NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Anaphylaxis: Initial assessment and the decision to refer following emergency treatment for anaphylactic episode.

1.1 Short title

Anaphylaxis

2 The remit

The Department of Health has asked NICE: 'to produce a short clinical guideline on the initial assessment and the decision to refer following emergency treatment for anaphylactic episode'.

3 Clinical need for the guideline

3.1 Epidemiology

a) The European Academy of Allergy and Clinical Immunology Nomenclature Committee proposed the following broad definition of anaphylaxis: a severe, life-threatening, generalised or systemic hypersensitivity reaction. This reaction is characterised by rapidly developing life-threatening airway, breathing and/or circulation problems, usually associated with skin and mucosal changes.

b) Most people with anaphylaxis do not get an accurate allergy diagnosis. The reasons for this include failure to be referred after the acute episode, or inappropriate referral. This may cause difficulties for the person such as anxiety for potential new episodes and incur avoidable costs for the NHS.

c) There is no overall figure for the frequency of anaphylaxis of all causes in the UK. Because anaphylaxis presents mainly in accident and emergency departments and outpatient settings, few counts of prevalence are available from NHS sources. Anaphylaxis may not be recorded, or may be mislabelled as something else, for example, asthma; it may also be recorded by cause, such as food allergy, rather than as an anaphylactic episode.

d) The American College of Allergy, Asthma and Immunology Epidemiology of Anaphylaxis working group summarised the findings from a number of important international epidemiological studies and concluded that the overall frequency of anaphylaxis lies between 30 and 950 episodes per 100,000 persons per year.

e) The same group provided data indicating a lifetime prevalence of between 50 and 2000 episodes per 100,000 persons, or 0.05–2.0%. More recent UK primary care data indicates a lifetime age-standardised prevalence of a recorded diagnosis of anaphylaxis of 75.5 per 100,000 in 2005. Calculations based on these data indicate that approximately 1 in 1333 of the English population have experienced anaphylaxis at some point in their lives.

f) A retrospective study of accident and emergency department attendances in the UK, identifying only the most severe cases and relating this number to the population served, estimated that approximately 1 in 3500 people had an episode of anaphylaxis during the study period 1993 to 1994.

g) Anaphylaxis may result from food allergy, drug allergy, venom allergy or latex allergy, or from a non-IgE-mediated reaction - most commonly an idiopathic one (that is, without a known cause). The relative likelihood of the reaction being caused by each of these varies considerably with age, with food being a particularly common trigger in children and medicinal products being much more common triggers in older people. Worldwide there are

1 million cases of venom anaphylaxis and 0.4 million cases of nut anaphylaxis each year in people younger than 45.

h) Data indicate a dramatic increase in the rate of hospital admissions for anaphylaxis. Between 1990 and 2004 they went from 0.5 admissions per 100,000 to 3.6 per 100,000; an increase of 700%.

i) Risk of death is increased in people with pre-existing asthma, particularly if the asthma is poorly controlled, and in asthmatics who do not use, or delay treatment with, adrenaline. There are approximately 20 anaphylaxis deaths reported each year in the UK, although this may be a substantial underestimate.

3.2 Current practice

a) There is considerable geographic variation in both practice and service provision, specifically in the review after emergency treatment for anaphylaxis and decisions about when and where to refer.

b) There is a lack of awareness among commissioners about the need for specialist allergy services. A survey by the National Allergy Strategy Group (NASG) and Allergy UK revealed that most primary care trusts do not commission allergy services. They assume that allergy can be dealt with in another specialty, such as dermatology or respiratory medicine, and do not appreciate that this does not provide adequate specialised allergy care.

c) Patients with anaphylaxis may be referred to inappropriate clinics that do not have the expertise to make a diagnosis. Surveys of GP understanding of allergy revealed they had inadequate knowledge, especially with more severe disease, including food allergy.

d) The Anaphylaxis Campaign (a national patient organisation) conducted a survey of its membership in November 2005. The results showed that many people felt:

- there is unequal access to allergy services
- severe allergies can have a significant effect on quality of life
- severely allergic people feel neglected by the NHS
- the knowledge of GPs about severe allergy and the specialist care available varies considerably
- there is a real need for help, advice and guidance, particularly after diagnosis.

e) Members of the Anaphylaxis Campaign responded to a second, online, survey in January–February 2006:

- 59% thought that the NHS was not well equipped to manage the needs of people with allergy
- 76% felt that their GP did not understand the health needs of the allergic person very well
- only 34% were initially referred to an allergy clinic (not necessarily a comprehensive service).

f) There is currently no relevant national guidance for England and Wales on the initial assessment of anaphylactic episodes or on the decision to refer following emergency treatment.

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.

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 and children who receive emergency treatment for suspected anaphylaxis.

b) Within this population, people who are at high risk of anaphylactic episodes, or for whom further anaphylactic episodes would have significant impact, have been identified as needing special consideration.

4.1.2 Groups that will not be covered

a) Adults and children who have received emergency treatment with conditions other than suspected anaphylaxis.

4.2 Healthcare setting

a) Primary, secondary and tertiary settings in which NHS healthcare is recieved.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

a) Clinical assessment after emergency treatment. This will include:

- history, including signs and symptoms, and identification of the possible cause
- physical examination
- measurement of serum mast cell tryptase levels to confirm the diagnosis.

b) Timing of assessment and confirmatory tests after the episode.

c) Provision of adrenaline auto-injectors.

d) When, where and to whom to refer after assessment.

e) Information and support needs for patients and carers, up to the point of referral and including information on the use of adrenaline auto-injectors if prescribed.

f) Assessment of risk for future episodes up to the point of referral.

4.3.2 Clinical issues that will not be covered

a) Initial assessment and diagnosis of anaphylactic episode (before emergency treatment).

b) Emergency management.

c) Prophylaxis after referral.

d) Management of associated comorbidities.

e) Identification and management of complications arising from testing or management.

4.4 Main outcomes

a) Further or repeat anaphylactic episodes.

b) Rate of referral between healthcare settings.

c) Measure of diagnostic utility of physical examination, history taking, serum mast tryptase measurement.

d) Admission rate for further anaphylactic episodes.

e) Mortality resulting from further anaphylactic episodes.

f) Health related quality of life.

g) Resource use and costs.

4.5 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative 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 be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see ‘Further information’).

The key health economic questions for this guideline appear to be the cost effectiveness of specialist allergy clinics for the diagnosis of anaphylaxis and the cost effectiveness of adrenaline auto injectors for the treatment of anaphylaxis. Further cost effectiveness analysis will be considered if any further questions are identified during the course of guideline development.

4.6 Status

4.6.1 Scope

This is the consultation draft of the scope. The consultation dates are 1 to 29 September 2010.

4.6.2 Timing

The development of the guideline recommendations will begin in December 2010.

5 Related NICE guidance

5.1 Published guidance

- Alitretinoin for the treatment of severe chronic hand eczema. NICE technology appraisal guidance 177 (2009). Available from www.nice.org.uk/guidance/TA177
- Pimecrolimus and tacrolimus for atopic eczema. NICE technology appraisal guidance (2004). Available from www.nice.org.uk/guidance/TA82
- Frequency of application of topical corticosteroids for eczema. NICE technology appraisal guidance 81 (2004). Available from www.nice.org.uk/guidance/TA81

5.2 Guidance under development

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

- Food allergy in children and young people. NICE clinical guideline. Publication expected January 2011.

6 Further information

Information on the guideline development process is provided in:

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

These are available from the NICE website (www.nice.org.uk/GuidelinesManual). Information on the progress of the guideline will also be available from the NICE website (www.nice.org.uk).