NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

QUALITY AND OUTCOMES FRAMEWORK (QOF) INDICATOR DEVELOPMENT PROGRAMME

Briefing paper

QOF indicator area: Chronic kidney disease

Potential output: Review of QOF CKD indicators

Date of Primary Care QOF Indicator Advisory Committee meeting: 11 & 12 June 2014

Contents

Introduction

As part of the NICE process for ensuring current QOF indicators remain up to date with the evidence base the NICE indicator team reviewed the soon to be published updated NICE clinical guideline on chronic kidney disease (CKD) due for publication in July 2014. This guideline updates and replaces 'Chronic kidney disease' (NICE clinical guideline 73).

The updated NICE guideline was reviewed to assess the potential impact on the current QOF CKD indicator set. In light of this review the current QOF indicators CKD001[1] and CKD003[2] and requires consideration by the Advisory Committee (AC). This briefing paper presents an assessment of NICE clinical guideline recommendations relevant to these indicators.

Topic suggestion

The recommendations quoted within this paper are taken from the unpublished guideline (available on request). The draft guidance (pre-consultation) and the underlying evidence are available from:

- Chronic kidney disease (update): guideline consultation

Classification of CKD

The soon to be published updated NICE guideline for CKD recommends that CKD should be classified using a combination of GFR and ACR categories. Previously CG73 recommended classification using the US National Kidney Foundation classification system as incentivised in current QOF indicator CKD001 for stages 3 to 5.

> *CKD001: The contractor establishes and maintains a register of patients aged 18 or over with CKD (US National Kidney Foundation: Stage 3 to 5 CKD)*

[1] 2014/15 QOF indicator CKD001: The contractor establishes and maintains a register of patients aged 18 or over with CKD (US National Kidney Foundation: Stage 3 to 5 CKD

[2] 2014/15 QOF indicator CKD003: The percentage of patients on the CKD register with hypertension and proteinuria who are currently treated with an ACE-I or ARB

Choice of antihypertensive agent

The soon to be published updated NICE guideline also replaces the term 'ACE inhibitor/ARB therapy' with 'renin-angiotensin system antagonists' to include renin inhibitors in addition to ACE inhibitors and ARBs (the 3 classes of renin-angiotensin system antagonists are ACE inhibitors, ARBs and direct renin inhibitors). The previous clinical guideline for CKD recommended treatment with ACE-I or ARB for people with CKD and hypertension and an ACR 30 mg/mmol or more as incentivised by QOF indicator CKD003:

> *CKD003: The percentage of patients on the CKD register with hypertension and proteinuria who are currently treated with an ACE-I or ARB*

The soon to be published updated NICE guideline for CKD recommends low-cost renin-angiotensin system antagonist for these people. In light of these changes there is a need for the Committee to review current QOF indicators CKD001 and CKD003 against the updated NICE guideline.

Overview of chronic kidney disease

Epidemiological summary

Definition

CKD describes abnormal kidney function and/or structure. It is common, frequently unrecognised and often exists together with other conditions (for example, cardiovascular disease and diabetes). CKD is usually asymptomatic, however, because of a lack of specific symptoms people with CKD are often not diagnosed, or diagnosed late when CKD is at an advanced stage. The update of the NICE clinical guideline for CKD reviews the classification of CKD. The soon to be published updated NICE guideline for CKD recommends classifying CKD using a combination of GFR and ACR categories (see appendix B).

Incidence, prevalence and evidence of variation by age, sex and ethnicity

The risk of developing CKD increases with age. The prevalence of established renal failure is also higher amongst the black and minority ethnic communities, in comparison to Caucasian populations.

Morbidity and mortality

As kidney dysfunction progresses some coexisting conditions become more common and increase in severity. Moderate to severe CKD is associated with an increased risk of other significant adverse outcomes such as acute kidney injury, falls, frailty and mortality. CKD can progress to established renal failure in a small but significant percentage of people. There is evidence that treatment can prevent or delay the progression of CKD, reduce or prevent the development of complications, and reduce the risk of cardiovascular disease. It is estimated that approximately 7000 excess strokes and 12,000 excess myocardial infarctions occurred in people with CKD in 2009–10 (relative to an age- and gender-matched population without CKD).

Impact on health services

Primary care

Patients with CKD form a significant part of general practice workload. The 2012/13 QOF prevalence for the CKD register (people aged 18 years and over) was 4.3% for England.

