NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Opioids in palliative care: safe and effective prescribing of strong opioids in palliative care of adults

1.1 Short title

Opioids in palliative care

2 The remit

The Department of Health has asked NICE to produce a short clinical guideline on: 'safe and effective prescribing of strong opioids in palliative care of adults'.

3 Clinical need for the guideline

3.1 Current practice

a) Each year more than 155,000 people in the UK die of cancer, and more than 11,000 of heart failure. To this can be added deaths from kidney, liver, and respiratory disease, and from neurodegenerative conditions. Many people with these conditions will develop troublesome pain, for which a strong opioid is needed.

b) The recently updated World Cancer Declaration includes a target to make effective pain control more accessible. Several key documents recognise the importance of effective pain control, including 'Improving supportive and palliative care for adults with cancer' (NICE cancer service guidance, 2004), 'Control of pain in adults with cancer (Scottish Intercollegiate Guidelines Network

guideline 106, 2008), and 'A strategic direction for palliative care services in Wales' (Welsh Assembly Government, 2005).

c) Pain is common in advanced and progressive disease. Up to two thirds of people with cancer experience pain that needs a strong opioid. This proportion is similar or higher in many other advanced and progressive conditions.

d) Strong opioids, especially morphine, are the mainstay of treatment for pain related to advanced and progressive disease, and their use has increased significantly in the primary care setting. However, the pharmacokinetics of the various opioids are very different and there are marked differences in bioavailability, metabolism and response between patients. A suitable opioid must be selected for each patient and, because drug doses cannot be estimated or calculated in advance, the dose must be individually titrated. Ensuring that this selection and titration is done effectively and safely would have a major impact on patient comfort.

e) Misinterpretations and misunderstanding have surrounded strong opioids for decades, and these are only slowly being resolved. Until recently many sources for prescribing advice have given varying and sometimes conflicting advice. These factors, along with the wide range of formulations and preparations, have resulted in errors causing underdosing and avoidable pain, or overdosing and distressing adverse effects. Despite repeated warnings, these problems have led on occasion to patient deaths, and have resulted in doctors facing the General Medical Council or court proceedings.

f) This guideline will clarify the clinical pathway, and improve pain management and patient safety. The target audience will be non-specialist healthcare professionals initiating strong opioids for pain in adults with advanced and progressive disease. Adults requiring

specialist referral, such as those with kidney failure, liver failure, breathing problems or swallowing problems will not be covered.

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 (18 years and older) with advanced and progressive disease[1], for whom strong opioids have been assessed as a suitable pain control method and who do not have significant kidney failure, liver failure, breathing problems or swallowing problems.

4.1.2 Groups that will not be covered

a) Children (younger than 18 years).

b) Adults without advanced and progressive disease.

c) Adults who have not yet been assessed to check whether strong opioids are suitable for them.

d) Adults for whom strong opioids have been assessed as unsuitable.

e) Adults who are unable to take drugs orally.

[1] Such as cancer, heart disease, liver disease, lung disease, kidney disease, HIV and terminal neurodegenerative or neuromuscular conditions.

f) Adults with significant kidney failure, liver failure, or breathing problems.

4.2 Healthcare setting

a) All settings in which care commissioned by the NHS is provided, including hospices, care homes and the community.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

a) First-line treatment with strong opioids in the patient group described in 4.1.1 a, considering:

- titration schedule
- formulation
- breakthrough pain
- patient information needs

b) Management strategies for intolerable side effects (including patient information needs) in the patient group described in 4.1.1 a.

4.3.2 Clinical issues that will not be covered

a) Assessment before starting strong opioid therapy.

b) Opioid use in adults who are unable to take drugs orally.

c) Opioid use in adults with kidney or liver failure, or breathing problems.

d) Non-opioid pain control.

e) Care in the last days of life.

4.4 Main outcomes

a) Reduction in pain intensity.

b) Reduction of opioid side effects.

c) Adverse events.

d) Toxicity.

e) Health related quality of life.

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’).

4.6 Status

4.6.1 Scope

This is the consultation draft of the scope. The consultation dates are 9 May to 3 June 2011.

4.6.2 Timing

The development of the guideline recommendations will begin in July 2011.

5 Related NICE guidance

- Neuropathic pain. NICE clinical guideline 96 (2010). Available from www.nice.org.uk/guidance/CG96
- Chest pain of recent onset. NICE clinical guideline 95 (2010). Available from www.nice.org.uk/guidance/CG95
- Low back pain. NICE clinical guideline 88 (2009). Available from www.nice.org.uk/guidance/CG88
- Rheumatoid arthritis. NICE clinical guideline 79 (2009). Available from www.nice.org.uk/guidance/CG79

- Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. NICE technology appraisal 159 (2008). Available from www.nice.org.uk/guidance/TA159
- Metastatic spinal cord compression. NICE clinical guideline 75 (2008). Available from www.nice.org.uk/guidance/CG75
- Osteoarthritis. NICE clinical guideline 59 (2008). Available from www.nice.org.uk/guidance/CG59
- Drug misuse: opioid detoxification. NICE clinical guideline 52 (2007). Available from www.nice.org.uk/guidance/CG52
- Drug misuse: psychosocial interventions. NICE clinical guideline 51 (2007). Available from www.nice.org.uk/guidance/CG51
- Naltrexone for the management of opioid dependence. NICE technology appraisal 115 (2007). Available from www.nice.org.uk/guidance/TA115
- Methadone and buprenorphine for managing opioid dependence. NICE technology appraisal 114 (2007). Available from www.nice.org.uk/guidance/TA114
- Improving supportive and palliative care for adults with cancer. NICE cancer service guidance (2004). Available from www.nice.org.uk/CSGSP

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).