

Quality-of-life measures in asthma — do they matter to the GP?

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SUMMARY

Asthma is a condition which incurs a great cost to the National Health Service, to the economy and above all to the patient in terms of loss of quality of life. Treatments for asthma need to be evaluated for their cost-effectiveness. Traditional outcome measures, such as airflow measurements have their limitations, especially in mild to moderate asthma. Quality-of-life measurements represent the impact of asthma on the everyday lives of asthmatics across the whole disease spectrum.

Disease specific quality-of-life questionnaires, such as the Asthma Quality-of-Life Questionnaire (AQLQ), provide reliable instruments in reflecting disease severity, but also in detecting changes in quality of life produced by different asthma treatments.

Quality-of-life measures are becoming increasingly important and are end-points of therapeutic asthma trials in primary care, but should be used in conjunction with more surrogate markers of asthma severity such as peak flow.

Keywords: asthma; morbidity; quality of life.

Introduction

TRADITIONALLY, our choice of asthma therapy has been based on the simple concepts of whether the treatment works and is safe. Governments have been alarmed by the escalating direct costs of health care. For example, in 1995, asthma cost the National Health Service (NHS) in England alone, £561 million, of which the drug budget was estimated to be £411 million.¹ The major part of this cost is incurred in primary care,² and there are great pressures upon general practitioners (GPs) from both health managers and the government to minimize the drug budget. In the brave new world of evidence-based medicine, asthma treatments have to be not only effective and safe, but also represent 'value for money'. This article attempts to introduce some basic concepts of health economics and, in particular, to promulgate the concept of evaluating the effect of asthma treatments on the basis of quality-of-life measures.

The cost of asthma

Asthma costs can be broadly divided into the following categories:

- Direct costs: costs of hospital care, consultations and drugs
- Indirect costs: time off work, loss of productivity
- Intangible costs: costs to people with asthma and their families because of restrictions of daily activities, and costs resulting from emotional and relationship problems.

Outcome measures that involve direct cost savings are clearly very attractive to NHS managers but may not be relevant to many patients with asthma. For example, in a survey carried out in 1990–91,³ only 14% of patients had visited hospital in an

emergency in the previous year. Hence, a treatment that was being evaluated in terms of reduction in emergency hospital visits/admissions would be unlikely to show any benefit for the majority of asthma patients.

Treatment regimes that produce indirect cost savings may be superficially attractive in improving the nation's productivity. However, increases in a local health commission's spending to produce savings in someone else's employment/unemployment budget are unlikely to be an attractive proposition for health care managers. The 'good of the nation' argument is often lost in the NHS sums!

However, the greatest cost to many patients with asthma is the negative impact on their quality of life or the 'intangible costs'.

The burden of asthma

Asthma mortality has declined slightly in the past few years (1959 deaths in the United Kingdom in 1988 and 1665 deaths in 1994¹), but it still carries a high morbidity. Numerous studies have been carried out on the impact of asthma on the quality of life of asthmatic patients. Among these, the National Asthma Survey was carried out in 1995 using questionnaires returned by 61 000 asthmatic patients.⁴ Of the respondents, 41% experienced asthma symptoms every day or most days, and 25% indicated that asthma restricted their day-to-day activities. Similarly, in school-age children, the survey showed that 25% had taken at least one week off school in the previous 12 months because of their asthma. In addition, a study by Donnelly and colleagues in 1987⁵ found that 23% of parents of children suffering from asthma stated that their children had low self-esteem and poor relationships with others. The Lifestyle Study of 1992⁶ revealed that 15% of working parents had to take at least one day off work in the three months before the study because of their child's asthma. It is easy to see how the 'intangible' cost of a child being awake throughout the night or being off school can be translated into the tangible cost of a day's work lost by the parent.

Assessing the economic value of treatments

There are four general types of health economic evaluation:

1. Cost minimization: a comparison is made of two treatments, the outcomes of which are equal. This approach is limited by the assumption that therapies are equally effective, and therefore, additional efficacy studies may need to be carried out to determine this.
2. Cost-benefit: all costs and outcomes are given a monetary value and this value is compared as an end point. This approach has difficulties, as many of the indirect costs have to be based on estimation and assumptions. Intangible costs are even more difficult to quantify.
3. Cost-utility analysis: the effect of the disease on the general health of the patient is quantified in a single measure, or 'utility', on a scale ranging from 'perfect health' to 'death' (Figure 1). The most widely known utility measure is the quality-adjusted year (QALY). This is calculated from a formula using the improvement in utility scores and the number of years over which this improvement has occurred.⁷ Utility measures are attractive to health economists, as they can compare and quantify the effects of various diseases on a

