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## Chronic Kidney Disease – Mineral and Bone Disorder (CKD-MBD) Dietetic Management Protocol

<table>
<thead>
<tr>
<th>Reference Number:</th>
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<tbody>
<tr>
<td>NHSCT/12/553</td>
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</table>

**Target audience:**
This protocol is for use by Renal Dietitians in the Renal Unit, Antrim Hospital.

**Sources of advice in relation to this document:**
Joanne McKee, Lead Dietitian  
Rebecca Getty, Assistant Director Acute Services Operational Support

**Replaces (if appropriate):**
N/A

**Type of Document:**
Directorate Specific

**Approved by:**
Policy, Standards and Guidelines Committee

**Date Approved:**
3 April 2012

**Date Issued by Policy Unit:**
11 June 2012

**NHSCT Mission Statement**
To provide for all the quality of services we would expect for our families and ourselves
Chronic Kidney Disease - Mineral and Bone Disorder (CKD-MBD)
Dietetic Management Protocol
Chronic Kidney Disease - Mineral and Bone Disorder (CKD-MBD)
Dietetic Management Protocol

Protocol and competency framework to enable named renal dietitians to recommend and request the prescription of appropriate phosphate binders and optimal doses from the patient’s GP, in stable dialysis patients attending Antrim Hospital Renal Unit.

Review date: March 2013

Target Audience and Responsibilities
This protocol is for use by Renal dietitians in the Renal Unit, Antrim Hospital. Responsibility for this protocol lies with the Lead Renal Clinician and Lead Renal Dietitian.

This protocol should be read in conjunction with:
Renal Association Clinical Practice Guidelines. CKD-Mineral and Bone Disorders (CKD-MBD) September 2010.

Introduction – Evidence for practice

Evidence increasingly links inadequate serum phosphate control to higher morbidity and mortality in patients with CKD stage 5\(^1\,2\). Consistent control of the markers of bone metabolism and disease within published targets is a strong predictor of survival in haemodialysis patients\(^3\) and is now a key therapeutic goal in the treatment of CKD\(^4\,6\).

Haemodialysis clears some of the excess circulating phosphate but rebound in serum levels occurs between sessions. Dialysis adequacy contributes to phosphate control but restriction of dietary phosphorous used in conjunction with phosphate binders remains fundamental to the management of MBD in CKD stage 5.

Treatment for hyperphosphataemia with phosphate binders can contribute to hypercalcaemia and needs to be monitored regularly. Haemodialysis patients have their serum phosphate and serum calcium (adjusted for albumin) checked monthly, and intact PTH checked quarterly.
**Recommended Targets for patients’ with CKD stage 5 maintained on dialysis**

- **Maintain serum calcium in the normal range and lowering elevated phosphorus levels toward the normal range** (K-DIGO 2009 Gloeline 4.1.1.)
- **Adjusted serum calcium should be maintained between 2.1 and 2.5 mmol/L or normal reference range for the laboratory used, with avoidance of hypercalcaemic episodes.** (Renal Association 2010® CKD-MBD Guideline 2.2)
- **Serum phosphate in dialysis patients maintained between 1.1 and 1.7 mmol/L.** (Renal Association 2010® CKD-MBD Guideline 3.2)
- **Dietary phosphate intake should be restricted in the treatment of hyperphosphatemia alone or in combination with other treatments** (K-DIGO 2009® Guideline 4.1.7)
- **The choice of phosphate binder should take into account CKD stage, presence of other components of CKD-MBD, concomitant therapies, and side-effect profile** (K-DIGO 2009® Guideline 4.1.4.) Tolerance and compliance with phosphate binding regime is also very important to outcomes therefore patient choice should also be considered – see flow chart.
- **In patients with hyperphosphatemia, the dose of calcium-based phosphate binders and/or the dose of activated vitamin D should be restricted in the presence of persistent or recurrent hypercalcaemia.** It is also suggested that the dose of calcium-based phosphate binders should also be restricted in the presence of arterial calcification and/or adynamic bone disease and/or if serum PTH levels are persistently low. (K-DIGO 2009® Guideline 4.1.5)
- **PTH - maintain PTH levels in the range of approximately two to nine times the upper normal limit for the assay.** Marked changes in PTH levels in either direction *within this range* are recommended to prompt an initiation or change in therapy to avoid progression to levels outside of this range. (K-DIGO 2009® Guideline 4.2.3) (Renal Association 2010® CKD-MBD Guideline 4.2.1)

**Aims**

Poor compliance with phosphate binders is a major factor in the management of MBD. Tailoring the dose of binder to the phosphorous load of each meal can help to improve phosphate control within normal limits in CKD.

