A randomized clinical trial of outpatient geriatric evaluation and management
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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 geriatric evaluation and management (GEM) service, an outpatient programme for the management of older persons at high risk of hospital admission, was examined. The main aim of the programme was to prevent disability among high-risk older outpatients. GEM participants received primary care from a GEM team, which comprised a geriatrician, gerontological nurse practitioner, nurse and social worker, including 24-hour-a-day on-call service. The team diagnosed and treated problems, adjusted medication regimens, provided counselling and health education, assisted with advance directives, and made referrals to other health care professionals and community services. The intervention lasted 6 months on average.

Type of intervention
Patient management and secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients older than 70 years of age, who were at risk of hospital admission and functional decline. The exclusion criteria were:

- residence in a nursing home,
- illness requiring frequent physician visits,
- communication barriers,
- anticipated travel more than 3 months per year,
- restrictive insurance, and
- refusal by the primary physician to consent to the person's participation.

Setting
The setting was an outpatient clinic. The economic study was carried out in the USA.

Dates to which data relate
The dates during which the effectiveness and resource use data were gathered were not explicitly reported. The authors stated that recruitment took place from May 1994 to July 1996. The price year was not reported.

Source of effectiveness data
NHS Economic Evaluation Database (NHS EED)
Produced by the Centre for Reviews and Dissemination
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The effectiveness evidence was derived from a single study.

**Link between effectiveness and cost data**
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness study.

**Study sample**
Power calculations were not explicitly reported. However, the authors stated that the final sample size was powered sufficiently to detect significant differences in the key health outcomes. An initial group of 23,801 individuals was screened from May 1994 to July 1996 to identify potentially eligible participants. Sixty-one per cent of the screened population responded to the mailed survey, and 34% of the 1,806 eligible respondents agreed to participate in the study. The final study sample comprised 568 patients, of which 274 were included in the control group and 294 in the GEM group. The patients in the control group had a mean age of 78.7 (+/- 5.8) years, 58.4% were male, and 96.4% were white. The patients in the GEM group had a mean age of 78.8 (+/- 5.3) years, 54.1% were male, and 96.3% were white. The participants were significantly younger and much more likely to be male than those who refused to participate in the study, (p<0.001).

**Study design**
This was a prospective, randomised clinical trial that was carried out in Ramsey County, Minnesota. The patients were randomised by computer algorithm within blocks of 8 participants stratified by the probability of repeated admission (Pra), an instrument that identifies older people that are more likely to use hospitals, nursing homes, home care, emergency rooms and medications. The length of follow-up was 18 months. At the end of the follow-up period, the study participants (96%) or their proxies (4%) completed 97% of the scheduled follow-up interviews. Research assistants who evaluated the clinical outcomes were blinded to the group assignment.

**Analysis of effectiveness**
The analysis of the clinical study was conducted on an intention to treat basis, and included 46 patients who dropped out of the study before receiving the allocated intervention. The health outcomes used in the effectiveness study were:

- changes in functional ability, which were estimated using the 45-item Sickness Impact Profile: Physical Functioning Dimension (SIP:PFD), where higher scores indicated greater disability;
- depressive symptoms, using the 30-item Geriatric Depression Scale (GDS);
- bed disability days (BDD);
- restricted activity days (RAD); and
- mortality.

The outcomes were assessed at baseline before randomisation, and then at 6, 12 and 18 months. The study groups were comparable at baseline in terms of demographic and clinical characteristics. However, compared with non-respondents, the respondents were significantly younger, had fewer mean admissions to hospital in the last year, and were more likely to be male and white. The final study sample differed from the general population of community-dwelling high-risk respondents in that the study participants were younger, had lower Medicare payments during the last year, and were more likely to be male. Statistical analyses were carried out to examine the impact of potential confounding factors among the baseline characteristics.

**Effectiveness results**
The results of the analysis in terms of SIP:PFD, BDD and RAD values suggested that the control patients were significantly more disabled than the GEM patients over the 18 months of follow-up.
The SIP:SFD scores in the intervention and control groups were, respectively:

13.5 (+/- 15.2) and 16.3 (+/- 14.4), (p<0.05) at 6 months,
14.8 (+/- 15.5) and 18.4 (+/- 16.6) at 12 months, (p<0.05), and
15.7 (+/- 17.9) and 18.9 (+/- 17.9) at 18 months, (p<0.05).

The BDDs in the intervention and control groups were, respectively:

1.2 (+/- 4.6) and 1.6 (+/- 5.3) at 6 months, (p>0.05),
0.9 (+/- 3.7) and 1.5 (+/- 5.2) at 12 months, (p>0.05), and
0.6 (+/- 2.8) and 1.5 (+/- 5.2) at 18 months, (p<0.05).

The RADs in the intervention and control groups were:

1.8 (+/- 6.0) and 2.7 (+/- 7.4) at 6 months, (p>0.05),
2.1 (+/- 6.7) and 3.4 (+/- 8.4) at 12 months, (p<0.05), and
2.1 (+/- 6.3) and 2.3 (+/- 6.6) at 18 months, (p>0.05).

Significantly smaller percentages of GEM participants experienced meaningful deterioration in their SIP:SFD scores (increases of 3+ points) during each of the three follow-up intervals. These significant differences remained after adjustment for potential confounding factors. In particular, the adjusted odd ratio for GEM patients versus controls with respect to the SIP:PFD score was:

0.62 (95% confidence interval, CI: 0.32 - 0.91) at 6 months,
0.73 (95% CI: 0.51 - 1.05) at 12 months, and
0.67 (95% CI: 0.47 - 0.99) at 18 months.

