NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

SCOPE

1 Guideline title

Parkinson’s disease: diagnosis and management of Parkinson's disease in adults in primary and secondary care.

1.1 Short title

Parkinson's disease

2 The remit

This is a partial update of Parkinson's disease (NICE clinical guideline 35). See section 4.3 for details of which sections will be updated. We will also carry out an editorial review of all recommendations to ensure that they comply with NICE’s duties under equalities legislation.

This update is being undertaken as part of the guideline review cycle and because new evidence has emerged on the treatment of Parkinson's disease.

3 Need for the guideline

3.1 Epidemiology

a) Parkinson’s disease is a progressive neurodegenerative condition resulting from the death of dopamine-containing cells of the substantia nigra in the brain. There is no consistently reliable test that can distinguish Parkinson’s disease from other conditions that have a similar clinical presentation. The diagnosis is primarily based on a clinical history and examination.

b) Parkinson’s disease is one of the most common neurological conditions. It is estimated to affect up to 160 people per 100,000, with an annual incidence in the UK of 15–20 per 100,000

c) People with Parkinson’s disease classically present with the symptoms and signs described as ‘parkinsonism’: these include bradykinesia (slow movements), rigidity, rest tremor (shaking) and postural instability (loss of balance).

d) The symptoms of parkinsonism are not always a result of Parkinson’s disease. Other causes include side effects of medication, vascular disease, and less common degenerative conditions such as progressive supranuclear palsy and multiple system atrophy.

e) Parkinson’s disease has historically been recognised as a primary movement disorder; however, other symptoms may be prominent, such as depression and dementia. In the later stages of the disease people may develop pain and autonomic disturbances (such as dizziness and fainting, and problems with sweating, heart rate, digestion, vision, and sexual function). These other symptoms are sometimes described as the ‘non-motor’ manifestations of Parkinson’s disease. The condition may progress to cause significant impairments, adversely affecting quality of life and indirectly that of family and carers.

f) Levodopa is currently the most widely used treatment for the symptoms of Parkinson's disease and acts by replenishing depleted striatal dopamine in the brain. Levodopa is given with a dopa-decarboxylase inhibitor to reduce the peripheral conversion of levodopa to dopamine (before it reaches the brain). This combination of drugs is referred to as a ‘levodopa preparation’.

3.2 Current practice

a) People with suspected Parkinson's disease are generally referred quickly without treatment to a specialist with expertise in the differential diagnosis of this condition.

b) For people with early Parkinson's disease, drug treatments such as levodopa, other dopamine agonists and monoamine oxidase B inhibitors may be considered.

c) In the later stages of Parkinson's disease other drugs may be used with levodopa (as adjuvants) to reduce the motor complications associated with prolonged levodopa use.

d) Options for non-pharmacological management such as surgery, physiotherapy, occupational therapy, and speech and language therapy may be discussed with patients.

e) Treatments for non-motor symptoms such as sleep disturbance and depression may also be considered.

f) Since the publication of NICE clinical guideline 35, there have been advances in several areas of the clinical management of Parkinson's disease, including surgery and drug treatments. The current guideline will investigate the developments in these areas and update the advice given in NICE clinical guideline 35.

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 by this update

a) Adults with a suspected or confirmed diagnosis of Parkinson's disease.

b) No patient subgroups have been identified as needing specific consideration.

4.1.2 Groups that will not be covered by this update

a) Children and young people with juvenile-onset Parkinson's disease.

4.2 Setting

a) Any setting in which NHS-funded care is delivered.

4.3 Management

4.3.1 Key issues that will be covered

Note that for pharmacological interventions, 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 the summary of product characteristics to inform their decisions for individual patients.

