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
Home intravenous therapy in cystic fibrosis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis and cost-utility analysis.

Study population
Adolescent and adult patients, attending two institutions in Brisbane, Australia, with an infective exacerbation of cystic fibrosis (as defined by an increase in dyspnoea with or without increased sputum production, fever, or a drop in forced expiratory volume in one second (FEV1) of 15% compared with previous best). The exclusion criteria were as follows: unstable disease; dwelling outside Brisbane; a history of non-compliance; inability to learn treatment techniques, including home physiotherapy; personal request; and patients having a lung transplant or being on their first admission. Fifty four patients (114 admissions) were considered candidates for study inclusion and after the application of the exclusion criteria, seventeen (28% male, 31 admissions: 18 hospital and 13 home) were included. The mean age was 22 years (range: 19 -41). Nine patients had one admission, five patients had two admissions, one had three, one had four and one had five admissions.

Setting
Hospital. The economic study was conducted in Brisbane, Australia.

Dates to which data relate
The dates associated with both effectiveness and resource use data were not reported. The price data were mainly derived from a single randomised trial. Although the price year was not clearly stated, a reference was made to 1992-93 per diem hospital charges.

Source of effectiveness data
Effectiveness data were 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 study.

Study sample
Of fifty four patients (114 admissions) admitted to hospital during the study period, seventeen (28% male, 31 admissions: 18 hospital and 13 home) were included in the study. The mean age was 22 years (range: 19 - 41). Nine patients had one admission, five patients had two admissions, one had three, one had four and one had five admissions. Power calculations were used to determine the patient sample size and demonstrated that a sample of 20 patients in each group was required to detect a clinically significant difference in the primary outcome with a 95% power at conventional 5% significance level (two-tailed).

**Study design**
The study was a randomized controlled trial (two-factor mixed) conducted in two centres. The duration of follow-up was 10 days after cessation of iv therapy. The loss to follow-up was not clearly stated although it appears that no loss occurred.

**Analysis of effectiveness**
The analysis of the clinical study was based on the intention to treat principle. The primary health outcomes used in the analysis were the quality of life (QoL) scores. In particular, the dyspnoea score was used to formulate the power calculations reported in the paper. Additional outcomes measured were the duration of the treatment, and the frequency of toxicity and complications. The treatment groups were shown to be comparable in terms of sex, age, proportions recruited from the two hospitals, FEV1 percentage of predicted value at admission, percentage drop in FEV1 from previous best, and type of iv line.

**Effectiveness results**
The differences in treatment duration and use of antibiotics had p values well above 0.05. No adverse drug reactions were observed in the study. The median duration of treatment was estimated to be 11 days for the hospital arm and 12 days for the home arm (p=0.2). No deaths, no short-term readmissions and no events attributable to the drugs used were estimated to have occurred. The comparison of complication rates and number of line changes required yielded p values of 0.57 and 0.5, respectively. As for QoL outcomes, "significant" changes from the start of therapy to 10 days after its end were observed in all scores (p<0.001). Such changes were estimated to be of a similar magnitude for home and hospital arms for dyspnoea (mean difference 2.5 approximately, p=0.25) and emotional scores (p=0.11). Hospital patients were estimated to be better in terms of fatigue, mastery and total scores (p<0.05). Home patients were estimated to be better in terms of family and personal life, sleep and total disruption (p<0.005).

**Clinical conclusions**
Home intravenous antibiotic therapy in patients with cystic fibrosis was estimated to be a feasible alternative to receiving therapy in hospital. Although there was no clinical compromise associated with home therapy, there were advantages and disadvantages in terms of quality of life.

**Measure of benefits used in the economic analysis**
The measure of benefits used in the economic analysis was quality of life (QoL) gain from the start of iv therapy to 10 days after its end.

**Direct costs**
Some quantities of resource use were reported separately from the costs. The costing included operating costs, costs of complications and costs associated with the equipment necessary to administer the antibiotic therapy. The boundary adopted was that of the hospital and community. The in-patient costs were calculated using per diem charges in one hospital in Brisbane, Australia, during 1992-93. According to the authors, Australian DRG reimbursement figures were "considered" in the analysis. Hospital acquisition costs were used to value antibiotics and equipment used by patients in the home therapy group. Staff costs spent on education or home visits were valued using hourly wages, whilst travel costs to the hospital were priced using a standard cents-per-km fee. The date of the price data was not stated.
Statistical analysis of costs
Mann-Whitney tests were used to test for differences in actual costs.

Indirect Costs
As for resource use quantities, only the proportion of those patients either studying or pensioned was reported. Although the costs associated with productivity losses arising while patients were at hospital were reported as being considered in the analysis, in the end it was not clearly stated whether or not such costs were included in the total cost estimates. The source of data was the interviews of patients and their families. No additional details were provided.

Currency
Dollars ($). It is unclear whether the currency is US or Australian dollars.

Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
Of all changes in QoL, those estimated to be of a similar magnitude for home and hospital arms were for dyspnoea and emotional scores. Hospital patients were estimated to present better results in terms of fatigue, mastery and total scores, whilst home patients were estimated to fare better in terms of family and personal life, sleep and total disruption.

Cost results
Home therapy was estimated to be considerably cheaper for families than hospitalization: mean $23.77 per day of hospitalization and $15.08 per day of home therapy. The average hospital cost (DRG 173) was $5,028.00 ($440.30 per day). The average cost to the hospital (10 days) of home therapy (preceded by 3 days in hospital) was $2,476.00.

Synthesis of costs and benefits
Although the two strategies were comparable in terms of effectiveness, a synthesis of the estimated benefits and costs using a cost per QALY measure would have been relevant however tentative the analysis might have been.

Authors' conclusions
Home intravenous antibiotic therapy in patients with cystic fibrosis was estimated to be a feasible, cost-effective alternative to receiving therapy in hospital. Although there was no clinical compromise associated with home therapy, there were advantages and disadvantages in terms of quality of life.

CRD COMMENTARY - Selection of comparators
The choice of the comparator is clear. As the authors stated, therapy during acute exacerbations of pulmonary disease usually involves the use of iv antibiotics to reduce the concentration of the Pseudomonas aeruginosa organism in sputum. Patients in this situation are commonly well enough for discharge within a few days but are obliged to stay in hospital to complete a course of iv antibiotics.

Validity of estimate of measure of benefit
The estimate of measure of benefit used in the economic analysis is likely to be internally valid. The authors argued in favour of the power of the study to detect clinically significant (5 units or more) mean differences between groups in dyspnoea scores. However, the analysis of benefits using a single measure incorporating quality of life effects is relevant to the efficiency question posed at the start of the study, and would add important information to that presented herein.
Validity of estimate of costs
Some resource use quantities were reported separately from the prices. Insufficient details of methods of quantity/cost estimation were given and it is therefore possible that important cost items may have been omitted (e.g. indirect costs).

Other issues
The authors’ conclusions were justified in terms of the statistical test performed in the study. The issue of generalisability to other settings was not addressed. However, appropriate comparisons were made with other studies. The results were not presented selectively. A synthesis of the estimated benefits and costs was not undertaken.

Implications of the study
Further analysis of the data (cost-utility approach for the combination of costs and benefits) is desirable in order to answer the research question regarding the efficient way to manage patients with cystic fibrosis.

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None stated.

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