

A Randomized Trial of Strategies for Assessing Eligibility for Long-Term Domiciliary Oxygen Therapy

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Rationale: Restricting oxygen administration to those who benefit is desirable. **Objective:** To determine the impact of alternative strategies for assessing eligibility for domiciliary oxygen on funded oxygen use, quality of life, and costs. **Methods:** We randomized applicants for domiciliary oxygen therapy to an assessment system that relied on data collected by oxygen providers at the time of application and judgments by Home Oxygen Program personnel (conventional assessment) or to a system of data collection by a respiratory therapist that included, in patients unstable at the time of initial assessment, a repeat assessment after 2 months of stability (alternative assessment). **Measurements and Main Results:** A total of 276 applicants were allocated to the conventional arm and 270 to the alternative assessment. In the year after application, oxygen use was lower in the alternative arm with no between-group differences in mortality, quality of life, or resource use in the community. Although alternative assessment applicants had on average higher assessment costs by \$155 per applicant, these costs were more than offset by decreased Home Oxygen Program costs of \$596 per applicant using Canadian cost weights. The comparable U.S. dollar figures were \$309 and \$432, respectively, and the difference in cost between strategies was therefore smaller using U.S. cost weights. **Conclusions:** Reassessment of applicants for domiciliary oxygen after several months of stability identifies an appreciable portion of initially eligible patients who are no longer eligible, thus reducing program costs to public funders without adverse consequences on quality of life, mortality, or other resource use.

Keywords: economic analysis; oxygen; randomized trial

Randomized trials have established that patients with resting Pa_{O_2} of less than 55 or Pa_{O_2} of less than 60 with associated morbidity live longer when they receive domiciliary oxygen (1, 2). As a result, health care systems in many countries include public funding of domiciliary oxygen for eligible applicants. The Home Oxygen Program (HOP), which is part of the Assistive Devices branch at the Ministry of Health and Long-Term Care, manages the public program for Ontario residents.

In 1998, we evaluated 237 recipients of home oxygen funded by the HOP and reported that 32% of these individuals did not meet HOP eligibility criteria (3). Many who did meet criteria were receiving oxygen at flow rates higher than those required to maintain rest or exercise saturation above 90%. Given that the HOP allocates approximately \$55 million each year to provide domiciliary oxygen for Ontario residents, these results suggested that substantial savings might accrue from changing the decision-making mechanism regarding funding of home oxygen.

The audit methodology involved a respiratory therapist (RT) visiting recipients of domiciliary oxygen in their homes to establish whether they were clinically stable and receiving optimal medications. If patients were not stable, the RT reassessed patients after they had recovered from their exacerbation. The RT obtained arterial blood gases and conducted a structured exercise test (4). The results of these investigations allowed us to determine whether individuals met HOP eligibility criteria.

In many jurisdictions in Canada and around the world, the process of establishing funding eligibility involves collaboration between the oxygen providers and the prescribing physicians. Patients undergo arterial blood gas testing, and the oxygen providers typically submit the results, together with appropriate supporting documentation, for adjudication of eligibility. If deemed eligible, the providers receive funding for up to 1 year, with a requirement for repeat testing, by oximetry, to confirm eligibility.

Guidelines for oxygen therapy in North America, Europe, and Australia emphasize the importance of clinical stability at the time of evaluating the need for long-term domiciliary oxygen therapy (5–9). Nevertheless, progressively earlier discharge of sicker patients means that the initial arterial blood gas testing often occurs at a time when the patient has not achieved clinical stability after admission for a respiratory exacerbation. Despite the recommendation that arterial blood gases be reevaluated, either at a set time interval or when the patient has achieved clinical stability, clinical practice does not always follow the recommendations of professional societies, and many patients are not reevaluated at the recommended time interval (10, 11).

In addition to our survey, at least two other recent reports have noted that, when reevaluating the requirements for long-term oxygen, after the initial prescription many patients no longer meet eligibility criteria (10, 11). Oba and colleagues (10) noted that appropriate standards of reevaluation were applied to only 35% of 55 patients, who returned to the oxygen clinic for follow-up and Chaney and coworkers (11) evaluated 283 patients in a therapist-managed oxygen clinic and noted that oxygen could be discontinued in over a third of these patients. Despite these observations, there are no reported comparison studies that evaluated the influence of different approaches for determining eligibility for long-term oxygen therapy. We therefore undertook a randomized trial comparing the current approach to eligibility assessment to an alternative approach, the key element of which entailed reassessment of patients unstable at the time of their initial assessment after 2 months of stability. We anticipated that this alternate approach would result in a lower rate of funding, but wished to know whether this might be associated with adverse consequences, such as deterioration in health-related quality of life or a lower threshold for use of health care resources, among those denied funding. We also wished to address the more remote possibility that decreases in funding frequency might be associated with increased death rates.

