

Management of medicines: A resource document for aspects specific to the National Service Framework for Renal Services

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1. Introduction

This document offers a resource on the specific medicines management issues relating to the treatment of people with renal disease.

It supports delivery of the National Service Framework (NSF) for Renal Services, and concentrates primarily on Part One of the NSF which deals with dialysis and transplantation. It is a dynamic document and will be revised as appropriate.

A complementary resource has been developed for the wider aspects of medicines management for the NSFs for Diabetes, Renal Services and Long-Term Conditions.

This document is intended mainly for health care professionals and managers in Primary Care Trusts and NHS Trusts and those implementing the NSF for Renal Services.

It may however also prove useful for people with kidney disease, carers and patient organisations.

Each chapter includes:

- Aim — what the treatment or process aims to achieve
- Rationale — why this is important
- How — actions that can be taken to achieve the aims

Highlighted throughout are examples of innovative practices that have been set up to help ensure safe and effective use of medicines. A contact name is provided should anyone be interested in setting up a similar scheme.

Although use of medicines should not be viewed in isolation, but as part of the overall management pathway, medicines are an essential component of the treatment of chronic kidney disease. People who are on dialysis or who have had a kidney transplant invariably need to take multiple medicines, many of which have complex regimens.

Despite the serious potential consequences of not taking medicines as prescribed, reported rates of medication non-compliance (either intentional or non-intentional non-compliance) in people with established renal failure are high.¹ It is important for health professionals to involve patients in treatment decisions as well as

supporting them in medicine taking and ensuring that they understand how their medicines should be taken. Patients must be given choice in the way they are treated.

Patients' beliefs and views about medicines have been shown to be a key factor influencing whether, when and how they take their medicines.²

People with renal impairment are at increased risk of adverse reactions to medicines because of reduced elimination of renally excreted medicines. They will be taking many different medicines and are often elderly, which contributes to the risk of adverse reactions. However, many adverse reactions are predictable and can be avoided or minimised by careful medicine prescribing and use.³

The National Service Framework for Older People states that all people aged over 75 should normally have their medicines reviewed at least annually and that those taking four or more medicines should have a review six monthly.⁴ Many people with chronic kidney disease will be in this age group. Aspects of medication review are discussed at the end of Chapter 7.

The UK Renal Pharmacy Group has recommended standards of practice for renal pharmacists, which cover medication review, medication counselling, discharge planning and renal medicines information (www.renalpharmacy.org.uk).

The references in this document that relate to recommended action are graded according to the following levels of evidence:

Level 1: Meta-analyses, systematic reviews of randomised controlled trials, or randomised controlled trials

Level 2: Systematic reviews of case-control or cohort studies, or case-control or cohort studies

Level 3: Non-analytic studies, eg, case reports, case series

Level 4: Expert opinion (in the absence of any of the above). This includes the views and experiences of people with renal failure and their carers

References

1. Carter S, Taylor D. A question of choice — compliance in medicine taking. A preliminary review. London: Medicines Partnership; 2003.
2. Horne R, Weinman J. Patients' beliefs about prescribed medicines and their role in adherence to treatment in chronic physical illness. *J Psychosom Res* 1999;47:555-67.
3. Building a safer NHS for patients. Improving medication safety. London: Department of Health; 2004.
4. National Service Framework for Older People. London: Department of Health; 2001.

2. Information needs of people with chronic kidney disease

AIM

To ensure that people with chronic kidney disease, and their carers, have enough information to make informed choices about medicines and to be involved in prescribing decisions. People also need to be able to understand how to use their medicines at all stages of treatment (pre-dialysis, during dialysis and after transplantation) and to be able to recognise serious side effects if they occur.

RATIONALE

Providing information to people with chronic kidney disease is an essential part of medicines management. Insufficient information, and poor understanding of the reasons for taking medicines, can potentially lead to excessive, inadequate or inappropriate medicine use.

This is important as non-compliance (intentional or non-intentional) with prescribed medicines can have serious consequences for people with established renal disease. For example, it has been reported that as many as one-third of late renal graft losses can be attributed to non-compliance.¹

Involving patients as partners in managing their own condition is key to more effective use of medicines.^{2,3} Patients' information needs (and those of carers) have to be addressed and information has to be tailored to meet the individual needs of each patient.

HOW

- Before treatment begins, people need enough information to make decisions with their health professionals about what is the best option for them. They need to understand the risks and benefits of different options. Some may decide that they do not wish to start treatment.
- Where hospital self-medication programmes are used, the person should be assessed to ensure that they are able to take their medicines unsupervised (see Chapter 12). For those not on self-medication programmes, training on use of medicines should be provided to the individual (or carer) where possible.

- People should be given the opportunity to discuss any questions they may have about their medicines. They should be involved in all treatment decisions, including the wish to stop treatment.
- Written information should, where possible, support verbal information, and be tailored to the individual.
- To reduce medication errors, effective communication is essential when patients move from one care setting to another.⁴ When a person is discharged from hospital, information about their treatment should be sent promptly to the GP. The person should also be provided with written information about their medicines and dosage, and details on how to obtain further supplies.
- Information should be given on whom to contact if patients encounter any problems with their medicines.

Package leaflet confusion

During discussion about their medicines, patients need to be made aware that the information contained in the patient information leaflet (PIL) in the medicines package may include statements that need clarification. For example:

- ACE inhibitors are used first line in renal hypertension but the leaflet may have a caution regarding use in kidney disease
- A medicine might be being used for an unlicensed or off-label indication, eg, amitriptyline or sodium valproate may be prescribed for post-herpetic neuralgia, while the leaflet may only refer to treatment of depression or epilepsy, respectively

If patients have any concerns about the information in the PIL, they can contact the specialist team, pharmacist or GP for reassurance and clarification

What do people know about their medicines?

A study carried out at University Hospital of Wales found that a high proportion of people undergoing haemodialysis had inadequate knowledge about their medicines.

The study involved 140 patients, who were each taking a mean of eight different medicines. Knowledge of medicine names and dosages was good but patients had poor understanding of the purpose of their various medicines (mean knowledge score was 46 per cent).

An information programme was initiated, the core element of which was provision of an A4 medicines information card listing medicine names, indications, dosage and any special instructions. This was written after obtaining a current medication history from the GP or community pharmacist. The majority of patients found the card helpful; some requested further information.

The hospital's renal inpatients receive information about their medicines from pharmacists, but outpatients attending the dialysis unit do not routinely see a specialist pharmacist. In the light of the study results, the pharmacy is planning to introduce an information service to dialysis patients. If resources are available, this will be extended to include medication review.

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2. Carter S, Taylor D. A question of choice — compliance in medicine taking. A preliminary review. London: Medicines Partnership; 2003.
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4. Building a safer NHS for patients. Improving medication safety. London: Department of Health; 2004.

3. Management of renal anaemia

AIM

To ensure that iron and erythropoietin and its derivatives (epoetins) are used appropriately to achieve target haemoglobin concentrations in people with anaemia caused by renal disease.

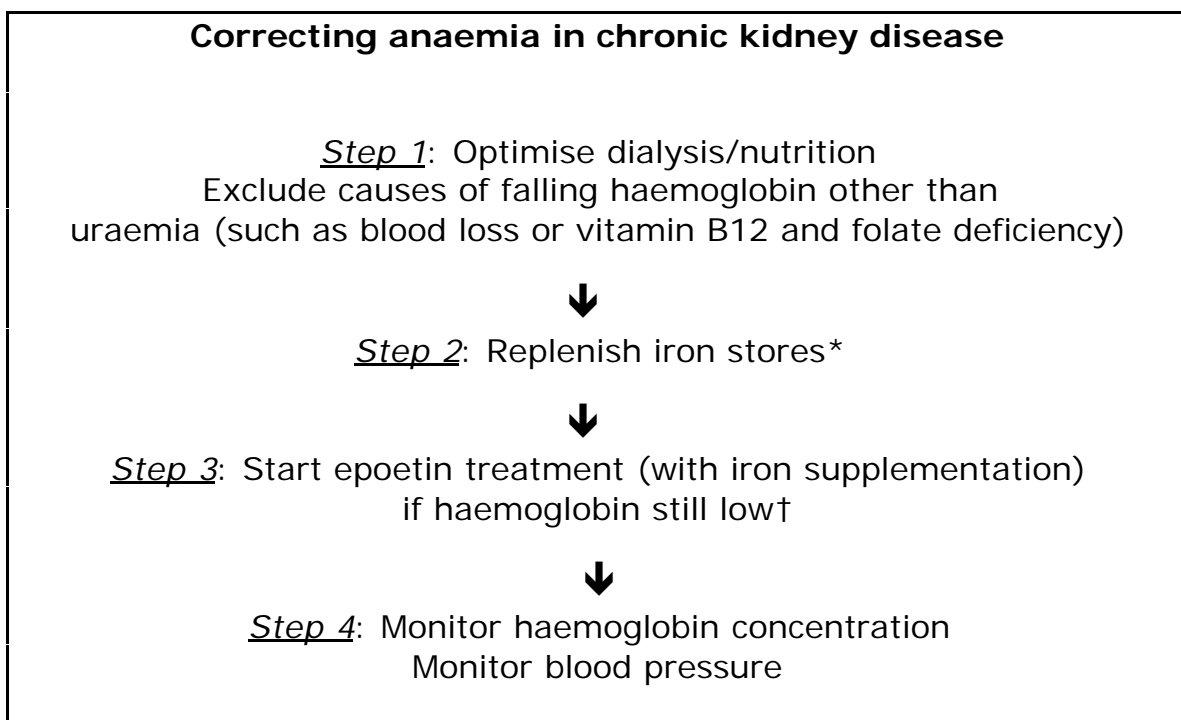
RATIONALE

Patients with established renal failure are often anaemic, mainly as a result of lack of production of the natural hormone erythropoietin by the kidney.