Secondary care

The total cost of CKD in England in 2009–10 was estimated at between £1.44 and £1.45 billion, which was approximately 1.3% of all NHS spending for 2009-10. More than half of this amount was spent on renal replacement therapy for the 2% of people with CKD who progress to renal failure. This highlights the importance of early identification and prevention of progression. Excess strokes and myocardial infarctions in people with CKD are estimated to cost between £174 and £178 million.

Current management in primary care

Primary care plays a significant role in the diagnosis of CKD. Diagnosis of people with kidney disease has improved since the introduction of national estimated GFR reporting and QOF CKD indicators. GPs also play an important role in the prevention of CKD progression, reducing or preventing the development of complications, and reducing the risk of cardiovascular disease.

NHS priorities and timeliness of guidance

The following national clinical guidelines, policy documents and national strategies were thought relevant to CKD to provide an assessment of the timeliness of indicators for the secondary prevention of CKD.

- National Institute for Health and Care Excellence, Early identification and management of chronic kidney disease in adults in primary and secondary care (update). Clinical guidelines, in progress, due July 2014

- National Institute for Health and Care Excellence Acute kidney injury: Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy. Clinical guidelines, CG169, August 2013.

- National Institute for Health and Care Excellence, Management of hyperphosphataemia in patients with stage 4 or 5 chronic kidney disease. Clinical guidelines, CG157, March 2013

- The Scottish Primary Care Collaborative (August 2010) Section 6 - Improving Care for People with Chronic Kidney Disease

- Department of Health (January 2004) National service framework: kidney disease

- National Institute for Health and Care Excellence, Peritoneal dialysis in the treatment of stage 5 chronic kidney disease. Clinical guidelines, CG125, July 2011

- NICE Pathway (May 2011 updated October 2013) Anaemia of chronic kidney disease

- British Society for Paediatric Endocrinology and Diabetes (November 2011) Growth Monitoring Guidelines for Children with Chronic Kidney Disease

- UK Screening Portal (April 2011) The UK NSC policy on kidney disease screening in adults

- Guidelines and Audit Implementation Network (February 2010) Northern Ireland guidelines for management of chronic kidney disease: practical points for use of estimated GFR and quality framework indicators

Review of recommendations

Summary of NICE guideline recommendations

Two recommendations from the soon to be published NICE clinical guideline for CKD has been identified as being relevant to QOF indicators CKD001 and CKD003 and which may potentially inform any subsequent indicator development.

Classification of CKD

Draft NICE recommendation 1.2.1

Classify CKD using a combination of GFR and ACR categories (see appendix B). Be aware that:

- increased ACR is associated with increased risk of progression
- decreased GFR is associated with increased risk of progression
- increased ACR and decreased GFR in combination multiply the risk of progression. **[new 2014]**.

Pharmacotherapy

Choice of antihypertensive agent

Draft NICE recommendation 1.6.3

Offer a low-cost renin-angiotensin system antagonist to people with CKD and:

- diabetes and an ACR of 3 mg/mmol or more
- hypertension and an ACR of 30 mg/mmol or more
- an ACR of 70 mg/mmol or more (irrespective of hypertension or cardiovascular disease). **[new 2014]**

Evidence summary

This is a summary of the evidence supporting the recommendations presented above. This section relates to the evidence summary table in appendix A of this briefing paper.

Clinical evidence

Classification of CKD

The previous clinical guideline recommended the subdivision of CKD stage 3 into 3a (GFR 45–59 ml/min/1.73 m2) and 3b (30–44 ml/min/1.73 m2). The GDG for the soon to be published updated guidance recommends further classification by the three ACR categories (ACR under 3 mg/mmol, 3–30 mg/mmol, and over 30 mg/mmol) for each GFR category (see appendix B).

The GDG noted evidence showing that all outcomes are significantly worse in people with an ACR of greater than 3 mg/mmol for all ages. The GDG also noted evidence of worse outcomes in all ages for people with an ACR of less than 3 mg/mmol and an eGFR of less than 60 ml/min/1.73 m2 for all ages.

The GDG also considered the use of the term ‘microalbuminuria’ to denote an ACR of 3-30 mg/mmol. However after consideration they felt an ACR value of greater than 3mg/mmol was considered to be clinically important proteinuria

and proposed adopting 3 categories of proteinuria: <3 mg/mmol, 3-30 mg/mmol, and >30 mg/mmol to classify CKD

The GDG considered that the updated recommendation and further classification of CKD using a combination of GFR and ACR categories will have a high impact on outcomes that are important to patients and set challenging but achievable expectations of health services.