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METHODS

Patients

All first-time applicants for domiciliary oxygen older than 18 years whose postal codes reflected their living close to our two assessment centers, Toronto and Ottawa, were included, with the exception of patients whose application for oxygen was based on a need for palliative care.

Randomization

The Methods Center at McMaster University constructed a 1:1 randomization schedule stratified by center (Toronto or Ottawa) using blocks of eight. For all applicants in the designated geographic areas, HOP advised the Methods Center and faxed the HOP applications. If the patient was randomized to conventional care, the assessment procedure then continued in the usual way, with the decision about eligibility made by HOP personnel. If a patient was randomized to the alternate assessment, the Methods Center first informed HOP that the patient was to be assessed by the alternative mechanism, and then contacted one of the two alternative assessment centers, Toronto or Ottawa, as appropriate.

Oxygen Eligibility in the Conventional Assessment

In the majority of cases in which the HOP grants funding for long-term oxygen, the patient has had an eligible arterial blood gas while in the hospital, and a representative of the physician has contacted the oxygen provider. A much smaller number of referrals come from a physician's office, or from a long-term care facility. The application form, containing the results of the arterial blood gases, plus relevant demographic information, is signed by a physician and submitted for adjudication.

The medical eligibility criteria include an arterial oxygen blood gas value (P_{aO_2}) of less than or equal to 55 mm Hg or an arterial oxygen saturation (Sa_{O_2}) of less than or equal to 88%. The criteria also include a P_{aO_2} of 56 to 60 mm Hg or an Sa_{O_2} of 89 to 90% with evidence of cor pulmonale, pulmonary hypertension, secondary erythrocytosis, hypoxemia on exertion, or nocturnal hypoxemia (the latter two require documented improvement with supplemental oxygen).

The oxygen provider usually supplied oxygen during the processing of the application, unless there was obvious concern that the application might not be granted. At 1 year, the HOP requires oxygen providers to obtain an oximetry record confirming desaturation ($Sa_{O_2} < 88\%$) without oxygen during at least 2 minutes of a 5-minute test, with improvement with supplemental oxygen.

Oxygen Eligibility in the Alternative Assessment Group

In the alternative arm, the RT contacted the applicant directly, and made an initial assessment. If the patient was stable at the time of their HOP application, the RT, involving the respiratory specialist if necessary, made the funding decision. Patients with a P_{aO_2} of more than 55 mm Hg whose application indicated that they desaturated with exercise underwent a standardized exertional oximetry test and received funding if the test revealed exercise desaturation that corrected with oxygen administration. If, at the time of their HOP application, the applicant had experienced an exacerbation within the previous 2 months, oxygen therapy was continued and the RT scheduled a repeat assessment 2 months after the period of instability. After 12 months of oxygen use, the RT reevaluated eligibility for oxygen by sampling arterial blood gases or by pulse oximetry if the original application had been approved on the basis of exercise desaturation.

Measures of Outcome

For the costs and quality-of-life outcomes, we monitored patients for 1 year after randomization, which for most patients was 13 to 16 months from the time they commenced oxygen. Beyond the 1 year from randomization, we monitored patients with respect to mortal status and oxygen use until they discontinued oxygen use (or up until December 31, 2003).

Oxygen Use

We determined whether patients were receiving funded oxygen by reviewing records of the HOP and records of the oxygen providers.

Cost Analysis

The cost perspective adopted for the analysis was that of the Ontario Ministry of Health and Long-Term Care for each patient for the year after randomization in 2004 Canadian dollars. The base case analysis was derived using unit costs from various sources in Ontario (*see below*). As a sensitivity analysis, we also calculated the cost in each arm of the study using unit cost estimates for the United States. The cost analysis involved three components. The first component included the cost of the assessment. To estimate the cost of assessment per applicant in the conventional arm, we divided the salary and benefits of the HOP program coordinator responsible for making the funding decision by the number of new applications over a 1-year period. We made the determination in the alternative arm assessment through detailed weekly accounting of time by the respirologist, RT, and secretarial support, multiplied by salary and benefit-cost estimates. U.S. cost estimates for a program coordinator, respirologist, RT, and secretarial support were obtained from a major medical center and from a physician-billing agency in Los Angeles, California.

