Clinical and economic impact of ambulatory care clinical pharmacists in management of dyslipidemia in older adults: the IMPROVE study

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
Pharmaceutical care provided by ambulatory care clinical pharmacists was compared to usual medical care with no pharmacist intervention for patients with dyslipidaemia.

Type of intervention
Primary prevention and secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Patients from nine Veterans Affairs Medical Centres (VAMCs) identified as high risk for drug-related adverse events were defined as eligible for enrolment. Patients were considered high risk if they met three or more of the following published criteria: 5 or more drugs in the regimen; 12 or more doses per day; 4 or more drug changes in the previous year; 3 or more concurrent diseases; history of noncompliance and treatment with drugs that require therapeutic monitoring. The inclusion criteria for the study included: patients who had been under the care of VAMC for at least 12 months, patients expected to be under the care of the same VAMC for the duration of the study, patients who lived reasonably close to the VAMC, and had a working telephone. This paper reported data on a subpopulation of patients with dyslipidaemia from a larger study. Patients were not eligible if: they had been seen in pharmacist-managed clinics (excluding medicine re-fill clinics); they had a life expectancy of less than 12 months; they required mental health care services; they had a poor understanding of written and spoken English, or were visually impaired.

Setting
Ambulatory care in primary and secondary care clinics for a VAMC in the USA.

Dates to which data relate
The date relating to the effectiveness and resource use data was not reported. The price year was 1998.

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

Link between effectiveness and cost data
Prospective resource use costing was measured for the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations were not reported in this paper. A power calculation for the larger study was reported separately in a previously published paper and this was based on the number of patients required to detect a 20% difference in the SF-36 health status questionnaire. A sub-sample of patients with dyslipidaemia as selected from the larger study that identified patients at high-risk of drug-related problems. The intervention (pharmaceutical care) group comprised 208 patients and 229 patients were in the control group (usual medical care). Seventy-eight pharmacists provided care to patients in the intervention group. No details were reported in the paper about patients who were invited to participate but who refused, or patients excluded for any reason from the initial sample.

**Study design**
This study was a prospective, multi-centred, randomised controlled trial carried out in nine VAMCs. Randomisation to the intervention or control arm was co-ordinated centrally but no other details about the method of randomisation were reported. Randomisation was not conducted strictly for patients with dyslipidaemia. After randomisation clinical pharmacists conducted blinded medical chart reviews to document medical conditions, including dyslipidaemia. It was not feasible to blind the patient or pharmacist for the purpose of assessment of outcome. Patients were followed-up for 12 months. However, it would have been possible to mask independent assessors. The LDL goal could not be determined in 58 patients in the intervention and 68 in the control group because of lack of information concerning risk factors.

**Analysis of effectiveness**
The analysis of the clinical study was based on intention to treat. The health outcomes used in the analysis were: number of patients having a lipid profile; lipid values (total cholesterol, high-density lipoprotein (HDL), triglycerides, LDL); number of patients requiring secondary prevention who achieved LDL goal of less than 100mg/dl. The authors' reported that it was not possible to determine the number of people requiring primary intervention due to missing information. The intervention and control groups were comparable in terms of age, gender, number of chronic conditions, and number of drugs prescribed.

**Effectiveness results**
More intervention patients had a serum lipid profile during the study (87%) than control patients (78%), (p<0.0211).

Patients in the intervention group had a greater absolute reduction in total cholesterol, (p<0.028) and LDL, (p<0.042) than the control group (6.56% to 1.21% reduction, p<0.022 and 13.2% to 5.47%, p<0.036, respectively).

The percentage of patients achieving LDL goal of less than 100mg/dl before randomisation was increased in both control, (p<0.05) and intervention, (p<0.05) groups but no difference between groups was seen at the end of the study, (p<0.97).

**Clinical conclusions**
Ambulatory care clinical pharmacists were responsible for developing and implementing a pharmaceutical care plan for patients with high risk of drug-related adverse events. These pharmacists were able to reduce total cholesterol and LDL in patients with dyslipidaemia.

**Measure of benefits used in the economic analysis**
No summary outcome measure was specified as the measure of benefit in the economic analysis.

**Direct costs**
The direct costs to the VAMC were reported. Quantities and costs were not analysed separately. Estimates for charges, rather than prices, were obtained from one of the nine VAMC decision support systems (DSS). DSS costs were not available from each participating VAMC. The DSS incorporates fixed costs, such as capital and overhead, and variable costs, such as, personnel and supplies. In addition, laboratory tests were valued using information from a Medicare.
system. Drugs were valued from the pharmacy departments of the individual sites or the VA Pharmacy Benefits Management Group. Clinic costs were estimated assuming three levels of care and six categories based on length and intensity of the visit. The primary analysis assumed medium-intensity, 30-minute costs for clinic attendance, which included the cost of a clinical pharmacist intervention. Hospitalisation costs were also included and valued using one of two methods: the primary analysis based the costs on weighted diagnosis related groups, which were multiplied by Medicare 1998 standard reimbursement rate (charge); the second method used DSS estimates of cost per day by service. It was not clear from the paper if overall costs were extrapolated from one VAMC or calculated for each of the nine VAMCs. All costs were reported as mean annual values but the dates relating to resource use were not stated. The price year was 1998. Discounting was not relevant because the costs were incurred over a short period of time (12 months). The perspective adopted was not stated but is likely to have been that of the healthcare provider.

