Measuring Renal Dietetic Outcomes in Patients on Haemodialysis with Hyperphosphatemia

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Epidemiological studies have shown a direct correlation between serum phosphate levels and mortality in patients on haemodialysis (HD).[1,2] Up to 29% of patients on HD in the UK have high phosphate levels (phosphate > 1.7 mmol/l).[3] Observational studies have also confirmed that patients on HD with a phosphate between 1.1 and 1.7 mmol/l have a lower risk of mortality than those with a phosphate level less than 1.1 mmol/l or more than 1.7 mmol/l.[2] In 2015, only 57.5% of patients on HD in the UK achieved a phosphate level between 1.1 and 1.7 mmol/l.[3]

Hyperphosphatemia is mainly dependant on dietary phosphate intake and, as a result, patients need dietary advice to follow a low phosphate diet, without compromising their protein intake. In addition, phosphate binders are prescribed to reduce the amount of phosphate absorbed via the gastrointestinal tract. Other factors affecting phosphate levels include: the effectiveness of dialysis prescription, which depends upon the dialysis duration and frequency of treatment and vascular access; medications, such as active vitamin D therapy and calcium mimetics; and, of course, patient adherence to diet and treatments.

The NICE Guidelines for the management of hyperphosphatemia in chronic kidney disease states that specialist renal dietitians are the best qualified staff to assess patients' dietary phosphate intake (considering food and drink choices, food additives) and tailor individualised dietary advice and phosphate binder distribution, while avoiding malnutrition by maintaining a protein intake at or above the minimum recommended.[4]

In 2015, following a successful joint bid to our commissioners and our Trust, we secured temporary funding for one year of an additional 0.2 WTE (whole time equivalent) band 7 renal dietitian (as additional staff for one day a week), with the aim to measure renal dietetic outcomes in phosphate management as well as patient related outcomes measures (PROMs) at one of our HD units. The aim of this article is to present the main findings of this project and to underline strength and weakness when measuring outcomes in dietetic practice.

Aim & objectives

Over the past 20 years many renal units in the UK have implemented either a patient group directive (PGD) or local agreements, which allow renal dietitians to amend doses of oral phosphate binders and sometimes to start these by following their local procedures.

In 2015, in Nottingham, we decided to implement a local agreement that would allow a renal dietitian to initiate, amend and stop oral phosphate binders as part of a project. The project aimed to evaluate the impact of its implementation by measuring renal dietetic outcomes measures.

This project was registered as a service evaluation in our Trust and had the following objectives:

- To reduce patients' prescription delays and improve the time efficiency for dietitians and clinicians in implementing any changes in phosphate binders
- To reduce phosphate binder wastage
- To improve patients' quality of life by reducing the number of tablets (phosphate binders) that patients will need to take in order to control their phosphate level without deterioration of their phosphate levels
- To measure key renal dietetic outcomes in the management of hyperphosphatemia in clinical practice.

Methods

A local agreement was developed with the dietetic department, pharmacy and our nephrologists, which allowed an experienced renal dietitian (with at least three years of experience in renal dietetics) to start, change and stop phosphate binders independently after completing internally developed competencies.

The scheme aimed to improve the cost effectiveness of binder usage. All patients with an elevated phosphate as well as all patients on a phosphate binder at our main dialysis unit were monitored via individual face-to-face consultations over a 12-month period. In addition to the number of contacts with patients by the renal dietitian, the following primary outcomes measures were recorded:

- Changes in bloods phosphate levels
- Changes in phosphate binders (number of binders per day taken by patients)
- Patient adherence to dietary recommendation and phosphate binder prescription
- Total cost of phosphate binders.

Secondary outcome measures were also recorded which will help with a future analysis of the data. These included:

- Nutritional status measured by Subjective Global Assessment (SGA), weight, percentage of weight loss and body mass index (BMI)
- Calcium and parathyroid levels
- Patient adherence to HD treatment (number of HD per week)
- Dialysis quality by measuring urea reduction ratio (URR)
- Alfacalcidol and Cinacalcet use.