This protocol aims to rationalise and expedite changes to phosphate binder medication prescription after the assessment of dietary phosphate intake and compliance with current binders by the Renal Dietitians, improving the management of MBD in maintenance haemodialysis (MHD) patients attending Antrim Renal Unit.

Responsibility for prescribing medications for patients’ attending Antrim Renal unit for haemodialysis lies with the General Practitioners on advice from the Renal Team. This protocol provides a systematic guideline allowing specified Renal Dietitians at Antrim renal unit to contact GP’s directly to advise on changes to prescribed phosphate binder regimes.
**Indications**

- Stable maintenance haemodialysis patients who attend Antrim Renal Unit
- Binders and dose to be decided according to the agreed protocol (Table 1 and flow chart 1)

**Contraindications**

- Post parathyroidectomy until stability established with their consultant
- Pregnant or breast feeding females, or those under 16
- Inpatients

**Limitations to practice**

- Vitamin D therapy (and Parathyroid Hormone levels) will influence serum Calcium and phosphate levels but adjustment of vitamin D therapy is not within the remit of this protocol. Any recent changes to Vitamin D therapy should however be noted before adjusting binder regime.
- Patients requiring doses higher than the agreed protocol maximum will be discussed with their Consultant Nephrologist.
- Changes to the binders for those patients also prescribed Cinacalcet should first be discussed with their consultant.
- Renal Dietitians who have been qualified at least 3 years, with >12 months renal experience and have completed competency based training in the use of the protocol and satisfactory supervised practice (appendix 1&2) Evidence of competence and supervised practice should be held within the dietetic dept/Renal unit. The number of supervised practices will be decided by the supervising Consultant Nephrologist. Where none of the Renal Dietitians specified to use this protocol are available, responsibility for the management of CKD-MBD reverts to the Renal medical team.

**Objectives**

Renal dietitians using this protocol will:

- Monitor monthly bone biochemistry trends (including intact serum PTH, Calcium and phosphate).
- Alert medical staff when these fall outside agreed ranges (see flow chart 1)
- Regularly assess the dietary phosphate content of MHD patients’ diet and advise re any changes to help reduce dietary phosphate load.
- Encourage compliance with phosphate binder regimes.
- Recommend changes to phosphate binder, dose or timing according to the agreed protocol (flow chart 1)
- contact the patient’s GP requesting the new type or dose of binder suggested. (standard letters, Appendix 3)
- give the patient written details of any changes to their binder regime including a reminder to pick up their new prescription.(appendix 4)
- ensure medical staff are alerted to update Emed medication records.

- Maintain Emed records to ensure consistent MDT communication of any changes made.

**Equality, Human Rights and DDA**
The policy is purely clinical/technical in nature and will have no bearing in terms of its likely impact on equality of opportunity or good relations for people within the equality and good relations categories.

**Sources of Advice in relation to this Document**
The Policy Author, responsible Assistant Director or Director as detailed on the policy title page should be contacted with regard to any queries on the content of this policy.

**Alternative Formats**
This document can be made available on request on disc, larger font, Braille, audio-cassette and in other minority languages to meet the needs of those who are not fluent in English.
<table>
<thead>
<tr>
<th><strong>Generic name</strong></th>
<th><strong>Brand name</strong></th>
<th><strong>Dose</strong></th>
<th><strong>Elemental Calcium content</strong></th>
<th><strong>Protocol max dose/day</strong></th>
<th><strong>Formulation</strong></th>
<th><strong>Comments</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium acetate</td>
<td>Phosex</td>
<td>1g</td>
<td>250mg</td>
<td>6</td>
<td>White, torpedo shaped tablets or capsule</td>
<td>May be swallowed whole or snapped in half – can be difficult to swallow. Efficacy independent of pH</td>
</tr>
<tr>
<td></td>
<td>Phoslo</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>667mg</td>
<td>169mg</td>
<td>9</td>
<td></td>
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</tr>
<tr>
<td>Calcium Carbonate</td>
<td>*Adcal</td>
<td>1.25g</td>
<td>600mg</td>
<td>3</td>
<td>Large, round white “chalky” tablets</td>
<td><strong>Must be chewed.</strong> Efficacy dependant on gastric pH High Calcium load</td>
</tr>
<tr>
<td></td>
<td>Calcichew</td>
<td>1.25g</td>
<td>500mg</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lanthanum Carbonate</td>
<td>Fosrenol</td>
<td>500mg</td>
<td>n/a</td>
<td>3</td>
<td></td>
<td></td>
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<tr>
<td>(Shire)</td>
<td>750mg</td>
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<tr>
<td></td>
<td>1000mg</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Must be chewed.</strong> Patients should be advised to take during or immediately after meals as can cause nausea. Calcium free but expensive</td>
</tr>
<tr>
<td>Sevelamer Carbonate</td>
<td>Renvela</td>
<td>800mg</td>
<td>n/a</td>
<td>15</td>
<td>White, torpedo shaped tablets</td>
<td><strong>Swallowed whole</strong> – slippery coating Anion exchange resin. Calcium free but expensive. Can help lower LDL cholesterol Contraindicated in bowel obstruction</td>
</tr>
<tr>
<td>(Genzyme)</td>
<td>2.4g</td>
<td></td>
<td>n/a</td>
<td>3</td>
<td>Powder dissolved in 60mls fluid</td>
<td></td>
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</tbody>
</table>

