Clinical Practice Guidelines for the Care of Patients with Chronic Kidney Disease

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<u>Clinical Practice Guidelines for the Care of Patients with</u> <u>Chronic Kidney Disease</u>

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Introduction:

The addition of a set of guidelines and audit measures specifically related to the care of patients with chronic kidney disease (CKD) reflects a worldwide recognition of the importance of early detection of CKD to facilitate interventions that will slow the rate of renal function decline to reduce the need for renal replacement therapy as well as to reduce the high risk of cardiovascular disease associated with CKD. This is further supported by the inclusion of specific sections on CKD in Part 2 of the National Service Framework for Renal Services and the latest Quality and Outcomes Framework of the General Medical Services (GMS) contract for General Practitioners. These clinical practice guidelines are intended to provide clear guidance on key aspects of the management of patients with CKD and the associated audit measures are a means whereby Nephrology Units can assess their performance against a nationally agreed set of outcome measures. The rationale for each guideline is intended to provide a concise review of the supporting evidence as well as more detailed guidance where appropriate. This document is intended to be complementary to the "UK Guidelines for the Identification, Management and Referral of CKD in Adults" compiled by the Joint Specialty Committee of the Renal Association and Royal College of Physicians ^{1,2} (also available on the Renal Association website www.renal.org/CKDguide/ckd.html). The latter provides detailed recommendations for all aspects of the detection and management of CKD as well as a comprehensive review of supporting evidence. Every effort has been made to make these outcome measures consistent with the National Service Framework for Renal Services

(http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Renal/ fs/en) ^{3,4} as well as other national and international guidelines. A recent Consensus Conference convened by the Renal Association and Royal College of Physicians of Edinburgh produced further recommendations for the practical management of early CKD

(http://www.rcpe.ac.uk/Whats_New/index.php#0802).

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Section 1: DETECTION AND MONITORING OF CKD

Guideline CKD 1.1

Amongst patients attending a nephrology clinic (excluding those on longterm dialysis), each measurement of serum creatinine concentration in the renal database and in clinic letters should be accompanied by an estimate of GFR (good practice).

Audit Measure: Proportion of renal database entries and clinic letters that include an estimated GFR with the serum creatinine.

Rationale: Renal excretory function has in the past generally been assessed by means of serum creatinine concentration and creatinine clearance measurements. Serum creatinine alone is a poor measure of excretory function because its relationship with GFR is non-linear and it rises outside of the laboratory normal range only after substantial loss of renal function. The Cockcroft-Gault (CG) formula has been used to estimate creatinine clearance from serum creatinine concentration but has the disadvantage of requiring the patient's weight, which is usually not available to laboratories. Creatinine clearance is critically dependent on an accurate 24-hour urine collection, which many patients find difficult and inconvenient to achieve. The 4-variable MDRD equation was developed from data obtained from a large cohort of patients with CKD who had had excretory function assessed by ⁵¹Cr-EDTA clearance¹. The MDRD formula is more precise than the CG formula² and its main advantage is that it does not require knowledge of the patient's weight. The MDRD formula has been recommended as the method of choice for estimating GFR by several national and international bodies. The Department of Health for England has endorsed the use of the MDRD formula by all

clinical biochemistry laboratories, in combination with an approach to harmonisation of the results of serum creatinine assays by the National External Quality Assurance Scheme, to allow comparability of GFR estimates between laboratories. Recently a modification of the MDRD formula has been proposed for use with standardized serum creatinine values ³. Due to variability in creatinine assays, clinicians should rely on laboratory-generated estimates of GFR, rather than calculating them directly using a formula or "GFR calculator". Owing to the underestimation of GFR at values close to normal, many laboratories have chosen not to report a specific value if it is >60 ml/min/1.73m². This approach was endorsed by the recent UK Consensus Conference on the management of early CKD.

