EDITORIAL

Once daily inhaled steroids for asthma: how useful are pharmaco-economic data?

The paper in this issue from Julian Guest et al. [1] is welcome, timely, and of interest. Using a case-control design and the powerful General Practice Research Database (over 30 million patient years of data from over 300 practices) the effect of changing patients from a twice-daily inhaled steroid to a once-daily inhaled steroid was examined over a 12-month period. On the one hand, switching to a once-daily steroid was associated with increased compliance and reduced cost. On the other hand, a comparison group of patients who changed from one twice-daily inhaled steroid to another showed only slightly increased compliance but with increased cost. Neither of these findings is perhaps surprising, but the data are useful, reflect British General Practice, and merit further attention. Anything which improves adherence with asthma therapy is important, and cutting drug costs is always a target. A number of inhaled steroids can now be prescribed once daily [2–7].

Several potential criticisms of the study are addressed in the discussion, the main one being the retrospective, non-randomised methodology. Individual patients and their doctors could have had a multitude of reasons for changing treatment, and the effects of altered devices or nursing interventions are not addressed. Although a sizeable study, the final numbers of patients involved in the different subgroups are small. Questions remain about the reliability of the data, particularly in terms of compliance and resource use.

The National Health Service (NHS) has a long-standing reputation for cost effectiveness. In fact,

there has been an undoubted, long-term emphasis on cost-containment. Respiratory medicine is a good example of a 'Cinderella, work-horse' speciality; prescriptions may be relatively low cost but they are of very high volume. Pharmacy advisers employed by Primary Care Organisations (PCOs) have exerted major pressure on prescribing in General Practice. This has been done with minimal clinical responsibility and scant regard for patient outcome. However, we have been slow to develop practical outcome measures in asthma, though this has not been for want of trying. Quantifying asthma severity and developing practical measures of airway inflammation has consumed much research effort, ever since the realisation that measures of airway diameter such as peak expiratory flow, even if recorded regularly at home, do not tell us the whole story. Both indirect estimates (eg bronchial responsiveness) and more direct ones (eg sputum eosinophil counts or exhaled nitric oxide) have been shown to be useful academically. However, neither are practical, as yet, for application in General Practice. As discussed in a previous issue of the Primary Care Respiratory Journal, there is currently a joint American Thoracic Society/European Respiratory Society Task Force focussing on outcomes of severity of asthma [8].

The rise of the discipline of pharmaco-economics has so far had relatively little direct influence on prescribing. Let us examine some of the possible reasons for this. Pharmaco-economic studies are of interest academically but have most often been applied to pharmaceutical company study data. They have often been co-opted by marketing depart-

ments and used to sell particular drugs. They serve to flag up less obvious costs of management - the indirect as well as the direct costs. In managing asthma, for example, the term 'indirect costs' includes the costs of emergency health care contacts such as 'out of hours' visits, Accident & Emergency department attendances, hospital admissions, and extra general practitioner (GP) appointments, as well as the cost of time off work, looking after the home and family, and loss of productivity, perhaps including social security benefits etc. Direct costs are usually dominated by actual drug costs. A drug which cured asthma, even if it were expensive, would have clear pharmaco-economic benefit.

Asthma outcomes in pharmaco-economics are often composite measures such as 'asthma-free days' or 'well-controlled asthma weeks', which are relevant but are unfamiliar and difficult to translate into practical management. However, health economic studies also clarify what constitutes 'value for money'. From the point of view of a health-care purchaser, for example, how much should be paid for a day, or a week, of controlled asthma (no asthma symptoms, no use of reliever medication, and no adverse effects) for a particular individual? This is, of course, a far greater level of sophistication than that to which the health service can generally aspire.

At present, pharmaco-economic data often fall wide of the mark because of the separation of health care costs as well as social security budgets. Hospital pharmacy costs for a particular drug often differ from community costs. Distinct and separate budgets cater for hospital costs as opposed to community drug costs, as well as different aspects of acute or chronic care. There is a clear need for sophisticated reform involving PCOs in correcting anomalies. Health economic studies need to provide high quality, unbiased data which genuinely inform purchasers as well as the doctors and nurses who work with patients. The economics need to be made relevant, with consensus definitions replacing over-technical terminology. They also need to fit into 'real-life' British General Practice.

Drug development by pharmaceutical companies usually comprises a package of drug studies aimed at establishing proof of principle, actual clinical efficacy, which are then used for obtaining regulatory approval, getting the drug licensed, and finally for marketing it. This involves placebo comparison studies, dose-ranging studies (defining clinically useful doses), comparator studies (comparisons with other currently used agents), and then positioning studies (aimed at placing the drug in clinical context, within treatment strategies or

guidelines). Much of the latter phases overlap with marketing. Pharmaco-economic studies aim to assess hidden (indirect) costs and benefits, as well as obvious (direct) drug costs. Increasingly they have been added to modern drug company study portfolios.

However, in addition, we should encourage companies to fund 'real-life' studies examining effectiveness (as opposed to efficacy), side effects, and cost/benefit outcomes in patients who are actually prescribed their products in real life, rather than the rigorously selected, homogenous populations usually studied in conventional clinical trials. For example, a prospective, randomised study of once- versus twice-daily prescriptions of an inhaled steroid, in sufficient numbers of unselected General Practice patients, would answer this question once and for all.

At present, there is clear evidence that in well-controlled asthma, inhaled steroids are effective once-daily, and many of our patients have been taking them this way for some time. This produces a cost saving, provided patients remain controlled. The most recently introduced compounds, mometasone and ciclesonide, have produced much new data (6), particularly in patients with milder disease or lower doses of inhaled steroid.

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