The second component involved the cost of oxygen reimbursed by HOP. The necessary information came from the HOP reimbursement database. For the U.S. analysis, we used cost estimates for oxygen from a major medical center in Los Angeles, California.

The third component involved the use of other health care resources. Every 3 months, patients completed a questionnaire that provided information on emergency room visits, hospitalizations, family doctor and specialist visits, visits to other health care professionals, tests, and procedures. Sources of unit costs included the Ontario Schedule of Benefits for Ensured Medical Services, the Ontario Case Costing Project, and local health care programs. For the U.S. analysis, the number of each type of visit, hospitalization, test, or procedure was multiplied by U.S. cost estimates. Medicare reimbursement rates (12) provided the source for physician fees, and charges in a major medical center in Los Angeles, California, the source for hospital-based costs. Patients who died before their first scheduled follow-up assessment were assigned a follow-up cost of \$0, and patients with no resource use data collected were assigned follow-up costs equal to the mean of their treatment group.

Health-related Quality of Life

We measured quality of life in patients whose cognitive status, and command of English, was sufficient to ensure valid completion of the questionnaires. A trained interviewer from the Methods Center who made the judgment as to whether patients were able to provide valid answers to the questions administered the questionnaires over the phone. The interviewer was blind as to whether the patient had undergone the conventional or the alternative assessment procedure. Patients unable to complete a telephone interview received a mailed version for self-administration.

We used a specific measurement instrument for health-related quality of life in patients with chronic lung disease, the Chronic Respiratory Questionnaire (CRQ). The CRQ has 20 items, divided into four domains: dyspnea (shortness of breath), fatigue, emotional function, and mastery (feeling a sense of control over the effects of the illness). The CRQ has well-established validity, responsiveness, and interpretability (13, 14).

As secondary measures of health-related quality of life, we administered the Health Utilities Index (HUI), an instrument that allows calculation of quality-adjusted life-years. In this instrument, the patient reports their experience, resulting in a rating of the utility or value of the health states from 0 (death) to 1.0 (full health).

Mortality

We used information from the oxygen providers, as well as our own efforts to contact patients, to determine if patients were alive or dead. We used the Ministry of Health and Long-Term Care's Registered Persons database to resolve inconsistencies with dates of death.

Ethical Issues

The University of Toronto Human Subjects Review Committee approved the project without provision for informed consent for individual patients. They did so on the grounds that the project was a matter of quality assurance.

Statistical Analysis

To analyze proportions receiving oxygen at various time points, we used methods suggested by DerSimonian and Laird (15) for pooling across 2×2 tables taking into account the stratification variable of assessment center. We calculated the relative risk of remaining on oxygen at 1 year, and the risk difference between the groups.

We also used survival curve methodology to examine the impact of the intervention on oxygen use. We constructed Cox regression models both with and without consideration of differences in baseline characteristics. Because the fully adjusted results did not differ appreciably, we present only unadjusted results. Examination of the survival curves made it evident that the assumption of constant hazards was not tenable, because the relative hazard of discontinuing oxygen varied markedly over time, sometimes greater in one group and sometimes in the other. We therefore conducted analyses for portions of the curves in which the constant hazards model was reasonable.

We analyzed the impact of the intervention on quality of life using generalized linear models and examined the impact of time, treatment, and the interaction between time and treatment.

We repeated the above analyses with adjustment for baseline characteristics of the two groups, including age, sex, initial diagnosis, smoking status, and the stratification variable of center. We note the instances in which there were appreciable differences in the results of unadjusted and adjusted analyses; when the results do not differ, we present analyses only adjusted for assessment center.

To examine the effect of the intervention on resource use, we tested the difference in distribution of hospital visits, specialist visits, and emergency room visits between the alternative and conventional arms using Fisher's exact test and categories of 0, 1, and more than 1 visit. We calculated the mean number of visits to the family practitioner, the difference between the number of visits, and its associated 95% confidence intervals, and tested the difference in means using an unpaired *t* test.

We used Cox regression and Kaplan-Meier survival methods to examine the differential mortality in the two groups.

To examine the effect of the intervention on overall costs, we calculated a total cost per applicant from each of the three cost categories and compared cost across groups using an unpaired *t* test. We also calculated confidence intervals in cost differences across the three cost categories. We repeated the comparison of cost differences and estimated confidence intervals for both the Canadian and U.S. cost analyses.

RESULTS

Between April 27, 2001, and March 11, 2002, we received 546 HOP forms and randomized 276 patients to the conventional assessment arm and 270 to the alternative assessment arm.

Of those randomized, 80 patients, 45 from the conventional group and 35 from the alternative group, died between the time the patient had started oxygen and the time we received the application form at the Methods Center. We did not consider these patients further.

