The Asheville Project: short-term outcomes of a community pharmacy diabetes care 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
A pharmaceutical care services (PCS) programme for patients with diabetes was studied. The PCS included patient education and training, clinical assessment, monitoring, follow-up and referral.

Type of intervention
Other: Supportive care aimed at improving treatment outcomes.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with diabetes. No age or other eligibility restrictions were imposed.

Setting
The study setting was the community (community pharmacies). The study was conducted in Asheville (NC), USA.

Dates to which data relate
The effectiveness and cost data were collected for two sub-groups of patients that were enrolled in the study in different time periods. Pre-intervention (baseline) data for sub-group 1 referred to March 1996 to February 1997. The corresponding data for sub-group 2 related to March 1998 to February 1999. The follow-up data were collected between March and November 1997 for sub-group 1 and between March and September 1999 for sub-group 2. All data included information on both the cost and effectiveness outcomes. The prices related to 1999.

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

Link between effectiveness and cost data
In terms of the follow-up data, the costing was carried out prospectively, alongside the collection of effectiveness data, on the same sample of patients. The baseline (pre-intervention) cost and effectiveness data were collected retrospectively.

Study sample
Patients who were employees, dependants or retirees from two self-insured employers were eligible for the study. The patients were invited to participate through individual letters and a general memorandum sent to all employees. The study sample consisted of those patients who responded to these invitations and contacted a participating pharmacist at...
least once. The total number of patients participating in the study was 85. Of these, 38 were City of Asheville employees who enrolled in March 1997 (sub-group 1) and 47 were MSJ employees who enrolled in March 1999 (sub-group 2). Overall, 43% of eligible patients enrolled in the programme. It was reported that the study had insufficient power to accept the null hypothesis of no difference in results. The authors were aware that patients who chose to participate in the programme might have differed in some important way from those who did not participate, and that this could pose a threat to external validity (selection bias).

**Study design**
The analysis was part of a larger study, the purpose of which was to assess the short- and long-term clinical, economic and humanistic outcomes of PCS, and possible factors that had an impact on these outcomes. Further details were reported elsewhere (see Other Publications of Related Interest). The basis of the analysis was a within-group comparison study ("before-after" study). The authors initially compared the two sub-groups to determine their comparability. The two sub-groups, which comprised employees of two different employers, had both received the intervention under assessment but on different dates. When no major differences were found in demographic factors and patient outcomes, the two sub-groups were combined for all subsequent analyses based on "before-after" comparisons. In addition, the follow-up results of sub-group 1 were compared with the pre-intervention results of sub-group 2, which, in this case, served as a control group (cohort analysis). The study was conducted in one centre with 12 pharmacies participating. The duration of the pre-intervention period was 12 months. The duration of follow-up was 9 months for sub-group 1 and 7 months for sub-group 2. No loss to follow-up was reported.

**Analysis of effectiveness**
It was stated that basis of the analysis was intention to treat, therefore selection bias due to drop-outs was avoided. The health outcomes measured included A1c, home blood glucose and lipid levels, a health-related quality of life score, and the patients' satisfaction with pharmacy services. Health-related quality of life was assessed using the Medical Outcomes Study 12-Item Short Form (SF-12), while patient satisfaction with pharmacy services was measured using the Larson and MacKeigan instrument. A preliminary analysis showed the two sub-groups to be comparable for baseline and follow-up outcomes. Therefore, they were combined for all subsequent analyses. In a follow-up analysis, the authors reported that they further controlled for covariates in multivariate models of outcomes, and most covariates were found not to be significant predictors (for further details see Other Publications of Related Interest).

**Effectiveness results**
The proportion of patients with A1c values in the optimal range (less than 7.0%) increased significantly from 42% at baseline to 57% at follow-up, (p=0.04).

A1c improved significantly, from a mean (+/- standard deviation, SD) of 7.5% (+/- 1.5) at baseline, to 7.0% (+/- 1.3) at follow-up, (p<0.01).

None of the other laboratory values showed significant differences.

The proportion of patients with optimal values for low-density lipoprotein cholesterol (LDL-C) and low- to high-density lipoprotein cholesterol (LDL-C/HDL-C) ratio increased slightly, whereas those for total cholesterol and HDL-C decreased slightly.

With the exception of HDL-C, other mean lipid values improved. None of the improvements were statistically significant (the power of the study was insufficient to accept the null hypothesis of no difference).

After the PCS intervention, the SF-12 Physical domain improved by 3.2% (from a mean value of 44.2 to 45.6) and the Mental domain improved by 3.7% (from 48.9 to 50.7). Neither change was statistically significant (the power of the study was insufficient to accept the null hypothesis of no difference).

There were significant improvements in the patients' satisfaction with pharmacy services for all domains, (p<0.01). There was a 28.4% improvement in the Technical domain (from 64.4 to 82.7), a 22.5% improvement in Consideration (from 64.1 to 78.5), a 16.5% improvement in Explanation (from 71.1 to 82.8), and a 15.0% improvement in the...
When comparing the results for post-intervention sub-group 1 and pre-intervention sub-group 2, the mean A1c (+/- SD) was 6.9% (+/- 1.4) for sub-group 1 after PCS and 7.7% (+/- 1.4) for sub-group 2 before PCS. This difference of 10% was statistically significant, (p=0.02).

Clinical conclusions
Patients who participated in the study experienced improvements in clinical and humanistic outcomes. The patients’ satisfaction with the PCS programme was high.