The adoption of the MDRD formula for universal laboratory-based estimation of GFR, and of the 5-stage classification of CKD based on these estimates, has been controversial on several grounds. Even after adequate correction has been made for overestimation of serum creatinine in some assays, the formula is not perfect, and its use can result in misclassification of some people as having early stage 3 CKD, due to systematic underestimation of 'true' GFR^{2,4} and imprecision, particularly when the GFR is >60 ml/min/1.73 m^2 . The formula has not been well validated in the very old, or in ethnic minority groups other than African-Americans. Its use is not valid in children, pregnant women, people at the extremes of body size², muscle mass or nutritional status, or in patients with acute kidney injury ⁵. Reduced GFR is common amongst the elderly, leading some to argue that this is not a disease state but part of normal ageing. The division of CKD into five bands based on

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GFR is seen by some as arbitrary. Concerns have been expressed that inappropriate 'disease labelling' of people newly informed that they have CKD will lead to anxiety and to adverse changes in illness behaviour ⁶. Some see the introduction of laboratory-based eGFR reporting as a form of screening, and argue that the case for screening the population for CKD has not been adequately supported by evidence ⁷. Others have argued, however, that if doctors request a measurement of serum creatinine they are requesting an estimate of kidney function, and that the eGFR provides a much better estimate⁸. Furthermore eGFR is a powerful predictor of cardiovascular risk and of progressive CKD, reduced GFR is not an inevitable consequence of ageing and the great majority of people newly recognised as having CKD already have diagnoses of vascular disease, hypertension, or diabetes mellitus. These arguments have been rehearsed in depth elsewhere ^{7,8}. We take the view that the advantages of the simple classification system adopted in the UK (and elsewhere in the world) greatly outweigh the potential disadvantages. The advantages include simplicity (estimated GFR approximates percentage of normal kidney function), and the opportunities both for improved prevention of cardiovascular disease and for systematic reduction in the late referral of patients with established renal failure.

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Guideline CKD 1.2

The stage of CKD, as defined by the US K/DOQI classification, should be noted in the patient records at each nephrology clinic visit and communicated in any letters generated (good practice).

Audit Measure: Proportion of patient record entries and clinic letters that include the K/DOQI CKD stage.

Rationale: K/DOQI has proposed a classification system for CKD based on GFR¹. This provides a useful framework for studying the prevalence and incidence of CKD in epidemiological studies but more importantly, facilitates the development of treatment guidelines and management plans based on disease severity. The K/DOQI classification has been endorsed by a large number of national and international professional organisations^{2,3}. We recommend that it should be incorporated into treatment guidelines for CKD and reported in all written communication. The UK Consensus Conference on early CKD has recently recommended that the K/DOQI classification should be modified by dividing CKD stage 3 into CKD 3A and 3B and that a suffix "p" should be used for all stages to denote patients with urine protein to creatinine ratio >100mg/mmol, who are at increased risk for progression (http://www.rcpe.ac.uk/Whats New/index.php#0802). Letters from Nephrology to Primary Care should include information on sources of further information regarding the 5-stage classification of CKD such as links to intranet and internet sites e.g. (www.renal.org/CKDguide/ckd.html).

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Guideline CKD 1.3

Amongst patients being investigated or treated for CKD, proteinuria detected by dipstick testing should be assessed by measurement either of the protein to creatinine or albumin to creatinine ratio, ideally on an early-morning urine specimen (good practice).

Audit Measures: 1. Proportion of CKD patients who had the results of a urine dipstick test recorded at the first clinic visit.

2. Proportion of CKD patients with a positive dipstick test for proteinuria who had a urine protein or albumin:creatinine ratio measured at their first clinic visit.

Rationale: Urine dipstick testing remains the most appropriate method to screen patients with CKD for proteinuria. In patients with a positive dipstick test, urinary protein excretion has traditionally been assessed by means of a 24-hour urine collection. If accurately performed this undoubtedly provides the most precise measurement of proteinuria but the clinical utility of 24-hour urine collections is limited by inconvenience to patients, inaccurate collections and the burden on laboratory staff having to process the specimens. Several studies have shown good correlations between the total protein or albumin to creatinine ratio on early morning spot urine sample and 24-hour urinary protein excretion ¹⁻⁵. Furthermore urine protein:creatinine ratio on a spot morning specimen has been shown to predict the risk of progression of CKD at least as reliably as 24-hour urinary protein excretion ⁶. If the urine protein:creatinine ratio is expressed in mg/mg the value obtained is approximately the same as the number of grams/24 hours of urinary protein excretion. On the other hand if the ratio is expressed as mg/mmol, 24h protein

