



National Institute for Health and Clinical Excellence (NICE) Guidelines for inhaled steroids for the treatment of chronic asthma

Introduction

The National Institute for Health and Clinical Excellence (NICE) has recently issued two technology appraisal guidelines reviewing Inhaled Corticosteroids (ICS) in the treatment of chronic asthma in adults and children aged 12 and over¹ and in children under the age of 12². This opinion sheet considers the key recommendations and how they complement the recommendations of the 2008 British Thoracic Society (BTS)/ Scottish Intercollegiate Network (SIGN) Guideline for the Management of Asthma.³

Methodology

The NICE appraisal committee comprises generalist health professionals and lay members who consider evidence and feedback from individual respiratory specialists, specialist organisations (such as the PCRS-UK) and pharmaceutical companies. The committee examined the comparative effectiveness and cost effectiveness:

- 1) of the different low dose ICS available at "Step 2" of the BTS/SIGN Guideline (see Figure 1).
- 2) of the effect of adding long-acting beta-2 agonists (LABA) to ICS, separately or in combination.
- 3) of and differences between the ICS/LABA combination inhalers available at the end of 2007
- 4) of the different high dose ICS (at "Step 4").

The Committee did not consider the dose response of ICS nor comment upon the safety aspects of ICS in the Guidance. Greater emphasis was placed on evidence from randomized controlled studies which may not actually reflect the situation found in everyday clinical practice (for example compliance with medication may be greater under controlled trial circumstances).

The Committee acknowledged that the delivery of ICS is inextricably linked to the choice of delivery device and the Guidance outlined below should be read in conjunction with NICE guidance on inhaler devices in children^{4,5} which emphasises the importance of choosing an inhaler

The Guidance is outlined in Table 1 (adults) and Table 2 (children).

How does this fit in with BTS/SIGN guideline?

The 2008 BTS/SIGN asthma guideline continue to advocate a "Step-up/Step down" approach to chronic asthma management. This approach in adults and children over 12 is shown in Figure 1. The NICE Guidelines are consistent with the BTS/SIGN Guideline except the cut off point for advice at age 12 is different (A 12-year old is a "child" according to BTS/SIGN and is an "adult" according to NICE")

Inhaled steroids should be considered for patients with the following;

- Exacerbations of asthma in the last two years
- Using inhaled beta-2-agonists/ or if symptomatic three times a week or more
- Waking at least one night per week due to asthma.

The initial dose of ICS should be started at a dose appropriate to the severity of disease, but will usually be 400mcg/day in adults and 200mcg/day in children of Beclometasone (BDP) or equivalent (in children under 5 years old, 400mcg BDP or

Table 1: Guidance for the use of ICS in the treatment of chronic asthma in adults and in children age 12 and over.

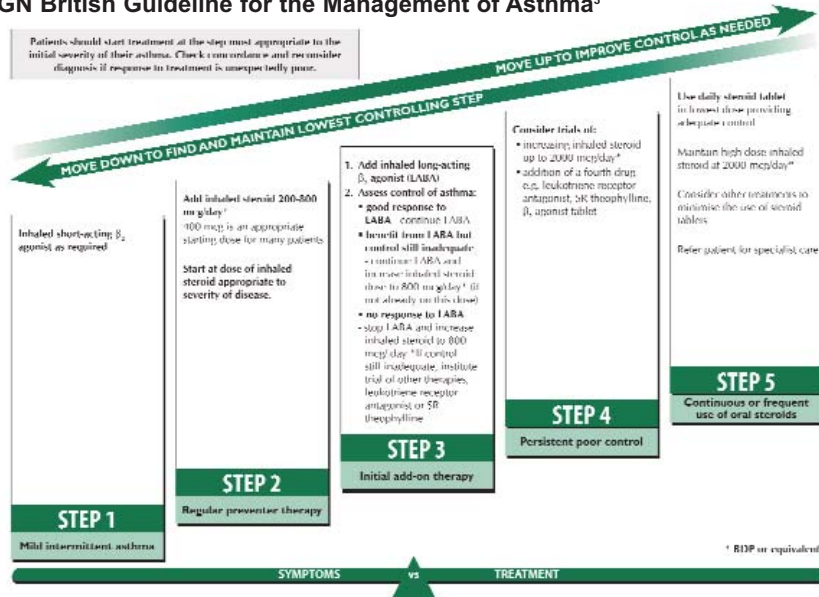
"The future discontinuation of chlorofluorocarbon (CFC)-containing inhalers will affect the range of devices available but does not affect this guidance.

