Cost effectiveness of nurse led secondary prevention clinics for coronary heart disease in primary care: follow up of a randomised controlled 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
A nurse-led secondary prevention clinic for patients with coronary heart disease (CHD) was examined. The intervention aimed to promote medical and lifestyle components of secondary prevention.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis; cost-utility analysis.

Study population
The study population comprised patients aged younger than 80 years with a working diagnosis of CHD, but without terminal illness or dementia, who were not housebound.

Setting
The setting was primary care. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness data and some resource use data were derived from a study performed between 1994 and 1995 and published in 1998. The costs were estimated using 1998-99 prices.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was performed, in part, prospectively on the same sample of patients as that used in the clinical study.

Study sample
There was limited information on the study sample since details of the design of the study had been published elsewhere (Campbell et al., see Other Publications of Related Interest). Overall, 1,343 patients were enrolled. There were 673 patients in the intervention group and 670 patients in the control group. The mean age of the patients was 66.1 (+/- 8.2) years in the intervention group and 66.3 (+/- 8.2) years in the control group.

Study design
This was a prospective, randomised clinical trial that was carried out at 19 centres in the northeast of Scotland. The unit of randomisation was the patient. The mean length of follow-up was 4.7 years. Data were evaluated at baseline, and 1 and 4 years.

**Analysis of effectiveness**

The analysis of the clinical study was conducted on an intention to treat basis. The outcome measures used were:

- changes in symptoms and risk factors,
- components of care (e.g. aspirin, blood pressure, lipids and exercise),
- quality of life, estimated using the SF-36 questionnaire, and
- the number of deaths.

**Effectiveness results**

Intervention patients generally showed significant improvements in all components of care at 1 year (aspirin, blood pressure, lipids and exercise), except for smoking. At 4 years these improvements were all sustained, except for exercise.

The number of deaths was 100 out of 673 (cumulative death rate 14.5%) in the intervention group and 128 out of 670 (cumulative death rate 19.1%) in the control group, (p=0.038). This improvement in survival remained statistically significant after adjusting for age, gender, general practice and secondary baseline prevention.

**Clinical conclusions**

The effectiveness analysis showed that the intervention improved all dimensions of care and led to fewer deaths over a 4-year timeframe.

**Measure of benefits used in the economic analysis**

The summary benefit measures were survival and quality-adjusted life-years (QALYs). These were discounted using an annual rate of 3.5%. The expected survival was estimated using Kaplan-Meier curves. The QALYs were estimated by combining utility values and survival data derived from the clinical trial. The utility values were directly obtained from the trial using the SF-36 questionnaire.

**Direct costs**

Discounting was relevant, owing to the long timeframe of the analysis, and an annual discount rate of 3.5% was applied. The unit costs and the quantities of resources used were not presented separately. The economic evaluation included costs to primary care and other costs to the National Health Service (NHS). Primary care costs covered running the clinic (nurse visits, materials and training) and increased prescribing (cardiovascular drugs). Other NHS costs covered admissions to NHS hospitals, outpatient attendances and admissions to private hospitals. The capital costs of the clinic were not considered. Only cardiovascular admissions were included in the analysis. The cost/resource boundary of society was adopted. Resource use was derived from trial-based data (missing data were imputed on the basis of average available data) and authors' assumptions. The costs came from Personal Social Services Research Units, the Scottish Drugs Tariff, and NHS hospital sources. Costs were expressed using 1998-99 values.

**Statistical analysis of costs**

A t-test was used to test the statistical significance of differences in the costs.
Indirect Costs
The indirect costs were not considered since most participants were older than working age.

Currency
UK pounds sterling (€).

Sensitivity analysis
Univariate sensitivity analyses were performed to estimate the impact of variations in cost assumptions on the results of the analysis. In particular, drug costs in the control group were reduced to zero for all years (scenario 1), the cost of secondary prevention clinic visits (2 visits in the first year) was doubled (scenario 2), and a combination of these two cost assumptions was considered (scenario 3). A cost-effectiveness acceptability curve was also constructed to determine the probability that the intervention was cost-effective at different levels of willingness of the NHS to pay for an additional QALY.

