A randomized trial of the efficacy of multidisciplinary care in heart failure outpatients at high risk of hospital readmission

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 6-month multidisciplinary outpatient management programme for patients with chronic heart failure (CHF) was examined. The team comprised a telephone nurse coordinator, a CHF nurse, a CHF cardiologist and the patient's primary physician. The telephone nurse contacted the patients within 72 hours after hospital discharge, then weekly for a month, twice in the second month and monthly thereafter. The patients had at least monthly follow-up visits with the CHF nurses. Close interaction with the primary care physicians was also carried out. The treatment plan included a 2-g sodium-restricted diet, and a recommendation to exercise by walking for 20 minutes for at least 4 days per week. The treatment plan was individualised and updated throughout the course of the study.

Type of intervention
Multidisciplinary care service.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with a primary diagnosis of New York Heart Association (NYHA) functional class III/IV CHF and at a high risk of readmission. High risk of readmission was defined as an age of greater than 70 years, a left ventricular ejection fraction (LVEF) of less than 35%, at least one additional CHF hospital admission in the previous year, ischaemic cardiomyopathy, peripheral oedema at hospital discharge, a weight loss of less than 3 kg while in the hospital, and peripheral vascular disease or haemodynamic findings of pulmonary capillary wedge pressure greater than 25 mmHg. Patients were excluded on the basis of valvular heart disease requiring surgical correction, active substance abuse, peripartum cardiomyopathy, hypertrophic cardiomyopathy with left ventricular outflow tract obstruction, restrictive cardiomyopathy, constrictive pericarditis, psychiatric disease or dementia likely to limit compliance, and other clinical conditions. A further exclusion criterion was residence in a nursing home or rehabilitation facility.

Setting
The setting was a hospital. The economic study was carried out at the Johns Hopkins Hospital and the Johns Hopkins Bayview Medical Center in Baltimore (MD), USA.

Dates to which data relate
The effectiveness and resource use data were gathered from December 1996 until December 1998. The price year was 1998.

Source of effectiveness data
The effectiveness data were derived from a single study.
Link between effectiveness and cost data
The costing was carried out prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Primary power calculations were performed in the preliminary phase of the study. These indicated that the sample size should be 100 patients in each study group, on the basis of an alpha-value of 0.05 and a power of 80% for an alternative hypothesis of a 35% relative reduction in the primary outcome measure. The study included English-speaking eligible patients admitted at the study hospitals between December 1996 and December 1998. A total of 1,252 patients were found to be ineligible, mainly due to lack of high-risk condition or NYHA functional class III/IV CHF. In particular, 11.9% of the patients refused to participate and 2.3% were excluded because their primary physicians declined to participate. A sample of 200 patients was enrolled in the study. There were 102 individuals in the intervention group and 98 in the control group. The mean age in the intervention group was 60.2 (+/- 13.8) years (range: 25 - 87), 64.7% were men, and 63.7% were white. The mean age in the control group was 63.7 (+/- 15) years (range: 26 - 88), 56.1% were men, and 64.3% were white. No patient was excluded from the initial sample. It should be noted that after inclusion in the study, patients in the final sample were no longer in NYHA functional class III/IV.

Study design
This was a prospective, randomised controlled trial, carried out in two centres, the Johns Hopkins Hospital and the Johns Hopkins Bayview Medical Center in Baltimore. The randomisation was performed by a coordinating centre using an automated telephone response system and random number schedules. The randomisation was stratified by site and by the presence of left ventricular systolic dysfunction, such as LVEF less than 45%. The patients were followed for 6 months and were assessed at baseline and at the end of the study. No patients were lost to follow-up. Assessors in the coordinating centre were blinded to the treatment assignment.

Analysis of effectiveness
The basis for the analysis of the clinical study was intention to treat. The primary health outcome was the composite of death from any causes and the total number of CHF hospital admissions. The secondary health outcomes were patient-assessed CHF symptoms, presence of ankle oedema, reaching goal weight, diet compliance, use of medications, quality-of-life scores and activity status. Quality-of-life scores were measured using the Minnesota Living with Heart Failure Questionnaire, which ranged from zero (best score) to 105 (worst score). The activity status was assessed using the Duke Activity Status Index, which ranged from 12 (best score) to zero (worst score). The study groups were shown to be comparable at baseline.

Effectiveness results
There were 7 deaths (6.9%) in the intervention group and 13 deaths (13.4%) in the control group.

There were 43 hospital admissions for CHF among 26 patients in the intervention group, and 59 hospital admissions for CHF among 35 patients in the control group. These differences did not reach statistical significance.