Renal anaemia has a major impact on quality of life, exercise capacity and sexual function. Early reversal of anaemia with epoetins can reduce symptoms and potentially influence survival.¹⁻⁴ There is some evidence that correction of renal anaemia helps to prevent some of the cardiovascular disease prevalent in people with established renal disease.^{1,4}

Correction of anaemia is beneficial in individuals established on dialysis and also in those who have not yet started dialysis (or do not wish to start dialysis) and those who have a failing renal transplant.

HOW



*Poor response to epoetin therapy is commonly caused by iron deficiency. It is therefore important to replenish iron stores, as necessary, before considering epoetin therapy. The Renal Association⁵ (Level 4) states that oral iron is poorly absorbed and tolerated in renal failure but will generally be sufficient in people not yet requiring dialysis and those on peritoneal dialysis. Many people on haemodialysis will require intravenous iron.

† Regular blood transfusions are an alternative to epoetin for correcting anaemia but carry risks of iron overload, transmission of viral infections and sensitisation to prospective renal transplants, and require a hospital visit.

- The National Institute for Clinical Excellence (NICE) has been asked to produce a clinical guideline on the management of anaemia in renal failure (www.nice.org.uk). The provisional date for publication of this guideline is July 2006.

Information required by people taking epoetin, carers and/or parents includes:

- Benefits and side effects of treatment, to help patients make informed decisions
- How to self-administer epoetin, if this route is chosen
- Correct disposal of sharps
- Need for regular blood pressure and haemoglobin monitoring
- Storage and transportation of epoetin according to manufacturer's recommendations
- Where care is shared between hospital and GP, a clear definition of the responsibility of each party
- How to obtain the next prescription
- Whom to contact if problems arise

Ideally, written information should be available to support verbal information, guided by local needs. Information needs of health professionals also need to be considered. Locally identified anaemia nurses have been shown to improve services to patients.

Epoetin administration

- Epoetin can be administered by intravenous or subcutaneous injection (**but NOT Eprex, see below**). Self-administration is encouraged for adults wherever possible; if necessary, epoetin can be administered by GP, practice nurse or district nurse. Children may prefer the intravenous route if it can be combined with other treatments, reducing the frequency of injections.
 - **Eprex** The Medicines and Healthcare products Regulatory Agency has advised that Eprex (epoetin alfa) should not be given subcutaneously in chronic kidney disease, following reports of pure red cell aplasia.⁶ (Level 4)

Storage

- Attention needs to be paid to epoetin storage requirements.
- If manufacturers indicate that epoetin needs to be refrigerated, it is important that a cold chain is maintained during transfer to the patient's home. Icepacks may need to be provided for transport from the pharmacy to home or home delivery arranged. Any transport system used should be validated.

Prescribing and supervision

- It is generally accepted that epoetin monitoring and prescribing should be continued under the guidance of secondary/tertiary care but in some circumstances it might be appropriate for the medicine to be prescribed in the community under a shared care guideline. Shared care guidelines highlight the roles and responsibilities of hospital clinicians and GPs. It is important that primary care professionals are involved in their development.
- The existence of a shared care guideline does not mean that a GP is expected to prescribe the medicine. Before accepting clinical responsibility for prescribing epoetin, GPs need to ensure that they are familiar with the medicine, the monitoring that may be required and any dosage adjustments that may need to be made. They should also be able to respond to adverse effects.
- When deciding whether epoetin should be provided in primary care or by the renal unit, the patient's views should be taken into consideration.

Communication

- GPs need to be informed promptly about initiation of therapy and any subsequent dose changes, with changes in therapy confirmed in writing.
- If shared care is used, the GP's co-operation should be sought early on.
- The person receiving treatment or the carer/parent should be aware of the individual roles and responsibilities for the prescribing and monitoring of treatment.

Measurements required for assessment before starting epoetin and treatment monitoring

The Renal Association Standards and Audit Measures⁵ (Level 4) (www.renal.org/Standards/standards.html) and European Best Practice Guidelines¹ (Level 4) give guidance on target levels and recommended intervals between measurements.

Iron

- Measurement of serum ferritin levels or percentage hypochromic red cells, regardless of haemoglobin concentration, to establish iron status. Replenish iron stores before considering epoetin therapy
- Monitor serum folate and vitamin B12 levels and correct if depleted

Haemoglobin

- Measurement of haemoglobin concentrations and analysis of trends to prevent levels falling below the target

Blood pressure

- Regular monitoring of blood pressure in patients receiving epoetin

Failure to respond to epoetin

- Eliminate other causes (for example, bleeding, low ferritin levels, infection, inflammation, raised parathyroid hormone levels, aluminium toxicity, malignancy, haemoglobinopathies, or pure red cell aplasia [PRCA])

References

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3. Canadian Erythropoietin Study Group. Association between recombinant human erythropoietin and quality of life and exercise capacity of patients receiving haemodialysis. *BMJ* 1990;300:573-8.
4. Harnett J D, Le H. Cardiovascular effects of erythropoietin. *Dial Transplant* 1993;22:536-40
5. Renal Association. Treatment of adults and children with renal failure: standards and audit measures. 3rd ed. London: Royal College of Physicians and the Renal Association; 2002 (www.renal.org/Standards/standards.html).

6. Committee on Safety of Medicines. Eprex (Epoetin Alfa) and pure red cell aplasia — contraindication of subcutaneous administration to patients with chronic renal disease. (www.mca.gov.uk)

4. Prevention of renal scarring: urinary tract infection treatment and prophylaxis

AIM

To ensure that:

- Urinary tract infections (UTIs) are reduced in children at risk of renal scarring by the use of prophylactic antibiotics.
- UTIs are diagnosed early and treated promptly and appropriately.

RATIONALE

Renal scarring is the commonest cause of hypertension and established renal failure worldwide.¹ It typically originates in early childhood.

Renal scarring is usually caused by a UTI in a child with vesicoureteric reflux (VUR).^{2,3} If the urine can be sterilised (by use of antibiotics) in those with VUR, scarring should not occur. If a breakthrough UTI occurs while taking antibiotic prophylaxis, it is important to start treatment with an alternative antibiotic immediately on the basis of clinical suspicion, even before formal laboratory results are obtained. Renal scarring is usually avoided if a UTI is treated within 48 hours of the onset of symptoms.

Occasionally the appearance of scarring will be caused by renal malformation that occurred during early development. In such cases, antibiotic prophylaxis may not be warranted.

A number of antenatal markers for the presence of VUR are recognised. The commonest is renal pelvic dilatation.⁴ Newborn babies in whom significant renal pelvic dilatation has been diagnosed during pregnancy should be started on antibiotic prophylaxis at birth and promptly investigated in the postnatal period, according to local practice.

HOW

- Although definitive evidence of benefit is currently lacking, antibiotic prophylaxis should be considered for children with VUR until age 4, after which the incidence of new scarring is low⁵ (Level 3).
- The dose and formulation of antibiotic should be appropriate for the child's age and weight or body surface area, eg, trimethoprim 2mg/kg at night.
- Symptoms suggestive of a breakthrough UTI should be acted upon rapidly and a diagnosis reached as soon as possible. It is important to treat such an infection promptly.
- Where local guidelines are being developed, the views of a paediatric nephrologist should be sought where possible.

UTI and transplant recipients

Adults and children who have had a renal transplant are also at risk of vesicoureteric reflux. They need to be monitored closely for urinary tract infection. Prophylactic antibiotics may be necessary.

