NICE National Institute for Health and Care Excellence

NICE guidance

Guidance on the use of inhaler systems (devices) in children under the age of 5 years with chronic asthma

Technology appraisal guidance
Published: 23 August 2000

www.nice.org.uk/guidance/ta10

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

1.1 For children under the age of 5 years with chronic stable asthma both corticosteroids and bronchodilator therapy should be routinely delivered by pressurised metered dose inhaler (pMDI) and spacer system, with a facemask where necessary.

1.2 Where this combination is not clinically effective for the child and depending on the child's condition, nebulised therapy may be considered and in the case of children aged 3 to 5 years, a dry powder inhaler (DPI) may also be considered.

1.3 Choice of device to be made within the pMDI and spacer range should be primarily governed by specific individual need and the likelihood of good compliance. Once these factors have been taken into account, choice should be made on the basis of cost minimisation.

2 Clinical need and practice

2.1 Asthma is a common disease that produces symptoms of wheezing and breathlessness. It affects the lower airways and results in narrowing (bronchoconstriction) of the airways with consequent reduction in the flow of gases between the airways and lung alveoli. It can be triggered by a variety of environmental factors such as infection, allergy, airborne chemicals and also exercise. There are a number of patterns of lower airways disease in early childhood that results in 2 predominant clinical patterns (acute wheezy episodes and recurrent day to day symptoms) that may occur separately or together in the child.

2.2 The overall prevalence of asthma in England and Wales is around 8% to 10% although not all cases are currently being treated. In all children under the age of 5 years about 9% of boys and 6% of girls are prescribed inhalers. There is a strong genetic component in the aetiology of this disease. There is also wide geographical variation in prevalence, with asthma being more common in, for example, urban rather than rural communities. It has a wide range of severity, is the cause of considerable morbidity and a rare cause of death.

2.3 The primary objective of asthma treatment is to achieve optimal control of the disease by reducing exacerbations, increasing lung function and limiting symptoms in order to maximise the quality of life of the child. This is currently best achieved by delivering both symptom relieving (bronchodilators – including beta-2 agonists and anticholinergics) and preventive anti-inflammatory drugs (typically corticosteroids) by inhalation. In the UK, asthma treatment is strongly influenced by the 1997 guidelines of the British Thoracic Society (BTS), which promote step-wise management of increasingly severe asthma. The 1997 BTS guidelines are mainly based on a consensus of expert opinion.

2.4 The estimated annual drug cost for asthma to the NHS in England and Wales in all age groups is approximately £115 million. In children under the age of 5 years this cost is about £8 million.

3 Information about the inhaler device

3.1 It is important to ensure that an inhaler device delivers the drugs to the airways consistently and in the appropriate quantity. There are a variety of inhaler devices that can be used in the management of asthma: hand-held inhalers that is, pressurised metered dose inhalers (pMDIs; which can be breath activated or manual) and dry-powder inhalation systems (DPIs) and nebulisers. All the metered dose inhaler systems require co-ordination of activation and inhalation and may be difficult to use, particularly for younger children. For this reason, a pMDI should be combined with a spacer device in young children. The purpose of the spacer device is to act as an intermediary chamber into which the pMDI can discharge the drug allowing the child to inhale over several breaths.

3.2 The inhalation devices have different mechanical characteristics which, combined with child and carer factors, leads to variation in both the quantity of drug delivered by the device and the amount actually deposited in the lung. Using the appropriate inhalation device is important to ensure reproducibility and consistency of drug dosing, as well as compliance for which child and carer acceptability and education regarding device usage may also be major factors.

3.3 The 1997 British Thoracic Society (BTS) guidelines recommend device choices for children under 5 years (see table 1).

Table 1 1997 BTS Guideline recommendations on device choices for children with chronic asthma under 5 years

Device	0 to 2 years inclusive	3 to 5 years inclusive
Metered dose inhaler plus spacer plus face mask	First choice	Second choice
Metered dose inhaler plus spacer	Second choice	First choice
Nebuliser (rarely needed)	Third choice	Third choice
Breath-actuated	Avoid	Not proven

Device	0 to 2 years inclusive	3 to 5 years inclusive
Dry powder	Avoid	Possible use for beta-2 agonist but not recommended for corticosteroids

3.4 Interpretation of the evidence base for effectiveness of inhaler devices is influenced by a number of potential factors – the drug being delivered by the device, the severity of asthma, whether the condition is acute or chronic and the ability of the child or carer to effectively use the device. Moreover, it is not possible to directly extrapolate to children under the age of 5 years, data collected in older children and adults, as the young child's anatomy and physiology may substantially alter the amount of drug delivered.

