NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Chronic kidney disease in adults

Date of quality standards advisory committee post-consultation meeting:
26 April 2017

2 Introduction

The draft quality standard for chronic kidney disease was made available on the NICE website for a 4-week public consultation period between 1 March and 28 March 2017. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 15 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the quality standards advisory committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the committee as part of the final meeting where the committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the committee should read this summary alongside the full set of consultation comments, which are provided in appendices 1-3.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be to be for these to be put in place?

3. Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.

4. Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please submit your example to the NICE local practice collection on the NICE website. Examples of using NICE quality standards can also be submitted.

Stakeholders were also invited to respond to the following statement specific questions:

For draft quality statement 1: Is the statement achievable and measurable, or would a narrower and more specific at-risk population be better?

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- Stakeholders supported the quality standard and felt that it includes the key areas for quality improvement.
- Concerns were raised around the removal of areas of care covered in the original quality standard (QS5). Stakeholders would like it to be made clearer how the updated priority areas were chosen and where else the previous areas of care are covered, for example in guidance.

Consultation comments on data collection

- IT arrangements will vary by CCG.
- Systems are in place to collect data but will require commitment and resources from primary care.

Consultation comments on resource impact

- There will be potential savings from a change in emphasis to preventative action from less people entering renal replacement therapy, needing kidney transplants and having reviews in nephrology services.
- There might be a lack of resource to deliver the statements, as well as additional costs from incentivising the prioritisation of early intervention.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

Adults with, or at risk of, chronic kidney disease (CKD) are offered eGFRcreatinine and albumin:creatinine ratio (ACR) testing at an agreed frequency. [2011, updated 2017]

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- Some concerns were raised that monitoring ‘at an agreed frequency’ is not precise enough, whilst others felt that this personalised approach would aid delivery of the statement.
- Stakeholders suggested distinguishing between those at risk and those with CKD, so that timeframes for each group are easier to determine.
- Difficulty in identifying the people who need monitoring in primary care: people with CKD are not having regular testing as they are not being put on CKD registers.
- Monitoring alone is not sufficient, appropriate action should also be taken in response.
- The need for accurate coding should be emphasised.
- Stakeholders suggested adding to the patient audience descriptor that information appropriate to the stage of CKD should be provided.
- Add people with Autosomal Dominant Polycystic Kidney Disease, people prescribed nephrotoxic medication and people on ACEi therapy with a rise in serum creatinine to the definition of ‘adults at risk of CKD’.
- Greater emphasis is needed on ACR and the different risk for CKD based on eGFR and ACR.
- Stakeholders suggested additional detail to add to the definition of ACR testing and the definition of ‘adults with CKD’.

Consultation question 5

Is the statement achievable and measurable, or would a narrower and more specific at-risk population be better?

Stakeholders made the following comments in relation to consultation question 5:

- The statement is achievable and measurable.
- Stakeholders suggested offering the option of no long-term monitoring to groups with low risk of progression.

5.2 Draft statement 2

Adults with chronic kidney disease (CKD) have their blood pressure (BP) maintained below the recommended target. [2011, updated 2017]

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- Stakeholders supported the statement and felt it is clear and measurable.
- There were concerns that the statement cannot be achieved for people with CKD who cannot tolerate hypotensive medications, and that frail people achieving the lower target would risk symptomatic hypotension.
- The lower limit of BP should be included.
- An additional data source for the outcome measures was suggested.
- Add detail to the patient audience descriptor on self-monitoring of BP, lifestyle changes and providing information.

5.3 Draft statement 3

Adults with chronic kidney disease (CKD) are offered atorvastatin 20 mg. [new 2017]

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Some stakeholders supported the statement and feel that it is clear and measurable, whereas others feel it is too restrictive and does not allow for personalised treatment.
- Stakeholders suggested amending the statement to allow a primary offer of atorvastatin and then an equivalent statin if that is not tolerated, and include discussion with the patient.
- There should be consideration of the risks and benefits of treatment, such as adverse events, and care should be personalised, for example statins might not be appropriate for frail or older people.
- Stakeholders queried who should be included in the population for this statement, such as people aged 18-49, people on dialysis and people aged 75 and over.
- Add detail on what to do if people with CKD are on a different statin.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- Psychosocial support due to a shortage of practitioners with the specialist knowledge needed and the high prevalence of psychological and social issues for people with CKD.
- Early testing and monitoring for renal anaemia.
- Provision of personalised information and a documented care plan, so that people with CKD can have a discussion with a healthcare professional and receive appropriate advice.

Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Statement number	Comments[1]
1	British Kidney Patient Association	General	This quality standard has removed 8 previous standards and there is no explanation of why this has been done. There is no mention of: education, care planning, referral to specialist care, psychosocial support, personalisation of care. The BKPA regrets this and would like NICE to reconsider; the proposed new standards do not do enough for kidney patients and simply removing the previous standards without explanation may lead primary care to believe that they are no longer considered important, especially as most of the QoF indicators for recording CKD status have been removed recently.
2	British Kidney Patient Association	General	We have highlighted the areas of greatest impact from removed quality standards. We accept that some of the areas are covered elsewhere. However please can you highlight clearly in the standards where these areas are covered e.g. link the retired anaemia standard to the anaemia guidance etc.
3	British Renal Society	General	The statements below from the 2011 version (numbered 2, 3, 4, 6, 7, 8, 9 and 10) are no longer considered national priorities for improvement but may still be useful at a local level. Could there be an explanation as to how this was decided? For example feedback from stakeholders.
4	Elcena Jeffers Foundation	General	NICE we are dealing with real life situation here. No one person are the same.
5	Merck Sharpe & Dohme	General	MSD welcomes the QS update
6	NHS England - Renal Services CRG	General	This quality standard has removed 10 previous standards and there is no explanation of the reason. There is no mention of education, care planning, referral to specialist care, psychosocial support, medication review or personalisation of care. The proposed new standards It would be very helpful to include an explanation if these areas are covered elsewhere e.g. to link the retired anaemia standard to the anaemia guidance etc.

[1]PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

ID	Stakeholder	Statement number	Comments[1]
7	Renal Psychologists Network (British Psychological Society)	General	We are concerned about the removal of quality statements 2, 3, 4, 6, 7, 8, 9 and 10. While it is appropriate to reduce replication, some of the statements which are to be removed are not covered elsewhere e.g. care-planning, referral to specialist services, psychosocial support. We wonder about the impact of removing these statements on patient care? What is the evidence that these statements are no longer a national priority?
8	Royal College of Nursing	General	Page 16: It would be helpful to know who has identified that *"some of these indicators are no longer considered national strategies for improvement"*. The last two priorities that have been removed are person-centred i.e. concern education/psychosocial care, and although might be more difficult to measure than quantitative biomedical measures, are of great value to patients.
9	Polycystic Kidney Disease Charity	Question 1	*Does this draft quality standard accurately reflect the key areas for quality improvement?* Yes, with the caveat of the comments above.
10	Renal Association	Question 1	Yes, but with an increased overall emphasis on ACR
11	Royal College of Nursing	Question 1	*"Does this draft quality standard accurately reflect the key areas for quality improvement?"* - The three key areas for quality improvement are important but the key area concerning *"People with progressive CKD whose eGFR is less than 20 ml/min/1.73 m2, and/or who are likely to progress to established kidney failure within 12 months, receive* ***unbiased personalised information*** *on established kidney failure and renal replacement therapy options"* from 2011 standard needs to be considered for inclusion (see comment 4 below)
12	Royal College of Physicians of Edinburgh	Question 1	The College agrees that this draft quality standard accurately reflects the key areas for quality improvement. The two strongest predictors of cardiovascular risk, renal progression, mortality and acute kidney injury (AKI) remain glomerular filtration rate (eGFR) and albumin creatine ratio (ACR). Also the strongest predictor of renal progression irrespective of aetiology remains blood pressure. Finally, statin therapy is associated with reduced cardiac adverse outcomes in chronic kidney disease (CKD) patients. The three statements are therefore welcome and in line with current "optimal practice". College Fellows did however note that a number of statements from the 2011 Quality Standard are no longer considered national priorities for improvement but agreed these may still be useful at a local level.

