

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

The epilepsies: pharmacological management of the epilepsies in adults and children in primary and secondary care (partial update of NICE clinical guideline 20)

1.1 Short title

The epilepsies – pharmacological management (partial update CG20).

2 The remit

The National Institute for Health and Clinical Excellence (NICE) has commissioned the National Clinical Guidelines Centre for Acute and Chronic Conditions to partially update 'The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care' (NICE clinical guideline 20, 2004). This will update the pharmacological management sections of the guideline and include the use of ketogenic diet.

3 Clinical need for the guideline

3.1 Epidemiology

- a) Epilepsy is a common neurological disorder characterised by recurring seizures. Different types of epilepsy have different causes. Accurate estimates of incidence and prevalence are difficult to achieve because of difficulties in identifying people who may have epilepsy and, sometimes, with diagnosing the condition. However, it has been estimated to affect between 260,000 and 416,000 people in England and Wales. Incidence is estimated to be

50 per 100,000 per year and the prevalence of active epilepsy in the UK is estimated to be 5–10 cases per 1000.

- b) The majority of people with active epilepsy (70–85%) can satisfactorily control recurrent seizures with anti-epileptic drugs. Other approaches may include surgery. Optimal management improves health outcomes and can also help to minimise other, often detrimental, impacts on social, educational and employment activity.

3.2 Current practice

- c) ‘The epilepsies’, NICE clinical guideline 20 (2004) stated that the annual estimated cost of established epilepsies was £2 billion (direct and indirect costs). Newer and more expensive AEDs are now being prescribed, and with an increase in treatment costs likely in coming years it is essential to ensure that anti-epileptic drugs with proven effectiveness and cost-effectiveness are identified.
- d) The evidence used to develop NICE clinical guideline 20 and the existing NICE technology appraisal guidance on epilepsy (‘Newer drugs for epilepsy in adults’, NICE technology appraisal guidance 76 [2004] and ‘Newer drugs for epilepsy in children’, NICE technology appraisal guidance 79 [2004]) showed no difference in effectiveness between newer and older anti-epileptic drugs, or between the newer drugs (as monotherapy) for seizure control. However, a recent large multicentre trial (the SANAD trial) evaluating newer drugs in newly diagnosed epilepsy (accepting some limitations) suggested that sodium valproate should be the drug of choice in generalised and unclassifiable epilepsies, and lamotrigine in partial epilepsies. We therefore consider it necessary to review new evidence regarding anti-epileptic drugs within an update of the NICE clinical guideline.

- e) The use of the ketogenic diet in children will be included in this update because of recent data from randomised controlled trials. This intervention will be considered in addition to pharmacological management.

4 The guideline

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

This scope defines what this guideline update will (and will not) examine, and what the guideline developers will consider..

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) Children (28 days to 11 years), young people (12 to 17 years) and adults (18 years and older) with a diagnosis of any type of epilepsy.
- b) Specific consideration will be given to any variation in the treatment or care needs of:
- women who are pregnant or of child-bearing age.
 - older people
 - people with learning disabilities.
- c) All seizure types and epilepsy syndromes will be included.

4.1.2 Groups that will not be covered

- a) Neonates (28 days or younger).

4.2 Healthcare setting

- a) Healthcare professionals who have direct contact with, and make decisions concerning, the care of people with epilepsy.
- b) Primary, secondary and tertiary care centres.
- c) The guideline will also be relevant to the work, but will not cover the practice, of those working in the occupational health services, social services, educational services and the voluntary sector.

4.3 Clinical issues that will be covered

- a) Pharmacological management (see sections d to g).
- b) Potential issues of generic vs brand prescribing, potential problems from withdrawal from drugs, polytherapy and drug interactions.
- c) Advice on treatment options will be based on the best evidence available to the development group. Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform their decisions for individual patients.
- d) Anti-epileptic drugs included in NICE clinical guideline 20, either as monotherapy or as adjunctive therapy:
 - acetazolamide
 - carbamazepine
 - clobazam
 - clonazepam
 - ethosuximide
 - felbamate
 - phenobarbitone
 - phenytoin

- piracetam
 - primidone
 - sodium valproate
 - stiripentol
 - sulthiame.
- e) Anti-epileptic drugs included in NICE technology appraisal guidance 76 and 79, 2004, either as monotherapy or as adjunctive therapy:
- gabapentin
 - lamotrigine
 - levetiracetam
 - oxcarbazepine
 - tiagabine
 - topiramate
 - vigabatrin.
- f) Anti-epileptic drugs not covered by previous NICE guidance, either as monotherapy or as adjunctive therapy:
- eslicarbazepine
 - pregabalin
 - rufinamide
 - zonisamide
 - lacosamide
 - nitrazepam
 - prednisolone
 - prednisone
 - hydrocortisone
 - adrenocorticotrophic hormone (ACTH).
- g) Drugs for status epilepticus, either as monotherapy or as adjunctive therapy:

- pentobarbital
 - propofol
 - midazolam
 - diazepam
 - lorazepam
 - phenytoin
 - phenobarbitone
 - fosphenytoin
 - paraldehyde
 - clonazepam
 - thiopental
 - isoflurane
 - leviracetam
 - sodium valproate
- h) Use of anti-epileptic drugs in women who are pregnant or are of childbearing age.
- i) Use of the ketogenic diet in children, using data from recent randomised controlled trials.
- j) Advice on treatment options will be based on the best evidence available to the development group. Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform their decisions for individual patients.

4.4 *Economic aspects*

- a) 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 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').

4.5 Status

4.5.1 Scope

This is the final scope.

4.5.2 Guideline

The development of the guideline recommendations will begin in May 2009.

5 Related NICE guidance

5.1.1 NICE guidance to be updated

This guideline will update and replace the following NICE guidance.

- The diagnosis and management of the epilepsies in adults and children in primary and secondary care. NICE clinical guideline CG20 (2004). Available from www.nice.org.uk/CG20. (partial update)
- Newer drugs for epilepsy in adults. NICE technology appraisal guidance 76 (2004). Available from www.nice.org.uk/TA76
- Newer drugs for epilepsy in children. NICE technology appraisal guidance 79 (2004). Available from www.nice.org.uk/TA79

5.1.2 Other related NICE guidance

- Medicines adherence. NICE clinical guideline CG76 (2009). Available from www.nice.org.uk/CG76

5.2 *Guidance under development*

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

- Transient loss of consciousness (TLoC). NICE clinical guideline.
Publication expected August 2010.

6 Further information

The guideline development process is described 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).