A randomized trial of strategies for assessing eligibility for long-term domiciliary oxygen therapy


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
Two strategies for assessing eligibility for long-term domiciliary oxygen therapy were examined. In the conventional strategy, data were collected by oxygen providers at the time of application and from judgments by Home Oxygen Program (HOP) Personnel. In the alternative strategy, a respiratory therapist collected data from patients unstable at the time of initial assessment and again at a repeat assessment after 2 months of stability.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised all first-time applicants for domiciliary oxygen who were older than 18 years and whose postal codes reflected their living close to the two assessment centres, Toronto and Ottawa, with the exception of patients whose application for oxygen was based on a need for palliative care.

Setting
The setting was community care. The economic study was carried out in Canada.

Dates to which data relate
The effectiveness and resource use data were gathered between April 2001 and 30th December 2003. The price year was 2004.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used for the effectiveness study.

Study sample
No power calculations to determine the sample size were reported. From the 546 HOP forms received, 276 patients were randomised to the conventional assessment arm and 270 to the alternative assessment arm. Of those randomised, 80 patients (45 from the conventional group and 35 from the alternative group) died between starting oxygen and the time the application form was received at the Methods Centre. A total of 231 patients were finally allocated to the conventional assessment group and 235 to the alternative assessment group.

Study design
This was a prospective multi-centre randomised controlled trial in which the patients were allocated to one of the two assessment groups. A 1:1 randomisation schedule stratified by centre (Toronto or Ottawa) and using blocks of eight was constructed. The patients were monitored for up to 1 year after randomisation. Beyond 1 year, patients were only monitored with respect to mortal status, mortality and oxygen use until they discontinued oxygen use (or up until 31 December 2003).

**Analysis of effectiveness**

The method of analysis (intention to treat or treatment completers) was not explicitly stated. The primary outcomes were:

- oxygen use, measured as the number of patients receiving funded oxygen;
- quality of life, measured with the Chronic Respiratory Questionnaire (CRQ) and the Health Utility Index (HUI); and
- mortality.

The study reported that patients in both arms of the study were well balanced with respect to their age, gender and current smoking habits.

**Effectiveness results**

Funding was received by 137 of 235 patients (58.3%) in the alternative assessment group and by 216 of 231 patients (93.5%) in the conventional assessment group. The relative risk of funding in alternative versus conventional assessment was 62.6% (95% confidence interval, CI: 55.9 to 70.1). The risk difference was 35.1% (95% CI: 28.1 to 42.2; p<0.0001).

Funded oxygen at 1 year after the start of oxygen use was being received by 102 of 235 patients (43.4%) in the alternative assessment group and by 137 of 231 patients (59.3%) in the conventional assessment group. The relative risk was 73.7% (95% CI: 61.5 to 88.3). The risk difference was 14.7% (95% CI: 5.7 to 23.6%; p<0.001).

Funded oxygen at 1 year after randomisation was being received by 62 of 235 patients (26.4%) in the alternative assessment group and by 65 of 231 patients (28.1%) in the conventional assessment group. The relative risk was 99.3% (95% CI: 73.1 to 134.8). The risk difference was 3.1% (95% CI: -4.9 to 11.0; p=0.96).

A relative hazard ratio of discontinuing oxygen in the alternative versus the conventional group was computed over the period of the trial. The hazard ratio was:

- 0.79 (95% CI: 0.37 to 1.68; p=0.54) in the first phase, which included the first 60 days after commencement of oxygen;
- 3.07 (95% CI: 2.0 to 4.7; p<0.001) in the second phase, 60 to 152 days;
- 1.09 (95% CI: 0.68 to 1.75; p=0.71) in the third phase, 152 to 364 days;
- 0.71 (95% CI: 0.47 to 1.07; p=0.1) in the fourth phase of the study, 1 year after assessment; and
- 1.18 (95% CI: 0.70 to 1.98; p=0.53) in the fifth phase of the study, after 1 year of commencement of the oxygen.

Both groups tended to improve their HUI3 scores over time and both baseline and follow-up scores were similar in the two groups. The results of the CRQ were similar. Scores improved over time in all four domains (dyspnoea, fatigue, mastery and emotional functions), with greater improvement in the first 6 months and a smaller further improvement in the latter 6 months. Mortality was very similar in the two groups, reaching 20% by the final follow-up, 1 year after randomisation (about 500 days after beginning oxygen). Cox proportional hazards showed no significant differences between the groups (hazard ratio 0.78, 95% CI: 0.53 to 1.15; p=0.21).
Clinical conclusions
The study showed that there were no differences in mortality or quality of life between the two arms of the study.

Measure of benefits used in the economic analysis
The authors did not develop a summary of benefits. In effect, a cost-consequences analysis was carried out.