ID	Stakeholder	Statement number	Comments[1]
13	Polycystic Kidney Disease Charity	Question 2	*Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place?* The results as evidenced by the National Kidney Audit raise the prospect of enhancing local data collection. This will need commitment from the local commissioners and primary care to engage in data collection as a priority.
14	Renal Association	Question 2	This will vary by CCG based on current IT and pre-existing arrangements. The views of stakeholders in primary care are crucial for this question.
15	Royal College of Nursing	Question 2	*"Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place?"* - Local systems are in place
16	Royal College of Physicians of Edinburgh	Question 2	Most CKD is managed in primary care, certainly CKD 3, often without referral to nephrology services. This is appropriate as the key management revolves around CV risk management. In addition the identification of CKD is part of the QOF. The College does not have detailed insight into primary care systems. Theoretically, systems will be in place to identify the cohort and ensure compliance with testing at an agreed frequency. Whether GPs have the resource to focus on this area is another issue.

ID	Stakeholder	Statement number	Comments[1]
17	Polycystic Kidney Disease Charity	Question 3	*Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.* The average cost of dialysis is £20,000-30,000 per patient per year. The indicative cost of a kidney transplant (including induction therapy but excluding NHSBT costs) is £17,000 per patient per transplant. The immuno-suppression required by a patient with a transplant costs £5,000 per patient per year. The cost savings of reducing the number of individuals entering RRT are self-evident, particularly given that ADPKD patients start RRT at an earlier age than other groups of CKD patients. Moreover, recent ERA-EDTA data shows that ADPKD patients on RTT in Europe increased by 60% between the periods of 1991–1995 and 2006–2010 - mainly because patients are living longer because of a reduction in deaths due to cardiovascular disease, due in turn to better treatment of high blood pressure and other risk factors. To identify those at risk and intervene early enough to reduce the cost of RRT would need a higher degree of priority. This may involve additional costs in terms of incentivisation (replacement QoF) and investment in education and enhanced awareness amongst healthcare professionals, commissioners and individuals of the risks of undiagnosed ADPKD.
18	Renal Association	Question 3	It depends on what resources are currently being committed and how these are offset by the change in emphasis. To be able to answer this question would require detailed work with several CCGs.
19	Royal College of Physicians of Edinburgh	Question 3	The resources to deliver this service are in place but one would be concerned with the current pressure on services to deliver acute care for the benefit of patient safety, preventative and proactive services may suffer. QOF is currently in place to assess this and may need more refinement to ensure patients are identified and robust measures are in place to ensure there is adequate follow-up and monitoring. The frequency should remain as previously detailed in the NICE guidance. In terms of resource saving, it is possible to model the upfront costs against potential savings later in disease prevention – certainly dialysis is very expensive. Most patients with CKD 4 and 5 will be in nephrology services with frequent review. However not all hospitals have EPR as yet. As these patients are in a host of general nephrology clinics it is not clear how many hospitals would yet be in a position to be able to track the cohort in a systematic way. However it is certainly becoming more possible with EPR. For the small number on dialysis systems are generally in place to track the cohort effectively. This can be done by the systems analysts on all units without extra resource.

ID	Stakeholder	Statement number	Comments[1]
20	Polycystic Kidney Disease Charity	Question 4	*Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please submit your example to the NICE local practice collection on the NICE website. Examples of using NICE quality standards can also be submitted.* No
21	Royal College of Physicians of Edinburgh	Question 4	In some areas, Fellows have reported there is close working between the nephrologists and primary care in CKD with joint guidelines and forums for shared learning. In addition e-consultation services for GPs are in operation in some locations.
22	British Kidney Patient Association	Statement 1	Please also consider including two further data sources. a) Rightcare data for CCGs, which includes renal. See here https://www.england.nhs.uk/rightcare/intel/cfv/data-packs/ and b) the National Diabetes Audit which shows how many with diabetes are also tested for CKD http://content.digital.nhs.uk/nda
23	British Kidney Patient Association	Statement 1	ACR testing needs greater emphasis given data from the national audit showing low and incomplete testing rates on patients at clear risk. This should be a focus area for quality improvement, which local audit could support and be able to demonstrate whether the QS is being met. Service specifications alone will not provide this.
24	British Kidney Patient Association	Statement 1	Please can you consider strengthening the need for accurate coding. Again the CKD audit showed that patients with CKD are not consistently being coded and will therefore not be able to get the right monitoring.
25	British Kidney Patient Association	Statement 1	"Evidence of local arrangements to ensure that adults with, or at risk of, CKD agree the frequency of eGFRcreatinine and ACR testing with their healthcare professional" implies the existence of an arrangement that may or may not include a discussion with the patient within it. We ask NICE to consider retaining the careplan QS to cover the need for patients to discuss, understand and be able to act on advice given which will make no sense if arrangements are made without their involvement. Please see our note further down.
26	British Renal Society	Statement 1	Please also consider including two further data sources. a) Rightcare data for CCGs, which includes renal. See here https://www.england.nhs.uk/rightcare/intel/cfv/data-packs/ and b) the National Diabetes Audit which shows how many with diabetes are also tested for CKD http://content.digital.nhs.uk/nda

