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Cost-Effectiveness of Pulmonary Rehabilitation

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Pulmonary rehabilitation has become an accepted modality of care for patients with chronic obstructive pulmonary disease (COPD) and other chronic lung diseases (1–3). However, rehabilitation typically involves multidisciplinary care and it is not always reimbursed by third-party payers. The American Lung Association (ALA) and the American Thoracic Society (ATS) formed a Health Policy Task Force that offered a position statement on the reform of the U.S. health care system. The statement was general, but it did specifically advocate pulmonary rehabilitation. In particular, the ALA and ATS noted, "The ALA/ATS also is concerned that some rehabilitation services, such as pulmonary rehabilitation may not be covered. Their [Clinton administration] criteria for continuation of such services indicates that 'improvement' must be documented. Many types of rehabilitation, including pulmonary rehabilitation, ensure non-deterioration in a condition—not necessarily improvement" (4).

Should rehabilitation services be included in basic benefit packages? How should these services be treated in health care reform? In this chapter we introduce several topics that may be useful in evaluating these issues. The chapter will review general issues in health care reform, the need for outcomes research, and the application of cost-effectiveness models. Then, we will consider the evidence that rehabilitation programs are valuable in relation to other alternative uses of health care resources. The relative cost-effectiveness of rehabilitation programs will also be addressed.

I. Why Is the Issue Important?

American health care is in a state of turmoil. Physicians' autonomy is being challenged as never before. They must submit their judgment to second opinions, have the hospital stays of their patients preauthorized, and undergo time-consuming and frustrating encounters with utilization review. What went wrong? Is this really necessary?

A. Is There a Crisis?

Some people argue that there is no health care crisis and that we need only minor changes in our current system. However, the problems in contemporary health care are hard to ignore. Three important problems in American health care are affordability, access, and accountability (5). The affordability problem results from the inability to pay for all health services that are desired. Health care costs in the United States have grown exponentially since 1940 and the rate of increase has continued to accelerate through the 1990s. Health care in the United States now consumes 14.5% of the gross domestic product, while no other country in the world spends more than 10% (6). The problem is not only that health care is expensive, but that the rate of increase in health care costs exceeds that of other sectors in the economy. For example, over the last few decades, health care costs have risen at a rate of about 11.5% per year. Since the rate of growth of health care costs exceeds that of other sectors of the economy, health care is steadily gaining larger proportions of the gross domestic product (GDP) at a rate of about 1% per year. As a result of devoting a higher portion of the GDP for health care, we have less to devote to other sectors. For example, in 1965, health care accounted for less than 5% of federal spending. By 1990 that figure had risen to 15% and it is projected to be 30% by the year 2000 (7). There are consequences of devoting an increasingly larger portion of the federal budget to health care. Unless we raise taxes or other revenues, we will have less to spend for other activities, such as defense, education, and criminal justice.

Access is the second major challenge. Even with our high expenditures on health care, 58 million Americans have no health insurance for part of each year and 38 million are uninsured throughout the entire year (8). Programs designed to serve the poor, such as Medicaid, have evolved peculiar rules of eligibility. The costs of Medicaid programs have grown dramatically and all states must now consider cost-cutting strategies (9). The accountability problem is perhaps the most challenging. Despite the fact that we spend more on health care than any other country in the world, we have a great deal of difficulty demonstrating that our high expenditures result in health benefits (10).

The three problems (affordability, access, and accountability) are connected. Access has become limited because health care is unaffordable, and care may be too expensive because there is poor accountability. Better accountability may preserve resources that could be used to provide greater access to care.

II. Opportunity Cost Problem

One of the problems in reforming health care is that advocacy groups often fail to consider the total picture. Successful lobbying to obtain reimbursement for a specific service may necessarily mean that another service is excluded. This is called the opportunity cost problem. Opportunity costs are the foregone opportunities that are surrendered as a result of using resources to support a particular decision. If we spend a lot of money in one sector of health care, we necessarily spend less money elsewhere. Part of the problem in the U.S. health care system is that we have tended to follow a "rule of rescue." The rule of rescue, in the words of philosophers, is a moral obligation to provide rescue services whenever saving a life is a possibility (1). However, the decision to invest in rescue may necessarily mean two decisions have been made. For instance, with limited resources, a decision to perform an expensive transplantation surgery for one person often means giving up the opportunity to perform less expensive rehabilitation services for large numbers of people. In some cases a transplant may have limited potential for producing a health benefit, while the rehabilitation services that are neglected have substantial potential to help other people. Indeed, the U.S. health care system is rich with applications of the rule of rescue. Large investments in dramatic and often futile care have resulted in the unfunding or underfunding of important opportunities in primary care, prevention, and rehabilitation (11).