References

1. Tsakiris D, Simpson HK, Jones EH, Briggs JD, Elinder CG, Mendel S, et al. Report on management of renal failure in Europe, XXVI, 1995. *Nephrol Dial Transplant* 1996;11 Suppl 7:4-20.
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3. Ransley PG, Risdon RA. Renal papillary morphology in infants and young children. *Urol Res* 1975;3:111-3.
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5. Vernon SJ, Coulthard MG, Lambert HJ, Keir MJ, Matthews JNS. New renal scarring in children who at age 3 and 4 years had had normal scans with dimercaptosuccinic acid: a follow up study. *BMJ* 1997;315:905-8.

6. Dose adjustment and nephrotoxicity

AIM

To ensure that:

- Medicine doses appropriate to an individual's glomerular filtration rate (GFR) are used to minimise risk of dose-related adverse effects.
- People with renal impairment are only administered nephrotoxic medicines if there is no suitable alternative.
- If nephrotoxic medicines need to be used, eg, calcineurin inhibitor immunosuppressants, there is close monitoring of renal function and appropriate dose adjustment.

RATIONALE

In renal impairment, reduced elimination of renally excreted medicines, eg, opiates, can cause accumulation and subsequent adverse effects on end organs other than the kidneys.

In addition, many medicines can reduce renal function, sometimes permanently. Such nephrotoxicity is more likely to be seen in people with a depressed GFR, particularly children. It is important to avoid any reduction in renal function in order to delay the onset of established renal failure.

HOW

- Ensure that GFR is formally measured or estimated in all people with renal impairment (see Panel 1). The need to assess GFR is particularly pertinent in children and the elderly as values of creatinine that appear to be low may indicate a significant loss of renal function.
- Encourage the use of appropriate guides (see Panel 2) to adjust doses and/or frequency for GFR. Such changes are especially important for people requiring haemodialysis and haemofiltration.
- In people under the age of 16 years, doses also need to be based on an accurate body surface area or weight measurement.

- Blood drug levels should be measured where clinically appropriate.
- Be aware of nephrotoxic medicines, and only use these (with careful monitoring) if there are no suitable non-nephrotoxic alternatives.
- Ensure that people with renal disease and their carers/parents are educated about nephrotoxicity associated with certain common medicines, eg, non-steroidal anti-inflammatory drugs (NSAIDs), including over-the-counter medicines, and the need to avoid such medicines where possible.

Panel 1: Estimating renal function

In adults, creatinine clearance (C_{cr}) can be estimated from the formula of Cockcroft and Gault:¹

$$C_{cr} (ml/min) = 1.23 [males] \text{ or } 1.04 [females] \times (140 - age[years]) \cdot weight[kg] / \text{serum creatinine } [\mu\text{mol/L}]$$

For children, the predicted GFR is usually calculated from the Schwarz formula² or a variant:

$$pGFR(ml/min/1.73m^2) = (40 \cdot height[cm]) / \text{serum creatinine}[\mu\text{mol/L}]$$

For neonates the constant is usually reduced from 40 to 30.

Panel 2: Guides to medicine dosage

The following reference sources may be helpful in prescribing for individuals with renal impairment:

British National Formulary. London: British Medical Association and Royal Pharmaceutical Society of Great Britain.

Medicines for children. 2nd ed. London: Royal College of Paediatrics and Child Health and the Neonatal and Paediatric Pharmacists Group; 2003.

Drug prescribing in renal failure; dosing guidelines for adults. Aronoff GR, et al, editors. 4th ed. American College of Physicians; 1999.

Renal drug handbook. Ashley C, Currie A, editors. 2nd ed. Oxford: Radcliffe Medical Press; 2003.

References

1. Cockcroft DW. Gault MH. Prediction of creatinine clearance from serum creatinine. *Nephron* 1976;16:31-41.
2. Schwartz GJ. Haycock GB. Edelmann CM Jr. Spitzer A. A simple estimate of glomerular filtration rate in children derived from body length and plasma creatinine. *Pediatrics* 1976;58:259-63.

6. Medicines for hypertension in chronic renal impairment

AIM

To achieve optimal blood pressure control in order to:

- Slow the deterioration of renal function in people with progressive renal impairment.
- Reduce the risk of cardiovascular disease in people with chronic renal impairment or established renal failure.

RATIONALE

Hypertension occurs in most people with significant renal impairment.

Hypertension itself may be a primary cause of renal failure (hypertensive renal disease), although this is not common in the UK.¹ It is more common in the African and Afro-Caribbean ethnic minorities. In diabetic nephropathy and most other forms of chronic progressive renal impairment, control of hypertension has been shown to slow the progression of renal damage.

Cardiovascular disease (usually cardiac failure or coronary artery disease) is the most common cause of death in people with established renal failure.¹ Left ventricular hypertrophy, which is caused by hypertension, has been shown to be a major risk factor for death in established renal failure.^{2,3}

Hypertension is thought to be a major contributory factor to the frequency and severity of cardiovascular disease in people with impaired renal function. Optimal control of hypertension is therefore very important.

The use of medicines is only part of the approach to control of renal hypertension. Retention of sodium is also a critical factor. It is important to control salt and water intake, and to optimise dialysis as far as is practicable. While most individuals receiving three times weekly haemodialysis need medicines for hypertension, fewer of those receiving CAPD (continuous ambulatory peritoneal dialysis) and APD (automated peritoneal dialysis) do, and less than 10% of people undergoing daily or prolonged three times a week haemodialysis need medicines for hypertension.

HOW

Adult hypertension

- In many conditions causing progressive renal impairment, especially diabetes, ACE inhibitors and angiotensin II antagonists are considered to have specific beneficial effects in addition to their effect on hypertension^{4,5} (Level 4). They are first-line medicines when not contraindicated.
- In established renal failure, it is important to optimise dialysis and to control salt and water intake before starting medication for hypertension.
- No class of antihypertensive agents is specifically contraindicated in renal impairment, but the doses of many agents will need to be modified.
- Shared-care guidelines between primary and secondary care can be developed for the control of hypertension in established renal failure.

Paediatric hypertension

- Clinicians managing hypertension in children need to be aware that “normal” blood pressure varies with age and is lower than in adults. There is a risk of overlooking significant hypertension. Nomograms are available to help interpret blood pressure readings.
- The treatment of hypertensive children is usually supervised by a paediatric nephrologist. Shared-care guidelines can be useful in certain circumstances.
- In contrast to the adult population, the vast majority of children needing treatment for hypertension have secondary rather than primary hypertension. The choice of drug is determined by the underlying cause which in around 90% of cases is renal in origin.
- In most cases, the benefits of controlling hypertension in children far exceed the potential adverse effects of the antihypertensive drugs used.
- Non-pharmacological treatment includes restricted salt intake, weight reduction and exercise.

Children's NSF and formulation issues

Guidance is being developed on the use of medicines in children in the National Service Framework for Children. The NSF's Standard for Hospital Services, which was published in April 2003, emphasises the need to ensure that formulations are appropriate to the age and ability of the child. An accompanying consultation document ("Emerging findings") notes that medicines should be available in the most suitable, and palatable, formulation. It comments that the use of "off label" or unlicensed medicines is unsatisfactory but that steps are being taken to increase the range of products and formulations licensed for use in children

(www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/ChildrenServices/ChildrenServicesInformation/ChildrenServicesInformationArticle/fs/en?CONTENT_ID=4015891&chk=rvoHyH).

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5. Ramsay LE, Williams B, Johnston GD, MacGregor GA, Poston L, et al, for the British Hypertension Society. Guidelines for management of hypertension: report of the third working party of the British Hypertension Society. *J Hum Hypertens* 1999; 13:569-92.

7. Medicines for the control of common uraemic symptoms

AIM

To help control common uraemic symptoms experienced by people on dialysis by the appropriate use of medicines.

RATIONALE

Three of the uraemic symptoms which people on dialysis find most troublesome are:

- Nausea and anorexia
- Pruritus (itching)
- Restless leg syndrome

Control of anaemia, a cause of other major symptoms, is considered separately (see chapter 3).

HOW

Nausea and anorexia

Nausea and anorexia are probably caused by retention of uraemic toxins and the first step in managing these symptoms is to optimise dialysis. There is no evidence to show that any medicines have specific benefit in uraemic nausea and anorexia.

Intervention

After optimising dialysis, cautious use of anti-emetic medicines with appropriate dose modification for renal failure could be helpful.

Pruritus

The cause of uraemic pruritus is still unclear. Inadequate control of calcium and phosphate and hyperparathyroidism may play a role. Cytokines that stimulate pruritus may be released in uraemia. Pruritus may be a symptom of "uraemic neuropathy". Optimising dialysis may help¹ (Level 3).

Intervention

- Optimise dialysis
- Optimise control of calcium and phosphate metabolism (see chapter 8)
- Medicines — antihistamines have been widely used but with little benefit. Ondansetron has been found to be effective in some people² (Level 3), although there is no definitive evidence to support this. This is an unlicensed indication and therefore clinicians would need to accept responsibility for prescribing it.