ID	Stakeholder	Statement number	Comments[1]
27	British Renal Society	Statement 1	ACR testing needs greater emphasis given data from the national CKD audit showing low testing rates on patients at clear risk. Consider further data source: http://content.digital.nhs.uk/nda which shows only 50% with type 1 DM, 66% Type 2 DM having urine albumin testing
28	British Renal Society	Statement 1	Adults who have, or may be at risk of, CKD: This section should include elements QS3 "People with CKD have a current agreed care plan appropriate to the stage and rate of progression of CKD", and QS6 "People with CKD are assessed for disease progression". We would like to see the QS including the need to provide people with CKD with information consistent with their stage of CKD with a documented plan of care
29	Diabetes UK	Statement 1	This statement is clear. But information on 'agreed frequency' of testing may be practically difficult to extract. It may be better to distinguish between adults with CKD, and those at risk in order to determine the frequency of testing. For example, people with diabetes are at risk of CKD which would suggest less often than annual monitoring compared to those with CKD. However, NICE care processes include annual monitoring for people with diabetes
30	NHS England - Renal Services CRG	Statement 1	This will require quite an extensive effort in primary care to identify these patients. Just monitoring them is not sufficient. It will be necessary to ensure that appropriate action is taken in response. The concept of "agreeing the timing" is too imprecise. Annual review is not sufficient for some of this subgroup. It is not clear how this standard will achieve the stated aim of "improving quality". Please also consider including two further data sources. a) Rightcare data for CCGs, which includes renal through the NCVIN. See here https://www.england.nhs.uk/rightcare/intel/cfv/data-packs/ and b) the National Diabetes Audit which shows how many with diabetes are also tested for CKD http://content.digital.nhs.uk/nda
31	Polycystic Kidney Disease Charity	Statement 1	We note that neither the National CKD Audit, which aims to improve the identification of chronic kidney disease (CKD) in primary care, understand and map the variations in patient outcomes and improve the consistency of the treatment of early stage CKD, nor the quality improvement project, ASSIST-CKD are significantly extensive to give complete data. There is concern on the overreliance of general practice to also give complete data, especially with the demise of QoF. This is a vital focus for quality improvement.

ID	Stakeholder	Statement number	Comments[1]
32	Polycystic Kidney Disease Charity	Statement 1	Autosomal Dominant Polycystic Kidney Disease (ADPKD) is the most common genetic renal disorder. It accounts for around 1 in 10 people on dialysis and 1 in 8 with a kidney transplant. The number of patients per full time general practitioner varies considerably in different areas, but if the average number of patients per GP is 1800, each GP could have one or two patients with ADPKD. There is considerable intra and interfamilial heterogeneity in the rate of ADPKD progression. Estimated glomerular filtration rate (eGFR) typically remains within normal range for many years despite a significant burden of cystic kidney disease because of compensatory hyperfiltration. Despite family histories, it is estimated that about 1 in 4 patients are diagnosed incidentally rather than by family or cascade screening techniques. Data on ADPKD patients on RRT are recorded on the UK Renal Registry. The first epidemiological study of UK Renal Registry data, covering period 1 Jan 2000 to 31 Dec 2011 (England and Wales) showed that the median age of commencing RRT was 55 years in the ADPKD group compared with 62 and 66 years in those with diabetes or 'other' PRD, respectively. The median age of starting RRT did not change within the ADPKD group over the 10-year period, despite the availability of reno-protective interventions for all patients with CKD over that period. Data on ADPKD pre-RRT patients is not systematically recorded. A national registry of ADPKD patients (RaDaR) was established in March 2016 aligned with the UK Renal Registry but recruitment is currently via secondary care. A large number of individuals with ADPKD remain undiagnosed in primary care, including young adults who may appear asymptomatic yet potentially have undiagnosed hypertension. Expert opinion is that 1 in 4 children has untreated hypertension with potentially high CVD risk in adulthood because ADPKD is often considered an 'adult' condition by clinicians and commissioners. ADPKD symptoms such as hypertension, renal and urinary tract infections, pain, aneurysms, can be managed by existing interventions, if care is timely. The new therapy (tolvaptan) delays ADPKD disease progression but is only available for use in selected patients after specialist assessment (2015 NICE TA 358) and requires a quality improvement focus to ensure uptake. Expert opinion is that ADPKD patients should have a baseline measurement of total kidney volume (TKV), to help with progression risk assessment and for inclusion in clinical trials and interventions such as tolvaptan. TKV is associated with eGFR decline and patients can potentially be stratified by age and height adjusted TKV. Gold standard for measuring TKV is MRI (stereology). However, in routine practice, ultrasound can be an appropriate surrogate. We therefore propose that this statement includes an explicit mention of ADPKD in the 'Adults at risk' section with additional reference to the 2015 NICE TA 358 guidance.