When confronted with the choice between two good programs, it is always tempting to do both. The difficulty is that it is expensive to offer multiple programs. The cost of programs is represented in the fees for health insurance or the cost of health care to taxpayers. A society can choose to offer as many health programs as it wants. However, programs require funding. Employees do not want the fees for their health insurance to rise and taxpayers do not want tax increases. The goal of formal decision models is to get higher-quality health care at a lower cost (11). This chapter focuses on the cost-effectiveness of rehabilitation services for patients with COPD. However, we must recognize the larger context. Pulmonary rehabilitation programs compete for limited resources with many other and different health care services. Thus, consideration of funding programs for the rehabilitation of patients with COPD must be taken in the context of all programs. This requires the application of generic methods for assessing cost-effectiveness and cost-utility.

A. Cost-Utility Versus Cost-Benefit

The terms "cost-utility," "cost-effectiveness," and "cost-benefit" are used inconsistently in the medical literature (12). The key concepts are summarized in Table 1. Some economists have favored the assessment of cost-benefit. These approaches measure both program costs and treatment outcomes in dollar units. For example, treatment outcomes are evaluated in relation to changes in use of medical services or the economic productivity of patients. Treatments are cost-beneficial if the economic return exceeds treatment costs. Patients with COPD who are aggressively treated with antibiotics, for example, may need fewer emergency medical services. The savings associated with decreased services might exceed treatment costs. Russell argued that the requirement that health care treatments reduce costs may be unrealistic (13). Patients are willing to pay for improvements in health status just as they are willing to pay for other desirable goods and services. We do not treat chronic lung disease in order to save money. Allowing patients to die would certainly be less expensive. Treatments are given to achieve better health outcomes.

Cost-effectiveness is an alternative approach in which the unit of outcome is a reflection of treatment effect. In recent years, cost-effectiveness has gained considerable attention. Some approaches emphasize simple, treatment-specific outcomes. For example, Nichol and colleagues estimated the cost per hospitalization prevented by vaccinating the elderly against influenza (14). The major difficulty with cost-effectiveness methodologies is that they do not allow for comparison across very different treatment interventions. For example, health care administrators often need to choose between investments in very different alternatives. They may need to decide between supporting transplantation for a few patients versus prenatal counseling for a large number of patients. For the same cost, they may achieve a large effect for a few people or a small effect for a large number of people. The treatment-specific outcomes used in cost-effectiveness studies do not permit these comparisons.

Table 1 Comparison of Cost-Effectiveness, Cost-Utility, and Cost-Benefit Analysis

Type of analysis	Compares	To
Cost-effectiveness	$ value of resources used	Clinical effects
Cost-utility	$ value of resources used	Quality of life produced
Cost-benefit	$ value of resources used	$ value of resources saved or created

Cost-utility approaches use the expressed preference or utility of a treatment effect as the unit of outcome. As noted in World Health Organization documents, the goals of health care are to add years to life and to add life to years (15). In other words, health care is designed both to make people live longer (increase the life expectancy) and to allow them to have a higher quality of life in the years prior to death. Cost-utility studies use outcome measures that combine mortality outcomes with quality-of-life measurements. The utilities are the expressed preferences for observable states of function on a continuum bounded by 0 for death to 1.0.0 for optimum function (16–24). In recent years, cost-utility approaches have gained increasing acceptance as methods for comparing many diverse options in health care (13,25). Recently, Kassirer and Angell urged the consistent use of these terms for all reports on cost-effectiveness analyses submitted to the *New England Journal of Medicine* (5).

III. Estimating the Effects of Rehabilitation Programs

COPD has a profound effect on functioning and everyday life. Current estimates suggest that COPD affects nearly 11% of the adult population and the incidence is increasing. Newer trends indicate that the rate of COPD among women is increasing to reflect the increase in tobacco use among women in the latter part of this century (26). Reviews of the medical management of COPD justify the use of symptomatic measures including bronchodilators, corticosteroids, and antibiotic therapy. In addition, long-term oxygen therapy has been shown to be beneficial in patients with severe hypoxemia (27). However, it is widely recognized that these measures cannot cure COPD and that much of the effort in the management of this condition must be directed toward preventive treatment strategies, improving symptoms, patient functioning, and quality of life.

There have been few controlled studies evaluating pulmonary rehabilitation programs or their components. Reports from these trials as well as nonrandomized studies typically suggest that the objectives can be achieved (2,28). In one of our recent studies, 119 COPD patients, were randomly assigned to either comprehensive pulmonary rehabilitation or an education control group. Pulmonary rehabilitation consisted of 12 4-hr sessions over an 8-week period. The content of the sessions was education, physical and respiratory care, psychosocial support, and supervised exercise. The education control group attended four 2-hr sessions that were scheduled twice per month, but did not include any individual instruction or exercise training. Topics included medical aspects of COPD, pharmacy use, breathing techniques, and a variety of interviews about smoking, life events, and social support. Lectures covered pulmonary medicine, pharmacology, respiratory therapy, and nutrition. Outcome measures included lung function, maximum and endurance exercise tolerance, symptoms, perceived breathlessness, perceived fatigue, self-efficacy for walking, CES-D depression, and the Quality of Well-Being Scale. In comparison to the educational control group, rehabilitation patients demonstrated a significant increase in exercise endurance (82% versus 11%), maximal exercise workload (32% versus 14%), and peak Vo_2 (8% versus 2%). These changes in exercise performance were associated with significant improvement in symptoms of perceived breathlessness and muscle fatigue during exercise (29,30).

