A cost-effectiveness analysis of a community pharmacist-initiated disease state management service for type 2 diabetes mellitus

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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 investigated the use of specialised care for Type 2 diabetes (Disease State Management (DSM) project). The goal of this intervention was to develop, implement and evaluate a standardised DSM programme for diabetes in community pharmacy to improve patient health outcomes and reduce health care costs. The specialised service was defined as one initial visit with six follow-up visits where medication review, goal setting and blood glucose monitoring took place. The control group was only assessed at baseline and then again 9 months later.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with Type 2 diabetes who were on more than three medications, were younger than 85 years old, and were capable of understanding and completing the questionnaires. Further, only those patients who had had a glycosylated haemoglobin (HbA1c) measurement in the 6 months prior to the study and one during the study period were included in the analysis.

Setting
The study setting was the community and secondary care. The economic study was carried out in New South Wales, Australia.

Dates to which data relate
The dates to which the effectiveness and resource use data related were not reported. The price year was 2001.

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

Link between effectiveness and cost data
The costing was undertaken prospectively on the patient sample used in the effectiveness study.

Study sample
It was unclear if the sample size was determined in the planning phase of the study. No power calculations were performed retrospectively on the basis of the existing sample size. Of the 239 patients recruited into the DSM study,
128 (54%) were in the intervention group and 111 (46%) were in the control group. Out of these, 95 of the intervention and 93 of the control patients completed the study and only 53 (intervention group) and 46 (control group), respectively, had both baseline and study HbA1c measurements. The patients in the intervention group had a median age of 65 years (range: 44 - 86) and 55% were female. The patients in the control group had a median age of 66 years (range: 41 - 88) and 57% were female.

**Study design**
The study was based on a prospective cohort study, with control and intervention groups matched on demographic and diabetes-related characteristics. Each of the control and intervention groups was based in three settings: rural and metropolitan community pharmacy settings and a hospital diabetes clinic. There were 9 intervention pharmacists and 20 control pharmacists. The patients in both groups were followed up for 9 months. Fifty-one patients dropped out of the study for various reasons, but they did not differ significantly from those who remained in the study in any of the characteristics considered.

**Analysis of effectiveness**
All of the patients included in the study were accounted for in the analysis. The primary health outcome was the HbA1c level. The authors reported that the HbA1c measurement gives an average of the blood glucose level over the past 6 to 8 weeks. The change in mean HbA1c, the change in the proportion of patients who achieved a clinically significant reduction in HbA1c (>1%) and the proportion of patients with an HbA1c greater than 7% were calculated before and after the study. No statistically significant differences between the groups were found in terms of age, gender and prognostic features. However, the authors reported that a higher proportion of patients in the control group were managed through the diabetes clinic (the results were not shown).

**Effectiveness results**
For the intervention group, the mean levels of HbA1c were 7.40 (standard deviation, SD=1.34) at 9 months' follow-up versus 7.86 (SD=1.37) at baseline. This represented a statistically significant reduction in HbA1c levels of 0.46%, (p=0.02).

For the control group, the mean levels of HbA1c were 7.38 (SD=1.08) at 9 months' follow-up versus 7.41 (SD=1.14) at baseline. This represented a reduction in HbA1c levels of 0.03%, (p=0.81).

A greater proportion (28%) of patients achieved a clinically significant reduction in HbA1c (>1%) in the intervention group than in the control group (15%). However, this difference was not statistically significant, (p=0.12).

There was a significant reduction in the proportion of participants with elevated HbA1c (>7%) at follow-up in the intervention group, (p=0.03), which was not achieved in the control group, (p=0.51).

**Clinical conclusions**
The specialised service resulted in a significant reduction in HbA1c.

**Measure of benefits used in the economic analysis**
The authors used the mean reduction in HbA1c levels achieved by the specialised care approach, compared with standard care, as the measure of health benefit.

**Direct costs**
The direct costs included in the analysis were those to the health care service. These costs were those associated with service provision, diabetes-related health care and medications. The costs associated with service provision included the total time the pharmacist spent in providing the service (i.e. in initial and follow-up visits and time spent conducting medication reviews), the cost of print-outs of blood glucose levels given to patients, and the cost and time taken with
telephone calls. The costs of diabetes-related health care included visits to the general practitioner, specialist, emergency department visits and hospital admissions.

The unit costs were derived from multiple sources. Pharmacist time was cost using the average award rate of an experienced community pharmacist. The health care resource costs were based on the Australian Medicare Benefit schedule fees. The cost of hospitalisation was based on the Casemix Standards for New South Wales. The costs of medications were derived from the Dispensed Price for Maximum Quantity listed in the Schedule of Pharmaceutical Benefits (PBS) minus the contribution to the PBS price made by each general patient and concession cardholder patient. Discounting was not relevant, as all the costs were incurred during 9 months, and hence was not performed. The study reported the average costs. The price year was 2001.

**Statistical analysis of costs**
The mean and SDs of the costs of both groups were calculated. Ninety-five per cent confidence intervals (CIs) were then calculated using Student's t-distribution.

**Indirect Costs**
The indirect costs were not included in the analysis, as these costs were not borne directly by the health care system.

