Scientific evaluation of community-based Parkinson's disease nurse specialists on patient outcomes and health care costs

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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
Community-based Parkinson's disease nurse specialists (PDNSs) working with general practitioners (GPs) were assessed.

Type of intervention
Other: Management care.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with Parkinson's disease (PD). Eligible patients had to be taking one or more anti-Parkinsonian medications and to have had either a hospital or GP diagnosis of PD. Patients aged 17 years or younger were not eligible to join the trial, nor were those with severe mental illness or cognitive impairment sufficient to preclude valid informed consent.

Setting
The setting was community care. The economic study was carried out in London, UK.

Dates to which data relate
The effectiveness and resource use evidence were collected between January 1996 and January 1998. The price year was 1995.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The same patients provided the effectiveness data and the cost data. The costing was carried out prospectively.

Study sample
Nine health authorities were randomly selected from 57 English health authorities, which were representative of the country but did not have well-developed community-based PDNS services. Of 863 eligible general practices in the nine health authorities, 438 (51%) agreed to participate and were asked to invite their patients to take part in the study.

Power calculations were reported. Initially, a sample size of 1,600 patients was considered sufficient to detect a 10%
difference in any outcome of initial prevalence of 50%, at 80% power and a 5% significance level. Of 3,124 eligible patients, 1,859 (60%) agreed to participate. Twenty-three patients died during the recruitment period, leaving a total of 1,836 patients in the study. Of these, 1,028 were randomised to the PDNS group and the remaining 808 to the control group.

**Study design**
The study was a randomised, multi-centred controlled trial. Randomisation was conducted using block randomisation lists, with patients being stratified within practice by age (<70, 70 - 77, >77 years), gender and disease duration (<5, 5 - 9, >9 years). The ratio of patients randomised to the PDNS and control groups varied in the different health authorities area, from 50:50 (PDNS:control group) in Gloucestershire to 70:30 in Bromley.

The follow-up period was two years for both groups. No blinding method for assessment of the outcomes was reported. The losses to follow-up were 163 (16%) in the PDNS group and 116 (14%) in the control group.

**Analysis of effectiveness**
The analysis is likely to have been conducted on the basis of treatment completers only. The primary health outcomes assessed were:

- survival,
- performance in the stand-up test and the dot-in-square test,
- bone fracture,
- global subjective well-being score, and
- PDQ-39 and EuroQol scores.

Adverse events such as fractures were also recorded.

The PDQ-39 is a disease-specific measure that scales the patients' responses to aspects of morbidity known to be affected by PD (range: 0 - 100, where a higher score represents worse function). EuroQol is a health-related quality of life measure (score range: -0.59 - +1, where a higher value represents better quality of life). The global subjective well-being score was derived from 1- and 2-year follow-up questionnaires, and represented an individual's change in health over the 2-year study period (range: 0 - 8, where a higher score represents worse well-being). The secondary outcomes were the proportions of patients taking medications and referred to hospital outpatients or PD specialist. Clinical outcome measures were assessed through face-to-face interviews and a self-completed questionnaire.

The authors stated that the two groups were comparable at baseline in demographic and clinical characteristics. Comparative data were not available for participants and those who declined to take part. However, the study sample as a whole was representative of the PD population of England and Wales in terms of duration of PD and age, except for a slight under-representation of patients aged 85 years or older.

**Effectiveness results**
All the patients in the study showed a decline in their PD health status.

The severity of PD was not significantly different in the PDNS and control groups, as shown by the results of the stand-up and dot-in-square tests.

There were also no differences detected in the proportion of each group who sustained a fracture over the trial period (13% versus 11% in the PDNS and control groups, respectively).

The 2-year mortality rate was 17% in the PDNS group and 18% in the control group, with no significant differences
between PDNS and control patients overall. Four years after randomisation, no between-group difference in mortality was seen (35% PDNS versus 38% control).

No differences in average EuroQol scores or in any scores on PDQ-39 dimensions of morbidity were observed between the groups. There was a significant difference in the global health question; the combined scores from years 1 and 2 differed between treatment groups, with PDNS patients doing significantly better (difference in means -0.23, 95% confidence interval, CI: -0.4 - -0.06; p=0.008).

The proportion of patients taking a controlled release form of L-dopa rose differently between the groups, from one third of each treatment group at baseline to 53% of PDNS and 45% of control patients, (p=0.016).

There was also a greater tendency for PDNS patients taking selegiline to discontinue doing so, (p<0.001).