Several studies have documented the benefits of exercise programs for patients with COPD. In a recent review, Casaburi summarized 37 reports of exercise training in the literature up to 1991 (31). These studies included 933 patients with COPD with an average $FEV_{1.0}$ of 1.1 L. A wide improvement in exercise performance was noted, with maximal level or duration being reported in 31 of the 32 studies in which exercise tolerance was evaluated. A few of these studies were controlled trials.

Cockcroft et al. randomly assigned 39 patients to a 6-week exercise training program or to a no-treatment control group (32). In comparison to the control group, patients in the exercise group experienced subjective benefits and increased the amount of distance they could walk in 12 min. However, the length of follow-up was only 2 months. McGavin and co-workers randomly allocated 24 patients with COPD to a 3-month unsupervised stair-climbing home exercise program or to a nonexercise control group. The 12 patients in the exercise group noted subjective improvements and an increased sense of well-being and decreased breathlessness. They also reported an objective increase in the 12-min walk distance and maximal level of exercise on a cycle ergometer. These changes did not occur in the control group. However, the length of follow-up was limited to 3 months (33). Ambrosino and co-workers randomly assigned 23 patients to a 1-month medical and rehabilitative therapy group and 28 patients to medical therapy alone (without exercise training). The experimental group improved in exercise tolerance and ventilatory pattern (as evidenced by decrease in respiratory rate and increase in tidal volume). Again, these changes were not present in the control group (34).

Developing exercise programs for patients with COPD is difficult for several reasons. First, principles of training that have been well studied for normals or for cardiac patients do not necessarily apply to patients with COPD (35,36). Adherence is often a major problem for the patient with COPD. Some studies suggest that the degree of benefit is associated with compliance to the exercise regimen (37). Although patients can benefit from exercise, the routine is typically not comfortable for them. Many participants in rehabilitation programs have become physically deconditioned over a long period of time. Exertion may be uncomfortable and commonly leads to the frightening symptom of breathlessness (dyspnea). Because of these problems, discontinuation of the exercise regimen is common.

In summary, some evidence suggests that rehabilitation is effective. Establishment of these benefits is a crucial step in estimating the cost-effectiveness of programs. However, there are limitations in the current evidence for the effectiveness of these programs. In particular, few studies have been systematic clinical trials and most studies have had limited follow-up.

IV. Economic Evaluations in COPD

Despite the interest and the cost-effectiveness of pulmonary rehabilitation, there have been relatively few investigations of this topic. Molken and Associates, in The Netherlands, systematically reviewed economic appraisals of asthma and COPD care for the years 1980–1991 (38). They found only 20 economic appraisals of treatments. Among these, only one used cost-utility methods. Two of the 20 studies focused on pulmonary rehabilitation, while the majority of the studies emphasized health education for asthma. Nine of the 20 studies focused on patients with COPD, while the others considered patients with other lung diseases. Their review suggested that use of control groups characterized less than half of the studies (eight of 20 studies), and most of these trials evaluated education for children with asthma. We extended the review through 1994, but found only one additional reference. The new study was a review rather than an original research contribution (39).

V. Cost-Benefit Studies

The literature on the cost-benefit of pulmonary rehabilitation programs was recently reviewed (40). Although the title of this review was "Cost-Effectiveness of Pulmonary Rehabilitation Programs," the majority of the studies that were reviewed emphasized cost-benefit. In other words, these were studies that considered the financial savings associated with investments in pulmonary rehabilitation programs. The various studies are summarized in Table 2. The studies are consistent in their methodology and in the obtained results. Dunham and colleagues considered the number of hospital days used by patients before and after a pulmonary rehabilitation program conducted by Loma Linda University. Initially, 80 patients participated in the study, but only 53 survived 1 year. The mean $FEV_{1.0}$ at entry to the study was 1.33 L. The study demonstrated that the average number of hospital days dropped from 17.41 for the year prior to the study to 7.78 the year following the study. The same effect was observed when patients who died were eliminated from the analysis (41).

