A multifaceted intervention in support of diabetes treatment guidelines: a cont trial

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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
The use of a multifaceted intervention for the treatment of diabetic patients. This included pharmacist case management, nurse and nutritionist counselling, provider didactic teaching and training, computerised compliance feedback, reminders, case management, and access to endocrinologist in support of staged diabetes management.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised diabetic patients.

Setting
The setting was an academic family practice clinic. The study was carried out in Seattle, USA.

Dates to which data relate
The effectiveness and resource utilisation data were collected between March 1, 1998 and April 30, 1999. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was performed prospectively on the same sample population as that used in the effectiveness analysis.

Study sample
No power calculations to assure a certain power were performed in the planning phase of the study. Diabetic patients who had at least two visits during the study period and two HbA1c measurements (before and after the intervention was implemented) were considered for the effectiveness analysis. The final study sample comprised 109 patients. There were 44 patients in the intervention group and 65 in the control group. A total of 36 attending and resident physicians provided primary care to the patients. The authors did not report that the study sample was representative of the study population.
Study design
This was a pre-intervention post-intervention, non-randomised controlled study. The study was multi-centred since the patients were from two sites corresponding to the same institution. The intervention was randomly allocated at site level by flipping a coin. Therefore, the units of randomisation were not the patients but the sites. The duration of follow-up was 14 months in both the pre- and post-periods. The authors reported that there were some losses to follow-up, but did not report how many.

Analysis of effectiveness
The analysis of the clinical study may have been conducted on the basis of treatment completers only, as the study sample did not appear to include those patients lost to follow-up. The primary health outcome assessed in the effectiveness analysis was the mean change between the intervention and control groups in HbA1c level, both overall and stratified by the value of the last HbA1c during the baseline period. The authors also reported the degree of aggressiveness of the medication administered to the patients. This was measured on a scale from 0 (no medication) to 6 (insulin with two different oral agents). The patients’ weight, systolic and diastolic blood pressures were also reported as measurements of behavioural changes in lifestyles.

The patient groups were comparable at analysis in terms of demographics, clinical measures, drug treatments and health care utilisation characteristics. Moreover, the authors stated that, following evidence from other studies performed at the same institution, the providers from both sites were comparable. Regression analyses and random-effects models were used to adjust for confounding factors associated with the treatment received by patients.

Effectiveness results
The change in the HbA1c levels between the baseline and the last measurement of the study period decreased by 0.07 (from 7.64 to 7.56) in the intervention group, and increased by 0.64 (from 7.57 to 8.20) in the control group.

Therefore, there was a significant decrease in the HbA1c levels (equal to 0.71%) between the intervention and the control groups during the study period, (p=0.02).

The decrease in HbA1c level was more important among intervention patients with baseline HbA1c levels above 8%.

There was no net change in the aggressiveness of the medication used, (p=0.98), nor in the total number of diabetic agents used between the control and intervention groups, (p=0.21).

During the study period, there was a decrease in the weight (-0.51 kg), systolic blood pressure (-1.2 mmHg) and diastolic blood pressure (-3.73 mmHg) in the intervention group. In the control group, while there was an increase in weight (0.90 kg) and systolic blood pressure (3.1 mmHg), there was a decrease in diastolic blood pressure (-0.81 mmHg). These differences were not statistically significant.

The effectiveness results did not change when regression analysis and random-effects models were used to adjust for confounding factors. Therefore, the authors reported unadjusted results.

Clinical conclusions
The multifaceted intervention showed a modest improvement in HbA1c levels over the study period, particularly in those individuals with initial HbA1c levels above 8%. The intervention was not associated with changes in the number or types of medications prescribed. Weight and blood pressure tended to improve in the intervention group, although the changes did not reach statistical significance.

Measure of benefits used in the economic analysis
No summary measure of health benefit was used in the economic analysis. Therefore, the analysis was categorised as a cost-consequences analysis.
Direct costs
The resource quantities and the costs were not reported separately. The direct costs considered in the economic analysis related to the health care institution. There were for outpatient visits, ancillary care providers, laboratory and radiology services, inpatient admissions, and prescriptions (both internally- and externally-filled). The cost data were obtained from clinical records, bill records and the average wholesale price from the Red Book. Adjustments were made to approximate billing records to costs. The price year was not stated. The authors reported the total costs at baseline and after the implementation of the intervention for each group, and also the difference in costs between the groups. Discounting was not performed, which was appropriate since the period considered at analysis was shorter than 2 years.