excretion is approximately 10 times this figure (based on an assumed average urinary creatinine excretion of 10mmol/day). It should be noted that agreement between urine protein: creatinine ratio and 24-hour protein may be reduced if proteinuria is in the nephrotic range ⁷ and that urine protein:creatinine ratio may be unreliable in patients with unusually large or small muscle mass². It has been argued that spot urine protein:creatinine ratio measurements should not be used to assess proteinuria because they are subject to wide variations depending on the time of day they were obtained⁸. The counter-argument is that this variation can be minimised by using a specimen of early morning urine and that use of spot urine protein:creatinine ratio will promote more widespread monitoring of proteinuria as an important marker of prognosis in CKD^{9,10}. The decision on whether to measure protein or albumin will depend on local factors including cost (albumin is more expensive to assay than total protein). As urine may contain variable amounts several different proteins, urine protein:creatinine ratio will generally be higher than albumin:creatinine by a variable amount. Both measures provide useful prognostic information but there is no simple method for extrapolating from one to the other. For detection of microalbuminuria an albumin:creatinine ratio is required. A detailed discussion of the relative advantages and disadvantages of spot urine protein creatinine ratio and 24hour urine collections has recently been published ^{8,9}.

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Guideline CKD 1.4

Nephrology Units should negotiate service agreements for the detection and monitoring of CKD, including criteria for referral to a Nephrologist (good practice).

Audit Measure: Proportion of Nephrology Units with specific service agreements for the detection and monitoring of CKD within a defined organisational area.

Rationale: The introduction of eGFR and the K/DOQI Classification is intended to improve detection of previously undiagnosed CKD and it is anticipated that this will lead to increased referrals to Nephrology. It is clear that Nephrology Services would not be able to cope if all patients with an eGFR<60ml/min/1.73m² were to be referred. It is therefore important that each Nephrology Department interact with Commissioners to agree referral criteria. It is recognised that commissioning arrangements and structures vary within the four countries of the United Kingdom and are in a constant state of flux. Application of this guideline will therefore depend on local circumstances. Guidance regarding indications for screening for CKD as well as criteria for Nephrology referral has recently been provided by a Joint Specialty Committee of the Renal Association and Royal College of Physicians ¹ and is available on the Renal Association website

(www.renal.org/CKDguide/ckd.html).

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Guideline CKD 1.5

A Nephrology Unit should establish an easily accessible non-visit-based Specialist advice service for Primary Care Physicians (good practice). *Audit Measures:* 1. Proportion of all new outpatient attendances that could have been avoided by appropriate non-visit-based specialist advice.

2. Number of requests for non-visit-based advice relative to the total number of referrals per month.

Rationale: The introduction of eGFR and the K/DOQI Classification as well as the recent inclusion of CKD in the GMS Quality Outcomes Framework will raise the profile of CKD in Primary Care and inevitably result in an increased number of queries as well as requests for advice. It is clear that the success of any initiative to improve the detection and management of CKD will depend critically on good co-operation between Primary Care and Nephrology Units. It is therefore vital that Nephrology Units establish easily accessible means for providing advice without requiring referral of the patient for an outpatient visit. Such means could include telephonic and e-mail advice, local websites or the "Clinical Advice Service" option within the "Choose and Book" initiative (where applicable). At present there is no remuneration structure for such a service but we have taken the view that it will benefit Primary Care and Nephrology Units as well as improving patient care. Audits that demonstrate benefit could provide valuable evidence to support efforts to obtain funding.

Section 2. TREATMENT OF PATIENTS WITH CKD

The comprehensive management of patients with CKD requires close cooperation between Primary Care and Nephrology Units. As discussed in depth in the "UK Guidelines for the Identification, Management and Referral of CKD in Adults", it is not necessary or desirable that Nephrology Units should manage all patients with CKD. Depending on local arrangements, Primary Care may also be responsible for certain aspects of the management of patients who are followed up by Nephrology Units (e.g. glycaemic control, smoking cessation). These Guidelines are intended to provide guidance for the management of all aspects of CKD, whether delivered by Primary Care or Nephrology Units. The audit measures are intended for use by any service providers wishing to assess the quality of service delivered.

Guideline CKD 2.1

Amongst patients with CKD blood pressure should be lowered to <130/80mmHg (evidence).

Audit Measure: Proportion of patients with CKD and follow-up for at least 6 months, whose last recorded blood pressure was <130/80mmHg unless specifically contraindicated.