**Currency**
Australian dollars (Aus$).

**Sensitivity analysis**
To assess the robustness of the study results, a scenario sensitivity analysis with best- and worst-case scenarios was performed. The parameters varied were the pharmacist's time spent providing the service and the cost of the medication, as these were considered to be the most uncertain values. In the best-case scenario, it was assumed that there was no difference in the cost of medications between groups at baseline and at the end of the study. In the worst-case scenario, the cost of medication was based on the full price listed, with no contribution made by the patient, as this would be the highest price the government would pay for medications.

**Estimated benefits used in the economic analysis**
The mean reduction in HbA1c levels achieved by the specialised service over standard care was 0.43% (95% CI: 0.34 - 0.52).

**Cost results**
The mean cost per patient in the intervention group was Aus$1,821.12 (SD=120.35) versus Aus$1,437.81 (SD=164.55) in the control group. This represented an increase in costs of Aus$394 (95% CI: 46.16 - 717.46) per patient.

**Synthesis of costs and benefits**
The net cost and the net effectiveness of the specialised service, compared with the standard service, were calculated and expressed as a cost-effectiveness ratio (i.e. the additional cost per benefit gained). Thus, the incremental cost per 1% reduction in mean HbA1c for the specialised service compared with standard care was Aus$891.42 (95% CI: 94.54 - 2,110.18).

In the best-case scenario, assuming that the costs of medications were the same, the cost of achieving a 0.43% reduction in HbA1c was Aus$166.72. In the worst-case scenario, where the government was assumed to pay all medication costs, the cost of achieving a 0.43% reduction in HbA1c was Aus$535.13.
Authors' conclusions
The specialised service resulted in a significant reduction in glycosylated haemoglobin (HbA1c), which should translate into improved health outcomes in the long term. Given the annual costs for each patient, the Aus$383 invested in the first 9 months were likely to result in a saving to the health care system in the long term.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used. It represented current practice in the authors' settings. You should decide if the comparator represents current practice in your own settings.

Validity of estimate of measure of effectiveness
The analysis was based on a prospective cohort study whereby patient groups were matched on demographic and diabetes-related characteristics. However, although this study design was appropriate for the study question, a randomised controlled trial (RCT) would have been a better study design to compare the effectiveness of the service. This is because well-conducted RCTs are considered the 'gold' standard study design when comparing health interventions. The authors excluded a large number of patients with no HbA1c measures at baseline and/or at follow up. Although the patient groups were similar in age, gender and prognostic features, the authors reported that a higher proportion of patients in the control group attended diabetes clinics than did those in the intervention group. The authors reported that the impact of this on the results was not known, but it was possible that the control group patients could have been better managed with respect to their diabetes. The authors undertook appropriate statistical analyses to test whether differences in the outcome measures were significant.

Validity of estimate of measure of benefit
The authors used HbA1c levels as the measure of health outcome. Even though this was an intermediate outcome rather than a final outcome, HbA1c was recognised to be a satisfactory single measure with which to prove the effectiveness of disease management programmes related to diabetes.

Validity of estimate of costs
All the cost categories relevant to the health care system perspective adopted were included in the analysis. Although the authors undertook a thorough costing exercise, they reported that several relevant costs were omitted from the analysis. Expenditure on development of the training model for intervention pharmacists was not included in the analysis, as the authors believed it represented a one-off cost and training resources developed in the project would be available for future use. The cost for the initial set up of the service was also omitted from the analysis, as the intervention pharmacists were recruited only if they had the necessary equipment and conditions.

The costs and resource use were reported separately, which will increase the generalisability of the authors' results. The authors appropriately reported the sources of the unit costs, and how the total costs were calculated. Appropriate statistical analyses of the costs were performed, and the authors reported 95% CIs around the incremental costs and cost-effectiveness ratios. Further, the authors undertook some scenario sensitivity analyses. Discounting was not relevant, as the costs were incurred during 9 months, and thus was not performed. For some resource use categories the authors used fees to proxy prices. The price year was reported, which will aid any possible inflation exercises.

Other issues
The authors made appropriate comparisons of their effectiveness findings with those from other studies, but they did not compare their cost-effectiveness results. They addressed the issue of generalisability to other settings. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis. The authors reported a number of further limitations to their study. For example, although there were no statistically significant differences in prognostic features between groups, there was a tendency for intervention patients to have more advanced disease, with more complications, higher mean HbA1c levels and a higher intake of insulin. This tendency could potentially influence the conclusion that the reduction in HbA1c was due only to the service. The authors also reported that the issue of excluding training costs was debatable.
Implications of the study
The authors reported that since they conducted the study, some pharmacists had continued to offer the service but at a cost to the patient. Ideally, pharmacists would be remunerated by the government to provide the service and, although the government was open to the idea, it was seeking further evidence of the benefit for more patients before it committed itself to subsidising the programme.

Source of funding
None stated.

Bibliographic details

Other publications of related interest


Indexing Status
Subject indexing assigned by CRD

MeSH
Australia; Blood Glucose; Community Health Services /organization & administration /utilization; Cost-Benefit Analysis; Diabetes Mellitus, Type 2 /therapy; Disease Management; Models, Organizational; Patient Care Team /organization & administration; Pharmacies /organization & administration; Pharmacists

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