Outcomes of Project Dulce: a culturally specific diabetes management program

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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 study evaluated the use of a culturally specific diabetes management programme that focused on culturally specific peer education (the Project Dulce) in adult diabetic patients from different minority ethnic backgrounds.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised low-income adult patients with diabetes mellitus. All beneficiaries from the San Diego County Medical Services (SD-CMS) were eligible to participate. The availability of laboratory results for glycosylated haemoglobin (HbA1c) at enrolment and one year after was the only inclusion criteria. The ethnic composition of the groups was similar. The patients were primarily Latinos (37% in the intervention group, 30% in the control group) or non-Latino whites (27% in the intervention group and 22% in the control group). The mean age was 51 years in the intervention group and 52 years in the control. The majority of the participants in both groups were female (70% in the intervention group and 58% in the control group).

Setting
The setting was a community health centre. The economic study was carried out in the USA (San Diego, CA).

Dates to which data relate
The effectiveness and resource use data for the intervention group were gathered between July 2000 and December 2002. The effectiveness and resource use data for the comparison group were gathered between January 1999 and June 2000. The price year was 2002.

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

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same patient sample as that used in the effectiveness study by collating claims data from the accounts database.

Study sample
A total of 188 SD-CMS beneficiaries (88% of the 213 eligible SD-CMS beneficiaries) participated and remained
enrolled for one year. A total of 160 patients enrolled in SD-CMS were selected as a historical comparison group (34% of the total 474 charts reviewed) on the basis that they had HbA1c tests values at two occasions approximately one year apart. No power calculations were reported.

**Study design**
The study was a comparative study with a historical control that was carried out in a community health centre contracted out by the SD-CMS. The duration of the follow-up was one year. The authors stated that all participants in the project remained enrolled for one year. The type of study design meant that no drop-out rates were reported. The research protocol was approved by the institutional review board at the University of California.

**Analysis of effectiveness**
All of the patients entered into the study were included in the analysis. The primary health outcomes were changes in HbA1c, systolic and diastolic blood pressure, total cholesterol, high-density lipoprotein (HDL) cholesterol and low-density lipoprotein (LDL) cholesterol. The baseline characteristics of the intervention and control groups were comparable, including the ethnic composition of the groups and the baseline levels of HbA1c, blood pressure and total cholesterol. The results were adjusted for age, gender and clinical outcome baseline values.

**Effectiveness results**
After adjusting for age, gender and baseline values, participation in the Dulce Project was related to significant improvements in all clinical outcomes but HDL-cholesterol.

The participants in Project Dulce had significant reductions in HbA1c (0.8%; p<0.001), systolic blood pressure (5.4 mmHg; p=0.001), diastolic blood pressure (8.0 mmHg; p<0.001) and total cholesterol (28.1 mg/dL; p<0.001).

**Clinical conclusions**
Project Dulce was effective in improving clinical outcomes for the control of diabetes mellitus and related conditions in a medically indigent, culturally diverse population.

**Measure of benefits used in the economic analysis**
There was no summary measure of benefit. In effect, a cost-consequences analysis was performed.

**Direct costs**
Only the direct costs for the health care service were reported. The key resource use categories included were inpatient and emergency hospitalisations, outpatient visits, and diabetes-related medications and supplies. The costing was based on individual patient level data. The estimation of the annual cost per patient was based on the amount paid by SD-CMS for each person in the time between their baseline and follow-up HbA1c test, adding up the estimated payments for Dulce services in this time period and then annualising these costs. The quantities for the intervention were reported separately from the unit costs. Discounting does not appear to have been performed, but it was not relevant as the time horizon for the analysis was one year. The cost price year was 2002.

**Statistical analysis of costs**
The costs were treated stochastically. Means, standard errors and critical p-values were reported for the cost comparison performed among the study groups. Non-linear 2-part cost models were used to estimate the effect of Project Dulce on costs by resource use categories (e.g. inpatient, outpatient, pharmacy), and on total cost adjusting for age, gender and baseline HbA1c values, using a non-parametric smearing estimate of the variance.

**Indirect Costs**
The indirect costs were not considered in the economic study. A rationale for their exclusion was not provided.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was reported.

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

**Cost results**
The cost analysis revealed that the total costs were higher for Dulce Project participants during the first year of disease management, $5,711 for the Dulce group compared with $4,365 for the control group, (p<0.001).

The main contributor to the total costs in both groups was the pharmacy costs.

Increases in diabetes-related medications and supplies accounted for 88% of the increase in pharmacy expenditure in the Dulce group. However, expenditures on hospital and emergency department care declined by $688 in the Dulce group compared with the control group, (p<0.061).

The authors provided a detailed breakdown of the costs per main resource use category for each group.

**Synthesis of costs and benefits**
A synthesis of the costs and benefits was not carried out because a cost-consequences analysis was performed.

**Authors’ conclusions**
The results demonstrated that this type of culturally specific diabetes management programme, which focused on peer education, can improve clinical outcomes for the control of diabetes and related conditions in a low-income, culturally diverse population.

**CRD COMMENTARY - Selection of comparators**
The comparator was usual diabetes care as would be practised in the community health centres contracted by the Medicaid programme. You should decide whether this represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
A comparative study with historical controls was used to estimate the measure of effectiveness. A randomised controlled trial would have been better. The authors did not report evidence that the study sample was representative of the study population. The authors recognised that the study design may lend itself to selection bias, thus increasing the uncertainty surrounding the effectiveness results.

**Validity of estimate of measure of benefit**
The main benefit measures used in the economic analysis were HbA1c and blood pressure levels. The relationship between both these surrogate outcomes and further diabetic complications and impact on quality of life could have been the object of further discussion in the paper.
Validity of estimate of costs
The authors explicitly identified the perspective adopted in the analysis. It seems that all the categories of cost relevant to the perspective adopted were included. The methods of costing and dates were reasonably well reported.

Other issues
The authors appropriately discussed the main limitations of their analysis, in particular the fact that their study design might have introduced a bias into the results. The authors did not compare their results with those from other relevant studies. They did not report the results selectively. The conclusions excluded the fact that the project was, overall, more costly than the previous programme.

Implications of the study
The authors stated that the Dulce Project provides evidence that an effective diabetes education and self-management training programme can be conducted by non-physician staff and result in improved clinical outcomes for diabetes control in low-income, culturally diverse populations. No suggestions for further research were stated.

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