Direct costs
The study reported three components of the cost analysis: the cost of the assessment, the cost of oxygen reimbursed by the HOP, and the cost of other health care resources. To estimate the cost of the assessment per applicant in the conventional group, the salary and benefits of the HOP coordinator responsible for making the funding decision was divided by the number of new applicants over a 1-year period. In the alternative assessment arm, the determination was made through a detailed weekly accounting of time by the respirologist, respiratory therapist and secretarial support, multiplied by salary and benefit-cost estimates. US cost estimates for a programme coordinator, respirologist, respiratory therapist and secretarial support were obtained from a major medical centre and from a physician billing agency in Los Angeles. The cost of oxygen came from the HOP reimbursement database. For the costing of other health care resources, every 3 months the patients completed a questionnaire that provided information on emergency room visits, hospitalisations, family doctor and specialist visits, visits to other health care professionals, tests and procedures. The sources of the unit costs included the Ontario Schedule of Benefits for Ensured Medical Services, the Ontario Case Costing Project, and local health care programmes. For the US analysis, the number of each type of visit, hospitalisation, test or procedure was multiplied by US cost estimates. The quantities and the costs were not reported separately. The price year was identified. Discounting was not performed.

Statistical analysis of costs
The quantities and the costs were treated stochastically. Fisher's exact test and t-tests were used to examine the effect of the intervention on resource use, which was appropriate.

Indirect Costs
In line with the perspective adopted, no productivity losses were considered.

Currency
Canadian dollars (CAD).

Sensitivity analysis
No areas of uncertainty were identified or investigated.

Estimated benefits used in the economic analysis
Due to the cost-consequences approach, see the 'Effectiveness Results' section.

Cost results
The study reported a summary of the results from the cost analysis using Canadian weight costs.

Costs for assessment and appeal were higher in the alternative assessment arm (CAD 168 versus CAD 13/applicant).

Oxygen costs were lower for applicants in the alternative assessment arm (CAD 2,501 versus CAD 3,907).

In addition to "up-front" programme and oxygen costs, there was no significant difference in the 1-year health care follow-up costs between the two groups (CAD 2,958 versus CAD 2,871).
The saving to the HOP from the alternative assessment was CAD 596 on average per applicant (95% CI: -903 to -291; p=0.0002), while the saving to the Ministry of Health was CAD 355 per applicant (95% CI: -1,958 to -1,259; p=0.66).

A cost analysis was also presented using US cost weights. In this analysis assessment and appeal costs were higher in the alternative assessment arm ($351 versus $42), but these costs were more than offset by higher oxygen use in the conventional arm ($2,265 versus $1,833).

There was no significant difference in the 1-year health care follow-up costs between the two groups ($4,947 versus $4,862).

The saving to the HOP from the alternative assessment was $432 on average per applicant (95% CI: -655 to -209; p=0.0002), while the total saving to the Ministry of Health was $38 per applicant (95% CI: -2,942 to -2,867; p=0.98).

Synthesis of costs and benefits
The costs and benefits were not combined because of the cost-consequences approach.

Authors’ conclusions
The reassessment of patients for domiciliary oxygen after several months of stability identifies an appreciable portion of initially eligible patients who are no longer eligible, thereby reducing programme costs to public funders without adverse consequences on quality of life, mortality, or other resource use.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. It represented standard practice for assessing eligibility for the HOP in Ontario. You should decide whether this represents current practice in your setting.

Validity of estimate of measure of effectiveness
The clinical study was a randomised controlled trial. It appears to have been reasonably well conducted and bias should, therefore, have been minimal. However, it is unclear whether the sample size was sufficiently large to obtain robust results. Appropriate statistical analyses were conducted and the results were presented clearly. The authors adopted oxygen use, quality of life measured using the CRQ and HUI, and mortality as the measures of effectiveness. These would appear to be valid measures of effectiveness.

Validity of estimate of measure of benefit
A cost-consequences approach was adopted. The comments in the ‘Validity of estimate of measure of effectiveness’ field (above) therefore apply.

Validity of estimate of costs
The analysis of the costs was consistent with the perspective adopted in the study, but a more detailed breakdown of the costs would have been more informative and helpful. The price year and the source of the data were provided. Resource consumption reflected actual patterns of care for the HOP in Ontario, but the costs are likely to be specific to Ontario and a major medical centre in Los Angeles. The unit costs and the resource quantities were not reported separately, thus hampering the transferability of the results to other settings.

Other issues
The authors compared their findings with those of other studies. They stated that this piece of research conforms to the trend that patients improve physiologically, and with respect to their quality of life, over the first 3 months after an exacerbation. The results of the study do not appear to have been presented selectively and the authors' conclusions appear to be an adequate reflection of the scope of the analysis. However, no power calculations were reported. There
was no summary measure of benefits, which means that it is difficult to make comparisons with other studies and technologies necessary to help decision-makers in the allocation of resources.

Implications of the study
The study suggests that optimising oxygen use requires patients to be reassessed, both at 3 months and at 1 year, after commencing oxygen therapy. Furthermore, consistent with the results of this trial, the Ontario HOP has adopted funding criteria that require a programme of reassessment at 3 months and then 1 year after commencement of oxygen.

Source of funding
None stated.

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MeSH
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