*Calcium carbonate contract preference
General information regarding phosphate binder medications

Timing and dose
- All the above binders should be taken with meals. In some instances, patients may also be advised to take them with larger snacks.
- Calcium carbonate preparations are also commonly used as Calcium supplements (when not taken with meals). When prescribed as a phosphate binder, the need to take them with meals should be stressed.
- Combination therapy – some patients benefit from a combination of Calcium and non-calcium based phosphate binders to maintain serum Calcium within the acceptable range while limiting tablet burden.

Side effects
- GI disturbance – indigestion, nausea
- Constipation – alternatively some complain of diarrhoea/looser motions
- Hypercalcaemia – Calcium based binders

Despite common side effects, tolerability can vary between binder types – it may take trials of several to find the most suitable. Patient preference for tablets which can be swallowed whole or chewed should be considered.

Drug interactions
- Calcium Carbonate binders require an acid pH to be effective. Alternative binders may be more effective in patients taking medications that reduce gastric acid secretion such as PPI's, antacids and sodium bicarbonate (eg. lansoprazole, omeprazole, ranitidine, cimetidine).
- Sandocal 400/1000 are soluble calcium supplements that are not licensed as phosphate binders – Calcium citrate is produced in solution which can accelerate the uptake of aluminium. They are occasionally prescribed as an alternative to Calcium carbonate tablets in the community by mistake, where there is perhaps confusion that the aim was calcium supplementation rather than phosphate binding.
- Some calcium carbonate preparations are also available with added cholecalciferol (Calcichew D3 and Adcal D3) which can occasionally be prescribed by mistake in the community. Patients’ with CKD stage 4/5 patients can not effectively utilise this inactive vitamin D and therefore it is not recommended.
- Phosphate binders will impair the absorption of oral Iron supplements – patients should be advised to take prescribed oral iron preparations at a different time of the day rather than meal times when phosphate binders are taken.
Check monthly bloods

**Phosphate > 1.7 mmol and rising**
- Check binders compliance
- Assess dietary phosphate
- Check PTH & Calcitriol script

Dietary phosphate high or current binders taken incorrectly.

Calcium 2.15-2.55 mmol/l

Binders currently not prescribed or not tolerated
- Prefers to swallow tablets
  - Calcium Acetate
- Prefers to chew tablets
  - Calcium Carbonate

Advise re diet and timing of binders

Review next monthly bloods

**Phosphate <1.1**

Assess dietary intake and review need for binders

Diet low in phosphate

Calcium >2.55 mmol/l and rising

Stop/reduce Calcium based binders
- Prefers to swallow tablets
  - Sevelamer Carbonate
- Prefers to chew tablets
  - Lanthanum Carbonate

Marked changes in PTH levels
- PTH < 130 pmol/l
  - >300 pmol/l

- Calcium <2.13 mmol/l
  - >2.55 mmol/l persistently
- Patients prescribed Cinacalcet

**Antrim Labs ranges**
- PTH 130-585 ng/l (x2-9)
- Calcium 2.15-2.55 mmol/l
- Phosphate 0.87-1.45 mmol/l

Discuss with consultant

**Flow chart 1**

Diet low in phosphate

Calcium >2.55 mmol/l and rising

Stop/reduce Calcium based binders
- Prefers to swallow tablets
  - Sevelamer Carbonate
- Prefers to chew tablets
  - Lanthanum Carbonate

Advise re diet and timing of binders

Review next monthly bloods

Dietary phosphate high or current binders taken incorrectly.