Areas from the original guideline that will be updated

a) Pharmacological management:

- Initial treatment of Parkinson's disease (monotherapy):
  - immediate-release levodopa
  - modified-release levodopa
  - dopamine agonists
  - monoamine oxidase B inhibitors
  - amantadine
  - anticholinergics

  - beta-blockers.
- Drugs to be used with levodopa (as adjuvants) in the later stages of Parkinson's disease:
  - dopamine agonists
  - catecholamine-O-methyl-transferase (COMT) inhibitors
  - monoamine oxidase B inhibitors
  - amantadine
  - intermittent apomorphine injections and continuous infusion.
- Pharmacological treatment of the following non-motor symptoms:
  - sleep disturbance and disorders
  - psychosis
  - autonomic disturbances
- Pharmacological treatment of dementia associated with Parkinson's disease:
  - memantine
  - rivastigmine
  - galantamine
  - donepezil.

b) Non-pharmacological management:

- occupational therapy
- speech and language therapy
- physiotherapy (including the Alexander technique).

c) Deep brain stimulation:

- referral criteria (including timing of referral)
- effectiveness of sub thalamic nucleus, globus pallidus interna, thalamus, and pedunculopontine nucleus stimulation.

Areas not in the original guideline that will be included in the update

d) Transdermal dopamine patches.

e) Duodopa (levodopa and carbidopa) intestinal gel.

f) Nutritional support.

g) Predictors of impulse control disorder as an adverse effect of dopamine treatments.

h) Managing dopamine treatment to reduce the risk of the development of impulse control disorder.

i) Information needs of people with Parkinson's disease about impulse control disorder.

j) Information needs of women of child-bearing age with a diagnosis of Parkinson's disease.

4.3.2 Issues that will not be covered

Areas from the original guideline that will not be updated by an evidence review

a) Diagnosis and monitoring:

- Clinical expert diagnosis (using UK brain bank criteria) compared with non-expert diagnosis and post-mortem gold standard.
- Other diagnostic tests (for example, acute levodopa and apomorphine tests, PET and SPECT imaging, magnetic resonance imaging, magnetic resonance spectroscopy, growth hormone stimulation test).

b) Monoamine oxidase B inhibitors, co-enzyme Q10, dopamine agonists, and vitamin E for neuroprotection.

c) Depression in Parkinson’s disease

d) Parkinson’s disease specialist nurse interventions

e) Communication with people with Parkinson’s disease and their carers

f) Palliative care

Areas from the original guideline that will be removed

No areas from the original guideline will be removed

Areas not covered by the original guideline or the update

g) Treatment of parkinsonism not caused by Parkinson's disease.

h) Treatment of other tremulous disorders (for example, essential tremor).

i) Non-pharmacological management of dementia associated with Parkinson's disease.

j) Interventions and management that will not be included:

- Radical therapies that are not commonly used: fetal cell transplantation; stem cells; genes that code for dopamine-producing proteins; glutamate-blocking drugs ; giant cell line-derived neutrophilic factor (GDNF); viral transfection.
- Comorbidities, unless treatment differs from that in people without Parkinson’s disease.
- Generic health problems for which the care for people with Parkinson’s disease does not differ from that for the general population (for example, constipation).

4.4 Main outcomes

a) Mortality.

b) Adverse events

c) Resource use and cost.

d) Cognitive function

- Addenbrooke's cognitive examination revised (ACER).
- Montreal Cognitive Assessment (MOCA).

e) Disease severity

- Unified Parkinson's Disease Rating Scale (UPDRS).
- Webster disability score

f) Non-motor features

- Non-motor symptoms questionnaire (NMS Quest).
- Parkinson's disease sleep scale (PDSS2).

4.5 Review questions

Review questions guide a systematic review of the literature. They address only the key clinical issues covered in the scope, and usually relate to interventions, diagnosis, prognosis, service delivery or patient experience. Please note that these review questions are draft versions and will be finalised with the Guideline Development Group.

4.5.1 Pharmacological management of motor symptoms

a) What is the comparative effectiveness of levodopa, monoamine oxidase B inhibitors, dopamine agonists and anticholinergics as first-line treatment of motor symptoms?

b) What is the comparative effectiveness of pharmacological interventions (monoamine oxidase B inhibitors, dopamine agonists, catechol-O-methyl transferase inhibitors amantadine, apomorphine) as adjuvants to levodopa?

c) What is the effectiveness of duodopa intestinal gel?

If duodopa is shown to be effective, then we will answer the following question:

d) What are the appropriate referral criteria for the use of duodopa intestinal gel?

