



Opinion

Considering the options in respiratory prescribing

Clinicians working in primary care may sometimes feel they are faced with a bewildering choice of therapeutic options when prescribing. This is most certainly the case when prescribing inhaled medication in respiratory care, as decisions about devices, drugs, doses, molecules, particle size and the appropriate use of combination therapies all have to be balanced in the course of the consultation. In recent years, however, even these decisions seem to have been superseded by the need to be mindful of cost. Yet, like so many other decisions in healthcare, financial considerations should not simply be restricted to the cost of medication; the focus of our attention needs to be on 'cost effectiveness'. However, defining cost effectiveness is not easy, especially when one of the main variables of the effectiveness of inhaled therapy is the user of that therapy, i.e. the patient. The many variables make arguments about cost effectiveness difficult to formulate.

What does cost-effectiveness mean?

To understand cost effectiveness, we need to define whether we mean:

Cost minimisation – where health outcomes are (or are assumed to be) equivalent so the cheapest option is deemed to be best.

Cost benefit – where health effects and resource use are both measured in monetary terms.

Cost effectiveness – where the cost of interventions are measured against outcomes, such as prevention of exacerbations or improvements in lung function.

Cost

When considering the costs of a treatment, the analysis should include the cost of poorly controlled disease as well as medication costs. From a broad

societal perspective this should include 'indirect costs' (i.e. the cost of lost productivity because a patient or relative has taken time off work because of uncontrolled disease) as well as the 'direct costs' to the health system, which includes the cost of primary and secondary care services as well as medication used.

The term 'cost effective prescribing' implies that the unit cost is not the 'be-all and end-all' of prescribing decisions, but that the relative effectiveness of that treatment is taken into account. For example, if cost were the only consideration, then oral steroids and short acting bronchodilators delivered via a pMDI would provide a cheap therapeutic option for both asthma and chronic obstructive respiratory disease (COPD) but this is clearly not an effective way of managing the patient's holistic well-being. The cost of the side-effects of this treatment would rapidly outweigh any pharmacy savings. Acknowledging that inhaled therapy affords the most effective treatment along with the lowest side effects, forces consideration of how this should be provided in the current evidence based yet financially driven climate.

Effectiveness

If the aim is to prescribe effective treatment with optimal all-round benefit at the lowest possible cost, the next consideration must be what is meant by 'effective' treatment.

In asthma care, both the British Thoracic Society/Scottish Intercollegiate Guidelines Network (BTS/SIGN) asthma guidelines¹ and the Global Initiative for Asthma (GINA) guidelines² recommend that treatment should aim to ensure that the patient has no symptoms, no need for the use of reliever inhaler, optimal lung function and no impact on day to day life. In COPD, the National Institute of Health and Clinical Effectiveness (NICE) guideline³ advise that effective treatment means maxi-

mum reduction in symptoms, improvement in exercise capacity and reduced risk of exacerbations, which in turn will mean fewer admissions and a reduction in overall morbidity and mortality. How can we include all these outcomes, when defining which treatments are the most cost-effective? Should we include failure to quit smoking in the cost effectiveness considerations of inhaled therapies for COPD? What are the cost implications of people who don't or won't access pulmonary rehabilitation? What about the different phenotypes for COPD and asthma?⁴ Should we consider these when considering effectiveness of treatments? The number of trials could be endless. As it is, there are already debates about how we measure effectiveness.

Interpreting the evidence

As part of cost-effectiveness deliberations, local guideline groups may review the evidence and look at numbers needed to treat (NNTs) to prevent (for example) an exacerbation of COPD. However, NNTs refer to the specific context in which they were studied, reflecting the use of a specific treatment for a specific duration in a specific population to a specific endpoint. If the guideline group uses NNTs to compare the results of different trials and different drugs, it is important to ensure that they have been calculated in the same way in each case. Differences in study design and use of NNT calculations may make comparisons misleading. Populations studied may not be comparable, primary outcome measures may not be equivalent, risk reduction may be expressed as absolute or relative reductions.

National guidance on inhaler devices

The BTS/SIGN asthma guidelines state that, apart from in the case of younger children when a pMDI and spacer will be the preferred option, there is no evi-

dence to suggest that any device is better than another and that in the absence of evidence, the most important points to consider are patient preference and cost.¹ Note that the term used is cost, not cost-effectiveness. Prioritising the former, as in this BTS/SIGN statement, may, of course, compromise the latter. NICE's technology appraisal of inhaler devices for older children adopted a patient-focused approach.⁵ It concluded that the key considerations for inhaler choice in this age group should be that the child and/or carers can and will use it and that it suits their lifestyle - there is no specific mention of cost or cost effectiveness. In the NICE guidelines on the use of inhaled corticosteroids in adults and children over 12, the advice given is that for people in this age group who require treatment with an inhaled steroid for their asthma 'the least costly product that is suitable for an individual, within its marketing authorisation, is recommended'.⁶ The point here is to understand how suitability is assessed – not just by the marketing authorisation, but by its suitability for that patient, perhaps using the same criteria as NICE does for children.