Restless leg syndrome

Restless leg syndrome occurs in 15% of people on dialysis, and can cause severe sleep disturbance and subsequent symptoms of sleep deprivation.

Intervention

As in non-uraemic individuals, clonazepam has been shown to be effective³ (Level 3). This is an unlicensed indication and therefore clinicians would need to accept responsibility for prescribing it. Other benzodiazepines are rarely effective.

Medicine monitoring in haemodialysis patients

At Hope hospital, Salford, the renal pharmacist identifies individuals on haemodialysis who she feels require close monitoring, perhaps because of prior evidence of compliance problems. A ward-based technician then provides these patients with a weekly supply of medicines in a dose administration aid (Venalink or Dosette). The technician is thus able to check on a weekly basis which tablets have been taken.

The technician provides a regular point of contact and develops a rapport with the patients, encouraging them to discuss any compliance issues or other medication problems while they are in the hospital for a dialysis session. The pharmacist can then review patients again as required.

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Medication review in haemodialysis patients

The two examples below show how pharmacy-run medication review clinics for haemodialysis patients can offer the opportunity to tailor treatment to the individual, to identify any problems, and to advise on correct administration (eg, when to take phosphate binders). In such schemes, individuals scheduled for review are generally asked to bring all their medicines with them when they come for dialysis. They then see the pharmacist while they are undergoing dialysis

(1) At Walsgrave hospital, Coventry, before seeing the patient the renal pharmacist accesses the latest blood test results and medication history from the computer.

Patients have a review of their medicines with the pharmacist. Around 25% of patients seen in the clinic have had their dose times altered to gain greatest benefit from their medicines. Over 25% have had the dose of one of their medicines reduced.⁴ Following the medicines review, the pharmacist updates the computer system with the medication history, and then writes to the GP about any suggested alterations in therapy. This letter is countersigned by the consultant.

The pharmacist also completes a "compliance card" which lists all medicines that the patient is taking. Patients are encouraged to take this card to the hospital clinic and also when visiting their GP or community pharmacist so it can be updated as necessary, and they are advised to bring it with them if admitted to hospital. The card thus acts as a means of communication between GP, community pharmacist and admissions doctor.

Contact: Clare Morlidge, renal pharmacist (clare.morlidge@uhcw.nhs.uk)

(2) At the Lister Hospital, Stevenage, an audit was carried out of 55 haemodialysis patients attending a medication review clinic run by the renal pharmacist. A mean number of six interventions per patient were recorded. Examples included:

- Not taking correct dose of phosphate binder
- Still taking oral iron while at the same time had been receiving IV iron for several months
- Should have been taking metoprolol but did not have any
- Vitamin D added because of high parathyroid hormone level

After interviewing the patient, the pharmacist discusses queries with the haemodialysis nephrologist and then advises the patient on any medicine changes. Patients are given a "medicines information card" with details of all their medicines and a phosphate binder information leaflet. An updated list of medicines is sent to the GP.

The pharmacy experience is that the clinic has led to improved interprofessional communication and that patients are pleased to have the opportunity to discuss their medicines. Giving patients a greater understanding of their medicines helps to encourage them to take responsibility for their treatment.

Contact: Alex Fotherby, principal pharmacist, renal services (alex.fotherby@nhs.net)

If development of a similar "compliance card" or "medicines information card" is being considered, it might be useful to have both an electronic and a paper version.

Medication review resource

“Room for Review” is a guide to medication review published by the Task Force on Medicines Partnership and the National Collaborative Medicines Management Services Programme (www.medicines-partnership.org/medication-review). It may be a helpful resource for identifying individuals who could benefit from a medication review and the level of review required, from prescription review to full clinical medication review.

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8. Calcium and phosphate management in renal impairment

AIM

To minimise the development of renal bone disease in people with renal impairment.

RATIONALE

People with established renal failure, and those approaching established renal failure, lose the ability to regulate the balance of calcium and phosphate in the body. Excess phosphate, normally cleared by the kidneys, accumulates and can lead to secondary hyperparathyroidism, which in turn leads to the release of calcium from bones and to the development of renal bone disease (osteodystrophy and a tendency to fractures).

Haemodialysis patients with elevated serum phosphate levels have been reported to have an increased risk of death, possibly related to an elevated calcium-phosphate product (the serum calcium level multiplied by the serum phosphate level).¹ Calcium and phosphate overload are major factors leading to soft tissue calcification,² where insoluble calcium phosphate is deposited in the blood vessel walls and soft tissues.

It is therefore important to be vigilant about the control of both hyperphosphataemia and hypercalcaemia.

HOW

Three general approaches (not sequential):

- Dietary regulation of phosphate
- Phosphate binders to reduce gastrointestinal absorption of dietary phosphate
- Supplementation with activated vitamin D to downregulate the parathyroid glands and reduce parathyroid hormone levels

<i>Dietary regulation of phosphate</i>	<i>Phosphate binders*</i>	<i>Vitamin D supplements*</i>
It is helpful for all individuals with (or approaching) established renal failure to be referred to a renal dietitian for advice on modification of dietary phosphate. Advice can be tailored to the individual, and accompanied by written information	<ul style="list-style-type: none"> • Aluminium hydroxide capsules (see caution below) • Calcium preparations (calcium carbonate, calcium acetate) • Magnesium carbonate capsules (unlicensed special) • Sevelamer hydrochloride 	<ul style="list-style-type: none"> • Alfacalcidol • Calcitriol

*For phosphate binders and vitamin D supplements, refer to appropriate formularies for products used locally.

Within the constraints of the formulary, it is useful to take patient preference into account when choosing phosphate binding agents — factors such as taste, number of tablets required, and whether the tablets need to be chewed, can all affect compliance.

The Renal Association says that choice of phosphate binder should be individualised as all agents carry different cost:benefit and risk:benefit ratios. For example, calcium salts may promote positive calcium balance and result in vascular calcification. Long-term use of aluminium salts may contribute to intellectual deterioration and other features of aluminium toxicity. Aluminium hydroxide should only be used where the benefit of achieving improved phosphate control is judged likely to outweigh this risk³ (Level 4).

Renal Association standards

The Renal Association has produced standards for phosphate, calcium and parathyroid hormone levels³
www.renal.org/Standards/standards.html

Multidisciplinary approach to phosphate management

Hope hospital, Salford, has developed a multidisciplinary approach to the management of haemodialysis patients who have consistently high phosphate levels, despite treatment with phosphate binders. Patients whose phosphate levels have been >2.5 - 2.6 mmol/L for two months are referred to the renal pharmacist and dietitian for review.

Phosphate binders can be poorly tolerated. The hospital's experience is that some patients with high phosphate levels have been prescribed an increased dose, when in fact the reason for the inadequate clinical response was that the medication was not being taken because the patient could not tolerate it.

Under the new scheme, patients are seen at least once a month, during a dialysis session. The dietitian reviews how the patient is getting on with their phosphate-restricted diet and the pharmacist establishes whether they are having problems taking their phosphate binder and which type of product they prefer. Patients keep their own records and are involved in the monitoring and in any decisions about choice of binders or dose changes.

Within two months, most patients' phosphate levels have been reduced. This is attributed to the new concordant approach to phosphate management.

Contact: Elizabeth Lamerton, renal pharmacist (elizabeth.lamerton@srht.nhs.uk) or Diane Green, renal dietitian (diane.green@srht.nhs.uk)

Shared-care guideline for sevelamer

Shared-care arrangements can have many benefits for patients with established renal failure. It means that patients are able to receive their care in an environment and at a time that suits them. It also means that they are regularly reviewed by their consultants but get ongoing care from their GPs.

For example, the Royal Free Hospital, London, shared-care plan for the phosphate binder sevelamer defines the following responsibilities:

Consultant

1. Supply sevelamer until the patient is stabilised on the drug.

2. Send a letter to the GP suggesting that shared care is agreed for this patient.
3. Clinical and laboratory supervision (including calcium and phosphate levels) of patient by routine clinic follow-up.
4. Alterations of sevelamer dosage.
5. Institution of other significant changes in patient's therapy.
6. Give the patient a record card on which details of medicines prescribed will be kept.
7. Evaluate adverse effects reported by the GP.
8. Communicate the results of tests performed in secondary care to GP.
9. Provide a review date and identify who is to perform this.
10. Back-up advice available at all times.

General Practitioner

1. Monitor the patient's overall health and well being.
2. Adverse drug reaction/interaction monitoring.
3. Prescribing (though not altering dose or updating the patient-held record card) of maintenance sevelamer therapy.
4. Return a copy of the standard letter to the consultant, accepting or declining shared care for sevelamer.

