Insulin therapy in patients with type 2 diabetes mellitus: shared care versus secondary outpatient care in The Netherlands


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 use of a shared-care setting involving cooperation between primary care (general practitioners, GPs) and an organisation (the "Diabetes Service"), which supports protocol-guided treatment and provides appropriate facilities for the management of patients with Type 2 diabetes initiating insulin therapy. The service consisted of a patient registration and recall system plus a laboratory. A dietician and a specific diabetes educator provided diabetes education. A supervising diabetologist could be consulted by telephone 24 hours a day. The patients were monitored at least at 3-month intervals and feedback was provided to the GP.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients aged 40 years or over with Type 2 diabetes, who switched from oral hypoglycaemic agents to insulin therapy. Patients who were temporarily transferred to insulin therapy during hospital admissions or intercurrent illness were excluded.

Setting
The study settings were a shared-care setting and an outpatient-care setting of a university hospital. The economic study was conducted at the University Hospital Vrije Universiteit in Amsterdam, The Netherlands.

Dates to which data relate
The effectiveness and resource use data were gathered from 1993 to 1994. The price year was 1996.

Source of effectiveness data
The effectiveness evidence came from a single study.

Link between effectiveness and cost data
The costing was performed retrospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations to determine the sample size were not reported. Eligible patients were selected using computerised patient records. Of the 65 eligible patients in the intervention group, 9 cases (12.3%) were excluded due to missing
records or a change of GP. Of the 58 eligible patients in the intervention group, 13 cases (22.4%) were excluded for missing records or a change of GP. Thus the final sample comprised 102 patients, 57 patients in the intervention group and 45 in the control group. The patients in the intervention group were aged 66.1 (+/- 12.5) years and 33.3% were men. The patients in the control group were aged 61.4 (+/- 12.3 years) and 51.1% were men.

**Study design**
This was a retrospective cohort study that was carried out in a single centre. The patients were followed for one year and no loss to follow-up was reported. No blinded assessment of the outcomes was performed. The outcomes were assessed at baseline and at the end of the 1-year follow-up period.

**Analysis of effectiveness**
All patients included in the initial study sample were taken into account when estimating the effectiveness. The primary health outcomes used in the economic analysis were the mean glycated haemoglobin (HbA1c) value and the proportion of patients with a HbA1c value of less than 7.0% (good glycaemic control) or greater than 8.5% (poor glycaemic control). The study groups were shown to be comparable at baseline in terms of the demographics and medical conditions. However, for both alcohol consumption and initial values of HbA1c, the results were significantly higher in the control group than in the intervention group.

**Effectiveness results**
In the intervention group, the mean HbA1c value changed from 9.1% at baseline to 7.9% at follow-up;

the proportion of patients with good glycaemic control increased from 3.5 to 22.8%, while the proportion of those with poor glycaemic control fell from 56.1 to 29.8%.

In the control group, the mean HbA1c value changed from 10.2% at baseline to 8.2% at follow-up;

the proportion of patients with good glycaemic control increased from 2.2 to 17.7%, while the proportion of those with poor glycaemic control fell from 75.6 to 35.6%.

**Clinical conclusions**
The effectiveness analysis showed that the two interventions produced similar outcomes.

**Measure of benefits used in the economic analysis**
No summary benefit measure was used. The effectiveness analysis showed that there were no differences between the two interventions. Hence, a cost-minimisation analysis was conducted.

**Direct costs**
Discounting was not relevant since the costs were incurred during less than two years. The unit costs were not reported separately from the quantities of resources used. The health service costs included in the economic evaluation were grouped into five categories. These were consultations by health care professionals (GP, diabetologist, dietician, diabetes nurse educator), use of medication (short-acting insulin, NPH insulin including pre-mixtures, sulfonylureas and metformin), materials (disposable needles and blood glucose test strips), laboratory tests, and overhead services. The cost/resource boundary adopted in the study was that of the health care sector. The costs were estimated using actual data derived from financial accounts for personnel, from the Dutch Central Agency for Healthcare Charges for GP visits and laboratory tests, from the Dutch Healthcare Insurance board for medications, and from wholesale prices for materials. The overhead costs were calculated on the basis of a direct allocation methodology, which considered the surface of structures used for the service. The authors made a number of assumptions used in the economic evaluation, to calculate the costs in cases of missing data. The most important assumption was that, for both settings, the costs of glucose monitoring were determined by the use of blood glucose strips, which in turn depended on the phase of the step-
up regimen. Resource use was estimated for 1993 to 1994. The price year was 1996.