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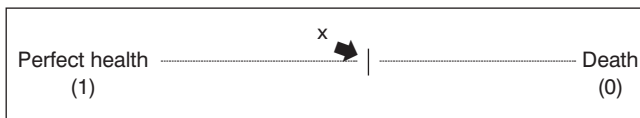


Figure 1. A utility scale (x = utility score).

patient population. For example, the value of employing an asthma care coordinator or a diabetic care coordinator in a health district can be compared using the relative improvements in utility scores. Financial resources within that health district can therefore be targeted appropriately. However, many of the utility scores are difficult to validate. Different scales may give different utility in the same patient and may not reflect a clinically significant change in health in asthmatics.⁸

4. Cost-effectiveness: this is probably the most familiar form of health economic analysis to GPs, but its usefulness depends on the outcome measure chosen. Therefore, the following question needs to be addressed: which outcome measure should be used in cost-efficacy analysis in asthma? Traditionally, efficacy has been assessed in terms of symptom improvement, bronchodilator use or by measurement of airflow in the lungs.

Airflow measurements

Asthma is characterized by chronic inflammation of the airways, but as yet there is no direct marker of airways inflammation, which is used widely in clinical practice.

Indirect markers of airways function, such as forced expiratory volume in one second (FEV₁) and changes in peak expiratory flow rate (PEFR), have traditionally been used to assess disease severity, but do not necessarily reflect the severity of the inflammation present. In addition, improvements in FEV₁ or PEFR may not be reflected in the general clinical state of the patient. This is especially true for mild asthma.

A one-year study of patients with mild asthma showed that inhaled budesonide produced a significant improvement in asthma symptoms and bronchodilator use in comparison with placebo, with very little change in FEV₁.⁹ Similarly, an analysis of studies using the St George's Respiratory Questionnaire, which reflects quality of life, showed that there may be a significant reduction in quality of life at levels of between 90% and 95% of predicted FEV₁.¹⁰

Symptom scores and symptom-free days

Symptom scores may also not be an effective marker of disease severity. The National Asthma Survey of 1990/91¹³ showed that most asthma sufferers admit to few symptoms on direct questioning, but do admit to moderate or severe restriction of their daily activities, i.e. they have become used to their asthma symptoms being part of normal life. Symptom-free days have been advocat-

ed as a useful outcome measure in cost-effectiveness analyses.¹¹ However, patients may modify their lives to avoid symptom-inducing activities. For example, poor asthma control may prevent an asthmatic taking part in a sporting activity, but the patient would still record a 'symptom-free' day.

Bronchodilator use

Bronchodilator use is another questionably useful marker of disease severity. At one end of the scale, patients do not use their bronchodilator unless their asthma is 'really bad', whereas others use their bronchodilator 'just in case'. The phenomenon of the surgery toilets being filled with bronchodilator aerosol before the patient seeing the doctor is well recognized!

Frequency of acute exacerbations

Both frequency of acute exacerbations and use of hospital services are very attractive end points to health economists, as the costs are quantifiable. However, reasons for oral steroid use or hospital admissions may reflect the expertise of the doctor concerned or local asthma policies rather than disease severity. For example, one doctor may use oral steroids as a pre-emptive course of action in a management plan rather than waiting until the asthma becomes too severe. In addition, while such outcome measures may be relevant in severe asthma, patients with mild to moderate asthma may not have acute exacerbations that require hospital admission,¹² but still exhibit significant psychosocial problems.

Quality-of-life measurements

Quality-of-life measurements reflect the impact of asthma on the everyday life of the patient and have the virtue that they can apply to patients with the mildest to those with the most severe asthma. Such measurements reflect the intangible costs of asthma and, in addition, can be a predictor of compliance.⁸ A patient who feels that a treatment is improving his or her quality of life, and is working effectively, is more likely to comply with the treatment.

Types of quality-of-life questionnaires

Several types of quality-of-life questionnaires are available:

- General health scales. These are 'utility' scales giving scores to general well-being, on a scale from 'perfect health' (1) through to 'death' (0); for example, Standard Gamble or Feeling Thermometers.¹³
- General quality-of-life questionnaires. These reflect problems in areas of life common to all diseases, such as the effect on mobility, work and sleep; for example, the Sickness Impact Profile (SIP)¹⁴ and Short-Form 36 Health Scores (SF36).¹⁵
- Disease-specific questionnaires. These reflect problems in daily life that are specifically affected by asthma; for example, symptoms, activity or trigger avoidance. Examples of these are shown in Table 1.

