NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Chronic kidney disease: management of hyperphosphataemia in patients with stage 4 or 5 chronic kidney disease.

1.1 Short title

Management of hyperphosphataemia.

2 The remit

The Department of Health has asked NICE: ‘To produce a short clinical guideline on management of hyperphosphataemia in patients with stage 4 or 5 chronic kidney disease.

3 Clinical need for the guideline

3.1 Epidemiology

a) For 2009, the Health Survey for England reported an overall prevalence of moderate to severe CKD (stages 3 to 5) of 6%; CKD stages 4 and 5 were reported at a prevalence of less than 1%. In the same year, the UK Renal Registry reported that 49,080 adult patients were receiving renal replacement therapy (RRT) in the UK. Of these patients, 25,796 were receiving RRT in the form of dialysis.

b) The most recent Renal Registry data from 2009 showed that only 61% of patients receiving haemodialysis and 70% of patients receiving peritoneal dialysis achieved serum phosphate levels within the recommended range.
c) Inadequate control of serum phosphate can directly and indirectly increase parathyroid hormone secretion, leading to the development of secondary hyperparathyroidism. Left untreated, secondary hyperparathyroidism increases morbidity and mortality and may lead to renal bone disease, with patients experiencing bone and muscular pain, increased incidence of fracture, abnormalities of bone and joint morphology, and vascular and soft tissue calcification.

d) An ageing population together with an increasing incidence of diabetes and better survival means that the number of patients requiring dialysis and adequate phosphate management is increasing. Between 2005 and 2009 the number of patients needing dialysis increased at a rate of 3.5% per year.

3.2 Current practice

a) For adult patients with stage 3 to 5 chronic kidney disease who are not on dialysis, the UK Renal Association clinical practice guideline recommends that serum phosphate levels be maintained between 0.9 and 1.5 mmol/l. For adult patients with stage 5 chronic kidney disease who are on dialysis, it is recommended that serum phosphate levels be maintained between 1.1 and 1.7 mmol/l.

b) For patients under 20 years of age, with stage 1 to 4 chronic kidney disease, the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative recommends serum phosphate levels be maintained within age-appropriate limits. For those with stage 5 chronic kidney disease, including those on dialysis, it is recommended that serum phosphate levels be maintained between 1.3 and 1.9 mmol/l for those aged 1 to 12 years, and between 1.1 and 1.8 mmol/l during adolescence.

c) Standard management of stage 4 and 5 chronic kidney disease involves maintaining acceptable levels of phosphate, calcium and parathyroid hormone. This can be achieved by the use of
phosphate binding agents, calcium supplementation, dietary management of phosphate, vitamin D preparations, calcimimetics or parathyroidectomy.

d) There is wide variation in the management of serum phosphate levels between renal centres in the UK. This, together with a rising prevalence of CKD and a growing number of people receiving dialysis, requires the development of a clinical guideline on the management of hyperphosphataemia.

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, children and young people with stage 4 or 5 chronic kidney disease who are not on dialysis and who are at risk of hyperphosphataemia.

b) Adults, children and young people with stage 5 chronic kidney disease who are receiving haemodialysis or peritoneal dialysis and are at risk of hyperphosphataemia.

c) Consideration will also be given to specific subgroups, as appropriate and when these have been reported by study authors.
4.1.2 Groups that will not be covered
a) Adults, children and young people with stage 1–3 kidney disease.

4.2 Healthcare setting
a) All healthcare settings, and at home.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered
a) Treatments for managing hyperphosphataemia including:
   - phosphate binders (including sevelamer hydrochloride, sevelamer carbonate, lanthanum carbonate, calcium-based phosphate binders (including calcium carbonate and calcium acetate), magnesium/calcium carbonate combinations (including magnesium carbonate/calcium acetate combinations), aluminium-based phosphate binders (including aluminium hydroxide)
   - prescribed supplements (such as calcium and nicotinamide)
   - dietary management of phosphate.

b) Efficacy of patient information/education in respect of adherence to dietary interventions.

c) The sequencing of treatments (diet, phosphate binders, vitamin D and dialysis) to effectively manage hyperphosphataemia.

4.3.2 Clinical issues that will not be covered
a) Diagnosing hyperphosphataemia.

b) Diagnosing and managing hyperparathyroidism.

c) Diagnosing and managing renal bone disease.
d) Primary management of chronic metabolic acidosis, except as a consequence of treating hyperphosphataemia.

e) Primary management of hypophosphataemia, except as a consequence of treating hyperphosphataemia

f) Treatments with the primary aim of increasing bone density.

g) Efficacy of choice/Type of dialysis, including extending dialysis duration, and changing dialysis membranes and fluids.

h) Efficacy of Vitamin D and its analogues.

i) Prognostic value of serum phosphate level and other biochemical markers, except when considered in the context of specified therapeutic intervention(s)

4.4 Main outcomes

a) Management of serum phosphate

b) Morbidity, including fractures, advancement of renal bone disease, vascular calcification, cardiovascular impact, and other related issues.

c) Adverse effects of therapy, immediate and long term.

d) Cardiovascular-related mortality.

e) Overall mortality.

f) For people not already receiving renal replacement therapy, effect of therapy on requirement for renal replacement therapy.

g) Health-related quality of life.

h) 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 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').

4.6 **Status**

4.6.1 **Scope**

This is the final scope.

4.6.2 **Timing**

The development of the guideline recommendations will begin in January 2012

5 **Related NICE guidance**

5.1 **Published guidance**

5.1.1 **Other related NICE guidance**

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).