/- 1.43) at baseline, 7.3% (+/- 1.4) at 3 months, (p<0.01 versus baseline), and 6.7% (+/- 0.8) after one year, (p<0.01 versus baseline) in the E+caSC group.

Body weight rose by 5.1 kg during the 12-month study period.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was conducted.

Direct costs
Discounting was not relevant since the costs were incurred during one year. The unit costs and the quantities of resources used were not reported separately. The economic evaluation included all health services relevant to the HMO.
These comprised personnel time, visits, overheads, documentation, software and other organisational aspects. The cost/resource boundary of the HMO was used. The costs were estimated from the HMO financial database for E+SMT and E-alone (per-member per-month expenses). The E+caSC costs were estimated by carrying out a cost study. The resource use data were mainly derived from the sample of patients that were included in the effectiveness study. The costs for the external DCCT study comparison were estimated using some specific assumptions. The price year was not reported.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
The indirect costs were not considered.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analyses were conducted.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The estimated per-member per-month costs were $0 for E-alone, $1.31 for E+caSC, $18 for E+SMT, and an average of between $9.70 (for patients not using pumps) and $14.06 (for patients using pumps) for the DCCT group.

**Synthesis of costs and benefits**
Not relevant due to the cost-consequences approach adopted.

**Authors' conclusions**
Patient education initiatives based on self-management training or computer-assisted self-care led to significant improvements in diabetes care in terms of a reduction in haemoglobin values. However, both initiatives led to an increase in costs, which, compared with standard care, was minimal for computer-assisted self-care but quite substantial for self-management training.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparators was clear. The three interventions were selected because they covered all possible strategies for the management of diabetes. In particular, E-alone represented the standard educational approach for diabetic patients. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis of effectiveness was mainly based on a quasi-experimental, longitudinal study. This design was chosen to reflect a real-world setting. However, the use of a randomised trial would have been more appropriate. The study sample is likely to have been representative of the study population and an appropriate follow-up was conducted. The method used to select the sample was unclear, and it was also unclear whether some patients were excluded from the
initial study sample or refused to participate. Further, no justification was provided for the choice of the sample size. The authors acknowledged that the main threat to the validity of the analysis was the baseline comparability of the study groups. Therefore, differences in the final outcomes may be due to differences in baseline values or patient selection. In addition, due to the lack of blinding, some assessment bias could have been introduced. These issues tend to cast doubts on the internal validity of the analysis. An external comparison was made with the results of a published clinical trial, but little information on this study was given.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted.

**Validity of estimate of costs**
The perspective of the study was reported and it appears that all the relevant costs have been included in the analysis. However, information on the quantities of resources used, price year and unit costs was not provided, which limits the possibility of replicating the study and conducting reflation exercises in other settings. Further, charges rather than true costs were used to estimate all expenses. This further reduces the validity of the overall analysis since charges are not considered the best proxies for costs. Statistical tests were not conducted and no sensitivity analyses were performed. Therefore, all estimates were specific to the study setting.

**Other issues**
The authors did not compare their findings with those from other studies, but each outcome of the study (costs, HbA1c and body weight) was compared with the results of a published study, which was considered a reference for evaluations of diabetes management initiatives. The issue of the generalisability of the study results to other settings was not addressed and no sensitivity analyses were conducted. Therefore, the external validity of the analysis was low. The study referred to patients with diabetes, but no distinction between Type 1 or Type 2 diabetes was made. This would have been relevant in terms of identifying the target population of the study. The use of an incremental cost-effectiveness ratio would have been interesting as both the new initiatives led to better effectiveness, as well as higher costs, than standard care.

**Implications of the study**
The study results suggested that modern information technology and computer algorithms can play a crucial role in models of diabetes management, which could be considered effective and cheap. The authors suggested that further randomised clinical trials, to confirm the results of the current analysis in Type 1 or Type 2 diabetes patients, should be conducted.

**Source of funding**
Partially supported by the National Institutes of Health (grant 1 R43 DK54553).

**Bibliographic details**

**PubMedID**
11911169

**Other publications of related interest**

Indexing Status
Subject indexing assigned by NLM

MeSH
Body Weight; Cohort Studies; Computer-Assisted Instruction; Diabetes Mellitus /blood /rehabilitation /therapy; Health Maintenance Organizations; Hemoglobin A, Glycosylated /analysis; Humans; Longitudinal Studies; Patient Education as Topic; Self Care; Treatment Outcome

AccessionNumber
22002007612

Date bibliographic record published
30/11/2004

Date abstract record published
30/11/2004