References

1. Block GA, Hulbert-Shearon TE, Levin NW, Port FK. Association of serum phosphorus and calcium x phosphate product with mortality risk in chronic hemodialysis patients: A national study. *Am J Kidney Dis* 1998;31:607-17.
2. Hsu CH. Are we mismanaging calcium and phosphate metabolism in renal failure? *Am J Kidney Dis* 1997;29:641-9.
3. Renal Association. Treatment of adults and children with renal failure: standards and audit measures. 3rd ed. London: Royal College of Physicians and the Renal Association; 2002.

9. Use of immunosuppressants

AIM

To ensure safe and effective use of immunosuppressants in people with kidney disease.

RATIONALE

Immunosuppressants are the mainstay of treatment for kidney transplant patients. Their importance for patient and graft survival needs to be highlighted early on. Immunosuppressants are also used in certain other types of kidney disease. Their use requires special care because of:

- graft rejection if dosage is too low or compliance is inadequate
- risk of adverse effects if used incorrectly
- need to monitor blood levels for many immunosuppressants
- potential for significant interactions with other medicines
- need to ensure continued supplies of some sophisticated (and often high cost) medicines

HOW

Medicine advice It is important that all people taking immunosuppressants, and/or their carers, are advised by a suitably trained specialist, ideally a pharmacist, before discharge from hospital. This advice can help them to make informed decisions about their treatment, aid concordance and increase compliance. The patient's own beliefs and views about medicines should be taken into account.

Good advice includes:

- How the medicine works and the benefits and risks of treatment
- Side effects and what to do if they occur
- Importance of compliance/potential consequences of non-compliance
- Practicalities of medicine taking and how it fits with daily life
- Any support needed
- Important interactions, including those with over-the-counter medicines
- How treatment will be monitored (and dose changed, or treatment stopped, as necessary)
- Supply, handling and storage

Shared care It is generally accepted that immunosuppressant monitoring and prescribing should be continued under the guidance of secondary/tertiary care but in some circumstances it might be appropriate for these medicines to be prescribed in the community within shared care arrangements (see section on prescribing and supervision, in Chapter 3).

Any shared-care guidelines will ideally be agreed before discharge from hospital.

In the case of post-transplant immunosuppressants, the guidelines will include:

- responsibility of hospital doctor
- responsibility of GP
- monitoring regimen
- triggers for referral to hospital doctor
- contact details of hospital professional, in case of problems

Safe handling of medicines Some immunosuppressants are potentially toxic if the powder is inhaled or the medicine touches the skin. Therefore, where possible, appropriate dosages and formulations should be supplied to avoid nursing staff or the patient/carer having to crush tablets or empty capsules. Advice can be sought from a pharmacist if modification of the formulation is needed.

Patient-held record Pharmacists are encouraged to provide people taking immunosuppressants with a written record of all their prescribed medicines. This is in addition to the manufacturer's patient information leaflet.

Supply of medicines It is important that immunosuppressant dispensing and supply takes place at a time and place suitable to the person taking the medicines. This is discussed further in chapter 14. Arrangements need to be agreed before discharge and may involve:

- Community pharmacy
 - Hospital pharmacy
 - Use of FP10s issued by hospital
 - Home care delivery contracts
 - Special delivery postal services
- The National Institute for Clinical Excellence (NICE) is currently carrying out an appraisal of immunosuppressive therapy for renal

transplantation. Its report is expected to be published within the next few months (www.nice.org.uk).

Self-medication

“Self-medication” schemes for people taking immunosuppressants after transplantation have been developed at many hospitals. These schemes prepare the patient for discharge, while ensuring that medicine use during the hospital admission is monitored. Self-medication is discussed further in chapter 12.

Self-medication schemes provide an opportunity to assess the individual’s ability to take his or her medicines. If problems are identified, steps can be taken to sort these out before discharge.

“Supply letters”

Certain medicines used in transplant recipients, particularly children, are not easy to obtain in primary care (eg, unlicensed medicines or unusual formulations). To aid the smooth supply of these medicines, many hospitals have developed standard letters that are used to communicate with the GP and the community pharmacist about on-going supplies.

In the paediatric transplant unit at Guy’s and St Thomas’ NHS Trust, these “supply letters” are issued to patients on discharge. One section of the letter is addressed to the patient and explains how, and when, to ask for more medicine and the other section is for the patient to take to the GP and to the community pharmacist of their choice. The letter gives an indication of the time required to obtain the medicine to enable the pharmacist to obtain supplies **before** the person runs out of his or her medicine.

One of the main reasons for developing these standard letters is to improve communication between primary, secondary and tertiary care so that patients do not experience problems in accessing the medicines that they need when they move from one sector to another. This is particularly important for transplant patients because even a short break in their treatment could have significant implications for the survival of their graft. Appendix 1 shows example letters.

Contact: Stephen Tomlin, principal paediatric pharmacist
(Stephen.tomlin@gstt.sthames.nhs.uk)

Using dose administration aids to help children learn about their medicines

Renal transplant patients are regularly prescribed a large number of medicines, including immunosuppressants, some of which have complex regimens.

In the paediatric transplant unit at Guy's and St Thomas' NHS Trust, a structured education scheme has been developed for the use of Dosette dose administration aids to help children take their medicines more effectively. Children (or parents/carers) are trained to fill their own Dosette under the supervision of a pharmacy technician or pharmacist. Without supervision, the use of dose administration aids might lead to confusion as the tablets/capsules are not individually labelled.

Starting at discharge, the child/parent packs their Dosette on a weekly basis. This gives them an opportunity to ask questions and to discuss any changes that may have been made to their prescription. After about 10 weeks, if pharmacy staff are satisfied with the child's (or parent's) knowledge and skills and the patient is happy, they are discharged from the scheme. The patient is given a "black book" with details of all their prescribed medicines and the doses. Feedback from patients and parents on the scheme has been positive.

Contact: Stephen Tomlin, principal paediatric pharmacist
(Stephen.tomlin@gstt.sthames.nhs.uk)

10. Use of growth hormone in children

AIM

To ensure that human growth hormone (somatropin) treatment is used appropriately in pre-pubertal children with chronic renal insufficiency.

RATIONALE

Growth failure is a prominent feature in children with chronic renal insufficiency.

Historically, growth hormone has been used to treat children with renal failure in many different clinical circumstances. The results of such treatment were difficult to interpret. More recently, multinational randomised controlled trials have demonstrated the correct indications for treatment in children with chronic kidney disease. It is vital to target children who will derive maximum benefit from therapy.

The National Institute for Clinical Excellence (NICE) has produced guidance on the use of growth hormone in children with growth failure (www.nice.org.uk).¹ Children with chronic renal insufficiency were considered as a separate sub-group in this document. The guidance below is based on the NICE recommendations.

HOW

- Ensure that use of growth hormone is restricted to pre-pubertal children with chronic renal insufficiency who have an optimised nutritional and metabolic status and in whom steroid therapy has been reduced to a minimum
- Growth hormone therapy should be initiated and monitored by a paediatrician with special expertise in the management of children with growth hormone disorder. Continuation of treatment can be maintained under a shared-care guideline with a general practitioner.
- Regular assessments of growth should be made and therapy should normally be discontinued if there is a poor response (defined as an increase in growth velocity of less than 50% from baseline in the first year of treatment).

- Following renal transplantation, growth hormone should be discontinued for at least one year to ascertain whether catch-up growth occurs.
- Parents should be made aware that it is not certain that treatment with growth hormone will result in an increase in final adult height.

References

1. National Institute for Clinical Excellence. Guidance on the use of human growth hormone (somatropin) in children with growth failure. Technology Appraisal Guidance No 42. London: National Institute for Clinical Excellence; 2002. (www.nice.org.uk)

11. Vaccination and infection prophylaxis

AIM

To ensure that:

- Immunocompetent individuals with renal disease are appropriately vaccinated.
- Individuals with renal disease who are immunosuppressed, both following transplantation or for other reasons, are appropriately vaccinated and protected through pharmacological prophylaxis against infectious diseases.

RATIONALE

Children with renal disease should follow the recommended childhood immunisation schedule as far as possible. However, alternative or additional vaccinations may be appropriate. In some instances vaccinations may need to be omitted (see Table).

People who are immunosuppressed are at risk of developing overwhelming infections. In those who have received a renal transplant these infections also pose a threat to the graft. In order to reduce these risks, vaccination and pharmacological prophylaxis against certain infections are essential.

HOW

See Table.

