

Pulmonary Rehabilitation Should Be Prescribed in the Same Way Medications Are Prescribed

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Introduction

In Europe and the United States investment in research and development for chronic respiratory diseases is directed primarily towards the development of new drugs. Obviously, pulmonary rehabilitation is not related to the systems of production, diffusion, publicity, and profitability implicit in the marketing of drugs (particularly bronchodilators and inhaled corticosteroids) that are currently administered chronically in patients with chronic obstructive pulmonary disease (COPD). However, there is clear evidence of the beneficial effects of pulmonary rehabilitation in patients with respiratory diseases such as COPD, not only in the short term, but in the long term as well.¹⁻⁴ These beneficial effects can be observed in many of the patients' functional variables, as well as in health-related quality of life and health care costs associated with hospital care. The benefits of pulmonary rehabilitation can be achieved even in advanced stages of the disease, when significant improvement through medical treatment is no longer possible. However, it is quite apparent that pulmonary rehabilitation is not applied on a grand scale. This contrasts diametrically with the success of the pharmaceutical industry in expanding the indications for and in marketing drugs for chronic respiratory diseases. With these considerations in mind, it is evident that we need to define more clearly the efficacy, effectiveness, and efficiency of pulmonary rehabilitation, so that the bodies that finance health services can evaluate its impact and consider it alongside successful pharmacoeconomic strategies.

Scientific Evidence of the Beneficial Effects of Pulmonary Rehabilitation

Current scientific evidence has led the principal European and American scientific societies to consider pulmonary rehabilitation as an essential part of the treatment of COPD.⁵ The fundamental pillar of a

pulmonary rehabilitation program is muscle training for both peripheral^{5,6} and specific respiratory muscles.^{7,8} Muscle training increases muscle mass and strength,⁹ reduces muscle fatigue,¹⁰ and increases aerobic capacity.¹¹ In recent years, numerous controlled studies have been published that demonstrate the considerable short-term and long-term benefits of such treatment.^{1-3,12} Furthermore, muscle training has biochemical effects in and of itself. In fact, in both animal models and in humans, muscle training induces beneficial changes on the systemic level both in the balance between inflammatory and anti-inflammatory mediators and in the concentration of molecules that participate in muscle repair.¹³ Scientific evidence thus leaves no doubt as to the benefits of a pulmonary rehabilitation program.

The Success of the Pharmaceutical Industry as an Example of Strategic Planning

In the last 50 years alone the pharmaceutical industry has grown exponentially and has become one of the most prosperous enterprises in the marketplace. Its economic success, however, is accompanied by a high level of financial risk. Pharmaceutical innovation, that is, the development of new drugs, involves a considerable investment of time, effort, and money. In fact, introducing a new drug on the market is extremely expensive, costing about €670 million (US \$800 million), and takes on average about 15 years. Of every 5000 new chemical entities synthesized, only 10 manage to reach the clinical phase and barely one of them is actually put on the market. The few drugs that are successful pay the costs of many other discoveries. It is estimated that only 3 of every 10 drugs that reach the market recover the average cost of research and development.

The Bayh-Dole law (1980) was conceived to promote the practical application of the work of research institutions. However, there is some concern over the complexity of the current systems for registering drugs in developed countries, as this may constitute an obstacle to further innovation. There has also been criticism of the tendency for innovative efforts to be directed exclusively towards the most lucrative markets. This generates a phenomenon known as forgotten diseases, that is, those that may represent real health care priorities, but for which treatments are of little economic interest to the industry.

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And...What Does Pharmacoeconomics Have to Do With Pulmonary Rehabilitation?