ID	Stakeholder	Statement number	Comments[1]
33	Renal Association	Statement 1	The specific question is – is the standard achievable and measurable?. Yes, with the caveat that there is still work to do on identification and monitoring, with a particular focus on ACR. The CKD classification system and primary care CKD registers have contributed to improvements, but a significant proportion of people with CKD who are not having regular testing (mainly because they have not been put on the CKD register despite having tests indicating CKD) The question about 'would a narrower and more specific at-risk population be better?' is discussed below and should be considered further.
34	Renal Association	Statement 1	With reference to 'evidence of local arrangements to ensure that adults…..agree the frequency of eGFRcreatinine and ACR testing with their healthcare professional'. Making the statement in a service specification is fine, but we would suggest that there should be an audit process (this should be locally defined and implemented in the first) to test if the QS is being applied, from the way it is written the quality measure is effectively asking for a statement in the patients care records that this has been discussed and agreed with the patient.
35	Renal Association	Statement 1	This should be stated in a service specification
36	Renal Association	Statement 1	Stage to include ACR testing
37	Renal Association	Statement 1	The majority of patients with stage 3-5 CKD have stage 3aA1 and are older people (>65). These patients have a negligible 5-year risk of progression to end-stage renal failure. Care should be taken in the QS to emphasise the major differential risk for CKD based on eGFR and ACR. We accept that this is a challenging area and anticipate that risk assessment will be further incorporated in the next update of the guideline. The major area of opportunity for QI in CKD now is around ACR testing and stratification of risk based on ACR. We would like consideration of a 12 monthly check of ACR in individuals with G3-G5 CKD and high or very high albuminuria as change in ACR is a very good risk marker and may identify a need for enhanced assessment and management (e.g. BP/glycaemic control).

ID	Stakeholder	Statement number	Comments[1]
38	Royal College of General Practitioners	Statement 1	Quality statement should include the fact that identification /diagnosis of CKD should be made on the basis of at least two eGFRs at least 3 months apart with ACR testing and CKD should be classified according to KDIGO/NICE guidelines. i.e. albuminuria assessment is an intrinsic part of CKD evaluation at diagnosis. (SF) Not giving timeframes for review is poor Data source (pg5)should ideally allow for people without diabetes to also have ACR assessed, which is often not done ACR testing (page 7) additional words should be added to sentence "can be used to assess progression of CKD *and risk of other complications"* as ACR is a predictor of CVD, hospital admission and AKI
39	Royal College of Physicians of Edinburgh	Statement 1	The list of adults at risk should also include those on long term medication such as NSAIDs (as detailed in recommendation 1.127) and with the recent publication of ACEI those on ACEi therapy who have experienced a 10% or more increase in serum creatinine on initiation. The latter point is critical as current guidelines on ACEi and monitoring on introduction appear not to be monitored. This is mentioned in the frequency of monitoring but the importance needs emphasis.
40	Polycystic Kidney Disease Charity	Question 5	In response to the question 5 for consultation; 'Is the statement achievable and measurable, or would a narrower and more specific at-risk population be better?' Our comments are below.
41	Renal Association	Question 5	The simple answer is yes – the majority of people with stage 3-5 CKD have stage 3a, and the majority of these are older people (>65) and have normal albuminuria (A1). The risk of end-stage renal failure for these individuals is negligible and can be checked in the Tangri calculator. One approach may be to state that older people with stable 3aA1 CKD and no other chronic disease comorbidities can be offered the option of no long-term monitoring, following discussion of risk. This would maintain the focus on ACR testing and may have health economic benefits.
42	Royal College of General Practitioners	Question 5	Response to question for consultation: this statement is achievable and measurable with the existing population
43	Royal College of Nursing	Question 5	"For draft quality statement 1: Is the statement achievable and measurable, or would a narrower and more specific at-risk population be better?" - It would be helpful to identify if the quality statement include the staging of albuminuria A1, A2 A3.