A similar result was reported by Hudson and associates. They began their study in 1966 at the University of Colorado School of Medicine and studied 44 patients (mean $FEV_{1.0} = 1.07$ L). Hospitalizations prior to a rehabilitation pro-

Table 2 Summary of Cost-Benefit Studies on Rehabilitation of Patients with COPD

Study	Design	Finding	Comment
Durham et al., 1984	Pretest-posttest using hospital records	Hospital days dropped from 17.41 to 7.78	One-third of the patients died, but the result holds with adjustments for mortality
Hudson et al., 1976	Pretest-posttest evaluation of 44 patients followed over 5 years	Hospital days dropped from an average of 12 the year prior to the program to 3 the year after; average hospital days remained at about 5 or 3 additional years	Results were similar with inclusion of 20 additional patients who died prior to the end of the study
Johnson et al., 1980	Pretest-posttest follow-up of 74 survivors from among 96 registrants in a program	Hospital days dropped from 38 preprogram to 12 postprogram	Results were similar when all 96 patients were included in the analysis
Wright et al., 1983	Pretest-posttest evaluation of 57 completers of a 10-week program	Hospital days dropped from 8.72 pretreatment to 0.60 after treatment	All preprogram hospital days were among 16 patients
Bria et al., 1987	Nonequivalent control group comparison of individual ($n=25$) versus group ($n=30$) treatment	Hospital days dropped by 5.43 days for the individual treatment and 4.52 days for the group treatment	Phone calls to program increased
Ries et al., 1994	Randomized comparison of rehabilitation versus education control in 119 patients	Hospital days were reduced by 2.9 in the rehabilitation group and increased by 1.6 days in the control group	Although not statistically significant, the results were in the expected direction
Sneider et al., 1988	Nonrandomized self-selection of 150 patients into three groups: interview only, education, and comprehensive rehabilitation; hospital days compared 5 years pre- and postprogram	Hospital days increased in the interview-only and education-only groups; days decreased by 1.53 days in the comprehensive rehabilitation group	Self-selection into groups rather than treatment may account for the results

gram and after the rehabilitation program were determined from hospital records. Hospital days dropped from 12 the year prior to the program to about 5 for each of 4 follow-up years. The results were more dramatic when the subset of patients who had been hospitalized prior to the program were separated. Among these 14 patients, the number of hospitalizations dropped from 38 to 10 in the first year and remained less than 17 throughout the rest of the 4-year follow-up. Among the 44 patients, approximately one-third of all preprogram hospitalizations were accounted for by a single patient who was hospitalized for 178 days. After rehabilitation, this patient was hospitalized for only 1 day over the next 4 years. Elimination of this one patient reduced the magnitude of the pre-post programs difference from about 7 days to about 4 days (42).

Another group, at Barlow Hospital, evaluated 96 patients and obtained follow-up data on 74 patients 1 year after completing pulmonary rehabilitation. The mean $FEV_{1.0}$ value was 0.87 L. There was an average of 38 hospital days prior to the program, which was reduced to 12 days after completion of the program (10).

Wright and associates, at St. Joseph's Hospital in Stockton, California, evaluated a 10-week outpatient education and exercise program among 74 COPD patients (mean $FEV_{1.0}$ not reported). Hospitalizations were obtained from patients' self-reports on a questionnaire. On average, the patients had been hospitalized for 8.7 days the year prior to the program and only 0.60 days the year following the program (43). A similar result was reported in an abstract of a program at the Basystate Medical Center in Springfield, Massachusetts. In this study 55 COPD patients (mean $FEV_{1.0} = 1.17$ L) were randomly assigned to pulmonary rehabilitation in the form of individual sessions ($n = 30$) or group sessions ($n = 25$). The pretreatment hospital days were not reported. However, there was a significant decrease in the number of hospital days for those in the individual treatment (mean = 5.43) and for those in the group treatment (mean = 4.52). The abstract suggests that many patients replaced hospital visits with phone calls to their providers (44).

One of the most detailed studies was reported by Sneider et al. from the Eisenhower Medical Center in Rancho Mirage, California. These investigators evaluated 150 patients who self-selected themselves into a pulmonary rehabilitation program. Using hospital records, Sneider et al. compared hospitalizations for the 5 years prior to the program with those for the 5 years after the program among three different groups of patients. One group was interviewed for the program but did not participate. A second group received the education component but did not complete the exercise portion. The third group completed all phases of pulmonary rehabilitation. There was a significant decrease in hospital days only for those who had completed the program. In the other two groups, there was a significant increase in the number of days of hospitalization (45).

More recently, in our randomized clinical trial at the University of California, San Diego, patients were assigned to either a comprehensive pulmonary rehabilitation program or an education control group. The mean $FEV_{1.0}$ for the 119 participants was 1.23 L. In comparison to baseline, rehabilitation patients decreased days of lung disease–related hospitalizations by an average of 2.4 days while the education control group increased hospital days by 1.3 days. Although they were in the expected direction, these differences were not statistically significant (29,46).