There are no drugs for COPD with effects as long-lasting as those of pulmonary rehabilitation. In fact, the vast majority of drugs (such as anticholinergics, β -adrenergic drugs) used for chronic respiratory diseases require daily and long-term administration. At this point we might well ask ourselves the following question: What would happen if pulmonary rehabilitation were sponsored and marketed by the industry? Access to this therapeutic intervention might then become more widespread and many more patients might therefore benefit from it. In view of its long-lasting benefits in terms of health-related quality of life and reduction in exacerbations and hospital admissions, it seems clear that a substantial reduction in health care costs would result. A minimal intervention program might possibly make the benefits of pulmonary rehabilitation last much longer, but such programs constitute a relatively recent field of clinical research.

Can the Principles of Strategic Planning Used in Drug Research Also Be Applied to Pulmonary Rehabilitation?

The answer is yes. In general, pharmaceutical companies use a 4-stage approach to strategic planning. The first stage is to identify the intellectual property measures currently under review and discussion, particularly the extension of the duration of patents, the broadening of the spectrum of patentability, the protection of trial data, and restrictions on the use of the international nonproprietary name. The second is to gather information on the national pharmaceutical market, including its segmentation (public vs private sectors), patterns of drug consumption in the home, and drug price trends. The third stage is to estimate the price differential between innovative and generic products. The final stage is to study the various clinical settings, specifically the number of exclusive drugs, bearing in mind that while exclusivity is not always due to patents, it is largely a result of intellectual property measures. If we could think of pulmonary rehabilitation as a drug, these factors that pharmaceutical companies consider in their strategic planning would clearly favor its wide-scale application. Firstly, there are no intellectual property or patent restrictions on pulmonary rehabilitation; secondly, pulmonary rehabilitation can be performed in the majority of public institutions and does not constitute innovative technology; thirdly, pulmonary rehabilitation represents a saving of effort and money compared to the research and development investment for any drug. But it is the last of the 4 strategic stages that most probably works against the widespread use of pulmonary rehabilitation as a treatment, as there are no studies that have systematically evaluated the various clinical settings in which it could be applied (especially in primary care) or that have demonstrated its cost effectiveness and cost efficiency. The absence of commercial interests and the lack of pharmacoeconomic studies can explain why patients do not have generalized or early access to pulmonary rehabilitation, and also make it difficult for health care professionals to prescribe it as a treatment.

Current scientific evidence demonstrates that the strategy to follow involves a protocol combining drug therapy and pulmonary rehabilitation, both administered on an individual basis tailored to the needs of each patient. Our group has promoted the evaluation of muscle compartments, for peripheral muscles as well as inspiratory and expiratory muscles, in order to define the ideal training strategy for patients.¹⁴ We believe that not all patients need or obtain the same benefits from a general-purpose exercise program.⁷ The concept of "individualized training" is consistent with the way in which a drug is prescribed—that is, taking into consideration the presence of such variables as bronchial hyperresponsiveness, hypoxemia, hypercapnia, low body weight, and obesity.⁷ The public health system must make its efforts to apply pulmonary rehabilitation consistent with an economic policy that makes it possible to observe its impact on health care costs. Evidently, the airway obstruction and inflammation that characterize COPD mean that bronchodilators and anti-inflammatory agents will be prescribed early and treatment will be uninterrupted.⁹ However, the anti-inflammatory effects of muscle training can be considered complementary to those obtained with inhaled drugs.¹³ In view of these considerations, it seems evident that the key to maintaining the benefits of pulmonary rehabilitation over time lies in the design and application of a program that is both simple and realistic (to facilitate long-term adherence), as well as in devising a regular maintenance strategy.^{1,3,15-18}

There is no drug that has beneficial effects on as many clinical variables as pulmonary rehabilitation; there is no drug with effects that are as long-lasting (up to 18 months) as those of pulmonary rehabilitation; and there is no drug with an research and development investment as low as the costs of the most sophisticated pulmonary rehabilitation program. Pulmonary rehabilitation is a useful and effective therapeutic strategy with predictable effects on both physiology and the perception of symptoms that translate into important clinical results in patients with chronic respiratory diseases. It should therefore be considered and applied in the same way as pharmacological treatments in patients with chronic respiratory diseases.

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