Table 1. Examples of disease-specific questionnaires.

Questionnaire	Use	Evaluating
St George's Respiratory Questionnaire (SGRQ) ¹⁶	Asthma and COPD	Symptoms, activity and effects on daily life
Living with Asthma Questionnaire (LWAQ) ¹⁷	Asthma	Effect on sport, social and leisure activities, sleep, work, colds, effect on others, morbidity, nebulizer use, sex and dysphoria status
Asthma Quality-of-Life Questionnaire (AQLQ/Juniper) ¹⁸ and variations for paediatric use	Asthma	Symptoms, emotions, exposure to and avoidance of environmental stimuli, and activity limitations from a patient's perspective

Which quality-of-life instruments should be used in asthma?

Generic instruments (SF36, SIP)^{14,15}

These have satisfactory properties as discriminative instruments in asthma, i.e. they can distinguish between patients who have mild, moderate or severe asthma.¹⁸ They are therefore useful for screening and cross-sectional surveys of asthmatic populations. They can also be used to compare morbidity between different diseases. However, in a study by Rutten-van Mólken and colleagues,⁸ comparing the effects of salmeterol and salbutamol using different quality-of-life instruments over a six-month period, the SIP was found to respond poorly to small but important changes that occurred as a result of treatment compared with more disease-specific questionnaires (see below).

Utility instruments

'Feeling Thermometer' and 'Standard Gamble'¹³ methods were also compared in the study by Rutten-van Mólken *et al.*⁸ These gave variable results regarding discriminatory properties and responsiveness to change/intervention. In the latter respect, the disease-specific questionnaires were found to be more appropriate.

Disease-specific questionnaires

The Asthma Quality-of-Life Questionnaire (AQLQ–Juniper),¹⁸ St George's Respiratory Questionnaire (SGRQ)¹⁶ and Living with Asthma Questionnaire (LWAQ)¹⁷ have been compared,⁸ and all were found to be reliable discriminatory instruments. However, the AQLQ was also more responsive to change produced by salmeterol/salbutamol. The ability of the LWAQ to detect such longitudinal change was found to be improved by the use of a quality-of-life diary,¹⁹ but compliance with using such diaries may be limited in longer clinical trials.

Practical use of quality-of-life questionnaires

Published studies evaluating asthma treatments in terms of validated quality-of-life measures are still in their infancy. Examples of such studies include the benefit of adding salmeterol to low-dose (400 mg) inhaled beclomethasone compared with increasing the beclomethasone dosage to 1000 mg per day.⁹ One attraction of using such disease-specific questionnaires is that a score can be developed that corresponds to the minimal clinically significant change (MCSC).

In the salmeterol versus salbutamol study,⁸ a clinically significant change was considered to be a 33 l/min improvement in morning peak flow rate or a 9% improvement in FEV₁. By estimating the cost of treatment to produce such an MCSC, different treatment regimens can be compared in terms of cost-effectiveness. In other words, the 'intangible costs' of improvements in quality of life can now be quantified.

What are the limitations of quality-of-life measurements?

Quality-of-life questionnaires are still relatively time-consuming to complete. The AQLQ still takes 10 minutes to complete, although attempts are being made to produce shorter validated questionnaires. There is a paucity of studies comparing the various quality-of-life instruments, and further studies need to be carried out to do this. In addition, the questionnaires measure only the functional improvement in the patient 'now' and give no indication of the effect of asthma on the patient in the future. For example, a therapy may have great benefits on the patient's present quality of life, but may do little to halt any inflammatory

process that could cause damage in the future. Furthermore, a stoical patient may apparently have a good quality of life but have poor lung function. Hence, quality-of-life measurements need to be used in conjunction with more surrogate markers of asthma control, such as FEV₁ or peak flow. However, there is a great need for more direct markers of inflammation or epithelial damage in the lung, which might help to predict the effect of a treatment on future lung function. The use of exhaled nitric oxide as a measure of airways inflammation is a step in this direction.²⁰

So, do quality-of-life measures in asthma matter to the GP? The answer is certainly yes. Validated disease-specific questionnaires, such as AQLQ, can represent the significant effect that asthma has upon the everyday life of our patients and are becoming an increasingly important feature of clinical trials in primary care. They can also be used to quantify the 'intangible costs' of asthma and, hence, to assess the cost-effectiveness of established and newly developed asthma therapies.

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