Rationale: The treatment of hypertension affords the dual benefit of slowing the rate of progression of CKD and reducing cardiovascular risk in patients with CKD. Whereas the evidence that blood pressure lowering confers renal and cardiovascular protection is clear, the optimal level of blood pressure control is less well established. Two large prospective randomised studies have investigated the effect of lower target blood pressures on CKD progression but have failed to provide clear answers ^{1,2}. Nevertheless, the MDRD study did show that the level of proteinuria at baseline significantly modulated the effect of blood pressure lowering such that a lower blood pressure target (125/75 vs. 140/90mmHg) was associated with a slower rate of decline in GFR among patients with >1g/day of proteinuria. Furthermore, secondary analysis revealed significant correlations between rate of GFR decline and achieved blood pressure prompting the authors to suggest blood pressure targets of <130/80mmHg for patients with <1g/day of proteinuria and <125/75mmHg for those with >1g/day of proteinuria³. Long-term follow-up of 840 patients from the MDRD study showed adjusted hazard ratios of 0.68 (0.57-0.82) and 0.77 (0.65-0.91) for ESRD and a composite end-point of ESRD and all-cause mortality, respectively for patients originally randomised to the low blood pressure target ⁴. Similarly, a meta-analysis of data from 1860 non-diabetic patients with CKD reported the lowest risk of CKD progression in patients with systolic blood pressure 110-129mmHg but a higher risk of progression associated with SBP<110mmHg⁵. A similar note of caution has been sounded by a secondary analysis of data from the Irbesartan Diabetic Nephropathy Trial⁶. Whereas the analysis showed improved renal and patient survival associated with lower achieved systolic blood pressure, there was a significant increase in all-cause mortality among patients with achieved systolic blood pressure <120mmHg. Caution should therefore be exercised in patients who may suffer harm from excessive lowering of blood pressure e.g. patients with autonomic neuropathy or postural hypotension.

There is a strong consensus among national and international renal, hypertension and diabetes organisations to recommend a target blood pressure of <130/80mmHg for all patients with CKD ⁷. Whereas there is some evidence to support a lower target of <125/75mmHg in patients with >1g/day of proteinuria there is concern that lower blood pressures may be associated with adverse outcomes in some patients.

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Guideline CKD 2.2

Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) treatment should form part of the antihypertensive therapy of patients with CKD and urinary protein excretion of >1g/day (urine protein to creatinine ratio >100mg/mmol or >1.0mg/mg) unless there is a specific contraindication (evidence). *Audit Measure:* Proportion of proteinuric CKD patients (as defined above) without contraindications, who had an ACEI or ARB on their last recorded list of chronic medications.

Rationale: Several large prospective randomised controlled trials among different groups of patients with CKD provide evidence that ACEI or ARB treatment affords significant renal protection in addition to that attributable to blood pressure lowering. Specifically, ACEI treatment has been shown to slow CKD progression among patients with type 1 diabetes mellitus and established nephropathy¹ as well as patients with non-diabetic CKD and proteinuria >1g/day²⁻⁴. Furthermore a recent randomised study has shown that ACEI treatment may afford significant renal protection (43% reduction in risk of doubling serum creatinine, ESRD or death) in non-diabetic patients with advanced renal disease (serum creatinine 264-440µmol/l)⁵. A metaanalysis of data from 11 randomized controlled trails that compared ACEI with other antihypertensives among patients with predominantly non-diabetic CKD showed a significantly lower risk of ESRD incidence (relative risk 0.69; 95%CI 0.51-0.94) associated with ACEI treatment after adjustment for differences in level of blood pressure control ⁶. The analysis also found greater renal protective benefit associated with ACEI treatment in patients with higher

levels of baseline proteinuria and no benefit could be shown for those with proteinuria <0.5g/day. This analysis did not however include data from the AASK study, which reported a lower incidence of the combined end-point of >50% GFR reduction, ESRD or death among African American patients with mild baseline proteinuria (mean 0.6g/day among males and 0.4g/day among females) randomised to ACEI treatment versus a calcium channel blocker or a β-blocker ⁴. We have selected a proteinuria threshold of >1g/day to recommend ACEI or ARB treatment because this has the most robust evidence to support it. It should be recognised, however, that some patients with lesser degrees of proteinuria may benefit from ACEI or ARB treatment. Nevertheless it must be conceded that current evidence does not support the use of ACEI or ARB treatment for all patients with CKD. The UK Consensus Conference on Early CKD has recommended that general practitioners may choose not to treat patients with an ACEI or ARB in the absence of significant proteinuria (<u>http://www.rcpe.ac.uk/Whats_New/index.php#0802</u>).