Group	Vaccine/prophylaxis required ¹⁻⁴ (Level 4)
Immunocompetent individuals (children and adults) with mild chronic kidney disease	<ul style="list-style-type: none"> ▪ Follow recommended childhood immunisation schedule ▪ No additional vaccinations or pharmacological prophylaxis required
Immunocompetent children with severe chronic kidney disease, awaiting treatment for established renal failure	<ul style="list-style-type: none"> ▪ Follow recommended childhood immunisation schedule ▪ Influenza vaccination ▪ Varicella and hepatitis B vaccination, if susceptible ▪ BCG vaccination, if not already received ▪ Role of pneumococcal vaccination in these circumstances requires further research ▪ No pharmacological prophylaxis required
Immunosuppressed children	<ul style="list-style-type: none"> ▪ Live vaccines such as BCG, MMR and oral polio vaccine (Sabin) are contraindicated. Oral polio vaccine (Sabin) can be substituted by inactivated oral polio vaccine (Salk). ▪ All other vaccines in the recommended childhood schedule can be administered ▪ If nephrotic, penicillin prophylaxis or pneumococcal vaccination are required to reduce the risk of pneumococcal infection ▪ EBV and/or CMV prophylaxis may be given, according to local protocols (see British Transplantation Society guidelines).⁴ Further research is needed into most appropriate antiviral agent ▪ Co-trimoxazole, as prophylaxis against <i>Pneumocystis carinii</i>, is required in the initial post-transplant period or following use of immunosuppressants for auto-immune renal disease
Adults with chronic kidney disease or immunosuppressed (eg, transplant recipients or those with nephrotic syndrome)	<ul style="list-style-type: none"> ▪ Pneumococcal vaccination ▪ <i>Haemophilus influenzae</i> type b (Hib) vaccination ▪ Influenza vaccination ▪ Live vaccines (eg, BCG, polio vaccine [Sabin]) are contraindicated ▪ EBV and/or CMV prophylaxis, according to local protocols (see British Transplantation Society guidelines)⁴ ▪ <i>Pneumocystis carinii</i> prophylaxis (as for children, above)
Adults with chronic kidney disease, including those on haemodialysis	<ul style="list-style-type: none"> ▪ Hepatitis B vaccination. Immune response may be attenuated — patients undergoing haemodialysis should be monitored for antibodies annually and re-immunised if necessary ▪ Influenza vaccine and Hib in some patients

Note: Home carers (of dialysis patients) who are negative for hepatitis B surface antigen should receive hepatitis B vaccine

Further information

References 1-4 give further information on immunisation and infection prophylaxis.

References

1. Renal Association. Treatment of adults and children with renal failure; standards and audit measures. 3rd ed. Royal College of Physicians of London and the Renal Association; 2002 (www.renal.org/Standards/standards.html).
2. Immunisation against infectious diseases. London; Department of Health; 1996 (www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/GreenBook/fs/en).
3. Good practice guidelines for renal dialysis/transplantation units. Prevention and control of blood-borne virus infection. London: Department of Health; 2002 (www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4005752&chk=AVH6Zr).
4. British Transplantation Society guidelines for the prevention and management of cytomegalovirus disease after solid organ transplantation; 2002 (www.bts.org.uk).

12. “Self-medication” in hospital

AIM

To encourage self-medication during hospital admission for appropriate individuals with renal disease.

The specific goals are:

- to enable individuals to use their medicines effectively.
- to encourage compliance with the prescribed medicines and, in transplant recipients, to improve long-term patient and graft survival.

RATIONALE

The rationale for setting up a self-medication programme is to be proactive in improving use of medicines and to ensure that individuals are fully informed about their medicines. This should lead to:

- Increased patient satisfaction
- Better preparation for discharge
- Effective use of medicines when the individual goes home

Self-medication programmes provide an opportunity for medication review and observation of how individuals are managing their own medicines. If difficulties are identified, staff can introduce any necessary training strategies. Self-medication also encourages the use of patients' own drugs.

Self-medication for whom?

Ideally, self-medication during hospital admission should be available for all people with renal disease. However, there are resource implications for this; also, some people may not be in hospital long enough to undergo the structured assessment that is required for successful self-medication. Therefore it may be more appropriate to target some groups of patients.

Newly transplanted patients are ideal candidates for self medication and can benefit from a well organised programme.¹⁻³ These patients, who will be in hospital for at least a week, arrive with one set of medicines and usually leave with a completely different set. Self-medication schemes will ensure that patients understand why their treatment has changed and get their commitment, as far as possible, to continue the new treatment that has been chosen for them. It is expected that transplant patients will have been involved in their treatment decisions.

Medication non-compliance remains a major barrier to the long-term success of transplantation, with the side effects associated with some immunosuppressants being intolerable for many people. A self-medication programme can help to improve compliance.

Where possible, all new renal transplant recipients should participate in a self-medication programme. Involvement in such a programme will ensure that, at the time of discharge, they are able to take their medicines as intended, appreciate the importance of immunosuppression (both for the graft and infection risks), and have a basic understanding of why they need to take each medicine that has been prescribed for them.

HOW

With structured self-medication programmes, people who have had a renal transplant can be helped to understand why they are taking their medicines, how to take them, possible adverse effects and how to alleviate them, duration of therapy and expected treatment outcomes. This empowers them to take more control of their medicines. Any specific difficulties, such as language or reading ability, can be addressed and the self-medication programme adapted as necessary to suit the individual's needs, during the post-operative period.

The example below describes the scheme that is in place at the Oxford Transplant Centre.

Oxford self-medication scheme

At the Oxford Transplant Centre all new transplant recipients are entered into the self-medication programme by post-operative day 3-5. The nurse conducts an initial assessment to establish how the patient usually takes their medicines, whether someone else helps, and whether large "easy read" labels are necessary.

The patient is given written information about the programme and a booklet covering all aspects of post-discharge care, including medicines. The pharmacist completes a medication record card and the discharge prescription and has a detailed discussion with the patient about all aspects of their medicines including:

- time of day to take
- quantities to take
- reason for taking
- expected adverse effects
- duration of therapy
- what to do if a dose is missed
- medicines to avoid
- where to get further supplies

At the end, some questions are asked to ensure the main points have been understood. After this teaching session the medicines are locked in the bedside cabinet and the nursing staff retain the key. At medicine administration times the nurse brings the key to the patient who, under supervision, organises the medicines needed, using their medication record card. The nursing staff offer support and encouragement, reinforcing why the medicines are being taken, when to take them, expected side effects, etc. After at least 48 hours' supervision, the patient's knowledge is evaluated and an assessment completed. If both the nursing staff and the patient are confident and happy to proceed, the patient begins to take their medicines unsupervised, as they would do at home.

Contact: Andrea Devaney, principal pharmacist, transplantation,
(andrea.devaney@orh.nhs.uk)

References

1. Partovi N, Chan W, Nimmo CR. Evaluation of a patient education program for solid organ transplant patients. *Can J Hosp Pharm* 1995; 48:72-8.
2. Traiger GL, Bui LL. A self-medication administration program for transplant recipients. *Crit Care Nurse* 1997; 17:71-9.
3. Girvan C, Wong K. An individualised teaching and self-medication program to promote compliance in newly transplanted pediatric patients. *Transplant Proc* 1999; 31 Suppl 4A: 73S-74S.

13. Supplementary prescribing and patient group directions

AIM

- To ensure that people with renal disease receive the medicines they need in a timely manner.
- To ensure that the skills of all health care staff are appropriately used so that the individual's pathway through renal services is as smooth as possible.

RATIONALE

Patient group directions (PGDs) and supplementary prescribing should be considered where appropriate. They offer another option to improve the quality of care provided to people with renal disease.

Definitions

A **PGD** is a written instruction for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.

Supplementary prescribing is a voluntary prescribing partnership between an independent prescriber and a supplementary prescriber to implement an agreed, patient-specific, clinical management plan with the patient's agreement.

PGDs —Specified qualified health professionals, including nurses and pharmacists, can work under PGDs to supply or administer a medicine in accordance with the PGD.¹

A PGD is appropriate for situations where the patient group and need can be pre-defined. In these cases there will be an advantage for the patient in not having to see a medical practitioner for an individual prescription. For example, PGDs for the treatment of peritonitis and exit site infections allow the specialist nurse to assess the individual, supply agreed therapy and administer the medicines immediately.

Supplementary prescribing — Supplementary prescribing will allow nurses and pharmacists to treat individuals in accordance with an

agreed clinical management plan. The doctor (independent prescriber) will be involved in the diagnosis and assessment of the patient. A clinical management plan will then be developed, which will have to be agreed by the independent prescriber and the supplementary prescriber.

The supplementary prescriber can then manage the ongoing care of the patient, including initiation of treatment and response to treatment, provided this is included in the clinical management plan. The guidance states that there should normally be an annual review between the independent and supplementary prescriber.

Supplementary prescribing could, for example, be used for tailoring immunosuppressants post transplant, dealing with anaemia and controlling blood pressure.

HOW

PGDs — Health Service Circular 2000/026¹ (Level 4) provides details of what information should be included in a PGD.