For the secondary outcomes, only the following differences reached statistical significance:

12% of patients in the intervention group reported a worsening of their symptoms, compared with 35% in the control group;

the presence of ankle oedema was 20% in the intervention group and 41% in the control group;

50% of the patients in the intervention group reached their goal weight, compared with 20% of those in the control group;

diet compliance was poor in 27% of the patients in the intervention group and 52% of those in the control group;
the mean value of the total score on the Minnesota Living with Heart Failure Questionnaire at the final visit was 35.7 (median 33; 25th and 75th percentile: 14 - 52) in the intervention group and 45.3 (median 51; 25th and 75th percentile: 22 - 64) in the control group;

the mean change from baseline was -28.3 (median -28) in the intervention group and -15.7 (median -15) in the control group;

in terms of the Duke activity status, the mean value of the total score at the final visit was 6.8 (median 6; 25th and 75th percentile: 5 - 9) in the intervention group and 6.0 (median 6; 25th and 75th percentile: 4 - 8) in the control group, (p=0.5).

No difference was found in the mean change from baseline.

The authors also stated that statistical analyses showed that only diabetes and an ischaemic cause of CHF independently predicted readmissions for CHF or death.

Clinical conclusions
The effectiveness analysis showed that, compared with the non intervention group, there were statistically significant improvements in quality-of-life scores and diet compliance in the intervention group. There was also a non statistically significant trend towards a benefit in terms of a reduction in deaths and hospital admissions in the intervention group.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used. A cost-consequences analysis was therefore conducted.

Direct costs
Discounting was not performed, or necessary, as the time horizon of the study was 6 months. The unit costs and quantities of resources were not reported. The health services included in the cost analysis were personnel, supplies, outpatient pharmacy and hospital stay. The cost/resource boundary adopted in the analysis appears to have been that of the hospital. The wages were derived from published studies and reflected the actual time spent with patients. The pharmacy costs were derived from actual wholesale prices. The supplies included medications, diet programme, transportation to the clinic, pill sorters and telephones. The inpatient costs were obtained by applying state-regulatory cost-to-charge ratios and annual inflation factors to actual charges. The quantities of resources used were derived from the trial and were collected between December 1996 and December 1998. The price year was 1998.

Statistical analysis of costs
Standard statistical analyses of the total costs were performed to test the significance of the results.

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

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analyses were conducted.
Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The intervention programme costs (personnel and supplies) were $908.

The outpatient pharmacy costs were $1,353 in the intervention group and $1,405 in the control group.

The inpatient costs were $11,315 in the intervention group and $8,789 in the control group, but the difference was not statistically significant.

There was no statistically significant difference in inpatient and outpatient resource use between the study groups.

Admissions in the intervention group were fewer, but more expensive than in the control group.

Synthesis of costs and benefits
Not relevant as a cost-consequences analysis was conducted.

Authors' conclusions
The multidisciplinary approach to the management of high-risk patients with chronic heart failure (CHF) improved quality of life and showed a trend towards an improvement in death and readmission rates at a cost similar to that observed with the standard care practice.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. Standard management of CHF patients was selected as it represented the routine management method for the condition in question. You should decide whether it represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness estimates were derived from a randomised controlled trial, which was appropriate for the study question. Details of the randomisation process were reported and power calculation were performed in the planning phase of the study. These factors enhanced the internal validity of the analysis. The study groups were shown to be comparable at baseline and no loss to follow-up was reported. The authors stated that, since they had specifically targeted patients at risk of readmission, their findings may not be generalisable to the whole population of patients with CHF. Further, not all patients with CHF may require such an extensive intervention. A further limitation was that since some secondary outcomes were assessed in an unblinded fashion while other outcomes were not, this may have created some bias in the results of the analysis. Finally, physicians caring for patients in the control group knew that their patients were enrolled in the trial and received expert's recommendations, thus their behaviour may not truly reflect usual care.

Validity of estimate of measure of benefit
No summary benefit measure was estimated due to the cost-consequences design. It is worth noting that quality-of-life scores were assessed in the analysis. Therefore, the use of quality-adjusted life-years as a summary benefit measure would have been an interesting addition to the study findings.

Validity of estimate of costs
Although not explicitly stated, the analysis of the costs appears to have been carried out from the perspective of the hospital. All the relevant categories of costs seem to have been included in the analysis. Standard statistical analyses of
the costs were performed and the price year was appropriately reported. Cost-to-charge ratios were used to reflect true costs in the economic evaluation. The source of the cost data was reported. The unit costs and the quantities of resources were not reported separately. The authors acknowledged that the study was not powered to detect statistically significant differences in the costs.

**Other issues**
The authors made several comparisons of their findings with those from other studies. The issue of the generalisability of the study results was not addressed and sensitivity analyses were not performed. Consequently, the external validity of the analysis was fairly low. A sample of selected patients with CHF was enrolled in the study and this was reflected in the conclusions. The authors presented the study results in detail and reported some of the limitations of their study.

**Implications of the study**
The authors suggest that future studies should assess which patient subgroups may benefit from the multidisciplinary care approach. Further research should focus on psychological and behavioural characteristics that may predict the need for specific intervention strategies.

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