ARB treatment has been shown to afford significant renal protection (risk reduction 16%⁷ and 20 or 23%⁸ for primary outcome of doubling of serum creatinine, ESRD or death) in two large randomised studies of patients with type 2 diabetes and established nephropathy ^{7,8}.

Two large prospective randomised controlled studies have reported significant reductions in cardiovascular morbidity and mortality associated with ACEI treatment among patients with a high risk for future cardiovascular events ^{9,10}. On the other hand the primary analysis of one study found no such benefit

among patients with stable coronary heart disease and low risk of cardiovascular events ¹¹. Interestingly a secondary analysis of the PEACE Trial data found a higher risk of death among patients with an estimated GFR of <60ml/min/1.73m² at baseline and a significant reduction in all cause mortality associated with ACEI treatment in this subgroup ¹². Whereas none of the above studies specifically included patients with CKD and all excluded patients with moderate or severe renal impairment, these data do provide support for the notion that ACEI treatment reduces cardiovascular risk in high-risk patients. As cardiovascular disease remains the most important cause of death among CKD patients it seems reasonable to recommend ACEI or ARB treatment for reduction of cardiovascular risk as well as slowing of CKD progression.

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Guideline CKD 2.3

Patients with diabetes mellitus and microalbuminuria should be treated with an ACEI or ARB, titrated to maximum licensed antihypertensive dose if tolerated, regardless of the initial blood pressure, unless these drugs are specifically contraindicated (evidence).

Audit Measures: 1. Proportion of patients with diabetes mellitus and microalbuminuria (without specific contraindications) who had an ACEI or ARB on their last recorded list of chronic medications.

 Proportion of patients receiving an ACEI or ARB for diabetes and microalbuminuria who received the maximum licensed antihypertensive dose on their most recent prescription.

Rationale: The presence of microalbuminuria in patients with diabetes mellitus represents the earliest stage of diabetic nephropathy and identifies patients at increased risk of developing overt diabetic nephropathy and a subsequent progressive decline in renal function. There is a large body of evidence indicating that in diabetic patients with microalbuminuria, ACEI or ARB treatment reduces or delays progression from microalbuminuria to overt nephropathy and reduces cardiovascular risk. Among type 1 diabetic patients a meta-analysis of 12 studies including 689 patients reported that ACEI treatment was associated with a marked reduction in the risk of progression to overt nephropathy (odds ratio 0.38, 95%CI 0.25 to 0.57)¹. Among patients with type 2 diabetes the evidence is somewhat less clear. On the one hand several studies have shown a reduction in the amount of microalbuminuria or a decrease in the risk of progression from microalbuminuria to overt nephropathy (risk reduction 24-67%) with ACEI treatment ²⁻⁶ but one relatively

large study found no renal protective benefit of ACEI over β -blocker treatment among hypertensive type 2 diabetic patients with normo- or microalbuminuria ⁷. It should also be noted, however, that subgroup analysis of the HOPE Study found that ACEI treatment was associated with a 25% reduction in the combined primary end-point of myocardial infarction, stroke or cardiovascular death as well as a 24% reduction in the incidence of overt nephropathy among type 2 diabetic patients with normo- or microalbuminuria ⁶. Two large trials have shown a renal protective benefit of ARB treatment among type 2 diabetic patients with microalbuminuria. Importantly Irbesartan treatment (at 150mg or 300mg/day) was associated with a *dose-dependent* reduction in the incidence of overt proteinuria (hazard ratio 0.30; 95%CI 0.14 to 0.61 for 300mg dose)⁸. In the other study Valsartan treatment reduced levels of albuminuria but follow-up data on the incidence of overt proteinuria were not reported ⁹. Based on the results of the above Irbesartan study ⁸ we recommend that the dose of ACEI or ARB should be increased to the maximum licensed antihypertensive dose (British National Formulary) or the maximum tolerated dose. Recent evidence suggests that doses of ARB higher than the currently licensed maximum may afford additional benefit ¹⁰. At present, however, the evidence is not strong enough to recommend higher doses of ARB as standard treatment for microalbuminuria.

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Guideline CKD 2.4

Patients with diabetes mellitus and CKD should achieve good glycaemic control as defined by HBA_{1c} of <7.5% (evidence).

Audit Measure: Proportion of patients with diabetic nephropathy and followup for at least 6 months, whose last recorded HBA_{1C} was <7.5%.