ID	Stakeholder	Statement number	Comments[1]
44	Royal College of Physicians of Edinburgh	Question 5	Fellows have indicated that the main issue is not whether the statements are achievable and measurable but their successful implementation. The current data available today indicates a sub-optimal achievement of these "targets". Based on previous data, <30% of patients at risk had an ACR (Guidelines 1.6.1. and 1.6.2) measured (e.g. hypertension, CVD, those at risk of CKD). This is an area requiring significantly more work to ensure delivery of this standard. The recommendation that the frequency of monitoring (eGFR creatiine and ACR) should be agreed with the person with, or at risk of, CKD and hence be individualised is a sensible approach to ensure it can be successfully delivered. With this in mind the validation of a risk equation for progression to end-stage renal failure is available for services to integrate into their pathways (http://kidneyfailurerisk.com/ and supporting references).
45	British Medical Association	Statement 2	This will not be a measure of quality at the level of a population because in many patients with CKD the ability to obtain control below the suggested level is limited by their tolerance of hypotensive medications, rather than the quality of the care offered. The ability to exception report for this would be required.
46	British Medical Association	Statement 2	Many patients with CKD are frail and the targets cannot be achieved without risking symptomatic hypotension or the risks associated with polypharmacy in this group.
47	British Renal Society	Statement 2	What the quality statement means for different audiences: Adults with CKD are supported to keep their blood pressure at a healthy level. We recommend that this include an emphasis on self -monitoring of BP and engagement with lifestyle changes. There is nothing included on information given to patients about BP or relating to people with Diabetes & CKD Consider further data source: http://content.digital.nhs.uk/nda which shows only 50% with type 1 DM, 66% Type 2 DM having urine albumin testing
48	Diabetes UK	Statement 2	This statement is clear and measurable
49	NHS England - Renal Services CRG	Statement 2	This seems sensible and distinguishes a higher risk group (group B) for tighter BP control
50	Polycystic Kidney Disease Charity	Statement 2	Hypertension is the earliest manifestation of ADPKD and is preferentially managed with ACE inhibitors or angiotensin receptor antagonists. We welcome the inclusion of a lower target, but question if the target range is sufficiently low for ADPKD patients? In the HALT-PKD trial, rigorous blood pressure control (95/60-110/75 mm Hg) was associated with a significantly lower annual rate of increase in TKV compared with a standard BP target (120/70-130/80 mm Hg).

ID	Stakeholder	Statement number	Comments[1]
51	Renal Association	Statement 2	Supported as written
52	Royal College of General Practitioners	Statement 2	Outcomes data source d) Incidence of end stage kidney disease should include UK Renal Registry data as well as local data collection Whilst correctly focussing on maintaining blood pressure below the recommended target, there should be consideration of advise about minimum BP levels where there is excess mortality.
53	Royal College of Physicians of Edinburgh	Statement 2	For blood pressure the targets remain contentious given the recent SPRINT study but from a pragmatic perspective the current targets are more achievable on a global scale. There should be a drive to encourage home monitoring and developing targets for these measures. Previous data demonstrates that only 29% of people with CKD G3-5 met their BP target of <130/80 mmHg. In addition, the NICE CG182 Recommendation 1.6.6 and 1.6.7 To improve concordance, inform people who are prescribed renin–angiotensin system antagonists about the importance of: • achieving the optimal tolerated dose of renin–angiotensin system antagonists and • monitoring eGFR and serum potassium in achieving this safely • In people with CKD, measure serum potassium concentrations and estimate the GFR before starting renin–angiotensin system antagonists. Repeat these measurements between 1 and 2 weeks after starting renin–angiotensin system antagonists and after each dose increase. This needs more work to deliver successfully, especially in primary care (Valente M, Bhandari S. A rise in serum creatinine on initiating ACEi/ARB: warning signal or treatment effect? BMJ 2017 editorial in reference to Schmidt, M., Mansfield, K. E., Bhaskaran, K., et al. Serum creatinine elevation following renin-angiotensin system blockade and long-term cardiorenal risks: a cohort study, BMJ 2017).
54	British Kidney Patient Association	Statement 3	This statement may be too restrictive. We are well aware that atorvastatin is recommended by other NICE guidance; a blanket recommendation will remove any element of personalisation in the case of a patient needing a statin but being unable to tolerate atorvastatin. Please consider amending this statement to allow for a primary offer of atorvastatin and then an equivalent if necessary.
55	British Medical Association	Statement 3	Many patients with CKD have degrees of frailty and at higher risk of adverse events and polypharmacy than the general population