There were no differences between PDNS and control patients in the proportion of patients taking anticholinergics, dopamine agonists or apomorphine, or in the average number of different types of anti-PD medication prescribed. In addition, no difference was observed in the proportion of patients in each group referred to hospital outpatients, day centres or ancillary therapists.

Clinical conclusions
The authors concluded that between PDNS and control groups only small differences in health outcome were observed. The significantly better responses to the global health question indicate that PDNSs helped preserve the patients’ sense of well-being.

Measure of benefits used in the economic analysis
No summary measure of benefit was used. The study was therefore classified as a cost-consequences analysis.

Direct costs
Discounting was not carried out as the costs were incurred during a time period of no longer than 2 years. The unit costs and the quantities were not analysed separately. The direct costs in the analysis comprised the cost of the PDNS, institutional costs, respite care and hospital cost, primary health care costs, therapy and drugs costs, and home help costs. The costs incurred by carers were not included, while those associated with apomorphine were reported separately from the main analysis. The resource use data were obtained from patient interviews. The unit costs were derived from standard sources of information from the Personal Social Services Research unit; the medication costs were from the Monthly Index of Medical Specialities 1996 net ingredient costs (MIMS 1996). Year 1996 prices were used. The mean annual costs per patient were reported.

Statistical analysis of costs
The costs were expressed as the mean +/- the standard deviation, and CIs were estimated using bootstrap estimation.

Indirect Costs
The indirect costs were not included.

Currency
UK pounds sterling (€).

Sensitivity analysis
No sensitivity analysis was reported.
Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
Among PDNS patients, the mean annual cost per patient rose from 4,050 in the year preceding the study to 5,860 in the second year of the study. Among the controls, the mean annual cost rose from 3,480 to 5,630.

The direct costs for patient health care increased by an average of 2,658 during the study, although not differentially between groups. The average increase was 266 lower among patients attended by a nurse specialist (95% CI: -981 - 449).

Synthesis of costs and benefits
Costs and benefits were not combined.

Authors' conclusions
Nurse specialists in Parkinson's disease (PD) had little effect on the clinical condition of patients, but they did improve their patients' sense of well-being, with no increase in the patients' health care costs.

CRD COMMENTARY - Selection of comparators
The choice of the comparator was explicitly justified by the authors. Standard care from GPs reflects the common practice in the authors' setting. You should judge whether this comparator is relevant in your own setting, or whether other comparators could also have been relevant.

Validity of estimate of measure of effectiveness
The analysis was based on a prospective randomised clinical trial, which was appropriate given the study question. The study demonstrated several main strengths. First, power calculations were carried out to prove statistical significance in health outcomes. Second, the method of randomisation was reported. Third, an appropriate statistical analysis was conducted to compare the groups at baseline. Finally, the study sample appears to have been representative of the study population. However, the absence of blinding assessments and the consequent losses to follow-up may threaten both the internal validity and generalisability of the study.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefits. Therefore, the analysis was categorised as a cost-consequences study. The benefits are therefore those associated with the effectiveness outcomes. The comments in the 'Validity of estimate of measure of effectiveness' field (above) therefore apply.

Validity of estimate of costs
Although the perspective adopted was unclear, it appears that all the categories of costs relevant to a health care perspective have been included, except for the cost of carers. The authors noted that costs for carers were difficult to calculate accurately because their hours of involvement with the patients were markedly skewed and the authors were unable to discern precise different degrees of carer involvement. Therefore, the authors might have underestimated the overall costs of the interventions. The costs and the quantities were not reported separately, which will hamper the extrapolation of this analysis to other settings. The resource use data were taken from a single study, while the unit costs were taken from national sources. The lack of any statistical or sensitivity analyses on the quantities potentially limits the interpretation of the findings. The price year was reported and this facilitates reflation exercises. Discounting was appropriately not carried out since all the costs were incurred during 2 years.
Other issues
The authors compared their findings with those from other studies, finding similar results even with hospital-based studies. The issue of generalisability to other settings was not addressed. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis.

The authors reported several limitations to their analysis. First, the potential contamination of controls from the spill-over effects of the nurse intervention (via the educative effects of PDNSs working with GPs and practice nurses); this would diminish the power of the study to detect PDNS efficacy. Second, the nurses included in the study may also not have been representative of experienced British PDNSs as a whole. Finally, some non-PD patients may have entered the trial as recruitment was based on GP records and information systems. However, randomisation would minimise the likelihood of bias resulting from this limitation, as such patients are likely to have been distributed proportionately in both arms.

Implications of the study
The authors did not make any specific recommendations for changes in policy or practice and/or the need for further research.

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