Rationale: The DCCT¹ and UKPDS² trials provided strong evidence that improved glycaemic control prevents the development of microalbuminuria as well as other microvascular complications in patients with type 1 and 2 diabetes mellitus, respectively. In contrast, evidence of the potential renal protective benefits of good glycaemic control in patients who already have microalbuminuria is not conclusive. Among patients with type 1 diabetes, only $2^{3,4}$ of 5 small studies ³⁻⁷ found a reduction in progression to overt nephropathy in patients randomised to improved versus normal glycaemic control. Nevertheless, the reported histological reversal of diabetic glomerular lesions in type 1 diabetic patients with normo- or microalbuminuria after pancreatic transplantation does suggest that improved glycaemic control is of benefit⁸. In the UKPDS Study improved alvcaemic control was associated with a delay in the development of overt proteinuria and slowing of the rate of increase in serum creatinine among type 2 diabetic patients with microalbuminuria². Unfortunately there are no data available regarding the effect of glycaemic control on the progression of established diabetic nephropathy. Nevertheless patients with all stages of diabetic nephropathy remain at increased risk of other microvascular complications and good glycaemic control should therefore be maintained to reduce this risk.

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 Fioretto P, Steffes MW, Sutherland DE, et al. Reversal of lesions of diabetic nephropathy after pancreas transplantation. *New Engl J Med* 1998;339:69-75.

Guideline CKD 2.5

Patients with CKD should have an annual formal assessment of their cardiovascular risk factors including measurement of HDL and total cholesterol, BMI, exercise, alcohol and smoking habits as well as a review of interventions to reduce cardiovascular risk (good practice). Audit Measure: Proportion of CKD patients with a formal assessment of cardiovascular risk documented in their records during the past year. **Rationale:** It is increasingly recognised that CKD is associated with a high risk of cardiovascular morbidity and cardiovascular disease is the most common cause of death among CKD patients. Whereas specific interventions for improving cardiovascular risk have not been widely studied in patients with CKD, it seems reasonable to ensure that CKD patients are afforded the benefit of treatments shown to reduce cardiovascular risk in other patient populations. One study has examined the effect of a combined approach of intensive intervention to reduce cardiovascular risk in patients with type 2 diabetes mellitus and microalbuminuria¹. Interventions included lower blood pressure targets, ACEI, aspirin and lipid-lowering treatment, tight glycaemic control, low fat diet, smoking cessation and exercise. In patients randomised to the intensive intervention arm of the study there was a significant reduction in cardiovascular events (HR 0.47; 95%CI 0.24-0.73) over a mean of 7.8 years.

 Gaede P, Vedel P, Larsen N, et al. Multifactorial intervention and cardiovascular disease in patients with type 2 diabetes. *New Engl J Med* 2003;348:383-93.

Guideline CKD 2.6

Smoking status and action taken should be documented in the patient record at each nephrology clinic visit (good practice).

Audit Measures: 1. Proportion of CKD patients with smoking status recorded in their last record entry.

2. Proportion of CKD patients who are current smokers that received an offer of assistance with smoking cessation during the past year of follow-up.

3. Proportion of smoking CKD patients who ceased smoking during the past year.

Rationale: Smoking has been identified as a risk factor for the development of progressive renal disease in the general population ¹⁻³ as well as in patients with essential hypertension ⁴ and diabetes mellitus ⁵⁻⁷. Other studies have found that smoking is associated with and increased risk of CKD progression among patients with primary glomerular nephropathies ⁸, IgA nephropathy or adult polycystic kidney disease ⁹ and lupus nephritis ¹⁰. Unfortunately few studies have examined the impact of smoking cessation on renal disease. In one relatively small study 16 patients who stopped smoking evidenced a slower rate of decline in renal function and a lower incidence of ESRD than 26 patients who refused to stop ¹¹. Whereas the evidence of benefit regarding smoking cessation and renal protection is limited, the clear evidence of smoking as a risk factor for cardiovascular and respiratory disease makes smoking cessation a critical intervention for improving survival in CKD patients.

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- Stengel B, Couchoud C, Cenee S, et al. Age, blood pressure and smoking effects on chronic renal failure in primary glomerular nephropathies. *Kidney Int* 2000;57:2519-26.

