NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Chronic kidney disease: Early identification and management of chronic kidney disease in adults in primary and secondary care.

1.1 Short title

Chronic kidney disease.

2 The remit

This is a partial update of 'Chronic kidney disease' (NICE clinical guideline 73). See section 4.3.1 for details of which sections will be updated. We will also carry out an editorial review of all recommendations to ensure that they comply with NICE's duties under equalities legislation.

This update is being undertaken as part of the guideline review cycle.

3 Clinical need for the guideline

3.1 Epidemiology

The classification of chronic kidney disease (CKD) developed by the Kidney Disease Outcome Quality Initiative (KDOQI) in 2002 provided a research focus for the last decade which has greatly improved understanding of CKD, its complications and the impact of CKD on healthcare resources.

CKD has been defined as evidence of reduced estimated glomerular filtration rate (eGFR) and/or structural or functional abnormalities other than GFR, sustained for at least 3 months. The early detection of CKD in England and Wales has been facilitated by the implementation of routine reporting of eGFR nationally, introduction of CKD indicators in the Quality and Outcomes Framework, increased awareness and education through guideline development and implementation, and local awareness-raising initiatives.

The KDOQI classification defines five stages of CKD using a reduction in GFR and the presence of other markers of kidney damage, such as albuminuria or haematuria. Normal kidney function is defined as an eGFR ≥ 90 ml/min/1.73 m^2 with no other evidence of kidney damage. This classification was included in the previous Chronic kidney disease guideline (NICE clinical guideline 73) but stage 3 CKD was subdivided into 3A (GFR 45-59 ml/min/1.73 m^2) and 3B (GFR 30-44 ml/min/1.73 m^2), which has been now adopted internationally. The suffix 'p' in all stages to denote significant proteinuria was also introduced in the previous version of this guideline (Table 1).

Table 1: NICE CKD classification

Stage	eGFR (ml/min/1.73 m^2)	Description	Qualifier
1	≥ 90	Kidney damage, normal or increased GFR	Kidney damage (presence of structural abnormalities and/or persistent haematuria, proteinuria or microalbuminuria) for ≥ 3 months
2	60-89	Kidney damage, mildly reduced GFR	
3A	45-59	Moderately reduced GFR ± other evidence of kidney damage	GFR < 60 ml/min for ≥ 3 months ± kidney damage
3B	30-44		
4	15-29	Severely reduced GFR ± other evidence of kidney damage	
5	< 15	Established kidney failure	

Use the suffix (p) to denote the presence of significant proteinuria when staging CKD (albumin:creatinine ratio (ACR) ≥ 30 mg/mmol, or protein:creatinine ratio (PCR) ≥ 50 mg/mmol)

CKD is recognised as a global public health problem. Adult (age 18 years and older) prevalence studies from the USA and Norway show a broadly similar prevalence of around 10-13%. In the UK, stage 3-5 CKD, an eGFR less than 60 mL/min/1.73 m^2, has been widely used in prevalence estimates. The two largest studies, using different methodologies, reported an adult prevalence of CKD stage 3-5 in the general population of between 6.1 to 8.5%. The only study reporting overall adult prevalence of CKD in the UK comes from the Health Survey for England 2009 (a much smaller study in terms of number of participants but a representative population). Male prevalence of CKD was 14% and female 13%. In keeping with other studies the prevalence rose with increasing age, rising to 44% of men and 43% of women aged 75 years and over. Although the prevalence of end-stage renal disease is known to be increased in certain minority ethnic groups, the prevalence of

CKD does not differ by ethnicity. Age, hypertension and diabetes are key predictors of new-onset CKD.

The main risk associated with CKD is cardiovascular morbidity and mortality. Other important complications include those related to decreased GFR, acute kidney injury, infection, cognitive impairment, impaired physical function and progression of kidney disease. Complications may occur at any stage, often leading to death without progression to kidney failure. Complications may also arise from adverse effects of interventions to prevent or treat the disease and associated comorbidity. The risk for any adverse outcome increases with lower GFR and is multiplied by co-existent proteinuria.

The goals of early identification and management of CKD are to alleviate the risk of associated adverse outcomes and prevent progression and complications, therefore improving patient outcomes and reducing the impact of CKD on healthcare resources.

3.2 Current practice

Implementation of the evidence-based Chronic kidney disease guideline (NICE clinical guideline 73) has significantly improved identification of CKD, and increased awareness and understanding of the potential associated adverse outcomes. This required the development, implementation and integration of new policies, models and pathways of care. CKD has gone from an under-recognised condition in primary care prior to 2006, to one where those affected are recorded in disease registers and increasingly managed in accordance with evidence-based guidance.