Therefore, we included 231 patients in the conventional assessment group and 235 patients in the alternative assessment group in this data summary.

Baseline Characteristics

Table 1 shows that the two groups were well balanced with respect to age, sex, and current smoking habits.

TABLE 1. BASELINE CHARACTERISTICS

	Alternative Assessment	Conventional Assessment
Total, n	235	231
Age, mean (SD)	73.7 (11.8)	74.6 (10.9)
Sex, no. female (%)	124/235 (52.8)	131/231 (56.7)
Smokers, no. (%)	17/232 (7.3)	15/231 (6.5)

Use of Oxygen

With respect to funded oxygen use, we achieved full follow-up in patients in both groups. In the alternative assessment arm, 23 patients were ineligible for domiciliary oxygen according to information submitted at the time of randomization. Another 64 patients were eligible on the basis of information at the time of randomization and, on assessment, proved stable. A total of 148 patients were eligible on the basis of information available at the time of randomization but proved unstable when assessed. Of these patients, 56 patients proved eligible on reassessment, 46 subsequently proved ineligible, 10 died before reassessment, and another 36 had oxygen discontinued before reassessment.

Among the 46 patients who were eligible on the basis of initial blood gases who proved ineligible on reassessment, the initial mean P_{O_2} on room air was 49.7 (SD, 4.8; range, 33–55) mm Hg. The mean P_{O_2} on reassessment was 70.3 (SD, 7.2; range, 60–89) mm Hg. Of these patients, 16 had a P_{O_2} between 60 and 65 on reassessment.

In the alternative assessment group, 137 of 235 patients (58.3%) received funding, and in the conventional assessment group, 216 of 231 (93.5%) received funding (relative risk of funding in alternative vs. conventional assessment, 62.6%; 95% confidence interval [CI], 55.9–70.1%; risk difference, 35.1%; 95% CI, 28.1–42.2; $p < 0.0001$).

In the alternative assessment group, 102 of 235 patients (43.4%) were receiving funded oxygen at 1 year after start of oxygen use. Of the conventional assessment group, 137 of 231 (59.3%) continued to receive funded oxygen 1 year after starting oxygen use (relative risk, 73.7%; 95% CI, 61.5–88.3%; risk difference, 14.7%; 95% CI, 5.7–23.6%; $p < 0.001$).

In the alternative assessment group, 62 of 235 patients (26.4%) were receiving funded oxygen at 1 year after randomization. Of the conventional assessment group, 65 of 231 (28.1%) continued to receive funded oxygen 1 year after randomization (relative risk, 99.3%; 95% CI, 73.1 to 134.8%; risk difference, 3.1%; 95% CI, –4.9 to 11.0%; $p = 0.96$).

Figure 1 depicts a survival curve in which the event is discontinuation of funded oxygen over the period of the trial. Table 2 presents the hazard ratios for the risk of discontinuing oxygen in the two groups in each of five phases evident in Figure 1. In this table, increased risk of discontinuing oxygen in the alternative assessment arm is represented as a hazard ratio of greater than 1.0. Each line in the table provides the relative hazard—conveniently conceptualized as the cumulative relative risk over time—of discontinuing oxygen in the alternative versus the conventional assessment group (Figure 1).

The first phase included the first 60 days after commencement of oxygen. Survival in the two arms did not start at 100% because some applicants were ineligible at initial assessment. For the subsequent 60 days, both groups moved in parallel, with some patients discontinuing oxygen either through death or for other reasons. The hazard ratio during this phase was 0.79 (Table 2).

In the second phase, 60 to 152 days, the curves diverge, with many more patients discontinuing funded oxygen in the alternative than the conventional arm. This divergence reflects the alternative assessment requirement to reassess initially unstable patients after 2 months. The hazard ratio for this phase is 3.07 (95% CI, 2.0–4.7; $p < 0.001$; Table 2).

In the third phase, 152 to 364 days, the groups move in parallel, with few patients dying or discontinuing oxygen, reflected in the hazard ratio of 1.09.