ID	Stakeholder	Statement number	Comments[1]
56	British Medical Association	Statement 3	Although the quality standard refers to being 'offered' atorvastatin, the measurement proposed does not measure this, it measures the proportion who receive it. Clinicians who offer personalised care with a full discussion of risks and benefits are likely to score lower on this metric than those who prescribe without involving patients in the prescribing decision.
57	British Medical Association	Statement 3	The nature of CKD is that EGFR naturally declines with age and so that will require the initiation of statins fro patients solely based on the fact that they are getting old and so will have fallen into the category of CKD
58	British Renal Society	Statement 3	This statement is possibly too restrictive. We are aware that atorvastatin is recommended by other NICE guidance; however a blanket recommendation would remove any element of personalisation in the case of a patient needing a statin and unable to tolerate atorvastatin. Please consider amending this statement to allow for a primary offer of atorvastatin and then an equivalent if necessary/not tolerated.
59	Diabetes UK	Statement 3	This statement is clear and measurable
60	NHS England - Renal Services CRG	Statement 3	This statement may be too restrictive especially since the evidence base was largely generated by an alternative statin. We realise that atorvastatin is recommended by other NICE guidance; a blanket recommendation will remove any element of personalisation in the case of a patient needing a statin but being unable to tolerate atorvastatin. Please consider amending this statement to allow for a primary offer of atorvastatin and then an equivalent if necessary. While this recommendation is evidence-based for those who are 50 or over, there is limited evidence that it is applicable to those aged between 18 and 49.
61	Renal Association	Statement 3	Supported as written with one specific suggestion, that consideration is given to including a focused discussion of the numbers needed to treat in discussion about commencing atorvastatin with people with stage 3a CKD and who have no other cardiovascular risk factors.
62	Royal College of General Practitioners	Statement 3	Statins – section 'What the quality statement means…' should include advice for healthcare professionals on what to do if patients are on a different statin e.g. simvastatin (as many will be). Should they be changed to atorvastatin?

ID	Stakeholder	Statement number	Comments[1]
63	Royal College of Physicians of Edinburgh	Statement 3	The use of statins in CKD has a significant evidence base for patients 75 years or younger but for dialysis and older patients it is more limited. NICE CG181 Recommendation 1.3.27 have indicted to offer atorvastatin 20 mg for the primary or secondary prevention of CVD to people with CKD and to increase the dose if a greater than 40% reduction in non-HDL cholesterol is not achieved (see recommendation 1.3.28) and eGFR is 30 ml/min/1.73 m2 or more. In patients with eGFR <30ml/min – issue will be titration which is not practical and potentially added expenses with measurements of HDL or LDL.
64	Astellas Pharma Ltd	Additional statement	Astellas would like support the proposed new stepwise strategy for the management of renal anaemia in primary care, as outlined on page 61 and 62 of the briefing paper, so that patients are investigated and treated before they develop anaemia symptoms. From an anaemia perspective we know that treatment is often delayed in primary care with many GPs not treating until patients' haemoglobin level falls below 90g/litre. NICE NG8 states anaemia should be investigated if Haemoglobin level falls below 110g/litre. Early testing and monitoring will contribute to a better support and management of anaemia in Chronic Kidney Disease (CKD) improving the patient's quality of life and health outcomes.
65	British Kidney Patient Association	Additional statement	"Evidence of local arrangements to ensure that adults with, or at risk of, CKD agree the frequency of eGFRcreatinine and ACR testing with their healthcare professional" implies the existence of an arrangement that may or may not include a discussion with the patient within it. We ask NICE to consider retaining the careplan QS to cover the need for patients to discuss, understand and be able to act on advice given which will make no sense if arrangements are made without their involvement. Please see our note further down.
66	British Kidney Patient Association	Additional statement	We should like to draw attention to two of the 2011 standards, QS3 "People with CKD have a current agreed care plan appropriate to the stage and rate of progression of CKD", and QS6 "People with CKD are assessed for disease progression". We suggest that they are joined as a standard for 2017 to combine personalised information and advice about risk to that patient and likelihood of disease progression. Please consider a quality standard which reads: 'People with CKD are provided with information consistent with their stage of CKD and the risk of progression of CKD. This should include documentation of the information provided and the monitoring and management strategy agreed'. This also relates to the new QS1 as mentioned previously. This focus on staging and communication will assist in delivering care that is proportionate to the requirements of patients.

