Pharmacist intervention to improve medication adherence in heart failure: a randomized trial


Record Status
This is an economic evaluation that meets the criteria for inclusion on NHS EED.

CRD summary
The study undertook a cost-consequence analysis of an intervention to improve medication adherence in low-income and medically vulnerable heart failure patients. The authors concluded that their pharmacy based intervention was effective in increasing adherence and reducing health care usage, but that the intervention should continue beyond nine months. The study was well reported and used appropriate methods. The study had limited evaluation of uncertainty, but the conclusions reached appear appropriate.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The study evaluated the costs and outcomes of an intervention to improve medication adherence in low-income and medically vulnerable heart failure patients.

Interventions
A complex pharmacist-centred intervention designed to improve patient medication adherence was compared against usual care. The intervention pharmacist assessed patient knowledge, provided plain language instructions for medication adherence, and used a system of icons to represent medication classes. The intervention pharmacist also had access to patient information from a study database. The intervention pharmacist received special training related to managing heart failure, treating older patients, communication techniques, and the pharmacotherapy of the cardiovascular drugs for heart failure. The pharmacist intervention was conducted for nine months, but follow-up continued to 12 months.

Usual care patients were served by a rotation of other pharmacists at the study pharmacy; these pharmacists did not have special training or access to the study database.

Location/setting
United States/Secondary Care

Methods
Analytical approach:
The study was based on a single clinical study. The follow-up time was 12 months. The study perspective was not explicitly stated, but it appears to have been conducted from a 3rd party payer perspective.

Effectiveness data:
The effectiveness data were derived from a randomised controlled trial. 314 patients were randomised by computer. The trial was conducted from February 2001 to June 2004. Each group was estimated to need 100 patients to achieve sufficient study power with alpha levels of 0.05 calculated for medication adherence and acute exacerbations.

The primary outcomes were medication adherence measured by overall adherence and drug specific adherence, and clinical exacerbations that required visits to the emergency department or hospitalisation. The authors referred to 'taking adherence'. Taking adherence referred to the percentage of prescribed medication that was taken. Scheduling adherence measured the consistency of dosing over time. Refill adherence was measured using a medical records database. Exacerbations were monitored through the same medical records database and reported as a risk ratio. To monitor taking adherence, and scheduling adherence medication containers were equipped with Medication Event Monitoring System (MEMS, AARDEX Ltd., Sweden) devices which tracked when pill bottles were opened and closed on a digital
chip in the lid. Overall taking and scheduling adherence were calculated with multiple imputation modelling to account for missing adherence data.

Other measured outcomes included disease-specific quality of life measured by the Chronic Heart Failure Questionnaire, and patient satisfaction with pharmacy services as measured by an internally developed and validated 12-item questionnaire. Drug-related adverse events were also monitored.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
As this was a cost-consequence analysis, multiple measures of benefit correspond directly to the outcome measures: adherence, disease-specific quality of life, and patient satisfaction.

Cost data:
Costs included fixed and variable costs. Fixed costs consisted of pharmacist training, material development, programming, and equipment. Variable costs consisted of pharmacist time delivering the intervention, physician time communicating with the pharmacist, and written materials. Pharmacist time with the patients was measured by direct observation by non-pharmacists at random 3 to 4 hour intervals.

Analysis of uncertainty:
Between group comparisons were made to measure statistically significant differences. T-tests or the 2-sample Wilcoxon test were used for continuous variables, and Χ² tests were used for categorical variables. Sensitivity analyses were undertaken with different assumptions made for patients with missing data.

Results
During the 9-month intervention period, overall taking adherence in the usual care group was 67.9% while 78.8% of intervention patients adhered, a 10.9% difference (95% CI 5 to 16.7%). The advantage dissipated in the 3 month post intervention period, as the difference narrowed to 3.9% (95% CI -5.9 to 6.7%). Overall scheduling adherence for usual care patients was 47.2% during the 9 month intervention, and 53.1% in the intervention group (difference=5.9%, 95% CI 0.4 to 11.5%). Advantages dissipated in the 3 month post intervention period, as differences became statistically insignificant. Refill adherence was statistically significantly better in the intervention group for all drug categories except angiotensin-converting enzyme inhibitors. Differences in self-reported adherence and adverse events were small and not statistically significant (p-value= 0.48).

There were 19.4% fewer exacerbations in the intervention group, with an incidence risk ratio of 0.82 (95% CI 0.7 to 0.95). Disease specific quality of life was greater in the intervention group, but the difference was not statistically significant at 6 months or 12 months (p-value= 0.52 at 6 months, 0.21 at 12 months). Patient satisfaction was statistically significantly higher in the intervention group (1.0 vs 0.7, p-value= 0.022). Costs for the intervention group tended to be less than the usual care group across all categories, but no differences reached statistical significance.

Authors' conclusions
The authors concluded that their pharmacy based intervention was effective in increasing adherence and reduced health care usage, but that the intervention should be continued beyond nine months.

CRD commentary
Interventions:
The interventions were well described and appear appropriate.

Effectiveness/benefits:
Definitions of effectiveness measures, inclusion and exclusion criteria, and analytical methods were well reported. Inclusion and exclusion criteria were explicitly reported. There were some differences in baseline characteristics between the two groups, and stratified randomisation may have alleviated some of these differences. As acknowledged by the authors there was some risk of unblinding of patients due to the shared pharmacy facility. Appropriate methods were used to impute missing data values, but the proportion of missing data was not reported.
Costs:
Costs appear to have been measured appropriately, as they were conducted alongside the trial with costs derived from the participating institution. It is unclear whether these costs would be transferable to another setting, as costs were reported in general categories of resource usage rather than specific items.

Analysis and results:
Results were thoroughly and clearly reported, with appropriate analytical methods. There was considerable uncertainty in the cost results but the analytical methods used did not allow further exploration.

The authors thoroughly discussed similar work, compared their findings, and appropriately acknowledged study limitations. As the authors acknowledged, the study only had one pharmacist delivering the intervention, the patient population was largely indigent, and patients who use other adherence aids such as pill boxes were excluded from the study. As the authors acknowledge, these factors may limit the generalisability of the study. The thorough reporting of other studies and their similar findings appears to lend some validity to the study results.

Concluding remarks:
The study was well reported and used appropriate methods. The study had limited evaluation of uncertainty, but the conclusions reached appear appropriate.

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