Baseline data collection was in December 2014 (month 0), where 119 haemodialysis patients' phosphate levels and their phosphate binder usage were recorded retrospectively. **Table One** summarises the demographics of these patients. The additional funding started in January 2015 (month one). By December 2015 a total of 139 haemodialysis patients were included in the project. The additional 20 were new dialysis patients (n = 139).

Number of contacts

Over 12 months, a 0.2 WTE renal dietitian (one day a week) saw a total of 378 face-to-face contacts (**Figure 1**). Each contact resulted in an alteration of the patient's dietary regime and/or phosphate binders (starting, changing or stopping).

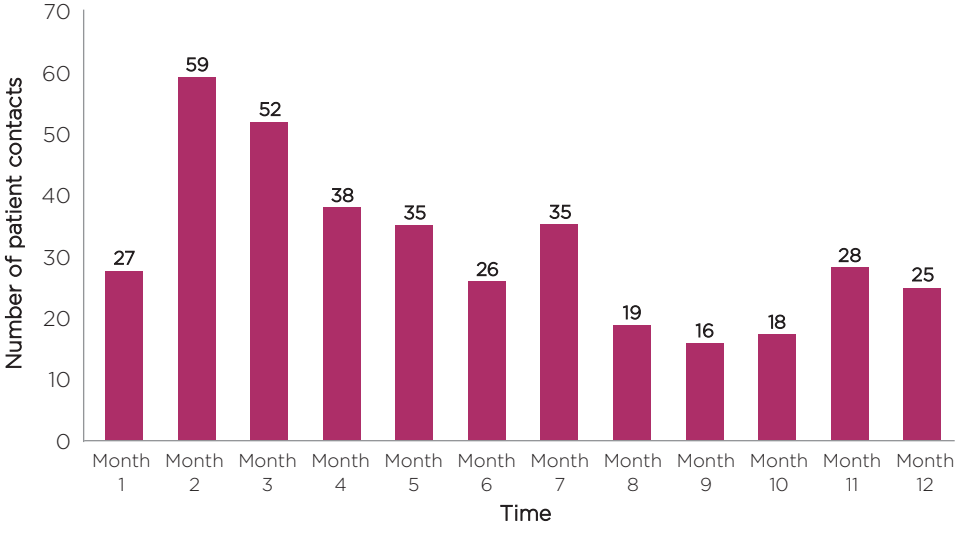
The number of face-to-face patient contacts reduced at month 6 and again at month 8, 9 and 10 (**Figure 1**). This is because there was a severe gap in staffing levels and the workforce had to be reprioritised. The project highlighted the difficulties in dedicating and protecting additional dietetic staffing during a period of staff shortages (and this was the main limitation of the project). At the end of the project, out of the 139 patients 14 patients had died and two patients were transferred to another centre. These patients were excluded from the data analysis leaving 123 patients.

While numbers of patient contacts are clearly not outcome measures, it is still useful to consider the staff:number of patient contacts ratio. In this project, the 0.2 WTE renal dietitian saw on average of seven patients a day.

Table One: Demographic and Clinical Characteristics of Patients. Data are Mean ± 1SD for Continuous Variables and Number (% of group total) for Categorical Values

Characteristic	n (119)
Age, yr	65.2 ± 14.7
Weight, kg	76.2 ± 20.5
BMI, kg/m^2	27.7 ± 7.1
Male	70 (59%)
Diabetes	47 (39%)
Type 1	6
Type 2	41
Subjective global assessment	
SGA 1-2	12 (10%)
SGA 3-5	27 (22.7%)
SGA 6-7	80 (67.3%)

Figure 1: Number of Renal Dietitian Contacts with Patients Over One Year



Phosphate levels

Phosphate levels dropped within the first two months from 1.75 mmol/l to 1.56 mmol/l. However, levels increased back to 1.73 mmol in July 2015 and to 1.71 mmol/l in December 2015 (**Figure 2**). As described phosphate levels can be influenced by other variables. While there is no doubt that high phosphate levels are correlated to high mortality rates in patients on HD,[1, 2] measuring renal dietetic outcomes looking at phosphate levels in isolation is not enough to show the benefit of renal dietetic input. **Figure 2** shows the average phosphate trend of patients on HD during the project.