The fourth phase is at 1-year reassessment. At this time, 15% of patients in the alternative assessment group and 30% of patients in the conventional group discontinued funded oxygen, leaving the two groups with the same proportion of patients using funded oxygen. The decreased risk of discontinuing oxygen

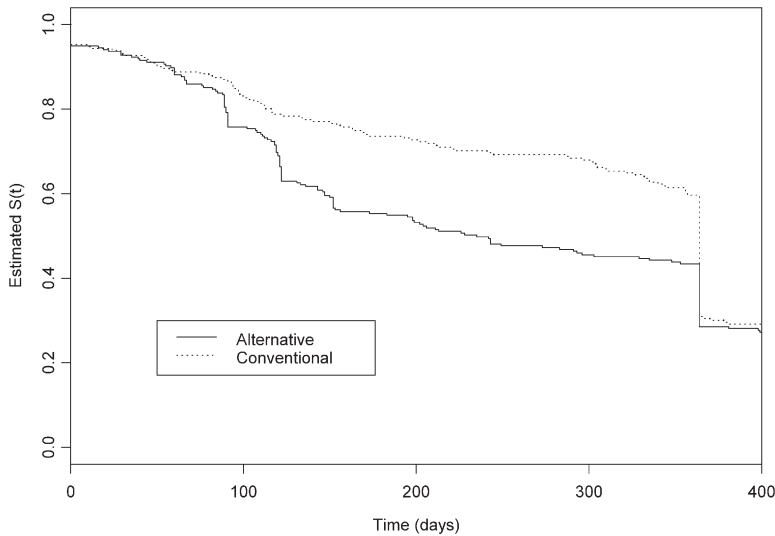


Figure 1. Use of funded oxygen presented as a survival curve with study events—discontinuation of oxygen, including death and moving away—to 400 days after applying for funded oxygen. The *x* axis represents time elapsed, and the *y* axis the proportion of patients receiving funded oxygen at any point in time. The value on the *y* axis would be 1.0 when all patients are receiving funded oxygen. The curve moves down on the *x* axis as the proportion receiving funded oxygen decreases.

in the alternative versus the conventional assessment is reflected in the hazard ratio of 0.71 (95% CI, 0.47–1.07; *p* = 0.10).

During the fifth phase, after 1 year, the curves move together, with a slow decrease in the proportion using funded oxygen. The hazard ratio for this period is 1.18.

Patients had the option of continuing oxygen, and paying themselves. Over the entire study period, we found 50 patients in the alternative assessment and 55 patients in the conventional arm who stayed on oxygen for at least 4 months after the HOP denied or discontinued funding.

Cost Analysis

In the alternative assessment group, of those still alive 1 year after randomization, 84.4% were still providing data for the economic analysis. This is similar to the 83.3% of those in the conventional group still providing data at 1 year.

Health care follow-up resources that were consumed, and thus costs, were similar in both groups. The number of hospital admissions, hospitalized days, length of hospital stay, visits to emergency departments, visits to family doctors, and visits to specialists did not differ between the two groups, nor were there appreciable trends.

Table 3 presents a summary of the results from the cost analysis using Canadian cost weights. Largely because of the increased time required by the RT for the alternative assessment process, costs for assessment and appeal were higher in the alternative assessment arm (\$168 vs. \$13/applicant). These costs were, however, more than offset by lower oxygen costs for applicants in the alternative assessment arm (\$2,501 vs. \$3,097). In addition to “up-front” program and oxygen costs, there was a

nonsignificant difference in 1-year health care follow-up costs between the two groups (\$2,958 vs. \$2,871). The saving to the HOP program from the alternative assessment was \$596 on average per applicant (95% CI, –903 to –291; *p* = 0.0002), and the saving to the Ministry of Health was \$355 per applicant (95% CI, –1,958 to 1,259). This total cost difference did not approach conventional levels of statistical significance (*p* = 0.66; Table 3).

Table 4 presents the U.S. cost analysis using U.S. cost weights. Assessment and appeal costs were higher in the alternative assessment arm (\$351 vs. \$42), but these higher costs were more than offset by higher oxygen use in the conventional arm (\$2,265 vs. \$1,833). Although the costs of personnel were higher in the United States than Canada, the cost of oxygen was lower. As a result, despite the significant difference in oxygen costs, appeal and assessment costs were higher in the United States, resulting in only a modest cost saving for the alternative assessment arm of \$38 per patient (95% CI, –2,942 to 2,867; Table 4).

Quality of Life

Of those still alive 1 year after randomization, 36.7% in the alternative assessment and 36.6% of those in the conventional group were still providing quality-of-life data.

Figure 2 presents the results of the assessment of the utility measure, the HUI3. Both groups tend to improve in their scores over time and both baseline and follow-up scores are similar in the two groups.

The results of the CRQ were similar. In all four domains (dyspnea, fatigue, mastery, and emotional function), scores improved over time, with greater improvement in the first 6 months and a smaller further improvement in the latter 6 months. There were small differences in the degree of improvement in the two groups.