An archive of PGDs is available on www.groupprotocols.org.uk. The PGDs on this site have only been approved for use in a specific locality and have not been endorsed centrally by the Department of Health. They could be adapted for use elsewhere, as an alternative to drawing up new PGDs. A project board is currently overseeing development of the website. The new site will become available in summer 2004.

Supplementary prescribing — Areas where supplementary prescribing could benefit the patient can be identified and suitable professionals (nurses and pharmacists) targeted to access the training programme to become supplementary prescribers.

PGD for vitamin supplements — a multidisciplinary model

Most children on dialysis, especially peritoneal dialysis, need vitamin supplementation because water-soluble vitamins are lost during dialysis. Great Ormond Street children's hospital is drawing up a PGD for vitamin supplementation. While most hospital PGDs focus on supply by nurses, this PGD will enable both pharmacists and nurses to supply.

Contact: Susan Patey, renal pharmacist (PATEYS@gosh.nhs.uk)

PGD for peritoneal dialysis peritonitis

Oxford Radcliffe Hospitals NHS Trust has produced a PGD for outpatient treatment of peritoneal dialysis peritonitis using vancomycin and ciprofloxacin. The protocol allows specialist peritoneal dialysis nurses to supply these antibiotics as initial blind therapy.

People undergoing peritoneal dialysis are trained to seek treatment immediately if their dialysis fluid is cloudy. The PGD enables them to receive prompt treatment, without having to wait to see a doctor.

In 2001, the unit treated 101 peritonitis episodes and the PGD was used for 29 of these. Situations when the PGD was not used included times when peritoneal dialysis nurses were not on duty (evenings and weekends) or where the patient fell into one of the exclusion categories requiring medical referral (eg, if they were taking a medicine that interacted with ciprofloxacin).

Peritoneal dialysis nurses also make regular visits to patients at home, especially in the early stages of treatment. The PGD allows initiation of treatment on these visits if the nurse identifies symptoms of peritonitis.

The success of the PGD has encouraged the renal unit to develop further PGDs to enable peritoneal dialysis nurses to treat exit site infections (with flucloxacillin, erythromycin or rifampicin).

All empiric antibiotic therapy for peritoneal dialysis patients at the Trust is drawn up in conjunction with the consultant microbiologist and reviewed annually.

The peritonitis PGD is included in Appendix 2.

Contact: Anne Millsop, renal pharmacist (anne.millsop@orh.nhs.uk)

Supplementary prescribing by pharmacists in renal disease

In the London area, renal disease has been identified as one of the specialist areas suitable for supplementary prescribing for pharmacists in secondary care. Work has started to identify candidates who may be suitable for supplementary prescriber training.

It is envisaged that, as supplementary prescribers, pharmacists could run clinics for patients with chronic renal disease, managing typical chronic medical conditions such as hypertension, anaemia and renal bone disease. The pharmacist could undertake regular review of the

patient, with the independent prescriber seeing the patient at pre-arranged times (or whenever there was clinical need). The most appropriate roles for pharmacist and nurse supplementary prescribers will need to be defined, with nurses already having a well-developed role in anaemia clinics.

With supplementary prescribing, patients will receive appropriate care from qualified health professionals while having quicker access to medicines as they will not have to wait to see a doctor. For the health service, supplementary prescribing will allow doctors more time to target patients with more complex needs.

Contact: Jatinder Harchowal, London Pharmacy Supplementary Prescribing Support Team, lead for secondary care
(jatinder.harchowal@bartsandthelondon.nhs.uk)

Further information on PDGs and supplementary prescribing

Department of Health: Mechanisms for nurse and pharmacist prescribing and supply of medicines

www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4069901&chk=//fUDQ

PGDs:

Royal Pharmaceutical Society fact sheet on PGDs —

www.rpsgb.org.uk/pdfs/factsheet10.pdf

www.groupprotocols.org.uk

Supplementary prescribing:

Department of Health 2003. Supplementary prescribing by nurses and pharmacists within the NHS in England. A guide for implementation.

Available at

www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4009717&chk=11s8x4

Supplementary prescribing. A resource to help healthcare professionals to understand the framework and opportunities. National Prescribing Centre; 2003. Available at

www.npc.co.uk/publications/healthcare_resource.pdf

References

1. NHS Executive. HSC 2000/026 Patient Group Directions (England Only). London: Department of Health; 2000.

14. Home delivery of medicines and dialysis fluids

AIM

To ensure that individuals with chronic kidney disease are able to obtain their renal medicines and dialysis fluids and a time and place that is convenient to them.

RATIONALE

People with chronic kidney disease need to be supported in their treatment regimen, whatever their modality of renal replacement therapy.

Many people choose to have their dialysis treatment at home, via peritoneal dialysis or haemodialysis. It is therefore important that efficient home delivery services are available to these patients to ensure that they receive the appropriate dialysis fluids and consumables when they need them at a time and place that is convenient and acceptable to them. It is now standard practice for renal units to tender for this service, and to contract with commercial providers, to comply with current EU procurement legislation.

People with renal disease should have easy access to the “high-tech” medicines that they require, eg, epoetins and immunosuppressants, via a delivery or collection system most appropriate to the individual.

HOW

To ensure NHS Trusts are able to contract effectively for delivery services to main renal units, satellite units and people’s homes, further guidance and a template are available from the NHS Purchasing and Supply Agency (PASA) (<http://www.pasa.nhs.uk/>). A specific renal template guidance and renal buyers’ contacts page is available to NHS staff at <http://nww.pasa.nhs.uk/renal>.

The guidance provided by PASA in the template document has been used successfully by numerous NHS renal units in England over the past 3-4 years. Some renal units have grouped together to form consortia, with PASA facilitation, and millions of pounds worth of product and service have been contracted for using this professional and standardised approach.

Services for home delivery of fluids and consumables for individuals undergoing peritoneal dialysis and haemodialysis have been operated for many years by several companies.

While some renal units have developed shared care agreements so that "high-tech" medicines, such as epoetins and immunosuppressants, can be prescribed in the community setting, others provide these medicines direct from the hospital. Various arrangements are used to facilitate the supply of these medicines and consumables. For example:

(a) Companies manufacturing epoetins operate a home delivery service. The prescription is issued by the renal unit and sent direct to the delivery company, which then delivers the medicine to the person's home at a convenient time. The service also provides refrigerators for storing the medicine at home. Nursing back-up is provided for any problems that may be encountered when administering the medicine.

(b) A similar "deliver to the door" scheme is offered by some of the pharmaceutical companies that manufacture immunosuppressant agents.

(c) Some hospitals have set up their own "medicines home delivery" service (not commercially sponsored). This allows people to receive all their medicines (eg, immunosuppressants, antihypertensives) via the post, to be delivered to an address convenient to them. (An example of such a service is described in the Panel below.) If they are not in to receive the parcel, either a redeliver card will be left or the parcel will be taken to an agreed local post office. This avoids people having to stay at home for each delivery and enables them to continue working.

(d) An alternative system to enable people with renal disease to readily obtain either epoetins or immunosuppressants is for the renal unit to issue an FP10 prescription, which can be taken to the community pharmacy of the patient's choice to be dispensed in the usual way.

Unwanted and unused medicines and fluids It is important that individuals/carers have clear information about the return and disposal of unwanted medicines to a pharmacy most convenient to them. The "home care" companies that deliver dialysis solutions and consumables to people's homes are also contracted to remove any unused stock in the event of a change in dialysis modality, transplantation, or the person's death.

Delivery service for transplant outpatients

A medication home delivery service for transplant outpatients was set up two years ago at the Oxford Transplant Centre.

All patients requiring a medicine to be delivered to their home will be seen by a pharmacist in the outpatient clinic who will review their medicines. Following the medication review, the prescription is faxed to a dispensing company for delivery of medicines within three working days to the chosen delivery address. The medicines are sent by the Royal Mail Special Delivery service.

This new system has resulted in patients spending less time in hospital. The average waiting time to see the clinic pharmacist is eight minutes and 85% of patients are seen within 15 minutes. Previously, patients might have waited three to four hours for their prescription to be dispensed by the hospital pharmacy (having already spent several hours in clinic). In turn, the new system allows faster turn around in the pharmacy for discharge prescriptions and dispensing of medicines for inpatients.

A questionnaire in January 2003 found that over 90% of 240 patients were enthusiastic about the home delivery service and said that having a pharmacist in the clinic was a positive development.

The clinic pharmacist has access to patient notes and test results which assists prescription monitoring. An audit to determine the usefulness of this service showed that the pharmacists made at least one intervention in 42% of prescriptions (the two most common interventions were for omitted medicines or incorrect dosage).