The adjusted odds ratio for RAD during the year after randomisation was 0.60 (95% CI: 0.37 - 0.96).

With respect to depression, at all four measurement times, more controls than GEM patients had GDS scores suggesting depression (11+). These differences reached statistical significance at 12 months (17.4% versus 9.3%; p<0.01) and 18 months (18.3% versus 8.8%; p<0.01). These results held in the adjusted analysis (adjusted odds ratio 0.43, 95% CI: 0.20 - 0.94)

During the follow-up period, 28 patients in each group died. There was no statistically significant difference in mortality between the groups. This result was confirmed in the sub-group of patients at higher risk of hospital admission and functional decline.

Clinical conclusions
The effectiveness analysis showed that the GEM service improved functional ability and depression symptoms in comparison with usual care.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was performed.
Direct costs
Discounting was not relevant since the costs were incurred during 18 months. The unit costs were not presented separately from the quantities of resources used. The economic evaluation included all Medicare expenditures, including health care services. More specifically, inpatient hospital care, physicians’ care, care in outpatient facilities, nursing home care, home care, durable medical equipment, and hospice care. The costs incurred in the year before randomisation were considered for the comparison. The cost/resource boundary of the study was that of the third-party payer. Resource use was estimated using patient-level data derived from the sample of patients included in the clinical trial. The costs came from Medicare reimbursement rates. The price year was not reported.

Statistical analysis of costs
The Wilcoxon rank-sum test was used to test the statistical significance of differences in the estimated costs. Further, logistic regression models were used to examine the relationship between expenditures and group assignment, adjusting for baseline SIP: PFD, GDS, general health Pra, and Medicare expenditures during the year before randomisation. To account for the skewed distribution of the costs, logarithmic transformations of Medicare's total expenditures for each participant were performed.

Indirect Costs
The indirect costs were not considered.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not performed.

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

Cost results
The total Medicare payments were $11,786 (+/- 19,218) in the control group and $11,345 (+/- 18,753) in the GEM group. There was no statistically significant difference between the groups. Logistic regression models that adjusted for baseline factors did not identify group assignment as a significant predictor of Medicare payments. GEM participants were, however, less likely to use home care. This difference was statistically significant at 12 months after randomisation (adjusted odds ratio 0.60, 95% CI: 0.37 - 0.98).

In general, Medicare spent more on the GEM recipients during the first 6 months of follow-up (when GEM services was delivered), but spent more on the controls from the 7th to the 18th month of the study. Apart from Medicare services, GEM participants underwent screening, which cost $84, and received non-covered GEM services, which cost $1,266.

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant since a cost-consequences analysis was carried out.

Authors' conclusions
Compared with usual care delivered by primary care physicians, the geriatric evaluation and management (GEM) programme had a beneficial effect on depression symptoms and functional outcomes in high-risk, community-dwelling older persons. The interventions had no effect on mortality rates and did not increase third-party payer costs. However,
the provision of the service cost about $1,350 per person.

**CRD COMMENTARY - Selection of comparators**
The selection of the comparator was appropriate since it reflected the standard approach for the management of individuals at high risk for hospital admission and functional decline. You should decide whether this is a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness analysis came from a clinical trial, which was appropriate for the study question. The methods of sample selection and randomisation were described. Study investigators were blinded to group assignment. The length of follow-up was appropriate. A small proportion of patients was lost to the follow-up assessment, but the analysis of the clinical study was conducted on an intention to treat basis. The authors noted some differences between the groups at baseline, and statistical analyses were performed to take the impact of potential confounding factors into account. Generally, the study sample was quite representative of the patient population. These issues tend to enhance the internal validity of the study. However, some selection bias could have affected the results of the analysis, owing to differences between those who participated and those who refused to participate. The authors noted also that some of the outcome measures used in the analysis had not been evaluated thoroughly.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments above in the 'Validity of estimate of measure of effectiveness' field.

**Validity of estimate of costs**
The analysis of costs was performed from the perspective of the third-party payer. As such, all the relevant categories of costs were included in the analysis. The costs were presented as macro-categories and a detailed breakdown of the cost items was not provided. This reduces the possibility of replicating the results of the analysis. Due to the skewed distribution of the costs, statistical analyses were performed. The costs were specific to the study setting and sensitivity analyses were not carried out. The price year was not reported, which makes reflation exercises in other settings difficult. Since only Medicare expenses were considered, the impact of the intervention on other costs not covered by Medicare was not examined.

**Other issues**
The authors reported the results of published economic evaluations and stated that the current analysis confirmed these findings. Differences among the GEM programme analysed in this study and those presented in other published studies were also highlighted. The issue of the generalisability of the study results to other settings was partially addressed when the authors stated that, in areas where the usual primary care of older persons in not ideal, cost-savings could be greater than those observed in the current analysis. This study referred to an elderly population at a high risk of hospital admission and functional decline.

**Implications of the study**
The study results supported the use of GEM programmes for the management of old patients at high risk of hospitalisation and functional decline. The authors noted that future GEM programmes should focus on the careful selection of the most appropriate recipients of the intervention.

**Source of funding**
Supported by grants from the National Institute on Aging and the Agency for Health Care Policy and Research (R01 - AG/HS11047), the Health Care Financing Administration, and the American Academy of Family Physicians Foundation.
Bibliographic details

PubMedID
11347776

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
Aged; Female; Geriatric Assessment; Humans; Male; Outcome and Process Assessment (Health Care); Outpatients; Patient Care Team

AccessionNumber
22001001143

Date bibliographic record published
30/06/2005

Date abstract record published
30/06/2005