To summarize, cost-benefit studies compare monetary investments in pulmonary rehabilitation against monetary savings attributable to the programs. To date, studies consistently suggest that the costs of pulmonary rehabilitation programs may be offset by reductions in health care costs. However, the interpretation of almost all of these studies can be challenged on various accounts. We reviewed seven different investigations. Four of the seven studies did not use a control group. Among the three studies using a control group, only one randomly assigned patients to the treatment or control conditions. The studies consistently show that pulmonary rehabilitation reduces hospital utilization and costs. However, a recent randomized experimental trial failed to show that this benefit was statistically significant.

Other methodological issues must also be considered. For example, patients with high rates of hospitalization are likely to be referred preferentially. In fact, many patients are referred at the point of a hospitalization. The selection process may also screen out patients who are unlikely to get better. Another problem is the changing health care scene with its emphasis on decreased length of stay and increased use of outpatient facilities. All in all, despite strong evidence that pulmonary rehabilitation reduces hospitalizations, randomized controlled clinical trials are needed to substantiate the cost-benefit of pulmonary rehabilitation.

One of the important problems in cost-benefit studies is that cost reduction may not necessarily translate into patient benefit. For example, recent policies of utilization review have greatly reduced hospital use. However, it has not been clearly established that reduced hospital use benefits patient. Further, these studies do not clearly evaluate the relationship between reduced hospitalization and reduced disability.

VI. Cost-Utility Studies

Despite the attractiveness of cost-benefit studies, there are also some disadvantages. Limiting the evaluation to only economic criteria may neglect the primary mission of health care. For example, the development of guidelines for appropriate care might exclude expensive services that save lives and produce changes in function. If cost is the only criterion, the cheapest alternative might always be selected. To choose between alternatives, it is necessary to value the health benefits of patient outcomes as well as the cost (47). Clinical measures of benefit are often poorly understood with respect to their implications for the patient. For example, improvement in arterial blood gas values may not mean much to a patient or to a public policy maker. On the other hand, restoration or preservation of the ability to perform activities of daily living, the goal of many therapies, is meaningful to all concerned. These outcomes are measurable, and a paradigm shift in medicine is beginning to embrace patient-centered reports.

Despite the improvements in measuring patient outcomes, determining the value of health services has been particularly difficult. In economics, the value of a product is related to the willingness of consumers to pay for it. For example, the value of a Mercedes Benz automobile is set by the price consumers are willing to pay to obtain the car. If the price is set too high, few cars will be sold. Health services are difficult to value because consumers rarely pay for them directly. Instead, the charges are paid by third parties. Third-party payment has left consumers out of the loop and made it difficult to establish whether the services are valuable to patients. Cost-utility analysis considers both costs and patient outcomes in determining the value of treatment. In contrast to cost-benefit analysis, which focuses on the dollar returns for investing in particular programs, cost-utility analysis considers the health benefit of a program, weighted by patient preferences for outcomes, in relation to the financial costs of the program.

There are several methods for evaluating patient outcome. One approach combines morbidity and mortality into a single index. Survival analysis is a common method for considering mortality outcomes. In survival analysis each patient is coded as 1.0 if he/she is alive and 0.0 if dead. Thus, a patient is given 1 year of credit for each year that he/she survives and no credit if he/she is dead. A patient who survives to 83 years would be given 83 points while someone in the same birth cohort who survives to age 50 would be given 50 credits. The appeal of survival analysis is that it is general and can be used to describe any patient cohort or disease classification. The disadvantage is that survival analysis does not recognize levels of wellness between death and optimum function.

We prefer methods of adjusted survival analysis that consider the continuum of wellness between death and optimum function. The outcomes are assessed using a general measure known as the Quality of Well-being Scale (QWB) (19–22). If a patient with COPD was limited by the illness in some, but not all, activities, his score on this scale might be 0.60 on the 0.0–1.0 continuum. Instead of being given a year credit for survival, he might be given 0.60 years for surviving the year in the disabled state. In other words, survival time is "quality adjusted." The outcome is defined as a quality-adjusted life year (QALY). A treatment that boosted the patient from 0.6 to 0.7 would produce the equivalent of one-tenth of a year of life. Aggregated across 10 patients, the treatment would produce the equivalent of 1 year. Determining the quality weights is a complex task that is described in several other papers (16–24). The goal of cost-utility analysis is to divide the cost of a program by the equivalents of life years that the program produces. Since the goal of all interventions in health care is to increase quality-adjusted life expectancy, programs and treatments with different specific objectives can be directly compared to one another.

