What to consider when conducting a cost-effectiveness analysis in a clinical setting


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
Use of lipid-lowering medications plus diet therapy in the treatment of patients with hypercholesterolaemia (>5.2 mmol/L) and the prevention of coronary heart disease. The intervention (an 8-week, home-based programme) was designed to lower the dietary saturated fat and cholesterol intake of patients with hypercholesterolaemia based on implementing the National Cholesterol Education Program step 1 diet. This involved using a videotape presentation, workbook, shopping guide, poster, cookbook, and a toll-free telephone number for a Rural Lipid Resource Center (RLRC) nutritionist. An optional step 2 programme consisting of written materials and a telephone consultation with the RLRC nutritionist was available at the physician's request. Usual care included referral to a local nutritionist and/or distribution of the American Heart Association pamphlets explaining the step 1 and 2 diets, and was delivered by the care providers (i.e. physicians, physician assistants, or nurse practitioners).

Type of intervention
Prevention and treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with hypercholesterolaemia (>5.2 mmol/L).

Setting
Primary care, secondary care, and the community. The economic study was carried out in the USA.

Dates to which data relate
The dates of the collection of effectiveness and resource use data were not explicitly specified. Some of the price data were from 1989 and 1992, but the final price year adopted in the study was not explicitly specified.

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

Link between effectiveness and cost data
Costing was prospectively performed on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. The study sample consisted of 13 patients receiving medication+diet and 12 patients receiving diet only (control group). 3 out of 16 patients who received medication+diet
refused to participate. The patients for this pilot study were selected from a larger study in which 16 clinics were randomly assigned to either the usual care programme or the Rural Lipid Resource Center intervention programme (a Physician Assist Model). The original 9 month evaluation was completed by 304 participants and the follow-up evaluation was completed by 153 patients, of whom only 16 either had been or were currently on lipid-lowering medications (7 from the intervention group and 9 from the usual care group). From the 12 matched patients in the control group, 8 were from the usual care subjects and 4 were from the intervention patients. 4 patients in each group completed the RLRC step 1 intervention programme.

**Study design**
This was a case-control pilot study of a subset of patients from a randomised, controlled study, carried out in 16 centres. The mean (SD) duration of follow-up was 19 (4) months after the original 9-month programme. A total of 151 patients who did not complete the 19-month follow-up, could be considered lost to follow-up from the original study. The unit of randomisation in the original study was the clinic.

**Analysis of effectiveness**
The principle used in the analysis of effectiveness was treatment completers only. The clinical outcome measures were the step 1 criteria including the consumption of 30% or less of energy from total fat, 8% to 10% of energy from saturated fat, and less than 300 mg cholesterol per day. The study participants underwent three evaluations, namely at baseline, 9 months, and 19 months (follow-up) after the end of the intervention. Patients in the control group were chosen based on a match with the medication+diet group in terms of age, gender, and clinic location.

**Effectiveness results**
The two pilot study groups were not significantly different in terms of dietary intake at baseline. However, all of the step 1 criteria were met by the medication+diet group but were not all met by the diet alone group. Mean (SD) cholesterol level per day was 176 (110) mg for the medication+diet group versus 195 (88) mg for the diet alone group. Energy from saturated fat was 9% (3%) versus 11% (3%) and energy from total fat was 29% (7%) versus 33% (8%).

At 9 months, the medication+diet group had 9% (3%) energy from saturated fat versus 12% (3%) for the diet alone group, (statistically significant). The corresponding values in terms of energy from total fat were 28% (6%) versus 31% (5%), (NS). The corresponding values in terms of cholesterol level per day were 196 (117) mg versus 184 (90) mg, (NS). At follow-up (19 (4) months), the medication+diet group had 9% (4%) energy from saturated fat versus 11% (3%) in the diet alone group; energy from total fat was 26% (9%) versus 32% (7%), and cholesterol level per day was 156 (105) mg versus 241 (142) mg.

**Clinical conclusions**
Although the medication+diet group continued to improve their diet between 9 months and follow-up, the diet alone group did not.

**Measure of benefits used in the economic analysis**
Changes in blood lipid concentration in terms of total cholesterol and low-density lipoprotein cholesterol (LDL-C) level were the measures of benefit.

**Direct costs**
Costs were not discounted despite a 19 (4) months follow-up period (and some of the costs materialising in this period). Quantities were not systematically reported separately from the costs. Cost items were reported separately. The cost analysis covered the costs of office visits, laboratory tests for lipid profiles and total cholesterol, secondary-cause laboratory tests, lipid-lowering medications, drug follow-up laboratory tests, RLRC step 1 intervention, RLRC step 2 intervention, RLRC lipid specialist, changes in diet, and travelling. The perspective adopted in the cost analysis was that of the patient and the health care administrator. The main sources of data for resource use components were a chart
audit and a cost questionnaire collected at 9 months and follow-up. The average food costs were estimated based on three 24-hour diet recalls collected at baseline, 3 months, 9 months, and follow-up. The source of cost data for food was data available in Nutritionist IV. The price date (used for direct costs) was not specified, except for food costs, which were for 1992.

