NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Anaphylaxis: assessment to confirm an anaphylactic episode and the decision to refer after emergency treatment for a suspected 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) A broad definition of anaphylaxis was proposed by the European Academy of Allergy and Clinical Immunology Nomenclature Committee and adapted by the UK Resuscitation Council. The current definition is a severe, life-threatening, generalised or systemic hypersensitivity reaction, characterised by rapidly developing life-threatening airway, breathing and/or circulation problems, usually associated with skin and mucosal changes.

b) After an acute episode of anaphylaxis, many people do not currently go through an optimal post acute process. The reasons for this include anaphylaxis not being recognised, or not being differentiated from less severe histamine-releasing reactions or

from other conditions that mimic some or all of its clinical features. Also, people may not be referred, or be referred appropriately, to a specialist. This can affect the likelihood of the person receiving a definitive diagnosis and can lead to anxiety, inappropriate management and recurrent episodes. It can also give rise to avoidable costs for the NHS and increase the need for acute care.

c) There is no overall figure for the frequency of anaphylaxis from 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 estimates indicate 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 population of England 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 be an allergic response (that is, immunologically mediated by immunoglobulin E [IgE] or other immune mechanisms) or a non-allergic response. Foods, insect venoms, latex and some drugs are common precipitants of IgE -mediated allergic anaphylaxis. Many drugs can also act through non-allergic mechanisms. A significant proportion of anaphylaxis is classified as idiopathic, in which there are significant clinical effects arising from histamine release but neither the precipitant nor the preceding inflammatory mechanisms (allergic or non-allergic) can be identified with certainty. The relative likelihood of the reaction being allergic, non-allergic or idiopathic varies considerably with age.

h) Food is a particularly common trigger in children and medicinal products are 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.

i) 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%.

j) There are approximately 20 anaphylaxis deaths reported each year in the UK, although this may be a substantial underestimate. Risk of death from an anaphylactic episode 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.

3.2 Current practice

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

b) There are professional guidelines on the emergency treatment and management of anaphylaxis, but there is currently no relevant national guidance for England and Wales on assessment after the event to confirm an anaphylactic episode or on the decision to refer after 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, young people 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.

c) Consideration will also be given to ensuring equity for all socioeconomic groups if the evidence shows that socioeconomic status affects access to services.

4.1.2 Groups that will not be covered

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

4.2 Healthcare setting

a) Primary, secondary and tertiary settings.

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 at the time of and after the episode.

c) Provision of adrenaline auto-injectors, including by whom.

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, including information and training 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 treatment.

c) Investigations (specifically IgE and non-IgE testing) to confirm the suspected cause of the anaphylactic reaction, as identified in the history.

d) Prophylaxis after referral.

e) Management of associated comorbidities.

f) 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 firstly the cost effectiveness of referral to specialist allergy clinics for the diagnosis of anaphylaxis (as opposed to for the acute event) and for the prevention of future episodes and the reduction in morbidity and mortality from future episodes. The second issue is the cost effectiveness of adrenaline auto-injectors for the treatment of anaphylaxis this includes the cost implications of

training in the use of the auto-injectors. Further cost effectiveness analysis will be considered if any further questions are identified during guideline development.

4.6 Status

4.6.1 Scope

This is the final scope.

4.6.2 Timing

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

5 Related NICE guidance

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).