Cost-effectiveness of medical nutrition therapy provided by dietitians for persons with non-insulin-dependent diabetes mellitus


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
Nutrition care of non-insulin-dependent diabetic patients as laid down by practice guidelines (practice guidelines care or PGC) was compared with basic nutrition care (BC). The PGC strategy consisted of a minimum of 3 visits to a dietitian with the dietitian monitoring the patient's individual glycemic control and assuming responsibility for nutrition prescription and recommending adjustments in medications to the physician. BC strategy consisted of 1 visit to a dietitian during which general principles of nutrition management were discussed.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with NIDDM who were free from serious diabetes complications or comorbidities. For the detailed characteristics of the population see "Other publications of related interest" below.

Setting
Three outpatient clinics specialising in the care of diabetic patients in Minnesota, Florida and Colorado, (USA).

Dates to which data relate
Data for both the effectiveness study and the cost analysis were collected in a 6 month period in 1993. All costs and prices are in 1993 US dollars.

Source of effectiveness data
Effectiveness evidence was based on a single study.

Link between effectiveness and cost data
Costing was based on the same patient sample as that used in the effectiveness study and was collected prospectively.

Study sample
247 patients aged between 38 and 76 years with newly diagnosed NIDDM but without serious complications of diabetes or comorbidities were recruited and, after signing consent forms, they were assigned randomly to two groups. Of the 179 subjects who completed the study, 85 were in the BC group and 94 in the PGC group. Adequate sample size was determined according to power calculations. In addition a non-randomized control group (N=62) was selected from
concurrent patients not receiving any dietary interventions.

**Study design**
The study was a randomised trial with non-randomized concurrent controls. Blinding was not possible. The study was conducted concurrently at 3 centres. There was no follow up beyond the 6 months of the trial. A dropout rate of 18% was reported and another 10% did not have complete laboratory data, and hence the analysis was based on data from 179 subjects (72% of the original enrollees).

**Analysis of effectiveness**
Analysis was based on the 179 patients who completed the trial. Primary health outcomes were: (1) fasting plasma glucose level 6 months after entry to the trial and (2) glycated haemoglobin level (HbA1c) 6 months after entry to the test.

**Effectiveness results**
Patients in the PGC group experienced a mean decrease of 1.1 (+/- 2.8) mmol/L in fasting plasma glucose level 6 months after entry to the study. Patients in the BC group experienced a mean decrease of 0.4 (+/- 2.7) mmol/L at the same time, which was not, however, statistically significant. Patients in the PGC group experienced a 0.93 (+/- 1.63) decrease in HbA1c percentage points. Patients in the BC group experienced a 0.69 (+/-1.67) decrease. The difference between the intervention groups (BC and PGC) was not statistically significant at the 5% level.

**Clinical conclusions**
Medical nutrition therapy provided by dietitians was beneficial to patients with NIDDM. Although both approaches achieved a degree of success, PGC achieved a greater magnitude of change in fasting plasma glucose and HbA1c levels compared with BC. This difference between intervention groups, however, did not reach statistical significance.

**Measure of benefits used in the economic analysis**
Two measures of benefits were used: (1) a unit (mmol/L) change in fasting plasma glucose level and (2) a percentage point change in HbA1c assay.

**Direct costs**
It was assumed that all costs other than nutrition care would be the same for both groups. Only the costs to the health care organisation were included. Discounting was not relevant given the 6 month period of the cost analysis. Costs were reported as 1993 dollars. Resources were documented prospectively. The costs of dietitians were calculated by recording the time dietitians spent with patients. It was estimated that, for every 3 hours of direct patient contact, 1 hour was spent in related responsibilities. Hours were multiplied by a weighted salary average plus fringe benefits. Support staff were costed similarly. Costs of supplies and educational materials were actual costs. Overheads were estimated according to a formula for each site expressed as a percentage of personnel salaries. Laboratory and assay costs were the market prices. Cost savings due to change in therapy were estimated assuming that the changes were maintained for 12 months.

**Statistical analysis of costs**
Mean costs with a plus or minus figure were given although it was not stated that these were confidence intervals.

**Currency**
US dollars ($).
Sensitivity analysis
Sensitivity analysis was carried out on 2 input factors: dietitian salary and the inclusion of an extra laboratory test. Variation in output was also tested. Levels of fasting plasma glucose were considered at the high and low ranges of the 95% confidence intervals. These were one way simple sensitivity analyses.

