General Practice Airways Group

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Dear Alana

Inhaled corticosteroids and long-acting beta2-agonists for the treatment of chronic asthma in children under the age of 12 years:
Systematic review and economic analysis

Thank you for sending the GPIAG the assessment report for comment.

We appreciate the great amount of care and diligence that has gone into this assessment. We are broadly supportive of the evaluation and the cautious tone taken in making firm recommendations on the use of specific technologies in management of childhood asthma. We recognize the paucity of evidence in this area, particularly in younger children. We are appreciative of the broad overview of paediatric asthma taken in the background and discussion sections, and pleased that 'real-world' factors of great relevance to the management of asthma in the community such as adherence and inhaler technique are recognized.

While recognizing the need for objectivity and rigour in the evaluation, and recognizing the constraints placed on the evaluation team by the type of clinical and economic analysis expected by the commissioners of the report, there are a number of points we would like to raise that we feel are of relevance to the application of this report to community settings.

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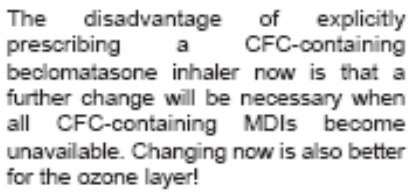
1. The exclusive use of data from randomised controlled trials in the clinical and economic evaluation sections raises important issues of generalisability of the outcomes to the broad and heterogeneous populations treated in primary care. In our earlier submission we presented references illustrating that patients entered into RCTs are not representative of those seen in everyday clinical practice
2. The data and analyses are treated as grouped mean data and no recognition is made of the marked individual heterogeneity of response seen in asthma care. While the 'average' patient may respond better to one intervention than another, this may disguise considerable individual variation in response. There is no attempt to take 'responder/ non-responder' considerations into account in the modeling.
3. It is recognized in the 'background' section that inhaled delivery systems may have a significant effect on outcomes, but it is said that this lies outside the remit of this evaluation. The choice of device is of great importance to us as community practitioners, and we feel it is unfortunate that this important aspect of the use of these technologies is omitted. Many of the technologies considered are available only through one system, and in practice, community practitioners tend not to separate the choice of drug from the choice of device. We would expect that any guidance would acknowledge that decisions on compound are inextricably linked to decisions about the device in the headline recommendations, not just buried in the body of the report.
4. Although the lack of comparative efficacy data is indeed lacking for many of the pairings considered, we feel that the assumption of equivalence made (of necessity) in the cost modeling limits the validity of the economic analyses; as is stated in the discussion, although one technology may be cheaper than another in terms of drug costs, if there is even a small increase in exacerbations associated with the cheaper technology, this may offset or even reverse the cost-benefits assumed in the equivalence model.

We would also like to comment that there appears to be an inconsistency in statements about the relative costs of the currently available combination ICS/LABA devices between the executive summary and the main text.

A final specific issue we want to raise relates to the impending discontinuation of inhalers containing CFCs. While we appreciate that this assessment report is necessarily based on a lot of data on CFC-containing inhalers, care needs to be taken that the final guidance issued to the NHS is appropriate. It would not be helpful for the guidance to state that CFC-driven BDP inhalers are the treatment of choice just as they are to be withdrawn. The worst case scenario would be that a clinician is encouraged by NICE guidance to initiate a CFC-containing form of BDP, for example, and then have to switch the patient again once this form of BDP is discontinued. We know that GlaxoSmithKline plan to discontinue Becotide and Becloforte (both CFC-containing forms of BDP) in September 2007, and we believe, though cannot confirm, that a considerable amount of corticosteroid prescribing is in these brands. We would recommend that NICE talks with relevant individuals at the Department of Health and the Department for Environment Food and Rural Affairs who are overseeing the phasing out of CFCs in line with the Montreal Protocol, in order to ensure compatible timing and messages.

At present the focus in the Assessment report is on the current situation with CFC-containing inhalers being available, but alluding to a future change. It may be better to focus the key recommendations in the Final Appraisal Determination (FAD) on the future situation in the knowledge that CFC-containing inhalers are in the process of being discontinued. It is important that NICE issues guidance that is timely and appropriate, and that causes the least disruption to continuity of patient care. For your information, we have attached the Opinion sheet that GPIAG has prepared for primary care health professionals on the topic of CFC discontinuations, which can be found on our website. A relevant extract is as follows:



We are keen to continue working with you to ensure that the best possible guidance is developed on the use of inhaled steroids in asthma management.

Kind regards,

Dr Mike Thomas,
On behalf of the General Practice Airways Group

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