Clinical and economic choices in the treatment of respiratory infections in cystic fibrosis: comparing hospital and home care

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 study examined home- versus hospital-based treatment with intravenous (i.v.) antibiotics for respiratory exacerbations in patients with cystic fibrosis (CF).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised adult patients (aged 16 years or older) with confirmed CF who experienced at least one respiratory exacerbation. A respiratory exacerbation was defined as an increase in lower respiratory tract symptoms requiring treatment with i.v. antibiotics. Patients were excluded if they received i.v. antibiotics for conditions other than respiratory infections, or if they received treatment at other hospitals (shared care).

Setting
The settings were the home and a hospital. The economic study was carried out in the UK.

Dates to which data relate
The dates during which the effectiveness and resource use data were gathered were not reported. The price year was 2002.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out retrospectively on the same sample of patients as that included in the effectiveness analysis.

Study sample
Power calculations were not reported. All eligible patients presenting at the authors' institution were recruited. Of the 220 patients identified over the study period, 120 were initially eligible but 4 were excluded (one refused access to medical records, one received shared care, one had final clinical values missing, and one had clinical records missing). Thus, the final study sample comprised 116 patients. The patients were retrospectively categorised into three groups:
"home" patients were those in whom the intention had been to treat at home in more than 60% of courses; "hospital" patients were those in whom the intention had been to treat in hospital in more than 60% of courses; and "both" patients were those in whom the intention had been to treat in hospital or at home in 40 to 60% of courses.

There were 47 patients (63.8% women) in the "home" group, 51 (41.2% women) in the "hospital" group and 18 (38.9% women) in the "both" group. The mean age of the patients was 26 years (range: 17 to 43) in the "home" group, 26 years (range: 16 to 47 years) in the "hospital" group and 25 years (range: 19 to 42 years) in the "both" group.

Study design
This was a retrospective cohort study that was carried out at the Manchester Adults CF Centre, a specialist centre in Manchester, UK. The patients were mainly allocated to the study groups on the basis of patient preference, which also depended on the severity of the presenting clinical symptoms and the competency of the patient to administer i.v. antibiotics. The length of follow-up was 1 year. Data were missing for 19 of the 454 treatment courses (14 home and 5 hospital patients).

Analysis of effectiveness
All of the patients included in the initial study sample were taken into account in the analysis of effectiveness. However, since some patients received almost equal amounts of home and hospital treatment, the three-group classification system was retrospectively applied. The main outcome measure was the forced expiratory volume in 1 second (FEV1). Treatment days were also reported. For treatment at home, spirometric testing was performed at the start and end of each course of i.v. antibiotics, while in hospital, spirometric testing was performed at admission, twice weekly and at discharge. Two baseline FEV1 values were established in each patient for the 1-year baseline period, which preceded the 1-year study period. The "best" FEV1 was the highest FEV1 during the baseline year, while the "average" FEV1 was the mean of all FEV1 values recorded during that period. The effectiveness of a treatment course was defined as lung function maintained at baseline "best" (i.e. the percentage decline in FEV1 was </=0%). Over the 1-year study period, clinical effectiveness was defined as lung function maintained at baseline "average" (i.e. the percentage decline in FEV1 was </=0%). However, a more realistic definition that took into account the continued decline in lung function in CF patients was a </=2% decline in FEV1. The study groups were comparable at baseline in terms of their demographics and treatment aspects.

Effectiveness results
The 116 patients received 454 courses of intravenous antibiotics during the 1-year study period. "Home" patients had a total mean of 63 days' treatment (range: 10 to 182), with a mean of 52 days at home and 11 days in hospital. "Hospital" patients had a mean total of 54 days' treatment (range: 8 to 308), with a mean of 45 days in hospital and 9 days at home. "Both" patients had a mean total of 66 days' treatment (range: 14 to 166), with a mean of 40 days at home and 26 days in hospital.

In terms of the effectiveness of treatment courses, the mean percentage improvement in FEV1 from their baseline "best" was statistically significantly higher for "hospital" patients than for "home" patients (mean difference 4.6%, 95% confidence interval, CI: 1.8 to 7.4; p=0.001). Overall, 13.6% of courses were classified as "effective". However, statistically significantly more hospital courses were classified as "effective" than home courses (17.4% versus 9.0%; p=0.001).

In terms of the 1-year treatment effectiveness, using the base-case definition (percentage decline in FEV1 </=0%), the effectiveness rate was 42.6% in the "home" group, 58.8% in the "hospital" group and 50% in the "both" group. The mean difference between the "home" and "hospital" groups was 10.1% (95% CI: 2.9 to 17.2; p=0.003).

When the percentage decline in FEV1 was defined as </=2%, the effectiveness rate was 42.6% in the "home" group, 62.7% in the "hospital" group and 55.6% in the "both" group. The difference between the "home" and "hospital" groups was statistically significant, (p=0.045).
Clinical conclusions
The effectiveness analysis showed that higher effectiveness rates were observed for patients treated in hospital in comparison with those treated at home.

Measure of benefits used in the economic analysis
The benefit measure was the effectiveness outcome derived directly from the clinical analysis.

