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

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NICE technology appraisal guidance 10

www.nice.org.uk/ta10

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1 Guidance

- 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 two 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 β_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 The Technology

- 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 i.e. 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 BTS Guidelines recommend the following device choices for children of under 5 years of age:

Age Group	1st Choice Device	2nd Choice Device	3rd Choice Device	Breath-actuated	Dry-powder
0-2 years inclusive	MDI + spacer + face mask	MDI + spacer	Nebuliser (rarely needed)	Avoid	Avoid
3-5 years inclusive	MDI + spacer	MDI + spacer + face mask	Nebuliser (rarely needed)	Not proven	Possible use for β_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/carer to effectively use the device. Moreover it is not possible to directly extrapolate to children under the age of five 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

4.1 **Delivery of corticosteroids by a hand held device**

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).

4.2 **Delivery of β_2 agonists by a hand held device**

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 which were aged 5 years or more. The remaining three studies demonstrated no difference when comparing β_2 agonist delivery via pMDI plus spacer with β_2 agonist delivery by DPI.

4.3 **Delivery of β_2 agonists or anticholinergics by nebuliser**

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.

4.4 **Cost Effectiveness**

There is currently a wide range in the cost of drug/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 The documentation and opinion available to the Appraisal Committee is set out in [Appendix B](#).

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 Further research

- 6.1 At present there is insufficient evidence regarding the most clinically and cost effective spacer (e.g. 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 [section 1](#).
- 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 one aspect for the provision of a comprehensive holistic approach to all aspects of asthma management. In particular, parents/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 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 is 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 Review of Guidance

- 9.1 Information on the review of the guidance on this technology is available on the [NICE website](#)

Andrew Dillon
Chief Executive
August 2000

Appendix A: Appraisal Committee members

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 R&D 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

Appendix B: Sources of Evidence

i) The following documentation and opinion was made available to the Committee:

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

b) Manufacturer/Sponsor submissions:

i. AstraZeneca

ii. Boehringer Ingelheim Ltd.

iii. Aventis Pharma (formerly Rhône-Poulenc Rorer)

iv. Boehringer Ingelheim Ltd.

v. Glaxo Wellcome

vi. 3M Health Care Ltd.

vii. Norton Healthcare

viii. Yamanouchi Pharma Ltd.

c) Professional/specialist group, patient/carer group and trade association submissions;

i. Association of British Health-Care Industries

ii. British Medical Association

iii. British Thoracic Society

iv. National Asthma Campaign

v. Royal College of Nursing

vi. Royal College of Paediatrics & Child Health

vii. Royal College of Physicians

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

a) Dr Andrew Bush, Reader in Paediatric Respiriology & Honorary Consultant Paediatric Chest Physician, Royal Brompton Hospital, London.

b) Dr C O'Callaghan, Senior Lecturer & Consultant Paediatrician, University of Leicester & Leicester Royal Infirmary Children's Hospital.

Appendix C: Guidance on inhalers for childhood asthma – patient information

'Understanding NICE Guidance', a summary of this guidance for patients and carers can be found on our website.

Changes after publication

March 2012: minor maintenance

About this guidance

NICE technology appraisal guidance is about the use of new and existing medicines and treatments in the NHS in England and Wales.

We have produced a [summary of this guidance for patients and carers](#). Tools to help you put the guidance into practice and information about the evidence it is based on are also [available](#).

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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