NATIONAL INSTITUTE FOR HEALTH AND CARE 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. In the UK 5.4 million people are receiving treatment for asthma, including 1.1 million children.

c) Studies of adults diagnosed with asthma suggest that up to 30% do not have clear evidence of asthma. Some may have had asthma in

the past, but it is likely that many have been given an incorrect diagnosis.

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. Occupational causes of asthma in adults are often unrecognised.

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) Other diagnostic strategies include blood or skin prick 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 combination- of them, is the most effective to accurately diagnose asthma.

e) It is recognised that asthma control is suboptimal in many people with asthma. This has an impact on their quality of life, their use of healthcare services and the associated costs. Asthma control can be monitored by measuring airway inflammation and by using validated questionnaires, but the most effective monitoring strategy is uncertain.

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.

It is based on the referral from the Department of Health, but now covers the diagnosis and monitoring of asthma and excludes other aspects of management. This is because there is evidence that incorrect diagnosis is a significant problem whereas management of correctly diagnosed asthma is straightforward in most cases. Also, NICE technology appraisal guidance covers some of the available asthma therapies. In the future NICE will consider whether further guidance on asthma covering the aspects omitted from the current scope is needed.

The areas that will be addressed by the current 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 suspected 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).

4.2 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 including diurnal and seasonal variations; 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

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.

j) Inhaler technique.

k) Assessment of asthma control using tests such as measures of pulmonary function (for example, spirometry and peak expiratory flow meters) and measures of airway hyper-reactivity.

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

4.3.2 Clinical issues that will not be covered

a) Tertiary care setting.

b) Severe, difficult to control asthma.

c) Sputum cell counts.

d) Treating asthma.

4.4 Main outcomes

a) Objective response to treatment.

b) Accuracy of diagnostic tests.

c) Frequency of asthma attacks.

d) Need for oral corticosteroids and short-acting beta-agonists.

e) Unscheduled use of healthcare services.

f) Health-related quality of life.

g) 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 final version of the scope.

4.6.2 Timing

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

5 Related NICE guidance

5.1 Published guidance and quality standards

- 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 guidance TA278 (2013).
- Asthma. NICE quality standard 25 (2013).
- 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).
- 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).
- 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).

- Measuring fractional exhaled nitric oxide concentration in asthma – NIOX MINO, NIOX VERO and NObreath. NICE diagnostics guidance. Publication expected April 2014.
- Bronchiolitis. 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: 5th edition
- The guidelines manual.

Information on the progress of the guideline will also be available from the NICE website.