

# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## SCOPE

### **1 Guideline title**

Asthma: diagnosis and monitoring of asthma in adults, children and young people

#### **1.1 Short title**

Asthma: diagnosis and monitoring

### **2 The remit**

The Department of Health has asked NICE: 'to prepare a guideline on the diagnosis and management of asthma'.

### **3 Clinical need for the guideline**

#### **3.1 Epidemiology**

- a) Asthma is a chronic inflammatory respiratory disease that can affect people of any age but often starts in childhood. It is characterised by attacks of breathlessness and wheezing, with the severity and frequency of attacks varying from person to person. The attacks are associated with variable airflow obstruction within the lung, which is often reversible with or without treatment.
- b) The World Health Organization estimates that worldwide 235 million people suffer from asthma and that it is the most common chronic condition affecting children.
- c) Studies in adult patients have suggested up to 30% of people with a current diagnosis of asthma do not have clear evidence of asthma. Some of these may have had asthma in the past, but it

seems likely that in a considerable number the diagnosis was never correct.

- d) The causes of asthma are not well understood. A combination of risk factors is associated with the condition. Risk factors include both genetic (the condition clusters in families) and environmental (such as inhalation of allergens or chemical irritants) influences.

### **3.2 Current practice**

- a) Asthma is diagnosed principally on the basis of a careful history taken by an experienced clinician. Initial clinical assessment includes questions about symptoms (wheezing, cough, breathing and chest problems) and any personal or family history of allergies, atopic disorders or asthma. Various tests can be used to support a diagnosis, but there is no single test that serves as a gold standard.
- b) A number of methods and assessments are available to determine the likelihood of asthma. These include measures of airflow obstruction (spirometry and peak flow) and measures of reversibility with bronchodilators, both of which are widely used in current practice. However, normal results do not exclude asthma and abnormal results could be indicators of other respiratory diseases.
- c) Testing for airway inflammation is increasingly used as a diagnostic strategy in clinical practice. This includes measuring sputum eosinophil counts and fractional exhaled nitric oxide (FeNO). However, there is some uncertainty about both the sensitivity and specificity of FeNO, particularly whether it can distinguish general atopy from asthma.
- d) Measures of airway inflammation can also be used to monitor asthma control.
- e) Other diagnostic strategies include blood or skin tests to detect allergic reactions to environmental influences, exercise tests to

detect evidence of bronchoconstriction, and measures of airway hyper-reactivity, such as histamine/methacholine PC20 and mannitol challenge. However, it is debatable which test or measure, or combinations of them, is the most effective to accurately diagnose asthma.

## **4 The guideline**

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health, but it was decided to cover only diagnosis and monitoring of asthma, and to exclude other aspects of management. This was because there is evidence that incorrect diagnosis is a significant problem whereas management of correctly diagnosed asthma is straightforward in the majority of cases and there are already NICE Technology Appraisals covering some of the available asthma therapies. This area of practice was therefore prioritised, and NICE will consider whether to follow with further guidance on asthma covering the aspects omitted from the current scope.

The areas that will be addressed by the guideline are described in the following sections.

### **4.1 Population**

#### **4.1.1 Groups that will be covered**

- a) Adults, children and young people who are being investigated for asthma, or who have been diagnosed with asthma and are having their condition monitored.
- b) Specific consideration will be given to subgroups based on age, broadly divided into younger children, older children, and older people (aged over 75 years).

#### **4.1.2 Groups that will not be covered**

- a) Infants (younger than 12 months).

#### **4.2 *Healthcare setting***

- a) Primary, secondary and community care settings in which NHS-funded care is provided.

#### **4.3 *Diagnosis and monitoring***

##### **4.3.1 Key clinical issues that will be covered**

###### **Diagnosis**

###### *Initial clinical assessment*

- a) The value of specific signs and symptoms in making a diagnosis of asthma. For example, wheezing, cough, breathlessness and other respiratory symptoms at night or symptoms varying according to season; symptoms in response to exercise; and symptoms after taking drugs such as aspirin, other non-steroidal anti-inflammatory drugs and beta-blockers.
- b) The value of a family or personal history of atopic disorders in making a diagnosis of asthma.
- c) Case identification of occupational asthma.