**Statistical analysis of costs**
The differences in median costs (direct, indirect, and total) between the groups were compared using the Wilcoxon rank sum test.

**Indirect Costs**
Indirect costs were not discounted despite a 19 month follow-up period (and some of the cost elements materialising in this period). Quantities were not systematically reported separately from the costs. Cost items, in terms of average hourly rate in the USA for non-agricultural workers, were reported separately. The cost analysis covered the costs of time away from work: time lost due to visits to dietician, lipid or heart specialist, and/or primary care provider, extra time spent shopping for food, and time away from work due to drug side effects. The perspective adopted in the indirect cost analysis was that of the patient. 1989 price data were used.

**Currency**
US dollars ($).

**Sensitivity analysis**
An implicit sensitivity analysis was performed on the impact on the cost-effectiveness ratio of compliance with a step 2 diet in the diet alone group.

**Estimated benefits used in the economic analysis**
The median decrease in total cholesterol at 9 months relative to baseline was 0.26 mmol/L (10 mg/dL) in the medication+diet group compared to 25 mmol/L (9.5 mg/dL) in the diet alone group. The median decrease in total cholesterol at follow-up (19 months) relative to 9 months was 0.57 mmol/L (22 mg/dL) in the medication+diet group compared to a median increase of 0.15 mmol/L (6 mg/dL) in the diet alone group. The median decrease in LDL-C at 9 months relative to baseline was 0.10 mmol/L (4 mg/dL) in the medication+diet group versus 18 mmol/L (7 mg/dL) in the diet alone group. The median decrease in LDL-C at follow-up relative to 9 months was 0.81 mmol/L (31 mg/dL) in the medication+diet group versus a median decrease of 0.25 mmol/L (9.5 mg/dL) in the diet alone group. The differences at any evaluation were not significant.

**Cost results**
The median total cost at 9 months was $439.13 (maximum-minimum: $2,985.57 to -$105.5) in the medication+diet group versus $185.45 ($2,001.98 to -$320.07) in the diet alone group. The corresponding values at follow-up were $956.54 ($13,442.6 to -$534.37) and $449.95 ($1,107.39 to -$728.55). Negative values reflect a decrease in diet cost as a component of indirect cost and total cost of care. The differences between the groups in terms of direct costs were reported to be significant in both evaluations.

**Synthesis of costs and benefits**
Costs per unit change in total cholesterol level and LDL-C level were calculated as the measures of cost effectiveness. At 9 months, the diet alone group had $24 ($43.91 versus $19.52) less cost per unit change in total cholesterol level, and $83 ($109.78 versus $26.49) less cost per unit change in LDL-C level, compared to the medication+diet group. However, at 19 months the medication+diet group had $17 ($30.86 versus $47.36) less cost per unit change in LDL-C compared to the diet alone group. The implicit sensitivity analysis showed that the diet alone strategy could remain a cost-effective option over the long-term in the case of adherence to step 2 diet.
Authors' conclusions
At 9 months, diet therapy alone was more cost-effective than medication+diet, while medication+diet was more cost-effective over the long-term (19 months after intervention).

CRD COMMENTARY - Selection of comparators
No explicit justification was given for the choice of the comparator (diet alone), but it appears to have represented the standard practice in the context in question in the study institution. You, as a database user, should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of benefit
The internal validity of the estimates of measures of benefit cannot be guaranteed due to the small sample size.

Validity of estimate of costs
Quantities were not systematically reported separately from the costs although some items were reported in this manner. Adequate details of the methods of cost estimation were given. The study lacked a specific price year. Cost results may not be generalisable to other settings. The costs of travelling and change in diet were included here as direct costs, contrary to the authors' classification, as they are irrelevant to the costs of lost productivity.

Other issues
In the interpretation of the cost-effectiveness results, caution should be exercised because of the small sample size, the fact that the analysis was based on treatment completers only, and the lack of a comprehensive sensitivity analysis. However, the authors pointed out that the study was intended as a pilot which could inform future economic evaluations in this field. The issue of generalisability to other settings or countries was not addressed although appropriate comparisons were made with other studies (which were reported to be few in number).

Implications of the study
The authors point out that the following elements should be considered when conducting a cost-effectiveness analysis of medical nutrition therapy: the effectiveness of the nutrition intervention, adequate sample size, confounding variables, compliance with diet and drug therapy, direct and indirect costs of care, and follow-up evaluation.

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