Contact: Andrew Prowse, transplant outpatient pharmacist
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15. End-of-life care

AIM

- To ensure that people with established renal disease are able to make informed decisions about their end-of-life care.
- To alleviate symptoms using appropriate medicines, taking account of the person's worsening renal function.

RATIONALE

End-of-life care for people with established renal disease can be described as palliative care. Palliative care aims for a holistic approach for individuals whose disease is incurable and encompasses physical, spiritual and psychosocial aspects.¹

The period of this care, often termed conservative management, may vary between days (when a person withdraws from dialysis) and years (when a person chooses not to initiate dialysis treatment). The principal aim is not to preserve life but to make life that remains of the highest quality possible. Treatment should promote the person's dignity and comfort.

HOW

- The renal multi-disciplinary team, the hospital and community palliative care services and the person's GP should work collaboratively to ensure that patients at the end of their life get the best possible support and care.
- People should have access to medicines or treatments that might help them during their end-of-life care.
- People with established renal disease and their carers need access to sufficient information on medicines to enable them to make informed choices on whether or not to accept treatment. These choices should be documented in the patient's notes.
- Ensure that prescribing and dispensing are carried out at locations that are convenient for the individual (or carer).
- It is important that individuals who choose not to initiate dialysis treatment, or choose to withdraw from dialysis, have the same rights as those who choose to undergo renal replacement therapy.

References

1. Rich A. The role of palliative care in patients with renal failure. Br J Renal Med 2000; Spring: 6-8.

16. Acknowledgements

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Penny Mawson, renal nurse, Guy's and St Thomas's NHS Trust, London
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UK

Appendix 1: Sample supply letters on unlicensed medication used by Guy's and St Thomas' NHS Trust

Date

Dear Parent/Carer/Patient,

Azathioprine Suspension 50mg in 5ml x 100ml* is an unlicensed medicine. **It is not kept in stock by your local chemist**, but they will be able to order it for you. In order to maintain a continuity of supply of this medicine you will need to:

1. Take this letter to your doctor and request a Prescription.
2. Present the Prescription together with this letter to your local Chemist as soon as possible after discharge from hospital, a minimum of **7 days** before the medicine expires^{*} /your supply runs out.

* Please note: this product has a maximum expiry of 1 month, which you should allow for when renewing your prescription.

If you have any questions or problems, please ring us on the phone number above.

Yours Sincerely,
Pharmacy Department.

.....
.....

Dear GP & Pharmacist,

Re: Patient

This patient has been discharged on **Azathioprine Suspension 50mg in 5ml x 100ml***. It is unlicensed, but available from: [company contact details] .

Please allow **5 days** for delivery. If you have any questions or problems, please ring us on the phone number above.

* Please note: this product has a maximum expiry of 1 month, which you should allow for when placing an order.

Yours Sincerely,
Pharmacy Department.

Date

Dear Parent/Carer/Patient,

Calcium Carbonate Suspension 600mg in 5ml x 500ml* is an unlicensed medicine made by the Production Unit at Guy's & St Thomas' Hospital Trust. **It is not kept in stock by your local chemist**, but they will be able to order it for you. In order to maintain a continuity of supply of this medicine you will need to:

1. Take this letter to your doctor and request a Prescription.
2. Present the Prescription together with this letter to your local Chemist as soon as possible after discharge from hospital, a minimum of **21 days** before the medicine expires*/your supply runs out.

* Please note: this product has an expiry date of one month after opening.

If you have any questions or problems, please ring us on the phone number above.

Yours Sincerely,
Pharmacy Department.

.....
.....

Dear GP & Pharmacist,

Re: Patient

This patient has been discharged on **Calcium Carbonate Suspension 600mg in 5ml x 500ml***. It is unlicensed, but manufactured and distributed by:

Order Processing Service,
Pharmacy Production Unit,
Pharmacy Department,
St. Thomas' Hospital,
Lambeth Palace Road,
London, SE1 7EH

Tel. (020) 7922 8316

Fax. (020) 7960 5644

To obtain supplies please post or fax a written order on letter headed notepaper. The order must be signed by a pharmacist. Please allow **14 days** for delivery. If you have any questions or problems, please ring us on the phone number above.

* Please note: this product has an expiry date of one month after opening.

Appendix 2: The Oxford Radcliffe Hospitals NHS Trust patient group direction for outpatient treatment of peritoneal dialysis peritonitis using vancomycin and ciprofloxacin

Protocol Users: Named level 1 registered nurses working on the Oxford Kidney Unit, including co-provider Units who have completed the training and passed the competencies for this protocol

Facilities Required: Anaphylaxis and resuscitation equipment only if the patient has not previously received IV or IP vancomycin

Clinical Situation / Conditions:

Vancomycin is used to treat infection caused by gram positive organisms in PD peritonitis, and Ciprofloxacin is used for gram negative organisms. For initial blind therapy give both together.

Confirmation of Clinical Condition:

Cloudy PD effluent, pyrexia, abdominal pain, vomiting, diarrhoea. Symptoms vary in severity and patients may not experience all of them. When PD fluid is sent to Microbiology for analysis the results show a raised white cell count (WCC) - greater than $100 \times 10^6/L$.

Patient Inclusion Criteria:

Patients who have had a Tenckhoff catheter inserted for Peritoneal Dialysis treatment and who display symptoms of PD peritonitis.

Patient Exclusion Criteria and Management of:

Refer to a doctor immediately if:

- 1) Allergy to vancomycin or ciprofloxacin*
- 2) Severe abdominal pain uncontrolled by oral analgesia*
- 3) Vomiting*
- 4) Unable to tolerate oral medication*
- 5) PD fluid contains faecal material*
- 6) Patient has a history of epilepsy*

Action to be taken if patient does not wish to receive or adhere to care under the protocol or are excluded as above:

Contact a doctor at the Oxford Kidney Unit

Treatment Available under the Protocol

Name of Medicine Supplied	VANCOMYCIN INJECTION 500mg or 1g	CIPROFLOXACIN 500mg TABLETS x 6 TTO Pack
Name of Medicine Administered (leave blank if the same as above)		
Legal Status	POM	POM
Dose, Dose Range & Criteria	1.5g - 2.0G 1.5g if < 60kg 2.0g if >60g via injection port of 1.36% (Baxters), 1.5% (Fresenius) PD bag. Clean injection port with an alcohol swab. Inject the drug after the flush stage of the exchange is completed.	1g stat then 500mg BD for 2 days
Method/Route of Administration	Intra peritoneal. This is an unlicensed route but is accepted practice on the Oxford Kidney Unit.	Oral
Frequency of Administration	2 stat doses 1 week apart.	1 course as above
Total dose that can be given	1 st dose at onset of symptoms of PD peritonitis; 2 nd dose 7 days later (unless original PD Fluid white cell count (WCC) less than 100 x 10 ⁶ /L, or organism grown is resistant to Vancomycin, in which case 2 nd dose would not be given)	
Contra-indications/Drug interactions	Allergy to vancomycin – Refer to doctor at Oxford Kidney Unit	Interacts with: warfarin, theophylline, phenytoin, ciclosporin, contact doctor at the Oxford kidney Unit. Also phosphate binders and iron – advise to leave at least 2 hours between preparations.. Contra-indications: Allergy to ciprofloxacin, history of epilepsy. Refer to doctor at Oxford Kidney Unit
Identification of Adverse Drug Outcomes - include side-effects & adverse drug reactions	Flushing of upper part of body (“Red man syndrome”), muscle spasm, anaphylaxis.	Rashes, convulsions, jaundice, pain or inflammation in limbs.
Management of possible Adverse Outcomes	Contact doctor at Oxford Kidney Unit	Contact doctor at Oxford Kidney Unit
Patient Information/Advice	Carry out next PD exchange 6 hours later Contact Oxford Kidney Unit if PD fluid is not clearing in 48 hours or symptoms get worse Give the patient an information leaflet.	Take whole course as instructed. May impair driving skills. Avoid antacids, iron and phosphate binders for 2 hours before and after dose. Contact Oxford Kidney Unit if PD fluid is not clearing in 48 hours or symptoms get worse

Additional Information

Information re: Follow-up Treatment

If PD fluid is still cloudy or patient still has symptoms, contact the Oxford Kidney Unit. If symptoms resolve and bags clear return in 1 week for follow up visit to PD nurse.

Arrangement for Medicine Supply

Vancomycin injection is ordered as stock.
Yellow outpatient prescription forms to be left in PD tray on renal ward. Pharmacist will re-supply ciprofloxacin TTO packs from these. For co-provider units ciprofloxacin packs will be supplied as stock by the pharmacy.

Arrangements for Medical Referral

Bleep or ring a doctor at the Oxford Kidney Unit.

Method of Documentation:

Yellow prescription forms.
Document in PD nursing notes and on proton drug, summary & CAPD complications screens.