###### *Objective tests*

The value of the following tests in making a diagnosis of asthma:

- d) Measures of lung function and airway obstruction including spirometry/flow volume loop, peak expiratory flow (PEF) variability, bronchodilator response (using PEF or forced expiratory volume in 1 second), and measures of airway hyper-reactivity, such as histamine/methacholine PC20 and mannitol challenge.
- e) Biomarkers of airway inflammation and allergy: skin tests for the common aero-allergens, serum total IgE, peripheral blood eosinophil count and FeNO.

- f) Measures of exercise-induced bronchoconstriction.

## **Monitoring**

### *Patient-reported symptoms:*

- g) Assessment of asthma control using self- or parental reports such as symptom scores or diaries, and validated asthma control questionnaires such as the asthma control test (ACT), the children's asthma control test (CACT), the asthma control questionnaire-7 (ACQ-7), and the Royal College of Physicians 3 (RCP3) questions.
- h) Use of tele-healthcare as a route for assessment.
- i) Monitoring adherence and inhaler technique.

### *Lung function:*

- j) Assessment of asthma control using tests such as measures of pulmonary function (for example, spirometry) and measures of airway reactivity.

### *Airways inflammation:*

- k) Assessments of asthma control using tests or measures such as FeNO.

## **4.3.2 Clinical issues that will not be covered**

- a) Management of asthma.

## **4.4 Main outcomes**

- a) Accuracy of diagnostic tests.
- b) Frequency of asthma attacks.
- c) Need for oral corticosteroids and short-acting beta-agonists.
- d) Frequency of unscheduled emergency treatments.
- e) Health-related quality of life.

- f) Time off school or work.

## **4.5 Economic aspects**

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually only be from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see 'Further information').

## **4.6 Status**

### **4.6.1 Scope**

This is the consultation draft of the scope. The consultation dates are 10 April to 8 May 2013.

### **4.6.2 Timing**

The development of the guideline recommendations will begin in August 2013.

## **5 Related NICE guidance**

### **5.1 Published guidance**

- [Bronchial thermoplasty for severe asthma](#). NICE interventional procedure guidance 419 (2012).
- [Roflumilast for the management of severe chronic obstructive pulmonary disease](#). NICE technology appraisal guidance 244 (2012).
- [Omalizumab for the treatment of severe persistent allergic asthma in children aged 6 to 11 years](#). NICE technology appraisal guidance 201 (2010).
- [Chronic obstructive pulmonary disease \(updated\)](#). NICE clinical guideline 101 (2009).
- [Respiratory tract infections](#). NICE clinical guideline 69 (2008).

- [Inhaled corticosteroids for the treatment of chronic asthma in adults and in children aged 12 years and over](#). NICE technology appraisal guidance 138 (2008).
- [Omalizumab for severe persistent allergic asthma](#). NICE technology appraisal guidance 133 (2007).
- [Inhaled corticosteroids for the treatment of chronic asthma in children under the age of 12 years](#). NICE technology appraisal guidance 131 (2007).
- [Inhaler devices for routine treatment of chronic asthma in older children \(aged 5–15 years\)](#). NICE technology appraisal guidance 38 (2002).
- [Guidance on the use of inhaler systems \(devices\) in children under the age of 5 years with chronic asthma](#). NICE technology appraisal guidance 10 (2000).

## **5.2 Guidance under development**

NICE is currently developing the following related guidance (details available from the NICE website).

- Omalizumab for the treatment of severe persistent allergic asthma in children aged 6 and over and adults (review of TA133 and TA201). NICE technology appraisal. Publication expected April 2013.
- Measurement of exhaled nitric oxide concentration in asthma – NIOX MINO and NObreath. NICE diagnostic assessment programme. Publication expected April 2014.
- Bronchiolitis: diagnosis and management of bronchiolitis in children. NICE clinical guideline. Publication expected April 2015.

## **6 Further information**

Information on the guideline development process is provided in the following documents, available from the NICE website:

- How NICE clinical guidelines are developed: an overview for stakeholders' the public and the NHS
- [The guidelines manual](#).

Information on the progress of the guideline will also be available from the [NICE website](#).