Patient adherence to diet & phosphate binders

Patient adherence to dietary advice and to phosphate binders were estimated subjectively by the renal dietitian using a scoring system 0-2 (0 = none, 1 = moderate, 2 = good adherence) at baseline and at the end of the project. This method was not validated and has several limitations.

For dietary adherence, the renal dietitian evaluated a patient's oral intake by conducting a diet history (as well as taking into account previous dietetic records). It is also worth remembering that the majority of these patients were already well known to the renal dietitian. For phosphate binder adherence the dietitian used motivational interviewing techniques, asking questions in a non-judgemental way. For example: *"What phosphate binder are you taking? Do you manage to take one tablet a day?"* The dietitian also called the GP to check if phosphate binder prescriptions were collected by patients.

It would have been useful to take into account trends of phosphate levels, dialysis adherence, measuring level of knowledge and confidence to implement a low phosphate diet. However, these were not included due to time constraints and a lack of resources. The following charts show the number of patients (n: 73) on phosphate binders and the changes in dietary and phosphate binders adherence at baseline and at the end of the project (**Figure 3 and 4**).

Number of phosphate binders

The total average of phosphate binder dosage was obtained by taking into account each phosphate binder and obtaining a mean by using total number

Figure 2: Phosphate Blood Levels (mmol/l) in Patients on Haemodialysis

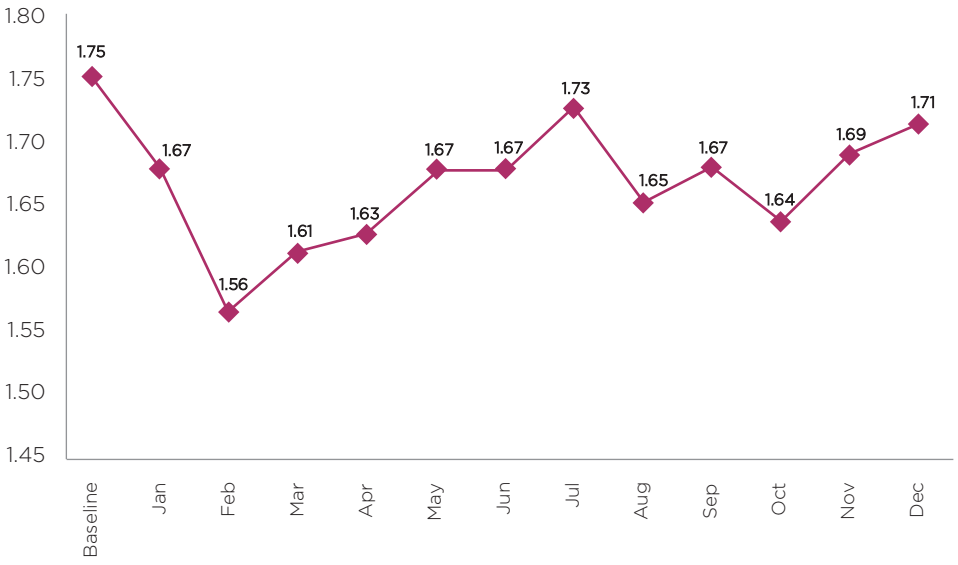


Figure 3: Low Phosphate Diet Adherence in Patients at Baseline and at the End of the Project (n: 73)

