Clinical medication review by a pharmacist of elderly people living in care homes: randomised controlled trial

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
The health technology studied was a clinical medication review (CMR) performed by a pharmacist for residents of elderly care homes. A CMR comprised a review of the general practitioner's (GP) clinical record and a consultation with the patient and carer. The pharmacist then formulated recommendations which could be accepted and implemented by the GP.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The eligible study population comprised all care homes (nursing, residential and mixed) in the Leeds area with 6 residents or more, aged 65 years or older and taking 1 or more medicines. Patients were excluded if they were involved in another clinical trial, were terminally ill (life expectancy under 1 month), or were already receiving a CMR by a pharmacist, or were excluded at their GP’s request. Participants with dementia were included in the eligible population.

Setting
The setting was nursing, residential and mixed care homes around Leeds, West Yorkshire. The economic study was carried out in the UK.

Dates to which data relate
The study began on 16 April 2002 and randomisation was curtailed on 30 June 2003. The patients were followed for 6 months (+/- 3 weeks) from randomisation. The price year was unclear but it appears to have been 2003.

Link between effectiveness and cost data
The costing was undertaken on the same sample of patients as that used in the effectiveness study. The data were gathered prospectively.

Study sample
A sample size of 1,600 was calculated to have a 90% power at the 5% significance level to detect differences of 1/6 standard deviation (SD) in measures of cognitive and physical functioning. A total of 2,779 patients were approached. Consent was obtained from 1,163 patients. Baseline data for 661 patients were obtained, and only these patients were randomised; the remaining 502 were not randomised because insufficient data were available at the cut-off date. In the end, 331 patients were allocated to the intervention group and 330 to the control group. Of the intervention group, 315
received the intervention, 15 died, 5 were in hospital and 1 record was lost.

**Study design**

The study was a randomised, controlled, multi-centre clinical trial involving 65 homes (13 nursing, 38 residential and 14 mixed). After collection of the baseline data, patients were randomised in randomly sized blocks of 2 to 8 patients using a computer algorithm. The assessor of cognitive and physical functioning was blinded to the randomisation. After 6 months, complete follow-up data were available for 277 patients in the intervention group and for 278 patients in the control group. In the CMR group, 51 patients had died and 3 were lost to follow-up. In the usual care group, 48 patients had died and 4 were lost to follow-up.

**Analysis of effectiveness**

Baseline values were presented but no statistical analysis of differences was reported. The groups appear to have been comparable. The primary outcome measure was the number of changes of medication per patient. The primary analysis was performed using a model which accounted for the effect of the nursing home as a random effect. The secondary outcomes were:

- the number of repeat medicines per patient;
- recorded medication reviews in the study period;
- falls;
- mortality;
- the number of hospital admissions;
- the number of GP consultations; and
- cognitive and physical functioning as measured by the Standardised Mini-Mental State Examination (SMMSE) and the Barthel Activities of Daily Living Index.

An intention to treat analysis was performed.

**Effectiveness results**

The number of medication changes was significantly greater for the intervention group compared with the control group, mean 3.1 (SD=2.7) per patient versus mean 2.4 (SD=2.6) per patient. The difference was 1.34 (relative risk 95% confidence interval, CI: 1.21 to 1.48; p<0.0001).

There was no significant difference in the number of medicines.

There was a significant difference in the number of falls between the two groups, mean 0.8 (SD=1.7) falls per patient in the intervention group versus mean 1.3 (SD=3.1) falls per patient in the control group. The difference was 0.59 (relative risk 95% CI: 0.49 to 0.70; p<0.0001).

There were no significant differences in the rate of hospitalisation, mortality, Barthel scores, SMMSE scores or GP consultation rate.

**Clinical conclusions**

The authors concluded that the higher medication change rate in the intervention group was the result of the CMR. The substantial and significant reduction in falls was considered important, and the authors believed that a possible link to a trend seen in the study for reduction in hospitalisations requires further investigation. The intervention showed no effect on overall mental and physical functioning, although the authors suggested that the low baseline levels for these patients
made it unrealistic to expect significant improvements.

**Measure of benefits used in the economic analysis**
The authors did not derive a summary measure of benefit. In effect, a cost-consequences analysis was performed. The authors reported no significant differences in most clinical outcomes, except for the number of falls per patient (see the 'Effectiveness Results' section). There was a significant increase in the number of medication changes but not in the number of prescriptions per patient.