**Statistical analysis of costs**
The statistical analysis used general estimating equations (GEE) to test the impact of treatment group on change in costs over one year, whilst controlling for other variables which affected resource use and costs. The stochastic cost data were log transformed. The authors reported that this was because the cost data were positively skewed and log transformation was required to meet the assumption of the statistical tests used (GEE). The GEE model included patient age, gender, an ordinal variable to account for the perceived level of pharmaceutical care (low, medium, high), treatment group and a site by treatment group interaction term. P values indicating the differences between groups were reported.

**Indirect Costs**
Indirect costs were not reported.

**Currency**
US dollars ($). No conversion rate or date was reported.

**Sensitivity analysis**
No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**
The reader is referred to the effectiveness results reported above.

**Cost results**
Due to the difficulty inherent in interpreting log transformed numbers, costs were back transformed after the statistical analysis and were reported in the paper as untransformed values. The costs in the year before and after randomisation and mean changes were presented.

The mean change in hospitalisation costs was $710 for the intervention and $670 for the control group, (p<0.88).

The mean change in clinic visit costs was $302 for the intervention and $372 for the control group, (p<0.13).

The mean change in all drug costs was $269 for the intervention and US$106 for the control group (p<0.42).

The mean change in lipid agent costs was $91 for the intervention and $56 for the control group, (p<0.37).

The mean change in laboratory test costs was $61 for the intervention and $54 for the control group, (p<0.74).

The mean change in total costs was $1583 for the intervention and $1213 for the control group, (p<0.19).

**Synthesis of costs and benefits**
Costs and benefits were not combined.

Authors' conclusions
The authors' concluded that clinical pharmacists could reduce total cholesterol and LDL in patients with dyslipidaemia without increasing overall healthcare costs.

CRD COMMENTARY - Selection of comparators
The selection of comparators was not explicitly described. This paper did not clearly outline what 'pharmaceutical care' for patients with dyslipidaemia entailed and did not define the process associated with 'normal' medical care. The lack of detail on the comparators limits the interpretation and transferability of the results to other settings.

Note: correspondence with the author indicates that these are fully described elsewhere - see Other Publications of Related Interest below.

Validity of estimate of measure of effectiveness
The randomised study design and the comparability of patients at baseline suggest that the measure of effectiveness has high validity, but the study may not have had sufficient power to detect a difference between the intervention and control group. (No power calculations around sample size related to the larger study, which provided a sub-group for this study).

Validity of estimate of measure of benefit
No overall measure of health benefit was reported but the analysis seemed to indicate that, overall, the intervention group was more effective at the same cost than the control group, suggesting that the intervention is the preferred option.

Validity of estimate of costs
The estimate of charges was based on just one of the VAMC, which meant that it was not possible to carry out comparisons between study sites. The method of statistical analysis for the cost data had some limitations in terms of informing health policy decisions. The majority of cost data will be positively skewed and truncated at zero (negative costs are not possible), which affects the type of statistical analysis that may be used. A number of options for analysis have been suggested: data transformation; standard non-parametric methods; standard parametric methods or non-parametric bootstrapping. The authors log transformed the positively skewed cost data. The main disadvantage with log transformation of cost data and non-parametric statistical tests is that they do not compare the arithmetic mean, which is considered to be the most relevant measure for health policy decisions. The main limitation of this study reported by the authors was that not all patients had pre and post-enrolment lipid profiles, which resulted in a smaller evaluable sample. The authors mention that the charge data were extrapolated from one study site but report that they feel their cost estimates were reasonable because "most health systems do not know their actual costs and these economic modelling techniques are commonly used". This paper compared changes in costs before and after the intervention and the difference, or lack of difference, in cost could be due to external or unobserved factors. It would have been more appropriate to compare directly the costs associated with 12 months of a control group versus an intervention group.

Other issues
This paper reports the only randomised, multi-centre, controlled trial to examine the effect ambulatory care clinical pharmacists can have on patients with dyslipidaemia. However, there are a number of issues that limit the internal and external validity of this economic evaluation. In particular, the study did not report a sensitivity analysis and the robustness of the study's findings could not be assessed. Furthermore, the selection of comparators was not explicitly described. The paper is best read in conjunction with the publications of related interest cited below because these give more detail regarding the design and results of the larger study.
Implications of the study
The authors suggest that ambulatory clinical pharmacists cost the same and are more effective than current practice in terms of reducing total cholesterol and LDL in patients with dyslipidaemia. However, the study does not clearly describe the nature of current practice in the VAMCs in the USA in terms of the process of pharmaceutical care and description of ambulatory care, which affects the generalisability of the study findings to other hospital sites and countries. It is not possible to assess whether the patient sample is representative of the population who may receive the intervention.

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Other publications of related interest


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