CKD indicators were introduced in the primary care Quality and Outcomes Framework (QOF) in April 2006. These stated a requirement for primary care to produce a register of adults with stage 3-5 CKD, to measure and record blood pressure annually, and to record the percentage of people with CKD, hypertension and proteinuria on treatment with angiotensin-modulating drugs. The CKD indicators have been modified and updated in successive years, and from April 2009, include the percentage of patients on the CKD register with urine albumin:creatinine ratio (ACR) or protein:creatinine ratio (PCR) measures recorded within the previous 15 months (see Appendix, Table 2).

In the QOF Framework report for 2010/11, 8245 general practices in England are included in the published results, covering almost 100% of registered patients in

England. Ascertainment of CKD stage 3-5 in adults aged 18 and older has improved from 2.4% of the population, immediately following introduction of CKD indicators, to 4.3% in the latest report. Nevertheless, considerable variation in practice still occurs and ascertainment is not yet reaching the prevalence expected from epidemiological study. Lower socioeconomic status is associated with late referral and more severe CKD at time of presentation.

Definition, and recognition, of progression of CKD are areas of uncertainty. Practitioners will commonly have to decide whether or not a change in GFR is a true change based on a few recent GFR or serum creatinine measurements. Although this may be straightforward in those who follow a linear pattern of progression over time these people are in the minority. In many people with CKD non-linear patterns and extended periods of non-progression are common. Whatever the pattern of progression, there will be time-varying risk factors such as blood pressure control, medical events and medicines management that affect a person's risk of progression. For example, episodes of acute kidney injury are associated with increased likelihood of progression of existing CKD and with subsequent development of new-onset CKD.

Improved recognition of CKD has seen the late referral of patients with end-stage kidney failure fall from over 30% to 19% in the latest UK Renal Registry Report, and in the past 4 years renal replacement therapy acceptance rates have been stable at 109 per million of the population. Nevertheless further improvements can be made.

4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

a) Adults (18 years and older)

b) Consideration will be given to the needs of subgroups:

- Older people (75 years and older)
- Black and minority ethnic people (BME) where these differ from the needs of the general population
- People at high risk of developing CKD (for example, people with: diabetes, hypertension, cardiovascular disease, or people recovering from acute kidney injury).

4.1.2 Groups that will not be covered

a) People receiving renal replacement therapy (RRT)

b) People with acute kidney injury and rapidly progressive glomerulonephritis

c) Children and young people under 18 years

d) Pregnant women.

4.2 Healthcare setting

a) Primary and secondary NHS healthcare, including referral to tertiary care.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

Areas from the original guideline that will be updated

Investigation of CKD:

a) Measurement of kidney function and markers of kidney damage, for example using creatinine-based and cystatin C-based equations.

b) Frequency of monitoring.

Classification and early identification:

c) Classification of CKD.

Self management:

d) Dietary interventions such as a low protein diet in people with CKD.

e) Effectiveness of self-management support systems for people with CKD including relevant information and support.

Blood pressure control:

f) The choice of renin-angiotensin-aldosterone system antagonists including aldosterone antagonists in people with CKD.

Reducing cardiovascular disease:

g) Efficacy and safety of antiplatelet and antithrombotic therapy (for example, aspirin, ticagrelor, clopidogrel, dabigatran and warfarin) in people with CKD.

Asymptomatic hyperuricaemia:

h) Uric acid lowering therapy in people with CKD.

Specific complications of CKD – renal bone disease:

i) Vitamin D supplementation in the management of renal bone disease in people with CKD.

Areas not in the original guideline that will be included in the update

j) The risk of developing CKD after an episode of acute kidney injury.

k) The management of acidosis with bicarbonate supplementation in people with CKD.

4.3.2 Clinical issues that will not be covered

Areas from the original guideline that will be not be updated

No new evidence has been identified to directly change the 2008 recommendations on:

a) Investigation of CKD: indications for renal ultrasound.

b) Defining progression of CKD and the risk factors associated with progression.

c) Blood pressure control: practicalities of treatment with ACE inhibitors/ARBs.

d) Managing isolated microscopic haematuria.

e) Specific complications of CKD: anaemia.

f) Information and support for people and their carers (except for that relating to self-management support systems).

Areas not covered by the original guideline or the update

a) The treatment of each of the specific causes of CKD, such as glomerular and tubulointerstitial disease, or nephrotic syndrome.

b) Management of pregnancy in women with CKD.

c) Management of anaemia in people with CKD.

d) Management of acute kidney injury in people with CKD.

4.4 Main outcomes

a) Mortality (all cause and cardiovascular).

b) Hospitalisation.

c) Cardiovascular disease.

d) Progression of CKD.

e) Complications of CKD.

f) Patient safety (serious adverse events).

g) Health-related quality of life.