Only a few attempts have been made to evaluate the cost-utility of rehabilitation programs for patients with COPD. In one experimental trial, patients with COPD underwent exercise testing and were given an exercise prescription. They were then randomly assigned to one of five experimental or control groups. The experimental groups were based on the principles of behavior modification or a variant of behavior modification known as "cognitive behavior modification." These methods involve setting goals, analyzing the reinforcers for walking, and using behavioral contracts. The experimental programs included six weekly sessions in the patient's home. One control group received attention but did not have the behaviorally based sessions, while the other control group received no treatment. After 3 months, the three experimental groups showed greater compliance with the exercise program than did the two control groups. These changes were reflected in changes in exercise tolerance measured 1 month after the treatment. However, there were no significant changes in spirometric parameters (48).

Several additional analyses were performed using the QWB measure (49). Over the course of 18 months, the experimental and control groups showed significant differences on a quality-of-life index (Fig. 1). These analyses pooled together the three experimental groups and the two control groups. These same patients were studied again 3 years after the beginning of the program. At this time, observed differences between the experimental and control groups remained for the quality-of-well-being measure (50). However, substantial increases in variability precluded statistically significant effects. The differences were used to calculate QALY and perform cost-utility studies. There is considerable debate about the economic value of behavioral and rehabilitation programs. The cost-utility analyses suggested that behavioral programs designed to increase adherence for patients with COPD produce a QALY for approximately $23,000. The cost per QALY has been analyzed for a wide range of medical, surgical, and public health interventions. The cost per QALY for the behavioral intervention is comparable to that of other widely advocated health care programs (51). Figure 2 shows the cost-utility of this program in relation to other widely advocated treatments or programs. The behavioral programs were significantly more cost-effective than coronary artery bypass sur-

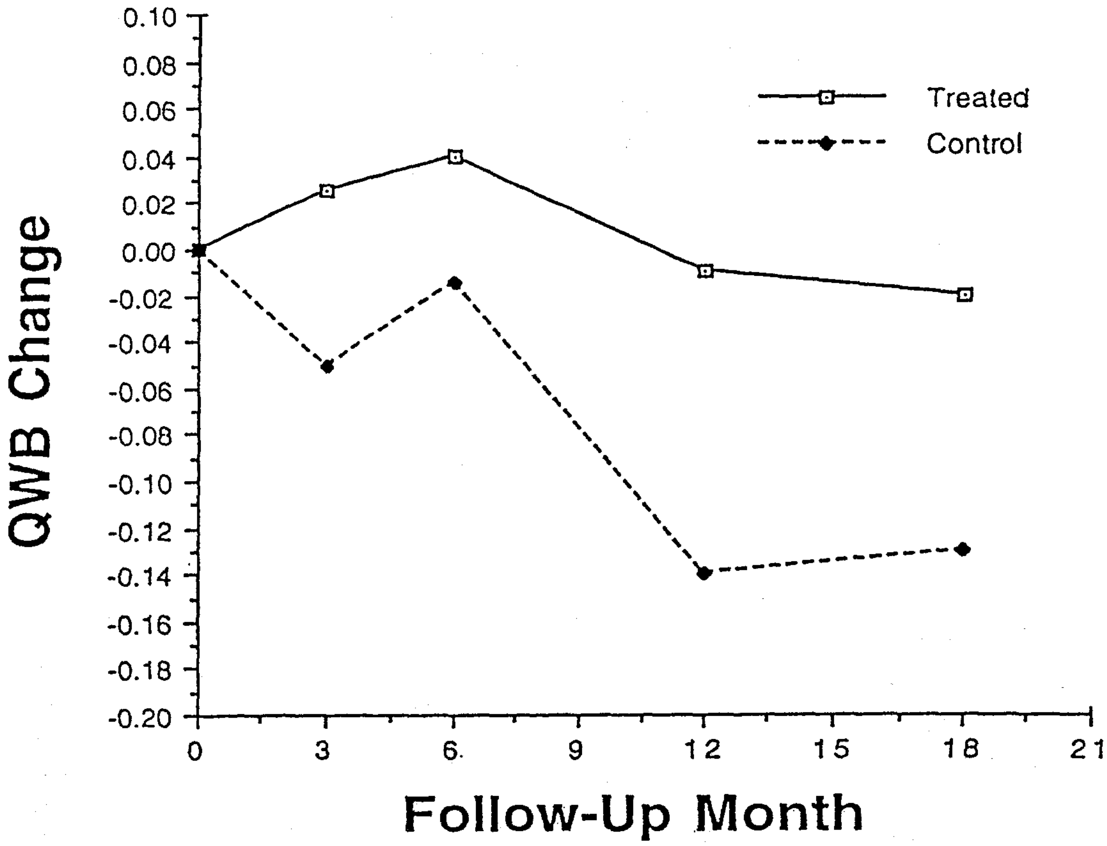

Figure 1 Quality of well-being differences between patients who had completed a behavioral rehabilitation program and controls during an 18-month follow-up. Scores did not change significantly for the treatment groups and showed significant decline for those in the control groups. (Adapted from Ref. 51.)

gery for one-vessel coronary heart disease ($670,000/QALY) or mammography screening programs ($175,000/QALY), but less cost-effective than pnemonococcal vaccine for the elderly ($1000/QALY) or laws requiring children to be in infant restraints and adults to wear seatbelts while in motor vehicles (<$100/QALY). Figure 2 also shows a hypothetical pay line where a policy maker might separate those programs to be supported from those not recommended for funding.