Measure of benefits used in the economic analysis
No summary measure of benefits was used in the economic analysis and the clinical outcomes were left disaggregated. In effect, a cost-consequences study was performed.

Direct costs
The study perspective was stated to have been that of a third-party payer. The costs included were for physician visits, emergency department visits, hospitalisation, laboratory tests, prescriptions, PCS claims and co-pay waivers. The costs were analysed in terms of diabetes-related costs and other diagnosis costs. The costs and the quantities were not analysed separately, although the total number of encounters per patient was reported. An encounter was defined as an insurance claim for a visit to a physician, emergency department, hospital or pharmacist, and as a prescription drug or a supply dispensed. The costs came from actual data, derived from insurance and prescription claims databases, documentation forms used by pharmacists during the intervention, and the patients’ medical records. The costs of sub-group 1 referred to 1996 to 1997, whereas the costs of sub-group 2 related to 1998 to 1999. All the costs were adjusted to 1999 prices using the Consumer Price Index for Medical Care. Discounting was irrelevant, as the baseline and follow-up costs were estimated for no longer than one year, and was therefore not conducted.

Statistical analysis of costs
The costs were treated stochastically, with mean values, SDs and median values being provided. The Wilcoxon signed rank test for paired data was used in the cost analysis.

Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was undertaken.

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

Cost results
The mean (+/- SD), total cost (diabetes-related plus other diagnoses cost) paid per patient per month (PPPM) was $525 (+/- 843) at baseline and $443 (+/- 622) at follow-up. There was a decrease of $82 in the costs (16% change from baseline). This was not statistically significant (insufficient power to accept the null hypothesis of no difference).
The diabetes-specific cost PPPM was $60 (+/- 83) at baseline and $112 (+/- 137) at follow-up. There was a statistically significant increase of $52 in the costs (87% change from baseline, p<0.01).

When comparing the costs for post-intervention sub-group 1 and pre-intervention sub-group 2, the total costs were $415 (+/- 702) PPPM for sub-group 1 at follow-up and $454 (+/- 777) PPPM for sub-group 2 at baseline. The difference in costs was not significant, but the study power was insufficient to accept the null hypothesis of no difference.

The diabetes-specific costs were $64 (+/- 54 PPPM) for sub-group 1 at follow-up and $51 (+/- 58) PPPM for sub-group 2 at baseline. The difference in costs was statistically significant, (p=0.03).

The cost of adverse effects was not relevant in the context of the study.

Synthesis of costs and benefits
The costs and benefits were not combined as no summary measure of benefit was derived.

Authors’ conclusions
The patients’ clinical and humanistic outcomes improved, with no concomitant increase in total direct health care costs. Health-related quality of life remained unchanged during the short follow-up period, but the patients’ satisfaction with pharmacy services improved significantly.

CRD COMMENTARY - Selection of comparators
The selection of the comparator was implicitly justified since it represented routine pharmacist care in the USA. You should consider whether the comparator reflects routine practice in your own setting.

Validity of estimate of measure of effectiveness
The basis of the analysis was a within-group comparison study ("before-after" study). This type of study entails potential threats to the internal validity, as the observed change may be due to a historical event such as the introduction of a new antidiabetic drug affecting the follow-up outcomes. The study sample was small, and the study power was insufficient to accept the null hypothesis of no difference in many cases. It was not known whether the study sample was representative of the patient population. It is likely that employees who chose to participate in the study were different from those who did not participate. Moreover, the employees and their dependants might differ from the general population. The pre-intervention and follow-up periods were of unequal duration, which might introduce bias into the study in terms of variance in the data. Statistical analyses, to assess the significance of the results and to account for potential confounding factors, were performed.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was, in effect, a cost-consequences study.

Validity of estimate of costs
The study perspective was stated to have been that of a third-party payer. As such, all the costs relevant to this perspective appear to have been included in the analysis. The costs and the quantities were not reported separately. A statistical analysis of the costs was conducted. Charges were used to represent costs, thus, the costs did not reflect opportunity costs. Discounting was irrelevant, as the costs were incurred during one year at most, and was therefore not carried out. The year to which the prices referred was reported.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. The generalisability of the results to other settings was not addressed. The authors acknowledged some of the limitations of the study. For
example, the small sample size, the lack of a randomised controlled design, and the missing data. The results of the study were adequately reported. The authors' conclusions reflected the scope of the analysis.

**Implications of the study**
According to the authors, the study demonstrated that pharmacists provided effective cognitive services. It also showed that pharmacists do not need to be certified by the American Diabetes Association as diabetes educators, in order to help patients with diabetes to improve clinical outcomes. Further research, to characterise more precisely the contribution of PCS to diabetes-specific and diabetes-related outcomes, is recommended.

**Source of funding**
None stated.

**Bibliographic details**

**PubMedID**
12688433

**Other publications of related interest**


**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Adolescent; Adult; Aged; Blood Glucose Self-Monitoring; Community Pharmacy Services /economics; Counseling; Diabetes Mellitus /diagnosis /economics /therapy; Female; Humans; Hypoglycemic Agents /therapeutic use; Insulin /therapeutic use; Male; Middle Aged; Outcome Assessment (Health Care); Patient Education as Topic; Patient Satisfaction; Pharmacists; Quality of Life

**AccessionNumber**
22003006275

**Date bibliographic record published**
30/09/2004

**Date abstract record published**
30/09/2004