Choice of antihypertensive agent

The previous clinical guideline for CKD recommended an offer of ACE inhibitors/ARBs to non-diabetic people with CKD and hypertension and ACR 30 mg/mmol or more.

The GDG noted low quality clinical evidence showing some difference in the occurrence of end-stage-renal disease, cardiovascular morbidity, and change in proteinuria and were wary of recommending one class of drug over the other based on this evidence. Instead, the GDG felt the drug with the lowest acquisition cost in each drug class should be the prescription choice.

Cost effectiveness

Classification of CKD

Due to the clinical nature of the classification of CKD, economic evaluations were not applicable.

Choice of antihypertensive agent

The GDG acknowledged that current price differentiations between ACE-I and ARB drug classes are likely to diminish as ARBs come off patent in the near future and considered it sufficient to recommend first line therapy as the drug with the lowest acquisition cost.

Assessment of recommendations against current practice

Current practice

Since the introduction of national estimated GFR reporting and QOF CKD indicators alongside increased public and health professional awareness of CKD, the late presentation of people with advanced kidney disease has improved. However the latest UK Renal Registry reports suggest late presentation of CKD remains at 19%[3]. Strategies aimed at earlier identification and (where possible) prevention of progression to established renal failure are therefore a high priority.

Health inequalities

The risk of developing CKD increases with age. The prevalence of established renal failure is also higher amongst the black and minority ethnic communities, in comparison to Caucasian populations. However, there is no evidence presented in the NICE guideline that directly shows that the recommendations outlined in this briefing paper can reduce health inequalities. [Relevance to inequalities: medium].

Will implementation of these recommendations lead to cost-effective improvements in the delivery of primary care?

These recommendations based on up to date evidence of clinical effectiveness and are likely to represent a minor-moderate shift in current practice.

Initial feasibility assessment

Currently CKD001 provides a register of people with CKD stage 3-5 adopting the US National Kidney Foundation classification of CKD. The soon to be published updated clinical guideline recommends that CKD should be further

[3] Gilg J, Rao A, and Fogarty D. UK Renal Registry 16th annual report: chapter 1 UK renal 6 replacement therapy incidence in 2012: national and centre-specific analyses, 2013.

classified using a combination of GFR and ACR categories. The further classification may result in the re-classification of some people with CKD and consideration needs to be given as to whether this warrants indicator development and piloting.

Currently CKD003 incentivises treatment with ACE-I or ARB for people with CKD and hypertension and proteinuria. The soon to be published updated NICE guideline recommends renin inhibitors in addition to ACE inhibitors/ARBs. The original levels of proteinuria in this subgroup (ACR 30 mg/mmol or more) remain the same. New codes may be required to account for the potential changes in drugs prescribing and consideration needs to be given as to whether this warrants indicator development and piloting.

Key considerations

The following key considerations summarise the main points made in the briefing paper and should be used by the Committee in their discussions.

- The classification of CKD is likely to change following publication of the updated NICE clinical guideline for CKD. Currently the QOF adopts the US National Kidney Foundation Kidney Disease classification. NICE is likely to recommend classification using a combination of GFR and ACR categories.
- Renin inhibitors in addition to ACE inhibitors/ARBs are also recommended in the updated NICE clinical guideline for CKD.
- The Committee is asked to consider whether QOF indicators CKD001 and CKD003 should be amended to reflect the soon to be published NICE clinical guideline for CKD and whether these changes warrant piloting and development.

Appendix A: Evidence summary

	Recommendation	Level of evidence	Key outcomes considered (for interventions)	Specific considerations highlighted by guideline developers	Cost-effectiveness evidence
Classification of CKD	1.2.1	Meta-analysis	• CKD progression (measured by change in eGFR and occurrence of end stage renal disease) • All-cause mortality, • Cardiovascular mortality • Acute kidney injury (AKI).	The GDG for the soon to be published updated guideline on CKD felt an accurate and clear classification of CKD is vital for appropriate management and treatment of CKD. The GDG considered that in terms of risk of progression, mortality or risk of developing AKI, there was no difference between CKD stages 1 and 2 in the existing classification system. However the GDG felt it would be inappropriate to combine stages 1 and 2 due to the confusion it may cause clinicians and people already diagnosed. The GDG agreed recommendation 1.2.1 would have a high impact	Due to the clinical nature of the classification of CKD economic evaluations were not applicable. However, the GDG felt that the inclusion of factors that increase the risk of CKD progression and/or associated adverse outcomes within the classification of CKD does not in increase the costs of CKD management. They added that doing so facilitates more appropriate CKD treatment which can help reduce cost and health consequences.

