General Practice Airways Group

Journal: Primary Care Respiratory Journal

Response to Appraisal Consultation Document
"Corticosteroids for the Treatment of Chronic Asthma in adults and children aged
On Behalf of the General Practice Airways Group
May 15, 2007

The General Practice Airways Group is largely in agreement with the findings of the Appraisal Consultation Document (ACD) and welcomes the incorporation of some of our previous comments into the ACD.

In preparing this response we have consulted with the British Thoracic Society who support the comments we are making here. We would like to make the following observations:

The title of the Appraisal ….
is still misleading and is at odds with the detail in the appraisal scope document. This is an appraisal of the "Comparative effectiveness and cost-effectiveness of Inhaled Corticosteroids for the treatment……."
If this were a true appraisal of inhaled corticosteroids (ICS) then the long term side effects of ICS especially at high doses should be included, based on observational data. This is not an appraisal of oral corticosteroids, and the scope quite clearly includes only inhaled steroids. The title should be amended to reflect the scope of the appraisal as outlined in para 4.1.2.

1 Do you consider that all of the relevant evidence has been taken into account?
In broad terms – yes we do – with one exception.

We welcome the recognition of the Appraisal Committee that the choice of delivery device is important when choosing an ICS, but are uncertain about the evidence behind the statement in 1.4 that "*use of a pressurised inhaler plus spacer is recommended in the first instance*."

Whilst accepting that this is the first choice for delivery of inhaled corticosteroids in children and delivery of high doses in adults, we are not aware of evidence which supports the preferential use of spacers in adults with good inhaler technique, for the delivery of low dose inhaled steroids.
There is not general agreement with the statement in para 4.3.6 that "*a pMDI (pressurised metered dose inhaler) and spacer device is usually considered in the first instance in routine clinical practice*". This is not the case in adults being prescribed low dose ICS where the pMDI alone is often the device of choice.

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Indeed there are disadvantages with the MDI-spacer approach:
a) Extra cost to the NHS and to the patient of the spacer device.
b) Use of a more cumbersome device for the patient.

In the absence of evidence that use of an MDI and Spacer is more effective or has less side effects for the delivery of low dose steroids in adults than the MDI alone, it would be more appropriate to say that
"*Use of a pMDI is recommended in the first instance. Use of a spacer device is recommended for delivery of high dose inhaled steroids or for patients with poor inhaler technique*."

2 Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate?

In broad terms, yes we do, and have no specific comments.

3 Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?

We have already expressed concerns under 1 above regarding the recommendation to use a spacer with MDI in adults, and do not believe that this reflects standard practice.

Para 4.3.8 and para 4.3.9.
We welcome the acknowledgement that use of a combination LABA/ICS minimises the chance that the ICS will be omitted by the patient. We were therefore disappointed that the endorsement for combination inhalers was diluted by the statement in 4.3.8 that "*separate devices in fully compliant individuals could be equally effective and equally or more cost effective*" and in para 4.3.9 that "*in the future delivery via separate inhalers in fully compliant individuals may become the preferred option*"

The Salmeterol multicenter asthma research trial (SMART) (Nelson HS, Weiss ST et al *Chest* 2006:129:15-26) in the USA has led to concerns expressed by the FDA in America and the MHRA in this country, that use of long-acting beta-2 agonists (LABA) without ICS increases the risk of asthma deaths. Evidence from SMART (USA study) and experience in this country suggests that many patients on ICS are

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non-compliant. Prescription of separate ICS and LABA inhalers increases the risk of non-compliance with the ICS compared to the combination as patients tend to preferentially use (or fill the prescription) for the LABA which they feel is working, at the expense of the ICS.

For many people with asthma requiring an LABA plus ICS, the prescription of separate inhalers is therefore potentially dangerous. The recommendation from NICE should be worded more strongly that "*LABA/ICS should be prescribed in combination and only in exceptional circumstances (when the patient is fully compliant) should separate inhalers be prescribed*".

Our final point is that there appears to be no section in the ACD for suggestions for 'Further research' as there is for most appraisals. We strongly recommend that the groups preparing the assessment report are asked for their views on the gaps in the research base for inhaled corticosteroids in asthma, and we have suggested the following research needs too -

1. Recognising the low adherence we see with ICS in practice and impact this has on asthma disease - what are the most cost-effective approaches to managing this?

2. More observational and real world studies in order that studies include the range of disease patterns that asthma manifests, and that the results of studies are generalisable to the heterogeneity of the patient population in primary care

3. The outcomes associated with a personal asthma action plan for patients in primary care (many studies are in secondary care)

4. Improving understanding of the unpredictable relationship between symptoms and measures of lung function

5. Longer term studies to explore the impact of treatment on long term control and exacerbations

6. Longer term studies to explore the impact of adherence on asthma outcomes related to different technologies

We look forward to seeing the Final Appraisal Determination, after you have considered all comments received on the ACD. If there are any specific points you wish to discuss further, please do not hesitate to contact me.

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