**Statistical analysis of costs**
The costs were reported as averages along with standard deviations, but no further statistical analyses of the costs were conducted.

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

**Currency**
Dutch guilders (Dfl). The exchange rate from Dfl into US dollars ($) was Dfl 1 = $0.5.

**Sensitivity analysis**
One-way sensitivity analyses were conducted to assess the robustness of the estimated costs to variations in the costs of medication, materials and overheads. The ranges used for medication and material costs were those derived from the standard deviations, while overhead costs were varied within a range of 50%.

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

**Cost results**
The cost per patient was Dfl 2,467 (+/- 600) in the intervention group and Dfl 2,740 (+/- 780) in the control group.

Medication costs represented the main cost component in both study groups.

Fixed costs played a more important role in the comparison group than in the intervention group.

The sensitivity analyses showed that total health care costs were sensitive to variations in the costs of medication. The changes were similar in the two study groups, with overhead costs having a greater impact in the control group.

**Synthesis of costs and benefits**
Not relevant as a cost-minimisation analysis was conducted.

**Authors' conclusions**
The study showed similar effectiveness results for the two settings for patient management in terms of glycaemic control and glycated haemoglobin (HbA1c). Overall, the costs per patient of the two interventions were also found to be similar. These ranged from Dfl 2,000 to Dfl 3,400 ($1,000 to $1,700) depending on the cost assumptions.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. The care delivered at the outpatient department of a hospital was selected, as it represented the conventional organisational structure for the management of patients with Type 2 diabetes initiating insulin therapy. You should decide whether it represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness analysis used a retrospective cohort study, which appears to have been appropriate for the study
question. However, the authors acknowledged that selection bias could not be ruled out due to the retrospective design. The lack of random allocation may have introduced some further bias. Also, the presence of confounding factors cannot be totally excluded, as there were some exceptions (alcohol consumption and initial values of HbA1c) in the baseline comparability of the study groups. The study sample was representative of the study population. The method of sample selection was reported. Power calculations were not reported and there was no evidence that the initial study sample was appropriate for the study question. These issues may have affected the internal validity of the analysis.

Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis, as the two groups were shown to be similar in terms of the main outcome measure. Consequently, a cost-minimisation analysis was conducted.

Validity of estimate of costs
The perspective adopted in the study was explicitly reported. It appears that all the relevant categories of costs have been included in the analysis. The indirect costs were not considered relevant from the study perspective. A detailed breakdown of the costs was provided, but the unit costs were not reported separately from the quantities of resources. The price year was reported, thus facilitating reflation exercises in other settings. The costs were treated deterministically in the base-case, but sensitivity analyses were conducted. The costs were fairly specific to the study setting, but the conversion rate from Dfl into US dollars was reported. However, caution should be used when generalising the cost results to other settings. The source of the cost data was appropriately reported for each cost component.

Other issues
The authors made some comparisons of their findings with those from other studies. The authors stated that the generalisability of the study results to other settings was limited due to different country-specific approaches for shared care and specific reimbursement systems. The study enrolled patients with Type 2 diabetes and this was reflected in the conclusions of the analysis.

Implications of the study
The main implication of the study is that patients with Type 2 diabetes could be effectively and efficiently managed both in a shared-care setting and an outpatient-care setting of a hospital. However, the authors suggest that the study results should be interpreted with caution, mainly due to the limited baseline comparability of the study groups. The authors also note that the proportion of patients with poor glycaemic control was still high at the end of the follow-up period, thus suggesting that there was further room for improvement. Future studies, based on prospectively collected data, should be carried out to further assess the cost-effectiveness of specific forms of shared care for the management of patients with Type 2 diabetes.

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Bibliographic details

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Subject indexing assigned by CRD

MeSH
Aged; Ambulatory Care Facilities; Clinical Protocols; Cohort Studies; Cost-Benefit Analysis; Diabetes Mellitus, Type 2