Table 5 describes the results of the statistical analysis of the quality-of-life measures. For each quality-of-life measure, there is a highly significant effect of time in that scores improved across the five measurements. The changes in the CRQ over 1 year were, on average, below the threshold of what patients consider important (minimal important difference, 0.5) (16). The effect on the HUI3 of 0.16 was substantial (minimal important difference, 0.05). Adjusted analyses for all quality-of-life measures were similar to those presented in Table 5, with the exception of the mastery domain of the CRQ, in which the effect of time did not reach the threshold for statistical significance (*p* = 0.07; Table 5).

TABLE 2. HAZARD RATIOS BETWEEN THE TWO GROUPS (ALTERNATIVE VS. CONVENTIONAL) IN THE FIVE DISTINCT PHASES EVIDENT IN THE SURVIVAL CURVE

Time Interval	Hazard Ratio	95% CI	<i>p</i> Value
1	0.79	(0.37–1.68)	0.54
2	3.07	(2.00–4.73)	< 0.001
3	1.09	(0.68–1.75)	0.71
4	0.71	(0.47–1.07)	0.10
5	1.18	(0.70–1.98)	0.53

Definition of abbreviation: CI = confidence interval.

TABLE 3. COST ANALYSIS COMPARING ALTERNATIVE AND CONVENTIONAL ASSESSMENT PROCESS, BY TYPE OF HEALTH CARE EXPENSE, CANADIAN COSTING

	Alternative Assessment	Conventional Assessment	Difference
Assessment and appeal costs	\$168	\$13	\$155
HOP Coordinator	N/A	4	
Respirologist	20	N/A	
Respiratory therapist	126	N/A	
Secretary	< 1	N/A	
Travel	6	N/A	
Blood gas	16	9	
HOP oxygen costs	\$2,501	\$3,097	(\$596)
			95% CI (–903 to –291), p = 0.0002
Health care follow-up costs	\$2,958	\$2,871	\$87
			95% CI (–1,477 to 1,651), p = 0.94
Hospitalizations	2,090	2,158	
GP visits	263	273	
Specialist visits	136	118	
Emergency room	44	36	
Clinic visits	10	5	
Tests/procedures	193	121	
Other professionals	222	160	
Total cost	\$5,627	\$5,982	(\$355)
			95% CI (–1,968 to 1,259), p = 0.66

Definition of abbreviations: CI = confidence interval; GP = general practitioner; HOP = Home Oxygen Program; N/A = not applicable.

Mortality

Figure 3 shows that the survival experience was very similar in the two groups, with mortality reaching close to 20% by the final follow-up, 1 year after randomization (~ 500 days after beginning oxygen). As one would anticipate, Cox proportional hazards showed no significant difference between groups (hazard ratio, 0.78; 95% CI, 0.53–1.15; p = 0.21).

DISCUSSION

Main Results and Associated Inferences

The results of this study show that an independent approach to patient assessment that emphasized the importance of clinical stability had an important impact on the use of funded oxygen.

The absolute difference in the proportion of patients funded was 36% (funding level < 60% in the alternative assessment arm and > 90% in the conventional arm). This resulted in a smaller, but still substantial (~ 15%) difference in patients funded over the year from the time oxygen was started.

The depiction of patient experience in the two survival curves (Figure 1) is enlightening. In the first 60 days after the start of oxygen, the curves move together as unstable patients in the alternative assessment arm waited 2 months for reassessment. The divergence that began at 60 days was a function of patients in the alternate arm being reassessed and found to be no longer eligible. The divergence over the next 3 months was a function of the variable time between commencement of oxygen and randomization, as well as some variability in time to stability after an exacerbation.

TABLE 4. COST ANALYSIS COMPARING ALTERNATIVE AND CONVENTIONAL ASSESSMENT PROCESS, BY TYPE OF HEALTH CARE EXPENSE, U.S. COSTING

	Alternative Assessment	Conventional Assessment	Difference
Assessment and appeal costs	\$351	\$42	\$309
HOP coordinator	N/A	5	
Respirologist	40	N/A	
Respiratory therapist	293	N/A	
Secretary	< 1	N/A	
Travel	4	N/A	
Blood gas	14	37	
HOP oxygen costs	\$1,833	\$2,265	(\$432)
			95% CI (–655 to –209), p = 0.0002
Health care follow-up costs	\$4,947	\$4,862	\$85
			95% CI (–2,798 to 2,968), p = 0.95
Hospitalizations	3,863	3,994	
GP visits	246	255	
Specialist visits	117	103	
Emergency room	245	201	
Clinic visits	13	6	
Tests/procedures	245	151	
Other professionals	218	152	
Total cost	\$7,131	\$7,169	(\$38)
			95% CI (–2,942 to 2,867), p = 0.98

For definition of abbreviations, see Table 3.

