Outcomes of a randomized controlled trial of a clinical pharmacy intervention in 52 nursing homes


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
An intervention designed to improve the quality of medication care in nursing home residents was considered in this study. It was based on a year long clinical pharmacy programme involving the development of professional relationships, nurse education on medical issues, and individualised medication reviews aimed at changing the drug use, mortality and morbidity in nursing home residents.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised all elderly residents of long-term care facilities.

Setting
The setting was nursing homes. The economic study was carried out in Australia.

Dates to which data relate
The dates during which effectiveness and resource use data were collected were not reported. The price year was not reported.

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

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were performed in the planning phase in order to assure a certain power to the study within the limited financial budget available for the analysis. The nursing home eligibility criteria were:

- at least 20 residents;
- within three hours’ drive from the study centre in Brisbane;
receiving a supply of drugs under the Australian government medication subsidy scheme;

informed consent by each home's management to participate in the study;

a record of hospitalisations, adverse events, and deaths.

Overall 3,230 residents participated in the study. Fifty-two nursing homes were enrolled from 116 invited homes (randomly selected from 134 eligible homes). A sample of 1,328 cross-sectional medication profiles was collected for 8 nursing home clusters (a total of 32 homes) in order to validate prescription claims data.

Study design
The study was a randomised controlled trial carried out in 52 nursing homes in Queensland and New South Wales. The 52 nursing homes participating in the study were matched on the basis of resident age, bed numbers and Resident Classification Instrument (RCI) into groups of 4 homes, yielding 13 clusters. A randomisation ratio of 1 (intervention) to 3 (control) was used. One home from each cluster was drawn from a hat and independently assigned to the intervention group (13 homes, 905 residents) and the remaining three homes to a control group (39 homes, 2,325 residents). Residents were followed for 12 months. All enrolled nursing homes completed the trial. Of the original 3,230 residents, 2,261 (70%) remained in the study nursing homes. Loss to follow-up was due to deaths or transfer to other homes.

Analysis of effectiveness
The basis for the analysis of the clinical study (intention to treat or treatment completers only) was not stated, but it seems that only treatment completers were considered.

The primary health outcomes assessed through nursing home records were:

mortality rates and number of hospitalisations in the 12 months preceding the beginning of the study;

number of residents who experienced adverse events in the 3 months prior to data collection;

a composite RCI score;

and resident survival from the start of intervention.

Survival curves were based on the Kaplan-Meier method. Survival hazard ratios were computed using Cox’s proportional hazard models in order to compare survival in both intervention and control groups. Drug use and prescription claims for 1 year prior to and during the trial were analysed for the overall sample and for a cohort of 1,692 individual residents in study nursing homes for whom such records existed. These data were obtained from a government database. Several statistical tests were used to compare the groups.

Effectiveness results
No statistically significant changes were observed in annual mortality rates, frequency of hospitalisations, number of residents with adverse events or changes in the RCI score between the groups. Cumulative survival in the intervention group was higher than for the controls with a hazard ratio of 0.85 (95% CI: 0.75 - 0.96, p<0.009), indicating that residents in the intervention groups were 15% more likely to survive longer than those in the control group. However, this results was not significant when the clustering effect was accounted for in the analysis, (p=0.13).

The baseline drug use was similar in both groups. However, in the trial period there was a decrease in the cumulative drug use in the intervention nursing home compared with control groups, which just failed to reach significance, (p=0.073). As earlier, when the clustering effect was not accounted for in the analysis, a drug use reduction of 14.8% was found in the intervention group compared to the control groups and the difference was statistically significant, (p<0.0005). Significant reductions in medication use were also apparent for some drug categories. On average, the intervention resulted in an overall shift in the drug use by one less drug per person.
Clinical conclusions
The intervention, designed to improve the quality of medication care in nursing home residents, was shown to lead to a reduction in drug use without adversely affecting survival or morbidity indices.

Measure of benefits used in the economic analysis
Health outcomes were not summarised into a single benefit measure, and, as such, a cost-consequences analysis was performed.

Direct costs
Discounting was not relevant because the costs were incurred over a period of time of less than two years. Costs and quantities were not reported separately and the boundary adopted seemed to be that of the nursing homes. The estimation of quantities and costs was derived from actual data based on prescription claims data. Neither the dates when quantities were measured, nor the price year were reported.

Statistical analysis of costs
No statistical analysis was carried out.

Indirect Costs
Indirect costs were not included.

Currency
Australian dollars (Aus$).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
Please refer to the effectiveness results reported earlier.

Cost results
The authors reported only the total costs of delivering the interventions. A net cost saving of Aus$16 per resident per year was estimated, subtracting the cost of delivering the interventions (about Aus$48 per resident per year) from the drug cost differences between the two groups (Aus$64 per resident per year based on the prescription claims data). The project net saving for a nursing home population of 74,236 in Australia was approximately Aus$1.2 million per year (approximately 0.47 million).

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
The authors concluded that the cost-effectiveness of applying this intervention to reduce drug use is apparent, given that the intervention leads to cost saving without adversely affecting the clinical outcomes of residents.
CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator was clear: the adoption of the intervention to improve the quality of medication care was compared with the routine management of nursing home where no specific prescribing programme was in use.

Validity of estimate of measure of effectiveness
The internal validity of the study is likely to have been enhanced by the randomisation process. However, adequate statistical analyses were not performed to compare the intervention and control groups. Therefore potential biases and confounding factors could affect the analysis results. Another limitation, the authors noted, may have been the low overall enrolment rate. A consequence of this may be that the results may only be applicable to nursing homes that were willing to participate in the study. Outcome measures seem to have been appropriate in order to reflect mortality and morbidity. However, their value in terms of quality of life or by the preferences of individuals is debatable, thus making comparison with other technologies difficult.

Validity of estimate of measure of benefit
Outcome measures were left disaggregated as several measures, which have been commented on above.

Validity of estimate of costs
The economic analysis of the study was not satisfactorily presented. For example, the perspective adopted in the study was not stated, costs and quantities were not reported separately, and it was not clear which costs exactly were included. In addition no statistical analyses of resources were performed.

Other issues
Although the authors made some comparisons with the findings of other studies, the results of the analysis are likely to be valid only within the study context. In fact, the issue of the generalisability to other setting was not addressed and no sensitivity analysis was conducted.

Implications of the study
The authors highlight the fact that an analysis with a longer time horizon could show even greater cost savings, given that curves of both drug use and survival rate in the two groups exhibit a constantly diverging trend over time in favour of the intervention group. As time goes by the differential between the survival rate curve of the two groups increases and the same occurs for the drug use curve, meaning that more extra years and more extra cost savings are gained in the intervention group, compared to the control groups. In addition, costs savings could be greater in other countries, because in Australia drugs are generally purchased at very low prices compared, for example, to the UK and USA.

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