Statistical analysis of costs
Statistical analyses were performed to compare the differences between the baseline and study periods for some resource use and costs for both study groups. The authors stated that t-tests were used since the differences were approximately normally distributed.

Indirect Costs
No indirect costs were reported.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analyses were performed.

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

Cost results
The total costs at baseline were $3,966 for the control group and $4,919 for the intervention group.

After the implementation of the intervention, the total costs were $3,186 for the control group and $3,555 for the intervention group.

The differences in costs between the baseline and study periods were -$780 for the control group and -$1,364 for the intervention group. The difference between the groups was $584, (p=0.55).

Synthesis of costs and benefits
Not applicable due to the cost-consequences analysis undertaken.

Authors' conclusions
The multifaceted intervention, in support of diabetes treatment guidelines, modestly improved glycaemic control in an academic family practice setting without incurring increased utilisation or additional costs.

CRD COMMENTARY - Selection of comparators
The comparator chosen was usual care for diabetic patients in the authors' setting. However, the authors did not describe what this usual care consisted of, although they did provide a table listing the elements of the intervention
which related to the comparator. The reader should decide the relevance of these approaches in relation to their own setting.

**Validity of estimate of measure of effectiveness**

This study was based on a controlled trial design. The authors stated that randomisation at the level of the sites was used to avoid contamination that would accompany randomisation at the patient level. The inclusion criteria used to select the patients for the effectiveness analysis may have represented a source of bias, as only patients with baseline and final HbA1c measurements were included and those lost to follow-up do not appear to have been considered. The study groups were shown to be comparable at analysis in terms of demographics, clinical measures, drug treatments and health care utilisation characteristics. The authors did not report any information about the patients lost to follow-up. The study sample was not shown to be representative of the study population. Some comparisons may not have reached statistical significance due to the lack of statistical power arising from the small sample size.

**Validity of estimate of measure of benefit**

The authors did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-consequences study.

**Validity of estimate of costs**

All the costs relevant to the perspective adopted (the hospital) appear to have been included. The resource quantities and the costs were not reported separately and the price year was not stated. This hinders reflation exercises to other settings. Appropriate statistical analyses of the costs were performed, and the tests used were justified according to the distribution of the data. In addition, adjustments to approximate billing records to costs were made, which reflects more the opportunity costs of the interventions. However, as the authors stated, not all of the resource use in the study may have been solely driven by diabetes-related care since there were multiple co-morbidities among the patients. Also, the authors reported the total costs associated with each of the study groups. Since the number of patients per group was different, it would have been more accurate to have reported the costs per patient in order to facilitate appropriate comparisons. All these facts introduce uncertainty into the reliability of the cost results. Discounting was not performed, but this was appropriate since the study period was shorter than 2 years.

**Other issues**

The authors made some comparisons of their findings with those from other studies, showing similarity in the results obtained. In terms of generalisability, they stated that the results should be applicable to other similar primary care settings since the intervention did not require additional personnel or infrastructure.

**Implications of the study**

The authors stated that modest improvements in HbA1c levels, as obtained with the multifaceted intervention, may result in large reductions in diabetes-related complications and long-term costs. They recommended further study around the greater improvements in HbA1c levels found among patients with the poorest glycaemic control (HbA1c above 8%). Moreover, they commented that the majority of patients did not reach recommended HbA1c targets and this would require further techniques to involve diabetic patients in their treatment.

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**Bibliographic details**

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
Blood Pressure; Body Weight; Cholesterol /blood; Diabetes Mellitus /physiopathology /psychology /therapy; Feedback, Psychological; Female; Hemoglobin A, Glycosylated /analysis; Hospitalization /statistics & numerical data; Humans; Insurance, Health; Length of Stay; Male; Middle Aged; Office Visits /statistics & numerical data; Patient Care Team; Practice Guidelines as Topic; Quality Assurance, Health Care

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