Estimated benefits used in the economic analysis
The estimated life-years were 4.590 in the intervention group and 4.483 in the control group. The difference was 0.110 (95% confidence interval, CI: 0.012 - 0.210; p=0.028).

The estimated QALYs were 3.175 in the intervention group and 3.051 in the control group. The difference was 0.124 (95% CI: 0.059 - 0.189; p<0.001).

Cost results
The estimated costs of the intervention per patient were 1,015 in the intervention group and 879 in the control group. The cost-difference over the 4-year period was 136 (range: 56 - 216; p<0.001).

Other NHS costs per patient were 2,005 in the intervention group and 2,238 in the control group. The cost-difference over the 4-year period was -233 (range: -766 - 299; p=0.390).

Synthesis of costs and benefits
Incremental cost-effectiveness and cost-utility ratios were calculated to combine the costs (to primary care) and benefits of the intervention relative to the comparator. The incremental cost per life-year saved with the intervention was 1,236 (95% CI: 268 - 17,983). The incremental cost per QALY saved was 1,097 (95% CI: 298 - 3,633).

In scenario 1, the cost-difference increased to around 1,000 per patient, with an incremental cost per QALY saved of around 9,000.

In scenario 2, the cost-difference increased by around 30%, with a proportional effect on the cost per QALY.

In scenario 3, the incremental cost per QALY was just over 9,000.

The cost-effectiveness acceptability curve showed that there was a 70% probability that the intervention was cost-effective if the NHS was willing to pay 5,000 for an additional QALY.

Authors' conclusions
Nurse-led clinics for the secondary prevention of coronary heart disease (CHD) in primary care were cost-effective in comparison with the threshold of 30,000 per QALY perceived by the National Institute for Clinical Excellence.

CRD COMMENTARY - Selection of comparators
The selection of the comparator was clear since it represented usual care at the authors' setting. You should decide whether this is a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness evidence came from a clinical trial, which was appropriate for the study question. The sample size was reported, but there were limited details of the design and characteristics of the study participants since the study had already been published. The long follow-up period and the use of intention to treat enhance the internal validity of the analysis of the clinical study. However, it was difficult to assess the robustness of the study, although the authors stressed that their evaluation was based on a well-conducted clinical trial.

**Validity of estimate of measure of benefit**
Survival and QALYs were used as the summary benefit measures. This was appropriate since they capture the impact of the intervention on life expectancy and quality of life, which are relevant aspects of care in the case of patients with established CHD. Discounting was applied, as recommended in recent UK guidelines. Both measures are comparable with the benefits of other health care interventions.

**Validity of estimate of costs**
The economic analysis was carried out from the broadest perspective, that of society. All relevant public and private costs were considered. The indirect costs were not included because their impact on the analysis was considered negligible, owing to the age of the study participants. However, the costs borne by patients (such as formal and informal caregivers) were not considered, which could have been relevant from the societal perspective. A detailed breakdown of the cost items was not provided and there was no information on the unit costs and resource use. Only the total costs were presented. This reduces the possibility of replicating the study. The costs came from typical NHS sources. Assumptions were made to estimate some resource use data. The costs were specific to the study setting and only few variations were investigated in the sensitivity analysis. The price year was reported, which will facilitate reflation exercises in other settings.

**Other issues**
The authors compared their findings with those from published studies that gave similar results, although some methodological differences were pointed out. The issue of the generalisability of the study results to other settings was not explicitly addressed, and limited sensitivity analyses were carried out. This reduces the external validity of the analysis. The authors noted some limitations to the validity of their study. For example, some data were incomplete and a substantial proportion of patients did not attend clinic visits, especially in the control group. The benefits of the intervention were not clearly defined, as other factors could have affected the results of the analysis. In particular, the uptake for some secondary preventive drugs was lower than recommended national standards. Further, newly recommended interventions, including smoking cessation therapies, could have improved secondary prevention.

**Implications of the study**
The study results supported the use of nurse-led clinics for the secondary prevention of CHD, which led to improvements in quality-adjusted survival at a low cost in comparison with usual care in the UK.

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Other publications of related interest


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