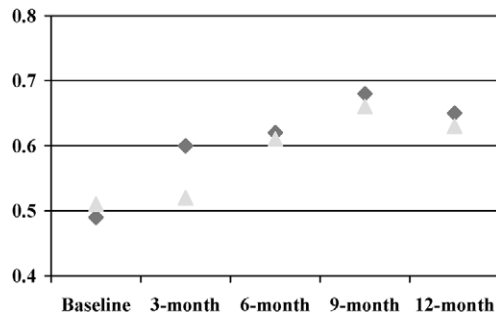


Figure 2. Health Utilities Index (HUI3) mean values. Both groups tend to improve in their scores over time and both baseline and follow-up scores are similar in the two groups. *Black diamonds*, alternative group; *gray triangles*, conventional group.

After the initial reassessments, there would be no reason for the rates of oxygen discontinuation to differ, and indeed, from 5 to 12 months, the survival curves had the same slope. At the 12-month reassessment, a large number of people in both groups discontinued oxygen. Approximately 15% more patients discontinued oxygen in the conventional assessment arm than the alternative arm at 1 year, eliminating the difference in rates of funded oxygen use that existed in the groups before that time.

The events at 12 months suggest two inferences. First, after an exacerbation, it takes some patients more than 2 months to recover. Approximately 15% of the total patient group in the alternative arm became ineligible for oxygen at the 12-month reassessment. This likely represents those who remained eligible at the 2-month reassessment but had improved sufficiently that they were no longer eligible at 12 months.

Second, the much larger drop in use in the conventional arm, and the similarity in rates of funding in the two groups just

after the 12-month reassessment, suggests that the 12-month reassessment was accurate.

Some of the 46 patients in the alternative assessment arm who were initially eligible but proved ineligible on reassessment might have, as a result of day-to-day variability, proved once again eligible had they been reassessed again. This might be particularly true for the 16 patients who had a PO_2 of between 60 and 65 on reassessment. For the remainder, this seems unlikely, especially considering the mean and SD of the PO_2 in this group (70.3; SD, 7.2 mm Hg). Furthermore, in considering such patients, the lack of difference in mortality, quality of life, and health resource use in the two arms is reassuring.

Although the alternative, independent assessment process required higher initial costs, using Canadian costs these were easily offset by lower oxygen costs at 1 year. Because U.S. personnel costs were higher, and oxygen costs were lower, the savings as a result of decreased oxygen use were smaller than those calculated using Canadian cost weights. The reduced funding costs for oxygen were not accompanied by any difference in health care resource use, or resulting follow-up costs.

The quality-of-life assessment is limited in that a large proportion of patients declined to complete the questionnaires. Available data show trends in favor of the conventional assessment arm in the CRQ, and weaker trends in favor of the alternative arm in the HUI. An appropriate conservative conclusion is that it is unlikely that the alternate assessment process influenced quality of life, although the limitations of the data leave this inference relatively weak.

The quality-of-life data also showed improvements over the course of a year. These results are consistent with individuals needing oxygen to maintain adequate saturation at the time they were first assessed, and some proportion of them not needing oxygen at 2 months, and a further group not needing oxygen to maintain saturation at 1 year. The extent to which the improvements in quality of life are similar regardless of oxygen supplementation is likely a reflection of systemic recovery from an exacerbation and not dependent on administered oxygen.

TABLE 5. STATISTICAL ANALYSIS OF QUALITY-OF-LIFE RESULTS WHEN BASELINE VALUES ARE INCLUDED AS OUTCOMES

	Magnitude of Effect	p Value
CRQ		
Dyspnea		
Time	0.41	0.003
Group	—	0.88
Interaction	—	0.16
Fatigue		
Time	0.64	< 0.001
Group	—	0.82
Interaction	—	0.39
Emotional function		
Time	0.38	< 0.001
Group	—	0.12
Interaction	—	0.74
Mastery		
Time	0.35	0.008
Group	—	0.35
Interaction	—	0.92
HUI3		
Time	0.16	< 0.001
Group	—	0.72
Interaction	—	0.59

Definition of abbreviations: CRQ = Chronic Respiratory Questionnaire; HUI3 = Health Utilities Index 3.

The magnitude of effect for time reflects the change from baseline to 12-month follow-up.