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Section 3. PREPARATION FOR DIALYSIS

Guideline CKD 3.1

To facilitate preparation for the management of established renal failure and treatment of CKD-associated complications, patients with CKD stage 5 as well as those with CKD stage 4 who are expected to progress to stage 5, should be followed up at a clinic that is able to provide counselling regarding treatment modalities and transplantation as well as dietary education and comprehensive management of anaemia, from at least 6 months prior to the onset of established renal failure (see relevant modules) (good practice).

Audit Measures: 1. Proportion of patients with CKD stage 4 that have a documented assessment of their risk of progressing to CKD stage 5.2. Proportion of patients with CKD stage 5 or CKD stage 4 expected to

progress to stage 5, who received predialysis and transplantation counseling at least 3 months before initiation of dialysis.

3. Proportion of patients with CKD stage 5 or CKD stage 4 expected to progress to stage 5, who received dietary education during the preceding 6 months.

Rationale: The need for timely preparation for dialysis is clear and is emphasized in Part 1 of the Renal NSF ¹. It should be noted, however, that not all patients with CKD stage 4 will progress to stage 5 and that unnecessary preparation may do harm to patients. Patients with CKD stage 4 should therefore undergo a formal assessment of their risk of progression. Risk factors for CKD progression are the subject of ongoing research but the most reliable markers at present are past rate of GFR decline and severity of

proteinuria². Preparation for initiation of dialysis requires multiple interventions to deal with both medical and psycho-social aspects. Patients require adequate counselling to assist them in dialysis modality choice and in coping with the psycho-social impact of starting dialysis. In addition there is a growing recognition that management of anaemia as well as calcium and phosphate abnormalities should be optimised prior to initiation of dialysis. Timely formation of vascular or peritoneal access is critical for minimising the risk and stress associated with starting dialysis. Finally, assessment and preparation for possible transplantation should be undertaken prior to initiation of dialysis. The above aspects all form part of the recommendations for dialysis preparation in Standard 2 of Part 1 of the Renal NSF¹. As these interventions span multiple disciplines it is clear that a multi-disciplinary team is required, but it is recognised that the composition of the team will vary between Nephrology Units. To ensure effective interaction between members of such a team and convenient access to all members for patients we regard a clinic that has available all required competencies as the standard of care. Whereas few studies have evaluated the impact of such clinics on patient preparation it is clear that late referral (less than 3 months before initiation of dialysis) for dialysis preparation is associated with significantly higher mortality ³⁻⁶ and lower quality of life ⁷.

- 1. Department of Health. National Service Framework for Renal Services, Part
 - 1: Dialysis and Transplantation. 2004.

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- Caskey FJ, Wordsworth S, Ben T, et al. Early referral and planned initiation of dialysis: what impact on quality of life? *Nephrol Dial Transplantation* 2003;18:1330-8.

Patients should have a functioning native arteriovenous fistula or a Tenckhoff catheter in place by the time that initiation of dialysis is required (evidence).

Audit Measures: 1. Proportion of patients in whom a native arteriovenous fistula is used for the first chronic haemodialysis treatment.

2. Proportion of patients electing to have peritoneal dialysis, who start peritoneal dialysis without the need for temporary haemodialysis.

Rationale: A native arteriovenous fistula (AVF) is widely regarded as the optimal form of vascular access for patients undergoing haemodialysis. The presence of a mature AVF at the time of first haemodialysis reduces patient stress and minimises the risk of morbidity associated with temporary vascular access placement as well as the risk of infection. Similarly, timely placement of a Tenckhoff catheter allows adequate training prior to the need for dialysis and avoids the need for temporary haemodialysis. Part 1 of the NSF for Renal Services recommends that patients should be referred for AVF formation at least 6 months prior to the anticipated date of initiation of haemodialysis and those opting for peritoneal dialysis should be referred for insertion of a Tenckhoff catheter at least 4 weeks prior to initiation of dialysis ¹. Renal Units should collaborate with Surgical Services to set up a robust system that facilitates timely referral for and formation of vascular access or Tenckhoff catheter insertion. This should include a system for prioritising cases according to expected date of dialysis initiation. In addition, provision should be made for adequate bed and theatre-time availability to meet anticipated need.

- 1. Department of Health. National Service Framework for Renal Services, Part
 - 1: Dialysis and Transplantation. 2004.

Patients with CKD in whom dialysis is anticipated, should be screened for hepatitis B and C as well as HIV infection. Patients who are Hepatitis B surface antigen and Hepatitis B surface antibody negative should be immunised and their antibody levels measured post vaccination (evidence).