VII. Other Results

Not all studies have supported the cost-utility of pulmonary rehabilitation. For example, our clinical trial that compared comprehensive pulmonary rehabilitation versus an educational control group demonstrated highly significant improvement in exercise performance and relief of symptoms. In the comprehen-

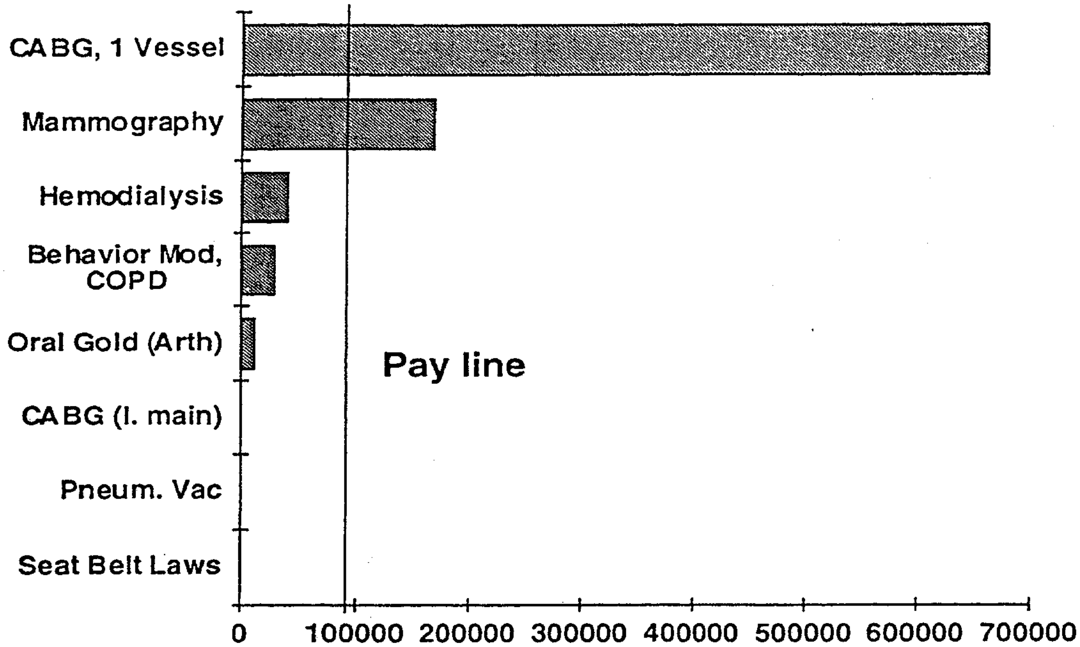

Figure 2 Relative cost/quality-adjusted life year for various programs. CABG, coronary artery bypass graft; 1 vessel, single-vessel disease; Mammography, screening all women older than age 40; Oral Gold, Auranofin for rheumatoid arthritis; CABG (l. main) is surgery for patients with left main artery disease; Pneum. Vac, pnemonococcal vaccine for adults older than 65 years; seat belt laws refers to policies requiring children to be in carseats and adults to use seatbelts. Behavioral modification for patients with COPD produces a QALY for about $23,000. This is significantly more cost-effective than CABG for one-vessel disease ($670,000/QALY) or mammography screening programs ($175,000/QALY), but less cost-effective than pnemonococcal vaccine ($1000/QALY) or seatbelt laws (<$100/QALY). The hypothetical pay line shows where a policy maker may draw the line between those programs to be supported and those not funded.

sive rehabilitation group, however, there were no significant differences between groups for measures of lung function, depression, or general quality of life. Both groups experienced reductions in quality of life over long-term follow-up, partly due to the mortality that is incorporated in the quality-of-well-being measure. For the exercise and symptom variables, the benefits in the comprehensive pulmonary rehabilitation group tended to relapse toward baseline after 18 months of follow-up (29).

The failure of pulmonary function to improve was not unanticipated. Nearly all previous studies have also failed to show significant changes in lung function (52–54). The failure to demonstrate benefits of pulmonary rehabilitation for measures of quality of life, e.g., well-being, and depression were somewhat unexpected. Long-term benefits beyond 12 months were observed only for measures of exercise endurance and perceived breathlessness.