4 Evidence

Delivery of corticosteroids by a hand-held device

4.1 The evidence base for pressurised metered dose inhalers (pMDIs) plus spacer versus dry-powder inhalation systems (DPI) for the delivery of corticosteroids in children with chronic asthma is relatively small and of poor quality. Two randomised controlled trials were identified, which recruited children of 5 years or under. These trials involved a total of 140 children, although the majority of these recruited children of 5 years or older. One of these trials was inadequately powered and compared a pMDI alone (not recommended by current BTS guidelines) versus DPI. The second and largest trial demonstrated no difference in steroid delivery via a pMDI plus spacer compared to DPI (at half MDI dosage).

Delivery of beta-2 agonists by a hand-held device

4.2 The evidence base for pressurised metered dose inhalers (pMDIs) alone or pMDI plus spacer compared to dry-powder inhalation systems (DPI) in children with chronic asthma is poor. Four randomised controlled trials were identified that recruited children of 5 years or less. These trials involved a total of 278 children, some of whom were aged 5 years or more. The remaining 3 studies demonstrated no difference when comparing beta-2 agonist delivery via pMDI plus spacer with beta-2 agonist delivery by DPI.

Delivery of beta-2 agonists or anticholinergics by nebuliser

4.3 The evidence for nebulised bronchodilators compared with bronchodilator delivery via hand-held device in children with chronic asthma is also poor. Three randomised controlled trials which recruited children aged 5 years or less, were identified. These trials were small and involved a total of 51 children, although

many of the children were aged 5 years or older. No differences were found between nebulisation, pMDIs or dry powder devices. These trials are likely to be of insufficient size to detect small differences between devices.

Cost effectiveness

4.4 There is currently a wide range in the cost of drug and inhaler combinations. No cost-effectiveness studies were identified that make direct comparison between asthma devices in children under the age of 5 years with chronic asthma.

4.5 See the section on sources of evidence for documentation and opinions available to the appraisal committee.

5 Implications for the NHS

5.1 Where the 1997 BTS guidelines are currently being applied in practice, the guidance is unlikely to result in substantial change in NHS costs. The impact of referral patterns is difficult to predict. It is likely however to strengthen and improve the quality of primary care-based asthma therapy, thereby reducing the need for admission or outpatient referral.

6 Recommendations for research

6.1 At present, there is insufficient evidence regarding the most clinically and cost-effective spacer (for example, small or large volume). This is reflected in the current lack of standardisation and variations in the usage of these devices. Further research in this area should be carried out in relation to optimising the reproducibility, consistency and acceptability of these delivery systems as well as their overall clinical and cost effectiveness.

6.2 Well-conducted, community-based trials in the management of asthma in young children and studies to investigate factors determining compliance (including health education and the acceptability of devices) in this group of children would enhance the future evidence base.

7 Implementation

7.1 Clinicians should review their current clinical practice for the management of chronic asthma in children under the age of 5 years against the guidance set out in the recommendations section.

7.2 Relevant clinical guidelines and protocols should be reviewed in light of this guidance and revised if necessary.

7.3 The appropriate selection of inhaler devices as described in this guidance, is only 1 aspect for the provision of a comprehensive holistic approach to all aspects of asthma management. In particular, parents or carers need education, support and guidance, on how to manage their child's condition. General practitioners, the practice nurse, the specialist asthma nurse, the health visitor and school nurse and other community health carers have an essential role in the provision of this service and advice on general management may result in additional improvements in clinical and cost effectiveness.

7.4 The Montreal Protocol has mandated that chlorofluorocarbon (CFC) propellant should be phased out, and in the UK, the transition to CFC-free propellants is currently under way. The majority of evidence reviewed (see paragraph 4) on the use of devices is based on the use of corticosteroids and bronchodilators with CFC propellants. CFC-free propellants may interact with spacers differently to CFC-propellants, and can therefore affect the dose of drug delivered by the spacer. In addition, not all spacers are compatible with all pressurised metered dose inhalers (pMDIs). The choice of spacer for the chosen pMDI should therefore be guided by the information in the Summary of the Product Characteristics.