Audit Measures: 1. Proportion of patients in whom dialysis is anticipated, with test results for Hepatitis B, C and HIV prior to the initiation of dialysis.
2. Proportion of Hepatitis B negative patients who have received a full course

of Hepatitis B vaccine before their first dialysis treatment.

3. Proportion of patients who have received a full course of Hepatitis B vaccine, who have a Hepatitis B surface antibody result documented in their records at the time of their first dialysis treatment.

Rationale: Patients on haemodialysis have a small but significantly increased risk of exposure to hepatitis B and other blood-borne viruses. Severe outbreaks of hepatitis B in Haemodialysis Units have resulted in considerable morbidity and even mortality among susceptible patients and staff. Vaccination provides effective protection against hepatitis B infection. Clinical trails have shown that patients on dialysis have a significantly lower response to hepatitis B vaccination than patients without renal failure. In order to achieve protective antibody levels in the maximum number of patients it is therefore important to administer the vaccine to patients well before the need for dialysis. In addition, patients who display an inadequate response or fail to respond require further time for administration of booster doses or revaccination. Patients starting on peritoneal dialysis should be regarded as

potentially requiring haemodialysis in the future and managed in the same way. Patients should also be screened for hepatitis C and HIV infection to facilitate appropriate treatment and implementation of isolation procedures on haemodialysis units. HIV testing is generally delayed until just before initiation of dialysis unless clinically indicated. Detailed guidelines (with supporting evidence) for the prevention of blood-borne virus infection in dialysis patients are provided by the Department of Health ¹.

References

 Department of Health. Good practice guidelines for renal dialysis/transplantation units: prevention and control of blood-borne virus infection. 2002.

Assessment of suitability for renal transplantation and referral where appropriate should be undertaken prior to the initiation of dialysis (good practice).

Audit Measures: 1. Proportion of dialysis patients with documentation of their suitability for transplantation at 6 months prior to their first dialysis treatment.
2. Proportion of patients considered potentially suitable for transplantation who had been referred for assessment at least 3 months prior to their first dialysis treatment.

3. Proportion of all patients on the transplant waiting list at 1 year after initiation of dialysis or transplanted prior to 1 year, who were placed on the transplant waiting list prior to their first dialysis treatment.

Rationale: Renal transplantation is associated with significantly improved survival versus continued dialysis in suitable patients. Several months is typically required to provide adequate counselling to patients, consideration of living donor options as well as assessment of their cardiovascular and other risks. Moreover the possibility of pre-emptive transplantation (before the initiation of dialysis) should be considered. Patients may be placed on the waiting list for a renal transplant up to 6 months before the expected start of dialysis. Part 1 of the Renal NSF therefore emphasizes the need for evaluation and preparation for possible transplantation to begin prior to initiation of dialysis in order to minimise the time that dialysis is required prior to transplantation and to facilitate pre-emptive transplantation ¹.

- 1. Department of Health. National Service Framework for Renal Services, Part
 - 1: Dialysis and Transplantation. 2004.

Nephrology Units should provide or facilitate the optimal management of patients with established renal failure who opt for non-dialytic treatment (good practice).

Audit Measure: Proportion of patients who die after opting for non-dialytic treatment, in whom there is evidence of a treatment plan or referral to Primary Care with a treatment plan.

Rationale: It is recognised that in some patients the risks and likely increase in morbidity associated with dialysis outweigh the potential benefits. Other patients decline dialysis treatment for a variety of reasons. Non-dialytic treatment of patients with established renal failure should be regarded as a specific management option and not as "no treatment". This implies that patients should continue to receive regular follow-up and have a clear treatment plan. Management goals should include prolonging survival where possible and optimising quality of life. The treatment plan should also include timely arrangements for palliative and end of life care. Such arrangements should be made in close consultation with patients and their families. The importance of adequate planning for end of life care and patient involvement in decision making has been emphasized in Quality Requirement Four of Part 2 of the Renal National Service Framework¹. Non-dialytic treatment may be delivered in Primary Care or by Nephrology Units, depending on a patient's wishes and resources available. If patients are transferred back to Primary Care for non-dialytic management it is important that Nephrology Units liase with General Practitioners to produce a clear treatment plan and offer support when required.

- 1. Department of Health. National Service Framework for Renal Services, Part
- 2: Chronic Kidney Disease, Acute Renal Failure and End of Life Care. 2005.