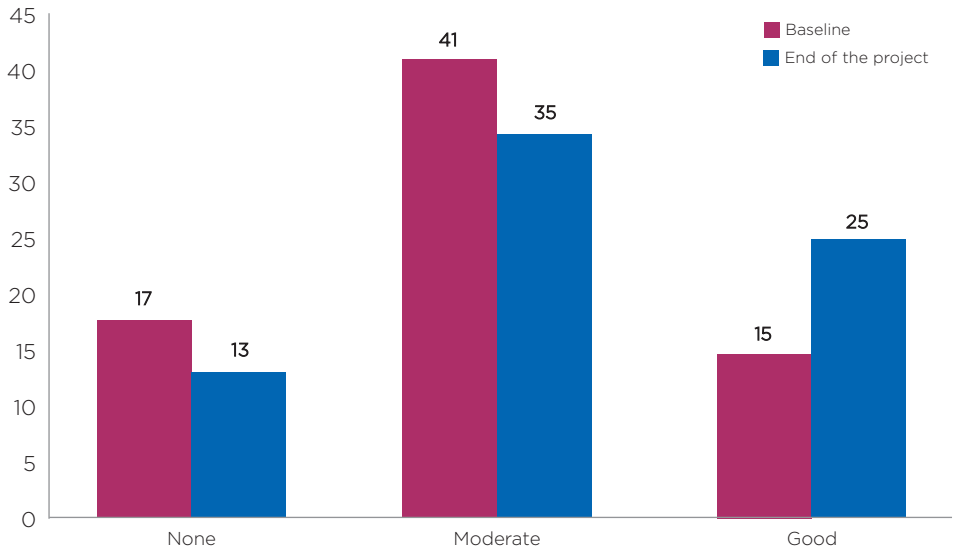


Figure 4: Phosphate Binder Adherence in Patients at Baseline and at the End of the Project (n: 73)

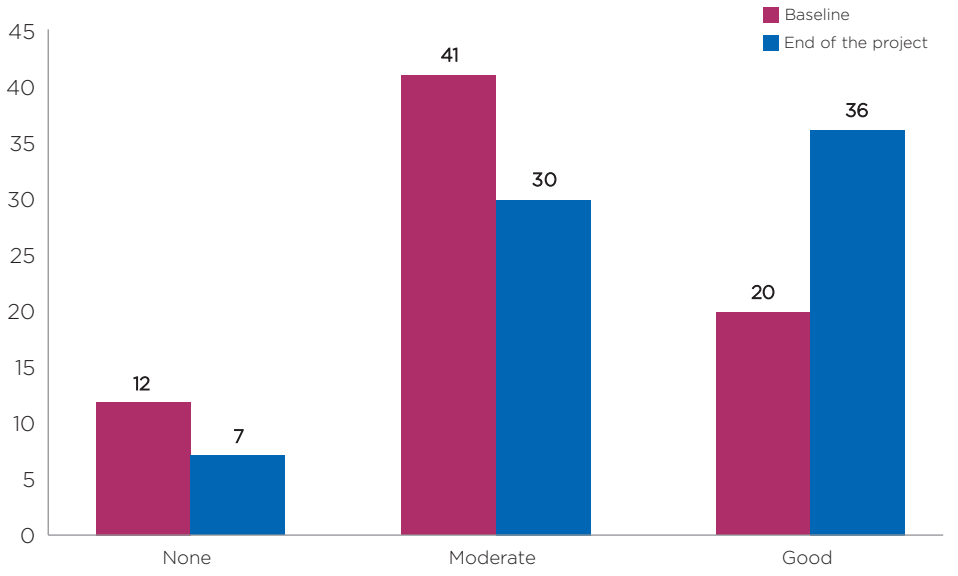


Table Two: Changes in Phosphate Binders

Phosphate binder name*	Doses	Month (baseline)	Month 6	Month 12	Growth rate
Calcichew (calcium carbonate)	1250 mg	3.38	2.71	2.50	-2.3%
Phosex (calcium acetate)	1000 mg	3.35	3.00	3.00	-0.8%
Phoslo (calcium acetate) **	667 mg	4.00	n/a	n/a	n/a
Fosrenol (lanthanum carbonate)	500 mg	4.50	4.00	n/a	-1.3%
Fosrenol (lanthanum carbonate)	750 mg	2.86	2.40	2.50	-1.0%
Fosrenol (lanthanum carbonate)	1000 mg	3.00	2.33	2.00	-3.1%
Fosrenol powder (lanthanum carbonate)	1000 mg	2.67	2.00	1.83	-2.8%
Fosrenol powder (lanthanum carbonate)	750 mg	n/a	1.00	2.00	-4.0%
Renagel (sevelamer hydrochloride)***	800 mg	6.40	4.77	4.75	-2.3%
Total		**3.77**	**2.78**	**2.65**	**-1.8%**