Clinical and Policy Implications

Limiting assessment of patients for eligibility for long-term oxygen to the period immediately after an exacerbation will lead to many patients receiving long-term oxygen in whom the benefit is, at best, uncertain. Many patients improve, physiologically and with respect to their quality of life, over the first 3 months after an exacerbation, and our data support previous findings that an appreciable additional group improves further between 3 months and 1 year (17–19). Thus, optimizing oxygen use requires that the patients be reassessed, both at 3 months and at approximately 1 year after commencing oxygen.

Our trial bears directly on the policy issues related to public funding of domiciliary oxygen, and only indirectly on the issue of the benefits of home oxygen on quality of life, mortality, and health care use. The reason is that a substantial number of patients in both groups chose to continue oxygen at their own expense after the HOP decision to deny or discontinue funding.

Consistent with the results of this trial, the Ontario HOP has adopted funding criteria that require a program of reassessment at 3 months and then 1 year after commencement of oxygen. Our results show that this policy, which is very similar to the alternative arm of this trial, will essentially eliminate the use of funded oxygen among those without mortality benefit, without adverse consequences on health care use, quality of life, or mortality. The dollar savings with reassessment when one applies U.S. costs is, however, smaller.

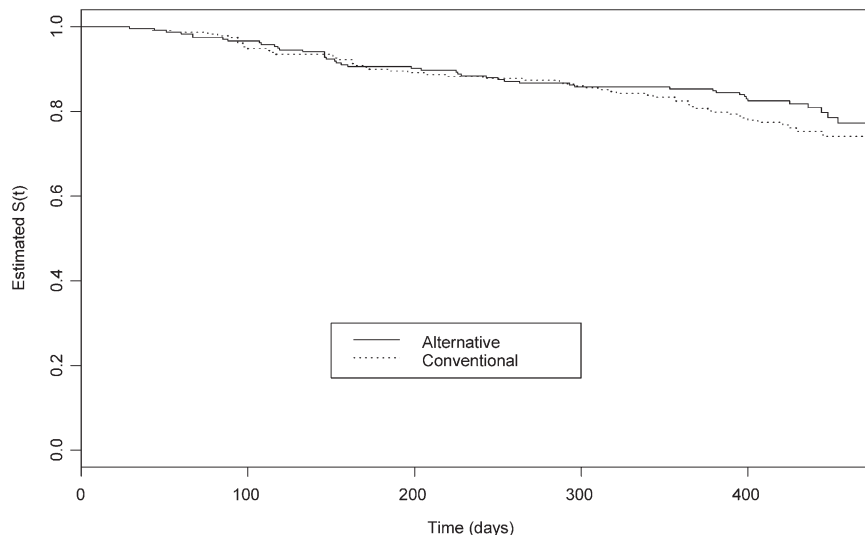


Figure 3. Survival curves for death in alternative and conventional groups. The survival experience was very similar in the two groups, with mortality reaching close to 20% by the final follow-up, 1 year after randomization (~ 500 days after beginning oxygen). As one would anticipate, Cox proportional hazards showed no significant difference between groups (hazard ratio, 0.78; 95% confidence interval, 0.53–1.15; $p = 0.21$).

Ethical Issues

We did not request informed consent from each trial participant, an omission some may consider questionable. Ordinarily, however, providers of health services make policy changes about provision without asking consent from the recipients of care. Indeed, while our trial was ongoing, the HOP changed eligibility criteria for long-term oxygen in areas of Ontario outside of the trial in a way that led to a large increase in the number of patients deemed ineligible. HOP did not offer Ontario residents a choice as to whether to continue with the former procedure or have their eligibility judged under the new rules.

One could question whether it is ethical for those responsible for health care provision to unilaterally make policy changes that may be detrimental to the health of care recipients without evaluating the impact of those changes. Indeed, until the results of our study were available, HOP could not be confident that their new rules represented good policy: the changes might have increased overall costs to the system, morbidity, and mortality, and decreased quality of life. Wisely, they decided to address the issue rigorously, and obtained a clear answer.

It was on this basis, we presume, that the University of Toronto Human Subjects Review Committee decided to classify our study as a quality assurance project, and in so doing judged that individual informed consent was not necessary. In other words, the results were necessary for the HOP to be confident that its policies were in the best interests of the public, to whom it is responsible, and was thus a matter of the quality of HOP programs. We agree that obtaining individual consent from trial participants would have been ideal. If, however, as we believe, our study would not have been feasible had individual informed consent been mandatory, a requirement for individual informed consent would have poorly served potential long-term oxygen recipients in Ontario.

Conflict of Interest Statement: None of the authors have a financial relationship with a commercial entity that has an interest in the subject of this manuscript.

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