- For adults and children aged 12 years and older with chronic asthma in whom treatment with inhaled corticosteroids (ICS) is considered appropriate, the least costly product that is suitable for an individual, within its marketing authorisation is recommended,
- For adults and children aged 12 years and older with chronic asthma in whom treatment with an ICS and long-acting beta-2-agonist bronchodilator (LABA) is considered appropriate the following apply:
 - ~ The use of a combination device within its marketing authorisation is recommended as an option.
 - ~ The decision to use a combination device or the two agents in separate devices should be made on an individual basis taking into consideration therapeutic need and the likelihood of treatment adherence.
 - ~ If a combination device is chosen then the least costly device that is suitable for the individual is recommended."

Table 2: Guidance for the use of (ICS) for the treatment of chronic asthma in children under the age of 12 years

- "For children under the age of 12 years with chronic asthma in whom treatment with an inhaled corticosteroid (ICS) is considered appropriate the least costly product that is suitable for an individual child (taking into consideration technology appraisal guidance 38* and 10*) within its marketing authorisation is recommended, *Guidance regarding choice of inhaler devices
- For children under the age of 12 with chronic asthma in whom treatment with an ICS and long-acting beta-agonist bronchodilator (LABA) is considered appropriate the following apply:
 - ~ The use of a combination device within its marketing authorisation is recommended as an option
 - ~ The decision to use a combination device or the two agents in separate devices should be made on individual basis, taking into consideration therapeutic need and the likelihood of treatment adherence

**Figure 1 : Summary of stepwise management in adults and children >12 years
BTS/SIGN British Guideline for the Management of Asthma³**



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For access to the full guideline visit <http://www.sign.ac.uk/guidelines/fulltext/101/index.html>

equivalent may be required due to the problems with drug delivery). The dose should be stepped down to the lowest dose at which effective asthma control is maintained.

The BTS/SIGN Guideline for the management of asthma fills in the gaps in the NICE appraisal concerning safety of ICS by emphasising the need to keep the dose of ICS low and suggests adding additional therapy (preferably at 400mcg BDP) before increasing the dose of ICS.

In children under 5 the preferred add-on therapy is a leukotriene antagonist (LTRA) and in older children and adults this is a LABA. Both NICE and BTS/SIGN guidance recognise the utility of combination inhalers. There may be an advantage in using combination inhalers in improving ICS compliance and the BTS/SIGN guideline states that combinations reduce risk by guaranteeing that LABA's are not taken without inhaled steroid.

The BTS/SIGN guideline also highlights the important role of the budesonide/formoterol combination used as reliever and maintenance therapy, a role not fully evaluated by NICE.

What does the NICE Guidance mean in primary care?

- The indications for prescribing inhaled corticosteroids are clearly described in the BTS/SIGN Guideline. (see above). The choice of drug is closely linked to the patient's ability to use the selected inhaler device; this is therefore an important consideration in deciding which inhaled steroid to prescribe.
- NICE recommends using the cheapest drug available in that device. It may be difficult to decide which is the cheapest drug due to the complex relationship between drugs, their delivery devices and available dosages. The situation is made more confusing by the different pricing structure of emerging CFC-free versions of the same product. Local formularies need to be dynamic to keep up with this situation and provide up to date lists of costings.
- NICE recommends the use of combination ICS/LABA inhalers at Step 3 "as an option" but has also left the door open for cheaper generic separate inhalers to be used. However, several studies have shown that there is an increased risk in asthma morbidity and mortality when LABA's are used without inhaled steroids. The use of a combination product may increase compliance and ensures that the LABA is always delivered with the ICS.

Future research

NICE acknowledges the need for further research into the use of ICS especially in the under 5's and longer trials in children looking at the comparative effects of ICS's including potential long term side effects on growth etc.

There is also a need to carry out more pragmatic studies in primary care situations where the effectiveness and cost-effectiveness of ICS can be carried taking account of factors such as compliance. ■

References:

1. Inhaled corticosteroids for the treatment of chronic asthma in adults and in children aged 12 years and over. NICE Technology appraisal guidance 138. www.nice.org.uk/T138
2. Inhaled corticosteroids for the treatment of chronic asthma in children under the age of 12 years. NICE technology appraisal guidance 131. www.nice.org.uk/T131
3. British Guideline on the Management of Asthma. British Thoracic Society, Scottish Intercollegiate Guidelines Network. <http://www.sign.ac.uk/guidelines/fulltext/101/index.html> (last accessed 01/09/08)
4. Guidance on the use of inhaler systems (devices) in children under the age of 5 years with chronic asthma. NICE technology appraisal guidance 10. www.nice.org.uk/TA010.
5. Inhaler devices for routine treatment of chronic asthma in older children (age 5-15 years) NICE technology appraisal guidance 38. www.nice.org.uk/TA038

Date of Preparation: August 2008

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