	Recommendation	Level of evidence	Key outcomes considered (for interventions)	Specific considerations highlighted by guideline developers	Cost-effectiveness evidence
				on outcomes. ACR is an independent risk factor for adverse outcomes in people both with and without diabetes mellitus and hypertension. The GDG noted evidence that the risk associated with albuminuria rises with increasing ACR and is evident at levels below 3mg/mmol. The GDG noted that all outcomes were significantly worse in people with ACR>3 mg/mmol (reported in the evidence as 30 mg/g), this held true for those aged both >65 and <65. Similarly in those with ACR<3 mg/mmol all outcomes were significantly worse for those with eGFR<60 ml/min/1.73 m2, again irrespective of age.	

	Recommendation	Level of evidence	Key outcomes considered (for interventions)	Specific considerations highlighted by guideline developers	Cost-effectiveness evidence
Choice of antihypertensive agent	1.6.3	Meta-analysis/ RCTs	• Progression of CKD (measured by change in eGFR or occurrence of end stage renal disease), • mortality (all-cause or cardiovascular), • cardiovascular events • occurrence of AKI	No evidence of differences in effects of antihypertensive at different levels of proteinuria was found. The GDG therefore agreed that the original guideline recommendation considerations for proteinuria should remain. It was noted that in primary care, the majority of patients with CKD will have no proteinuria. The GDG noted that for people with non-diabetic CKD and no proteinuria, the NICE hypertension guidelines should be followed.	The GDG concluded that there was a class effect for ACEs and ARBs and that within each drug class, drugs with greater acquisition costs were unlikely to confer additional clinical benefits compared to those with lower acquisition costs. The GDG acknowledged that current price differentiations between ACE-I and ARB drug classes are likely to diminish as ARBs come off patent in the near future and considered it sufficient to recommend first line therapy as the drug with the lowest acquisition cost.

Appendix B: Classification of chronic kidney disease using GFR and ACR categories

GFR and ACR categories (including stages of CKD from previous guideline)			Albuminuria categories (mg/mmol)		
			<3 Normal to mildly increased	3–30 Moderately increased	>30 Severely increased
			A1	A2	A3
GFR categories (ml/min/1.73 m²)	≥90 Normal and high	G1 (Stage 1)	No CKD*	G1 A2	G1 A3
	60–89 Mild reduction related to normal range for a young adult	G2 (Stage 2)		G2 A2	G2 A3
	45–59 Mild–moderate reduction	G3a (Stage 3a)	G3a A1^	G3a A2	G3a A3
	30–44 Moderate–severe reduction	G3b (Stage 3b)	G3b A1	G3b A2	G3b A3
	15–29 Severe reduction	G4 (Stage 4)	G4 A1	G4 A2	G4 A3
	<15 Kidney failure	G5 (Stage 5)	G5 A1	G5 A2	G5 A3

Increasing risk

Increasing risk

** By definition, in the absence of evidence of kidney damage, these categories are not CKD.*

^ Consider using eGFRcystatinC to confirm the diagnosis of CKD in people with an eGFRcreatinine of 45–59 ml/min/1.73 m2, sustained for at least 90 days ***and*** *no proteinuria (albumin:creatinine ratio [ACR] less than 3 mg/mmol).*

Abbreviations: ACR, albumin:creatinine ratio; CKD, chronic kidney disease; GFR, glomerular filtration rate

Appendix C: Related QOF indicators

Related existing QOF indicators from 2014/15 indicator set

CKD relates to an existing QOF clinical domain as defined in the 2014/15 GMS Contract guidance. The QOF indicators for chronic kidney disease are outlined below.

QOF domain 2014/15: Chronic kidney disease (CKD)

Indicator	Points	Achievement thresholds
Records		
CKD001. The contractor establishes and maintains a register of patients aged 18 or over with CKD (US National Kidney Foundation: Stage 3 to 5 CKD)	6	
Ongoing management		
CKD002. The percentage of patients on the CKD register in whom the last blood pressure reading (measured in the preceding 12 months) is 140/85 mmHg or less	11	41-81%
CKD003. The percentage of patients on the CKD register with hypertension and proteinuria who are currently treated with an ACE-I or ARB	9	45-80%
CKD004. 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 preceding 12 months	6	45-80%

Related indicators from the NICE menu of indicators

There no CKD related indicators on the NICE menu of indicators, available from: http://www.nice.org.uk/aboutnice/qof/indicators.jsp

Related indicators under consideration by the Advisory Committee

There no CKD related indicators under consideration by the Advisory Committee.