Estimated benefits used in the economic analysis
The mean decrease in fasting plasma glucose 6 months after entry was estimated to be 1.1 (+/- 2.8) mmol/L and 0.4 (+/- 2.7) mmol/L for PGC and BC groups, respectively. The respective decrease in HbA1c was estimated to be 0.93 (+/- 1.63) and 0.69 (+/- 1.67) percentage points.

Cost results
The total cost of PGC for n=94 was $10,534.33 and total cost of BC for n=85 was $3,565.55. The average cost per patient in the PGC group was $112.07 and in the BC group was $41.95. The cost per patient in the PGC group without the extra HbA1c assay was $95.07. The net savings in the cost of drugs due to changes in therapy over 12 months were $31.49 and $3.13 per patient in BCG and BC groups, respectively.

Synthesis of costs and benefits
Each mg/dL (or 0.0555 mmol/L) of change in the fasting plasma glucose level from entry to the 6 month follow up was achieved at a cost of $5.75 in the BC group and $5.84 in the PGC group. If savings in drug prescriptions were included in the net ratio, the figures were $5.32 in the BC group and $4.20 in the PGC group. Using the other measure the cost per percentage point in HbA1c was $60.80 in the BC group and $120.51 in the PGC group. Taking the net ratios the costs were $56.26 in the BC group and $86.65 in the PGC group. No incremental analysis was undertaken, only an analysis of average cost-effectiveness ratios being reported. The results were found to be sensitive to changes in values of outcomes within the 95% confidence interval. More specifically, the fasting plasma glucose level increased in the BC group if lower limit outcome value was applied.

Authors' conclusions
The nutrition interventions that follow practice guidelines can lead to substantial improvements in metabolic control and these outcomes can be achieved with a reasonable economic investment. Cost-effectiveness is enhanced when dietitians are engaged in active decision making about intervention alternatives based on the patient’s needs.

CRD COMMENTARY - Selection of comparators
No justification was given for the comparators used. The two intervention strategies were compared to an alternative in which no dietary intervention was provided. You, as a user of this database, should consider whether this comparison is relevant in your setting.

Validity of estimate of measure of benefit
In this paper the authors have not given full details of the clinical results. The effectiveness study was claimed to be a randomised controlled trial, but the estimated effectiveness measures were derived in before-after fashion for each intervention group. No observed changes in the non-randomised control group over the study period were implicitly assumed to justify this comparison. However, potential biases due to selection process of "active" participants can not be ruled out. In the current study the authors did not discuss the fact that the changes in outcome measures between the two intervention groups were not statistically significant. Consequently, the relevance of any comparison of average cost-effectiveness ratios between these two interventions is questionable. Moreover, the clinical evidence indicated that the 6-month change in fasting plasma glucose was not statistically significant in the BC group. This was reflected in the sensitivity analysis, where the value of this outcome measure actually increased when lower limit values of 95% confidence interval was applied. Omission of this relevant information raises concerns about the selective use of effectiveness data, which enhances the performance of the more intensive dietary interventions in the economic evaluation.
Validity of estimate of costs
Adequate details of costing methods, sources and dates were provided. Quantities and costs were reported separately in essential parts. The outcomes and intervention costs were estimated for the 6-month study period only, but the potential savings due to changes in therapy were assumed to be maintained over a 12-month period. The authors did not give any justification for this assumption, which would have been necessary in the absence of adequate follow-up and given the significant contribution of these savings to the cost-effectiveness of PGC strategy.

Other issues
The authors’ conclusion may not be justified for several reasons. Any comparison of the average cost-effectiveness between the two intervention strategies (PGC and BC) is irrelevant since there was no statistically significant differences in the outcome measures used. Even if there had been a difference in outcomes an incremental analysis should have been used instead of average cost-effectiveness ratios. Potential biases due to use of non-randomised controls and the unblinded nature of the effectiveness study cannot be ruled out. Of specific concern are the estimated cost savings due to a change in therapy, which in fact were recommended by the (unblinded) dietitians participating in the experiment. Moreover, the claim that both interventions are cost effective in improving glycemic control in NIDDM patients may not be justified without relevant comparisons to the cost-effectiveness of other strategies available for this purpose.

The generalisability to other settings was addressed by carrying out sensitivity analysis on salaries and on the number of laboratory tests use. This, together with the multi-centre design, improves the generalisability to other settings within USA. The results may not, however, be generalised to other countries.

It is possible to envisage nutrition advice being given by a practice nurse or as written information. Incremental costs from this base would be different, but the authors have not justified the employment of a dietitian to give basic care.

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Other publications of related interest

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