*The table includes the phosphate binders used in Nottingham in 2015. **No longer in production; ***Sevelamer has now become generic (sevelamer carbonate)

Table Three: Cost Comparison for Consultant Time *versus* Dietetic Service Provision

	Cost per year
Total annual fee for two hours per month for a consultant	£1,267 (threshold point 4 of the consultant salary scale)
Total annual fee for two hours per month for a band 7 dietitian	£537 (Mid-point band 7 salary scale)
Total potential hospital saving	£730 (All costings at mid-point based on 1.4.15 rates)

of patients (including those patients not on a phosphate binder). The average number of tablets dropped from 3.77 tablets a day to 2.65 (**Table Two**). This reduction of phosphate binders happened as a result of renal dietetic intervention and, in 2015, led to a significant cost saving, despite not changing phosphate bloods levels.

Financial consideration

The estimated total cost for phosphate binders at baseline was £66,522.41 (average annual cost per patient £367.28). This was an estimate based on the assumption that patients will continue on the same dose and type of phosphate binders from baseline (month 0) for 12 months. The actual cost of phosphate binders during the project reduced to £47,132.53 at the end of the 12 months (average annual cost per patient £283.93). In addition, the total cost of the 0.2 WTE renal dietitian at band 7 per year (£8,767) needs to be deducted from the cost saving. Therefore, this project made a potential net cost saving of £10,622.88 on phosphate binder prescriptions, as a result of additional renal dietetic intervention.

It is important to take the points below into consideration:

- This cost saving was made in the community (GP practice prescriptions) rather than in the hospital setting
- Sevelamer carbonate is now available as a generic version and, therefore, it is unlikely that the project will achieve the same financial benefit when calculated on today's cost of such phosphate binders, but the estimated cost saving was correct at the time that this service evaluation took place.

In addition, it could be argued that the funding of a renal dietitian dedicated to phosphate management is less than that of a consultant. Assuming that two hours a month would have been spent in patient assessment and changing in phosphate binder medication the predicted cost saving is summarised in **Table Three**.

Conclusion

This project aimed to measure key renal dietetic outcomes in the management of hyperphosphatemia in clinical practice by trying to answer a simple question: *What will happen to the health/treatment of patients on HD on phosphate binders as a result of renal dietetic intervention?* This reflects the NHS Outcome framework 2016 to 2017.[5]

In this current climate, it is essential to include a financial component which justifies dietetic treatments, as well as measuring patient-related outcomes and nutritional-related outcomes. This suggests that a holistic approach is needed when measuring dietetic outcomes in clinical practice by using a patient-centred approach, as well as considering where we, as a dietetic profession, can make a difference. Now that dietitians can become supplementary prescribers, this will increase the opportunity to advance the role of renal dietitians in the management of those patients on HD with hyperphosphatemia and the cost-effectiveness of dietetic service provision in this group of patients.

The local level agreement has now been implemented with a member of staff and at present we are exploring ways to implement this across the service.

References: **1.** Kidney Disease Improving Global Outcome (2009). Mineral Bone Disorder. Accessed online: http://kdigo.org/home/mineral-bone-disorder/ (May 2017). **2.** Renal Association (2015). Clinical Practice Guideline: CKD Mineral and bone disorders. Accessed online www.renal.org/guidelines/current-guidelines#sthash.TBFxB0zc.dpbs (May 2017). **3.** UK renal registry (2015). Accessed online: www.renalreg.com (May 2017). **4.** NICE Guidelines (2013). Chronic kidney disease (stage 4 or 5): management of hyperphosphatemia. Clinical guideline [CG157]. Accessed online: www.nice.org.uk/Guidance/CG157 (May 2017). **5.** Department of Health (2016). NHS Outcomes framework 2016 to 2017. Accessed online: www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017 (May 2017).

BDA The Association of UK Dietitians
PENG Parenteral & Enteral Nutrition Specialist Group

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