4.5 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of

the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see ‘Further information’).

4.6 Status

4.6.1 Scope

This is the final scope.

4.6.2 Timing

The development of the guideline recommendations will begin in September 2012.

5 Related NICE guidance

5.1 Published guidance

5.1.1 NICE guidance to be updated

This guideline will update and replace the following NICE guidance:

- Chronic kidney disease. NICE clinical guideline 73 (2008).

5.1.2 NICE guidance to be incorporated

None.

5.1.3 Other related NICE guidance

- Patient experience in adult NHS services. NICE quality standard (2012).
- Patient experience in adult NHS services. NICE clinical guideline 138 (2012).
- Early identification and management of chronic kidney disease in adults. NICE commissioning guideline 37 (2012).
- End of life care for adults. NICE quality standard (2012).
- Chronic kidney disease. NICE review decision (2011).
- Hypertension. NICE clinical guideline 127 (2011).
- Peritoneal dialysis. NICE clinical guideline 125 (2011).
- Chronic kidney disease. NICE quality standard (2011).
- Diabetes in adults. NICE quality standard (2011).

- Anaemia management in people with chronic kidney disease. NICE clinical guideline 114 (2011).
- Chronic heart failure. NICE clinical guideline 108 (2010).
- Prevention of cardiovascular disease. NICE public health guidance 25 (2010).
- Medicines adherence. NICE clinical guideline 76 (2009).
- Depression in adults with a chronic physical health problem. NICE clinical guideline 91 (2009).
- Febuxostat for the management of hyperuricaemia in people with gout. NICE technology appraisal 164 (2008).
- Type 2 diabetes. NICE clinical guideline 66, partially updated by CG87 (2008).
- Lipid modification. NICE clinical guideline 67 (2008).
- Cinacalcet hydrochloride for the treatment of secondary hyperparathyroidism in patients with end stage renal disease on maintenance dialysis therapy. NICE technology appraisal 117 (2007).
- Brief interventions and referral for smoking cessation. NICE public health guidance 1 (2006).
- Type 1 diabetes. NICE clinical guideline 15 (2004).
- Guidance on home compared with hospital haemodialysis for patients with end-stage renal failure. NICE technology appraisal 48 (2002).

5.2 Guidance under development

NICE is currently developing the following related guidance (details available from the NICE website):

- Osteoporosis fragility fracture risk. NICE clinical guideline 146. Publication expected August 2012.
- Acute kidney injury. NICE clinical guideline. Publication expected August 2013.
- Type 1 diabetes (update). NICE clinical guideline. Publication expected July 2014.
- Type 2 diabetes (update). NICE clinical guideline. Publication date to be confirmed.
- Lipid modification (update). NICE clinical guideline. Publication date to be confirmed.
- Management of hyperphosphataemia. NICE clinical guideline. Publication date to be confirmed.

6 Further information

Information on the guideline development process is provided in the following documents, available from the NICE website:

- 'How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS'.
- 'The guidelines manual'.

Information on the progress of the guideline will also be available from the NICE website.

Appendix

Table 2: Quality and Outcomes Framework CKD Indicators, Points Available and Practice Underlying Achievement 2008-2011 (reproduced from: Stevens et al. NDT 2012)

Indicator	Points Available	Underlying Achievement (All Practices)		
		2008/2009	2009/2010	2010/2011
CKD 1: The practice can produce a register of patients aged 18 years and over with CKD (US National Kidney Foundation: Stage 3 to 5 CKD). (R)	6	(Ascertained CKD prevalence 4.1%)	(Ascertained CKD prevalence 4.3%)	(Ascertained CKD prevalence 4.3%)
CKD 2: The percentage of patients on the CKD register whose notes have a record of blood pressure in the previous 15 months. (P)	6	97.5%	97.6%	97.5%
CKD 3: The percentage of patients on the CKD register in whom the last blood pressure reading, measured in the previous 15 months, is 140/85 or less. (IO)	11	73.3%	73.9%	74.2%
CKD 5: The percentage of patients on the CKD register with hypertension and proteinuria who are treated with an angiotensin converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB) (unless a contraindication or side effects are recorded). (P-T-O)	9*	87.3%	91.8%	90.5%
CKD 6: The percentage of patients on the CKD register whose notes have a record of a urine albumin: creatinine ratio (or protein: creatinine ratio) test in the previous 15 months. (P)	6†	-	77.7%	82.2%

*increased from 4 points to 9 points in 2009; †introduced in 2009

R = register, P = process, IO = intermediate outcome, P-T-O = process linked to outcome