7.5 The dosage of drug delivered may vary considerably according to the static charge on spacer devices. It therefore advised that spacers be washed in a household detergent and allowed to air dry. If there are concerns about the possibility of contact dermatitis using this method, the mouthpiece of facemask should be rinsed in water and dried.

8 Clinical audit advice

8.1 To enable clinicians to audit their own compliance with this guidance it is recommended that, if not already in place, management plans are recorded for each child with chronic asthma. These plans should record the type of devices prescribed.

8.2 This information should be incorporated into local clinical audit data recording systems and consideration given (if not already in place) to the establishment of appropriate categories in electronic record systems.

8.3 Prospective clinical audit programmes should record the proportion of treatments adhering to the guidance. Such programmes are likely to be more effective in improving patient care when they form part of the organisation's formal clinical governance arrangements and where they are linked to specific post-graduate activities.

9 Appraisal committee members

The 4 technology appraisal committees are standing advisory committees of NICE.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each evaluation committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor R L Akehurst
Dean, School of Health-Related Research Sheffield University

Professor David Barnett (Chairman)
Professor of clinical pharmacology, University of Leicester

Professor Sir Colin Berry
Professor of morbid anatomy, St Bartholomew's and Royal London School of Medicine

Dr Sheila Bird
MRC Biostatistics unit, Cambridge

Professor Martin Buxton
Director of health economics research group, Brunel University

Professor Yvonne Carter
Professor of general practice and primary care, St Bartholomew's and Royal London School of Medicine

Dr Karl Claxton
Lecturer in economics, University of York

Professor Duncan Colin-Jones
Professor of gastroenterology, University of Southampton

Professor Sarah Cowley
Professor of community practice development, Kings College, London

Dr Nicky Cullum
Reader in health Studies, University of York

Mr Chris Evennett
Chief executive, Mid-Hampshire Primary Care Group

Ms Jean Gaffin
Formerly executive director, National Council for Hospice and Specialist Palliative Care Service

Mrs Sue Gallagher
Chief executive, Merton, Sutton and Wandsworth Health Authority

Dr Trevor Gibbs
International medical operations director, GlaxoWellcome Research and Development Ltd

Mr John Goulston
Director of finance, The Royal Free Hampstead NHS Trust

Professor Philip Home
Professor of diabetes, Medicine University of Newcastle

Dr Terry John
General practitioner, The Firs, London

Dr Diane Ketley
Research into practice programme leader, NHS Modernisation Agency

Dr Mayur Lakhani
General practitioner, Highgate Surgery, Leicester and Lecturer, University of Leicester

Mr M Mughal
Consultant surgeon, Chorley and South Ribble NHS Trust

Mr James Partridge

Chief executive, Changing Faces

Dr L J Patterson
Consultant physician and medical director, Burnley General Hospital

Professor Philip Routledge
Professor of clinical pharmacology, University of Wales

Professor Andrew Stevens
Professor of public health, University of Birmingham

10 Sources of evidence

The following documentation and opinions were made available to the committee:

- Assessment report: The effectiveness of inhaler devices for young children with asthma; Prepared by Payne N and Beard S, Trent Institute for Health Services Research, School of Health and Related Research, University of Sheffield; Wright, Brocklebank, D and Ram F, Bradford Hospitals NHS Trust; Taylor RS, National Institute for Clinical Excellence. March 2000.

Manufacturer or sponsor submissions:

- AstraZeneca
- Boehringer Ingelheim Ltd.
- Aventis Pharma (formerly Rhône-Poulenc Rorer)
- Boehringer Ingelheim Ltd.
- Glaxo Wellcome
- 3M Health Care Ltd.
- Norton Healthcare
- Yamanouchi Pharma Ltd

Professional or specialist group, patient or carer group and trade association submissions:

- Association of British Health-Care Industries
- British Medical Association
- British Thoracic Society
- National Asthma Campaign
- Royal College of Nursing
- Royal College of Paediatrics and Child Health

- Royal College of Physicians

The following experts were invited to make submissions to the Committee:

- Dr Andrew Bush, Reader in paediatric respirology and honorary consultant paediatric chest physician, Royal Brompton Hospital, London.
- Dr C O'Callaghan, Senior lecturer and consultant paediatrician, University of Leicester and Leicester Royal Infirmary Children's Hospital.

ISBN: 978-1-4731-5664-7