Direct costs
The analysis of the costs was carried out from the perspective of a secondary care provider (National Health Service trust). It included i.v. antibiotics, sputum microbiology, blood drug level assays, standard home kits, clinic appointments, inpatient days and home visits (which included travelling time from the clinic to the patients' home and vice versa). Both variable and fixed resources were considered. The unit costs and the quantities of resources used were not presented separately. Resource use was estimated using data derived from the sample of patients included in the effectiveness analysis. Data were derived from clinical records. The costs were derived from the hospital finance departments and the British National Formulary. Discounting was not relevant as the costs were incurred during less than 2 years. Other resources were assessed in the analysis, although they were not assigned a cost. Such resources were mode of transport to hospital, time spent preparing and administering injections, phone calls to/from clinic, visits from CF or community nurses, help from family or friends in preparing and administering home treatment, and time off work, college or school (for both the patient and care-giver).

Statistical analysis of costs
Confidence intervals and differences in mean costs between the groups were calculated using non-parametric bootstrapping.

Indirect Costs
The indirect costs were not considered.

Currency
UK pounds sterling (€).

Sensitivity analysis
Sensitivity analyses were not carried out.

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

Cost results
The total cost per patient over the 1-year time horizon was 13,528 (95% CI: 1,357 to 51,898) for "home" patients, 22,609 (95% CI: 2,873 to 99,828) for "hospital" patients and 19,927 (95% CI: 5,149 to 45,813) for "both" patients. The difference between "home" and "hospital" patients was 9,080 (95% CI: 2,971 to 15,189; p<0.001).

For other resources that were not given a cost, 25 of 40 "home" patients, 17 of 34 "hospital" patients and 3 of 7 "both" patients were in full or part-time work or education. Sixty-five per cent "home", 93% "hospital" and 67% "both" patients took time off from work or education during treatment.

The length of time taken off from work or education during the most recent infective episode was 0 to 7 weeks.
In general, hospital treatment resulted in higher costs associated with time off work, while home treatment led to higher costs due to informal carers.

**Synthesis of costs and benefits**  
An incremental cost-effectiveness ratio (ICER) was calculated to combine the costs and benefits of the interventions. The ICERs for the three groups were reported, but the main comparison focused on "hospital" versus "home" treatments.

When only one treatment course was considered, the mean ICER for "hospital" over "home" treatment was 42,048 (95% CI: 17,300 to 113,478).

When effectiveness was defined as a percentage decline in FEV1 ≤0%, the ICER for "hospital" over "home" treatment was 46,098 (95% CI: -374,044 to 362,472).

When effectiveness was defined as a percentage decline in FEV1 ≤2%, the ICER for "hospital" over "home" treatment was 73,885 (95% CI: 1,236 to 269,023).

The cost-effectiveness acceptability curve showed that, if a decision-maker was willing to pay up to $262,500 for one extra patient with a decline of ≤2% in FEV1 over 1 year, there would be a 95% probability that "hospital" care would be cost-effective. However, using a definition of effectiveness defined as a decline of ≤0% in FEV1 over 1 year, even if the decision-maker was willing to pay $10 million for one extra patient, the probability that "hospital" treatment would be cost-effective did not reach 95%.

**Authors' conclusions**  
Hospital treatment for respiratory exacerbations in patients with cystic fibrosis (CF) was both more effective and more costly than home treatment in the UK. However, the additional effectiveness was achieved at a cost that might be too high from the perspective of the health care service provider. The analysis also showed that treating patients partly at home and partly in hospital reduced both the cost and effectiveness in comparison with hospital treatment.

**CRD COMMENTARY - Selection of comparators**  
The authors justified the choice of the comparators, which were appropriate for the objective of the study. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**  
The clinical evidence came from a retrospective study. This study design is usually associated with some limitations, owing to the lack of random allocation of patients to study groups and the retrospective nature. Thus, some selection bias might have affected the results of the analysis. It was noted, however, that a randomised trial would not have been feasible given the characteristics of the patients. The authors stated that study groups were quite comparable at baseline, but the baseline comparability was not established by statistical tests. Moreover, the gender distribution appears to have differed between groups. A third group was required on account of the actual care received by patients, although the main comparison was between the "home" and "hospital" groups. Further, the lack of blinding could have introduced some assessment bias. Power calculations were not reported and no justification for the sample size was provided. Thus, it was unclear whether the study was appropriately powered to detect statistically significant differences between the groups. The evidence came from a single centre that might not be representative of other institutions. These issues tend to limit the internal validity of the analysis.

**Validity of estimate of measure of benefit**  
The summary benefit measure was specific to the study setting. It will not be comparable with the benefits of other health care interventions. Two different definitions were considered in the analysis. The impact of the intervention on quality of life was not investigated, but the authors stated that the analysis of the relationship between quality of life and
clinical recovery was complex. Further, most studies used changes in FEV1 as the main end point.

Validity of estimate of costs
The conduct of the cost analysis was consistent with the stated perspective. A detailed breakdown of the cost items was provided, but the unit costs were not presented separately from the quantities of resources used. This might limit the possibility of replicating the analysis in other settings. The authors did not investigate the issue of variability in the cost estimates, although statistical analyses were carried out to determine the variability in the baseline costs. The authors reported the price year, which will facilitate realignment exercises in other settings. The sources of the costs were reported for each item. These issues strengthen the cost analysis.

Other issues
The authors stated that other studies had compared home and hospital treatments for CF patients, but most of these studies had small groups of patients and were not full economic evaluations. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not performed, which limits the external validity of the analysis. It was pointed out that the cost estimates were specific to the study setting. Thus, caution is required when extrapolating the results of the economic analysis to other centres. The authors admitted that adherence was not assessed, although this might have represented a key issue.

Implications of the study
The study results suggest that potential methods to improve outcomes at home should be developed to improve the effectiveness of home-treatments for CF patients with respiratory exacerbations.

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