Usefulness of clinical pathway for community-acquired pneumonia as both an educational and a cost-management tool: an intervention study to compare the usefulness of management with a critical pathway to historical control of conventional 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 use of a clinical pathway (CP) for patients with community-acquired pneumonia (CAP). The pathway consisted of the management of examinations, treatments, ambulation and diet of the patients, oxygen saturation monitoring, and education for the patients and their family about their condition, hospitalisation, medication, tests and daily activities after discharge.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised consecutive CAP patients classified under category 3 of the American Thoracic Society and admitted to the hospital. Patients were hospitalised if they required fluid supplementation due to difficulty in oral intake or dehydration, or if they required oxygen inhalation due to difficulty in breathing. Patients were excluded if they had had obvious episodes of aspiration, had chest drainage due to lung or chest suppuration, or suffered from pneumonia relating to air channel blockage caused by lung cancer. Also excluded were those who had serious breathing difficulty and needed an artificial respirator, those who were in a state of shock and needed vasopressor drugs, and those who were participating in a clinical trial of new antibiotics. Patients who had social reasons for not being able to be treated with the CP, such as having no carer, were also excluded.

Setting
The setting was secondary care. The economic study was conducted at the St. Luke's International Hospital, Tokyo, Japan.

Dates to which data relate
The effectiveness data for the CP group came from a single study conducted between April and December 2000, while those for the control group came from between April and December 1999. The resource use data related to the same periods. The price year was not stated.

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

Link between effectiveness and cost data
The cost data for the single study were collected retrospectively from the same patient sample as that used in the effectiveness analysis.

**Study sample**

Power calculations were not used to determine the sample size. The study sample comprised 43 hospitalised patients with CAP who were treated with the CP (intervention group) and 33 patients with CAP who were treated with conventional methods (historical control group). The median age was 64 years in the intervention group and 63 years in the control group. The proportion of males was 29% (females 71%) in the intervention group and 19% (females 81%) in the control group.

**Study design**

This was a non-randomised trial with historical controls that was carried out in a single centre. The duration of follow-up was one week after hospital discharge. No loss to follow-up was reported.

**Analysis of effectiveness**

The basis for the analysis of effectiveness was not stated, but it was likely to have been treatment completers only (for the cost analysis this was both intention to treat and completers only). The outcomes assessed were:

- the reduction in variance caused by the physicians;
- the success rate of initial antimicrobial therapy (initial antibiotics were effective in treating the symptoms and did not have to be changed to other antibiotics until discharge); and
- the re-hospitalisation rate within a week due to the original symptoms.

In this paper, "variance" was defined as the cases in which hospital stay after the planned date was extended for more than 2 days for CP patients and for 10 days for the control group patients, on the assumption that they (control group) also received the CP. In terms of baseline characteristics, no significant differences were observed between the intervention and control groups in terms of their age, gender ratio, rate of co-morbidity, body temperature, number of white blood cells, amount of arterial blood gas and X-ray results. The intervention group contained more cases of bacterial pneumonia than the control group, 17 cases versus 11 cases, (p<0.05). The control group contained more cases of mixed infection than the intervention group, 7 cases versus 0 cases, (p<0.05). The overall accuracy rate for initial antimicrobial examination was similar between the two groups, 80.6% (intervention group) versus 87% (control group).

**Effectiveness results**

The rate of variance was 28% for the intervention group and 66% for the control group.

For both groups, the patients' physical status attributed more to the variance (intervention group 24% versus control group 45%) than delays caused by physicians (5% versus 21%).

Delays caused by the physicians were significantly less among the intervention group, (p<0.05).

The patients' physical status included the following aspects: failure of the initial treatment, the need for treatment for co-morbidity and induction of home oxygen therapy, having aspiration during hospital stay, and adverse effects of treatment.

The success rate of initial antimicrobial therapy was 85.7% for the intervention group and 84.8% for the control group. The difference was non significant.

There were no cases of re-hospitalisation within a week of discharge among either group.
Clinical conclusions
The CP was effective in reducing the delays caused by physicians. However, the CP did not have clear effects on the success rate of initial antimicrobial therapy and the patients' re-hospitalisation rate.

Measure of benefits used in the economic analysis
No summary benefit measure was used in the economic analysis. In effect, a cost-consequences study was performed.

Direct costs
The direct costs reported were the total medical costs (including oral antibiotics given at discharge) for intention to treat and per protocol series. The length of hospital stay was also reported as a factor relating to cost management. Discounting was not relevant due to the short period of analysis (less than one year). The costs and the quantities were not reported separately. The cost data were calculated on the basis of health insurance invoices for the hospital. The price year was not explicitly stated.

Statistical analysis of costs
The cost data were treated stochastically. Differences between the intervention and control groups were examined using the Mann-Whitney U-test (two-tailed) with a significance level of <0.05.

Indirect Costs
The indirect costs were not included.

Currency
Japanese Yen (Y).

Sensitivity analysis
No sensitivity analysis was undertaken.

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

Cost results
In the intention to treat analysis, the median total costs were Y277,460 for the intervention group and Y325,515 for the control group, (p<0.05).
The median length of hospital stay was 8 days for the intervention group and 11 days for the control group, (p<0.01).
In the per protocol analysis, the median total costs were Y264,270 for the intervention group and Y305,645 for the control group, (p<0.05).
The median length of hospital stay was 8 days for the intervention group and 9 days for the control group, (p<0.01).

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

Authors' conclusions
The clinical pathway (CP) is an effective educational tool for physicians in the treatment of hospitalised patients with community-acquired pneumonia (CAP), and also an effective cost-management tool. The CP contributed to a significant reduction in delays caused by the physicians and the patients' hospital stay. It also helped to reduce the total medical costs significantly.

CRD COMMENTARY - Selection of comparators
The rationale and justification for the choice of the comparator was clear. Traditional care was described in the paper and can be assessed by the reader in terms of its applicability to other settings.

Validity of estimate of measure of effectiveness
The study used a non-randomised study with historical controls, which may be associated with some bias. In addition, confounding factors may be present due to variations in practice and patient characteristics over time. However, the authors stated that they chose the study design in order to minimise treatment bias caused by doctors being exposed to both treatment pathways, as in the case of a prospective randomised study. As they pointed out, a randomised controlled trial in this patient domain and intervention would require a multi-centre setting such that blinding could be achieved, but there may be variations across centres that would generate bias. The approach taken, therefore, was justified with a discussion of appropriate caveats. Statistical analyses were appropriately undertaken, although it is unclear whether the sample size was sufficient since no power calculations were undertaken. The patient sample appears to have been representative of the study population, but there were some clinical differences between the two groups that may have impacted on the overall results.

Validity of estimate of measure of benefit
No summary health benefit was used in the economic analysis due to the cost-consequences approach.

Validity of estimate of costs
The reporting of the costs was clear. The validity was enhanced as the cost analysis was conducted from both an intention to treat and per protocol point of view. Statistical analyses were appropriately performed. However, the generalisability of the cost data is limited in that the costs and the quantities were not reported separately and a price year was not given.

Other issues
The authors compared the results of their study with similar studies and found similar reductions in cost and hospital days. The issue of generalisability to other settings was not discussed. The limitations of the study in terms of the study design were discussed.

Implications of the study
The CP in this study offered some economic advantages without affecting the clinical outcomes. However, the authors stated that there is a need to improve their CP in the future by examining the appropriateness of various hospitalisation periods and whether the same clinical path can be used for patients suffering from bacterial pneumonia and atypical pneumonia. Satisfaction with the CP from the patient and clinician points of view also needs further analysis.

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