**Direct costs**
The study calculated medication costs only. A secondary outcome of the trial was the cost of 28 days of repeat medicines per patient at end date. The net ingredient costs of medications, excluding dispensing costs, were used to estimate NHS drug costs. Drug costs were from the British National Formulary. The unit costs were not reported separately. The price year was not reported but it appears to have been 2003.

**Statistical analysis of costs**
The costs were adjusted for care home type (as a random effect). The difference in the mean costs was described using a boot-strapped CI.

**Indirect Costs**
Productivity costs were not included.

**Currency**
UK pounds sterling (€).

**Sensitivity analysis**
Further analysis of uncertainty was not reported.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The mean drug cost per patient per 28 days was 42.24 (SD=38.33) in the intervention group and 42.95 (SD=41.01) in the control group. The mean difference was -0.70 (95% CI: -7.28 to 5.71), which was not significant.

**Synthesis of costs and benefits**
The costs and benefits were not combined.

**Authors' conclusions**
There was no significant difference in the medication costs between the two groups, nor was there a significant change from baseline to end point. In combination with the increased rate of medicine change in the intervention group, the authors interpreted this result as demonstrating how savings from stopped drugs could be "recycled" to address new therapeutic issues, i.e. to start additional drugs, with no change to the overall cost.

**CRD COMMENTARY - Selection of comparators**
The comparator was usual care given by GPs, which the authors justified as current practice and a suitable comparator for the stated objective of measuring the impact of a pharmacist-conducted CMR. You should decide whether this represents a suitable comparator in your own setting.

**Validity of estimate of measure of effectiveness**

The analysis was based on a randomised controlled trial, which was an appropriate design for the study question. However, there were some issues with study design because of time constraints, which might have compromised the internal validity of the design. The authors explained that the randomisation procedure was curtailed and the sample size much reduced, as the complexity of baseline data collection requiring the diary availability of study staff, patients, homes and practices was such that the target sample could not be achieved within the allotted timescale. In addition, these issues with baseline data collection meant that the order in which full sets of data were obtained and patients randomised was unselectable and unpredictable, although not strictly random. The analysis of effectiveness was handled credibly. It would appear that the study was underpowered in terms of the original sample size calculation (661 patients instead of 1,600). The power calculation was based on a secondary rather than a primary end point, so it is even more unclear whether the sample size was appropriate.

**Validity of estimate of measure of benefit**

The authors did not derive a summary measure of benefit. A cost-consequences analysis was described.

**Validity of estimate of costs**

It was unclear which perspective was adopted for the economic analysis given that all non-drug health care resource use costs were excluded. In addition, medication dispensing costs, which represent a direct cost to the NHS, were also excluded. Because the primary analysis focused on the changes in medications and costs of these medications, this approach is understandable and the omission of dispensing costs is unlikely to have affected the conclusions. However, the study encompassed other clinical outcomes, such as falls and hospitalisations, and therefore it would have been appropriate had the study assessed all the relevant health care costs. The authors did not justify their approach or the lack of a cost-effectiveness analysis combining costs and health outcomes. Given that only one category of cost was included, very little detail was provided: neither a breakdown of medication types nor medication unit costs were provided. The price year was unclear. Discounting was not relevant, as the costs were incurred during a short time, and was not performed.

**Other issues**

The authors compared their findings with other studies but appeared to have selected only those which supported their hypothesis. The issue of generalisability was not addressed. The results were reported in full. The authors acknowledged the sample size and randomisation issues in the study, and also pointed out a limitation of the service model examined, while noting that a clinical trial of an ongoing pharmacist-patient relationship would be prohibitively expensive to conduct. The authors’ conclusions reflected the scope of their analysis, although this incomplete study cannot fully determine whether increased rates of change in medications can be definitively linked to improvements in clinical outcomes. In this light, their interpretation and recommendations favour the intervention somewhat more than the evidence suggests.

**Implications of the study**

The authors proposed that medicine management of elderly care home residents can be improved via regular CMRs conducted by a trained pharmacist with access to the patient, carer, medical record and primary health care team.

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**Bibliographic details**