4.5.2 Pharmacological management of non-motor symptoms

a) What is the comparative effectiveness of pharmacological interventions for daytime hypersomnolence?

b) What is the comparative effectiveness of pharmacological interventions for nocturnal akinesia?

c) What is the comparative effectiveness of pharmacological interventions for drooling?

d) What is the comparative effectiveness of pharmacological interventions for orthostatic hypotension?

e) What is the comparative effectiveness of pharmacological interventions for thermoregulation?

f) What is the comparative effectiveness of second generation antipsychotics for psychotic symptoms?

g) What is the comparative effectiveness of antidepressants for depression in Parkinson's disease?

4.5.3 Pharmacological management of dementia associated with Parkinson's disease

a) What is the comparative effectiveness of rivastigmine, mementine, donepesil and galantamine for cognitive enhancement in dementia associated with Parkinson's disease?

4.5.4 Non-pharmacological management of motor and non-motor symptoms

a) What is the effectiveness of physiotherapy compared with usual care?

b) What is the effectiveness of occupational therapy compared with usual care?

c) What is the effectiveness of speech and language therapy compared with usual care?

d) What is the effectiveness of nutritional support compared with usual care?

4.5.5 Deep brain stimulation

a) What are appropriate referral criteria for deep brain stimulation?

b) Is there an increased benefit in receiving deep brain stimulation in the earlier, rather than the later, stages of Parkinson's disease?

c) What is the effectiveness of deep brain stimulation (subthalamic nucleus, globus pallidus interna, thalamus, and pedunculopontine nucleus stimulation) plus best medical therapy compared with best medical therapy alone?

4.5.6 Managing and monitoring impulse control disorder as an adverse effect of dopaminergic treatment

a) What factors should healthcare professionals consider as potential predictors for the development of impulse control disorder as an adverse effect of dopaminergic treatment?

b) How should dopaminergic treatment be managed in people who have developed impulse control disorder as an adverse effect?

c) What are the information needs of people with Parkinson's disease and their families and carers about the potential for impulse control disorder when considering dopaminergic treatment?

4.5.7 Palliative care

a) What are the needs of people with Parkinson’s disease for advance directives and palliative care plans throughout the course of their disease?

4.5.8 Information needs of people with Parkinson's disease and their families and carers

a) What are the information and communication needs of people with Parkinson's disease and their families and carers?

b) What are the specific information needs of women of childbearing age with Parkinson's disease?

4.6 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.

4.7 Status

4.7.1 Scope

This is the consultation draft of the scope. The consultation dates are 5 August to 10 September 2014.

The development of the guideline recommendations will begin in November 2014.

5 Related NICE guidance

5.1 Published guidance

5.1.1 NICE guidance to be updated

This guideline will partially update and will replace ‘Parkinson's disease’. NICE clinical guideline 35 (2006).

5.1.2 Other related NICE guidance

- Psychosis and schizophrenia in adults. NICE clinical guideline 178 (2014)
- Neuropathic pain: pharmacological management NICE clinical guideline 173 (2013)
- Falls NICE clinical guideline 161 (2013).
- Urinary incontinence in neurological disease NICE clinical guideline 148 (2012)
- Patient experience in adult NHS services: improving the experience of care for people using adult NHS services. NICE clinical guideline 138 (2012)
- Generalised anxiety disorder and panic disorder in adults NICE clinical guideline 113 (2011)
- Donepezil, galanamine, rivastigmine and memantine for the treatment of Alzheimer's disease NICE technology appraisal guidance 217 (2011).
- Percutaneous posterior tibial nerve syndrome for overactive bladder syndrome NICE interventional procedure guidance 362 (2010).
- Depression with a chronic physical health problem NICE clinical guideline 91 (2009).
- Dementia NICE clinical guideline 42 (2007).
- Subthalamotomy for Parkinson's disease NICE interventional procedure guidance 65 (2004).
- Deep brain stimulation for Parkinson's disease NICE interventional procedure guidance 19 (2003).

5.2 Guidance in development

- Care of the dying adult. NICE clinical guideline. Publication date to be confirmed.

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.