There are several potential explanations for the absence of long-term benefits in this controlled trial of comprehensive pulmonary rehabilitation. One explanation is that short-term behavioral interventions, such as rehabilitation, are inadequate to produce long-term change. Long-term maintenance of behavior change has also been difficult to demonstrate in research on smoking cessation (55), weight loss (56), and exercise adherence (57). The finding that patients experience behavior change during treatment that is not maintained after treatment is consistent across a variety of different behavioral interventions (58). It is also important to recognize that few controlled studies have followed patients longer than 6 months. Thus, conclusions about long-term effectiveness may be premature.

The failure to obtain significant differences on quality-of-life outcomes is a problem because these measures are the denominator in the cost-utility ratio. With a small denominator, the ratio tends to be large, discouraging support for the program. In this study, the small effect on the quality of well-being may be explained by the insensitivity of these measures to small changes in general health status from interventions of this type. However, this measure has been used in a variety of outcomes studies and has shown significant associations with clinical measures for patients with lung diseases (20,59,60). It is possible that questionnaires that are more specific to lung diseases may offer a more sensitive assessment. For example, one recent trial did show that patients improved on measures of quality of life relevant to lung disease following a rehabilitation program (15).

VIII. Summary of Cost-Utility Studies

Most observational studies support the cost-benefit of pulmonary rehabilitation. Although these studies rarely use control groups, they often have long-term follow up. The outcome measures have emphasized the financial savings that may be attributable to participation in pulmonary rehabilitation. In contrast to cost-benefit studies, cost-utility analysis emphasizes patient-reported outcomes and measures of quality of life. One experimental trial estimated the QALYs contributed by participation in a behavioral rehabilitation program. The cost per QALY was comparable to that of many widely advocated medical and surgical treatments. However, another randomized clinical trial showed positive effects for exercise performance and relief of symptoms, but not for pulmonary function, quality of life, or depression.

Future research is necessary to evaluate these issues further. We have five specific suggestions. First, more controlled clinical trials are needed in which COPD patients are randomly assigned to comprehensive pulmonary rehabilitation or to control conditions. The outcome measures should include pulmonary function, quality of life, and cost. Follow-up should be at least 2 years. Second, if comprehensive programs are shown to produce positive outcomes in terms of functioning and quality of life, research will be necessary to demonstrate which components of the comprehensive program are essential to the package. Third, better research is necessary to determine whether standardized measures of functioning and quality of life, commonly applied in cost-utility studies, are sensitive and reliable measures of outcome in pulmonary rehabilitation. A fourth need for future research is an estimate of the duration of benefit for rehabilitation treatments. Evidence suggests that the treatment effect may attenuate over the course of time. Methods for making the benefit long-lasting should be developed and evaluated. Finally, we encourage more studies that consider the cost-utility of pulmonary rehabilitation in relation to other investments of health care resources. For example, managed-care organizations may limit their services to those deemed basic or essential. Other services might be added to the basic benefits package if they produce health benefit at a reasonable cost. Studies documenting the cost-utility of pulmonary rehabilitation, in comparison to other programs, are needed to justify inclusion in the basic services package.

IX. Conclusions

Rehabilitation programs for patients with COPD are widely advocated. Studies on the cost-benefit of these programs consistently demonstrate that following pulmonary rehabilitation, patients are hospitalized less often than they were prior to the program. Since the cost of a rehabilitation program approximates just 1 hospital day, reductions in hospital days are meaningful. However, few of the evaluations have used systematic experimental designs, and it is usually not possible to rule out other explanations for reductions in hospital days.

Only two studies have evaluated the cost-utility of pulmonary rehabilitation programs. One of these showed that rehabilitation produces one QALY, or the equivalent of one well-year of life, for about $23,000. This compares favorably with many widely advocated health care programs. For example, commonly accepted mammography screening programs cost about $175,000 to produce one QALY. However, the other cost-utility study of pulmonary rehabilitation failed to demonstrate that pulmonary rehabilitation produced significant benefits when measured in QALY units.

Cost-effectiveness analysis and outcomes research present important research challenges. Currently, there are too few studies that systematically evaluate the effectiveness of various treatments. For example, only one clinical trial has evaluated the health benefits of pulmonary rehabilitation. The new outcomes research paradigm emphasizes the documentation of benefits using outcome measures that capture the patient's perspective. Another challenge is in showing the relative cost-utility of rehabilitation interventions. Many cost-effectiveness analyses measure benefits using measures specific to lung diseases. These studies cannot be used for general policy analysis. For example, changes in exercise tolerance for pulmonary patients cannot be compared directly with changes in blood glucose for patients with diabetes mellitus. However, programs for these two patient groups compete for the same resources. New methods in outcomes research use general metrics, such as the QALY, to facilitate cross-illness comparisons. In the future, it will become increasingly important to document that expenditures on pulmonary rehabilitation are a good investment of resources in relation to alternative uses of the same funds. To accomplish this, we encourage continuing studies that apply cost-utility methodologies.

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