Combination therapies

In some cases, we need to be especially mindful of the marketing authorisation. For example, some prescribers are still advised, by local guidelines or computer software, to reduce the dose of combination therapies for COPD to doses below those which are licensed; prescribers may also be advised to prescribing Seretide™ (salmeterol xinafoate and fluticasone propionate) via a pMDI instead of the dry powder inhaler option, which again flouts the licence which is based on submitted evidence. Clinicians need to remain vigilant to these pressures, and should not prescribe off-license or outside guideline recommendations without considered and compelling reasons. In the same way, licensing for COPD prescribing can be deter-

mined by lung function. For example, Seretide™ is licensed for people with a pre-bronchodilator FEV₁ <60% predicted, whereas Symbicort™ (formoterol fumarate and budesonide) is licensed in people with an FEV₁ of <50% predicted. Local prescribing guidelines may not always reflect these differences. Indeed in some areas of the country Fostair™ (formoterol fumarate and beclometasone dipropionate) has been included in local COPD formularies based on clinical data for asthma. Fostair™, however, is not licensed for use in COPD, and should not be used in COPD until further marketing authorisation is granted based on evidence of effectiveness.⁷

High cost treatment options

Poorly controlled asthma and COPD can result in loss of productivity, unscheduled healthcare and hospital admissions, with high associated healthcare costs. Asthma UK's figures remind us that the majority of asthma admissions and deaths are avoidable.⁸ Cost cutting exercises which involve prescribing 'cheaper' devices for patients who cannot use them is poor practice and likely to increase overall total costs to society. Many respiratory specialists describe how too many people end up in 'difficult asthma' clinics for want of a carefully selected device to deliver the appropriate treatment effectively and a written, personalised asthma action plan.⁹

Switches

Tempting though they may seem from a cost perspective, wholesale switches from one device to another without a face to face consultation and patient consent can result in impaired asthma control.¹⁰ If all patients could use the same device, we would not have the plethora of devices already on the market with more to come.^{11,12}

Summary

Although it would be convenient to be

able to provide a list of 'cost effective' prescribing for inhaler devices, because of individual patient factors such as ability to use inhalers, personal preference influencing adherence, it is not possible to do so. Cost effective prescribing means that the right drug is given through the right device to the right patient. Consideration must be given to the many aspects of the drug, the device and the individual, so that the most appropriate inhaler is chosen with that individual patient and their condition in mind.

References

- British Thoracic Society-Scottish Intercollegiate Guideline Network. British Guideline on the Management of Asthma. *Thorax* 2008;**63**(Suppl 4):1-121. Updates available from <http://www.brit-thoracic.org.uk>
- Global Initiative for Asthma (GINA). The Global Strategy for Asthma Management and Prevention, Updated 2011. Available from: <http://www.ginasthma.org> (accessed July 2012)
- National Institute for Health and Clinical Excellence. National clinical guideline management of chronic obstructive pulmonary disease in adults in primary and secondary care. *Thorax* 2004;**59**(Suppl 1):S1-23 (Updates available from <http://www.nice.org.uk>)
- Thomas M, Taylor DR. Assessing inflammatory phenotypes and improving the cost-effectiveness of asthma and COPD care in the community. *Prim Care Respir J* 2011;**20**:349-350.
- NICE (2002). Technology Appraisal 38: Inhaler devices for routine treatment of chronic asthma in older children (aged 5–15 years) Available from <http://publications.nice.org.uk>
- NICE (2008). Technology Appraisal 138: Asthma (in adults) – corticosteroids. Available from <http://www.nice.org.uk>
- Electronic Medicines Compendium. Summary of product characteristics and patient information leaflets on prescription medication 2012. Available from <http://www.medicines.org.uk>
- Asthma UK. Facts for journalists 2012 Available from <http://www.asthma.org.uk>
- PCRS Opinion sheet – asthma action plans - http://www.pcrs-uk.org/opinions/asthma_action_plans_rev_aug_2008.pdf
- Doyle S, Lloyd A, Williams A, et al. What happens to patients who have their asthma device switched without their consent? *Prim Care Respir J* 2010;**19**:131-139.
- Pearce L, Levy M. PCRS-UK Opinion sheet – inhaler devices 2011. Available from http://www.pcrs-uk.org/opinions/inhaler_devices_final.pdf
- Heslop K, Loveridge C. PCRS-UK Tailoring inhaler choice 2012. Available from http://www.pcrs-uk.org/opinions/os49_tailoringinhalerchoice.pdf