Calcium 2.15-2.55 mmol/l

Binders currently not prescribed or not tolerated
- Prefers to swallow tablets
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Advise re diet and timing of binders

Review next monthly bloods

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  - >300 pmol/l
- Calcium <2.13 mmol/l
  - >2.55 mmol/l persistently
- Patients prescribed Cinacalcet

Discuss with consultant
References


5. Renal Association Clinical Practice Guidelines. CKD-Mineral and Bone Disorders (CKD-MBD) September 2010

Bibliography


University Hospital Birmingham NHS foundation Trust. Protocol to enable renal dietitians to recommend directly to the general practitioner, appropriate/optimal dose and choice of phosphate binding drugs for stable haemodialysis patients. (March 2007)


Appendix 1

Criteria for Competence

**End Competence:** To recommend directly to the patients GP, appropriate type and dose of phosphate binding medication for maintenance haemodialysis patients attending Antrim Renal Unit.

Name of Renal Dietitian : .............................................

Name of Supervisor : .............................................

<table>
<thead>
<tr>
<th>Competency Assessment</th>
<th>Date</th>
<th>Supervisor signature</th>
</tr>
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<tbody>
<tr>
<td>3 years post registration experience</td>
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<tr>
<td>1 yr haemodialysis renal experience</td>
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<td><strong>Demonstrates a knowledge of:</strong></td>
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<tr>
<td>• CKD-MBD</td>
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<td>• interpretation of calcium, phosphate and PTH blood results</td>
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<td>• other medications which can effect Ca, PO4 and PTH levels</td>
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<tr>
<td>• indications, contraindications and limitations of practice of this protocol</td>
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<tr>
<td>• binders included in this protocol, including contraindications, maximum doses, side effects, Calcium content and potential drug interactions</td>
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<td>• the role of alfacalcidol</td>
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<tr>
<td>• incident reporting process</td>
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<td>Date competency assessment completed:   /   /   .</td>
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Signature of supervisor ..........................................................

Designation .................................................................

Copies of completed competency and supervised practice forms to be kept in the Renal Unit and Dietetic Dept.
# Appendix 2

## Supervised Practice Record

Name of Renal Dietitian: ..............................................................

<table>
<thead>
<tr>
<th>Date</th>
<th>Details of practice eg. MDT Bone mtg</th>
<th>Comments</th>
<th>Observed by:</th>
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Date sufficient satisfactory supervised practices completed: __/__/__.

Signature of supervisor ..........................................................

Designation .................................................................

Copies of completed competency and supervised practice forms to be kept in the Renal Unit and Dietetic Dept.
Appendix 3

Standard Letter to GP Requesting Change in Phosphate Binder Regime

Dr

Date:

Dear Dr

Re:        DoB:       Address       Hospital number ANT

Consultant Nephrologist: Dr

This patient’s phosphate dietary phosphate intake has been reviewed and their phosphate binder regime reviewed.

Previous binder regime:                    with meals
Amended binder regime:    with meals

The patient has been advised of the importance of taking this medication with meals to maximise its efficacy and phosphate dietary advice has been reinforced. Their renal unit medication kardex has been updated to include this change.

The advice on these changes is within the agreed NHSCT Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD) Dietetic Management Protocol. For a copy of the protocol or more information, please do not hesitate to contact the Renal unit or myself.

Yours sincerely

Renal Specialist Dietitian       Non-medical prescriber
counter signator
Appendix 4

Information Sheet to be Given to Patients to Inform Them of Any Change of Phosphate Binders or Dose

Date: ___/___/____.
Name: ____________________________

Your phosphate binder or dose has been changed today.

PHOSPHATE BINDERS  …………………………………

NEW DOSE

Breakfast  …………
Lunch  …………
Evening meal  …………
Bedtime snack  …………

It is essential that your phosphate binders are taken with EACH MEAL for them to work effectively.

Your GP will be contacted regarding this change. Please call at your Health Centre to collect a new prescription, if the binder has been changed.

Please start the new tablet/dose as soon as possible.

A reminder about any changes to your diet also suggested today are overleaf.

If you have any questions, please do not hesitate to contact me at the above number.

Renal Specialist Dietitian