ID	Stakeholder	Statement number	Comments[1]
67	British Kidney Patient Association	Additional statement	Please consider retaining or refreshing QS10 from 2011 “People with established renal failure have access to psychosocial support (which may include support with personal, family, financial, employment and/or social needs) appropriate to their circumstances.” NICE should be aware that there are not enough practitioners available to meet the needs of kidney patients. The BKPA itself provides some funding for these posts and offer a patient counselling service. There are multiple signals that identify this QS as needing to continue in the guideline. These include: the very high prevalence of psychological and social problems in patient with kidney failure; over-representation of these problems in lower socio-economic groups who in complex diseases get less from the healthcare system (‘ the inverse care law’), the identification by patients and caregivers (AJKD 2016 68 444-454) that they mainly prioritise outcomes relevant to daily-living and well- being. Maintaining this QS would reinforce this.
68	British Renal Society	Additional statement	Adults who have, or may be at risk of, CKD: This section should include elements QS3 "People with CKD have a current agreed care plan appropriate to the stage and rate of progression of CKD”, and QS6 "People with CKD are assessed for disease progression". We would like to see the QS including the need to provide people with CKD with information consistent with their stage of CKD with a documented plan of care
69	British Renal Society	Additional statement	Removal of QS10 ‘People with established renal failure have access to psychosocial support (which may include support with personal, family, financial, employment and/or social needs) appropriate to their circumstances’ would have a detrimental effect on the provision of psychological support services for people with kidney disease, Primary care are unable to provide the specialist support that is required and NICE should be aware that there are not enough practitioners available to meet the needs of kidney patients in NHS trusts. The BKPA provides some funding for these posts and offer a patient counselling service. With a high prevalence of psychological and social problems in people with ESRD, who require support from diagnosis to death and at various key stages of their disease progression we would like you to consider maintaining this QS or including it in QS1 as part of monitoring.

ID	Stakeholder	Statement number	Comments[1]
70	Renal Psychologists Network (British Psychological Society)	Additional statement	We are very concerned about the impact of withdrawing the quality statement in relation to psychosocial support. We had hoped for a fuller consideration of this statement. We note comments about limited evidence base in relation to psychosocial issues but would highlight the strong research evidence base that shows very high rates of depression and anxiety in a CKD population. Depression is the most common Psychiatric disorder in CKD patients. Untreated depression is a risk factor for CKD progression. Studies have shown that depression and poorer quality of life is associated with both morbidity and mortality in ESRF patients and is an independent predictor of survival. We are concerned that the psychosocial support statement which was included in the 2014 revision has been removed due to it no longer being considered a 'national priority'. This seems at odds with the discussions in the renal community at a national level which are recognising the very high patient need in this area. We feel that there is a need to use the quality standards to improve the recognition and treatment of depression. We hope that Nice would reconsider this issue.
71	Royal College of Nursing	Additional statement	*"Does this draft quality standard accurately reflect the key areas for quality improvement?"* - The three key areas for quality improvement are important but the key area concerning *"People with progressive CKD whose eGFR is less than 20 ml/min/1.73 m2, and/or who are likely to progress to established kidney failure within 12 months, receive* ***unbiased personalised information*** *on established kidney failure and renal replacement therapy options"* from 2011 standard needs to be considered for inclusion (see comment 4 below)
72	University Hospital Coventry and Warwickshire	Additional statement	My comment is in relation to quality statement 10 from the 2011 that is no longer being considered a national priority as noted in the draft quality standard which states. **"People with established renal failure have access to psychosocial support (which may include support with personal, family, financial, employment and/or social needs) appropriate to their circumstances."** Taking this out of the new Nice guidelines is a risky strategy for reasons that: 1) Shortage of specialist psychosocial support in many areas only adds to medical staff cost/time in trying to assist patients with their social concerns that impacts on their health and adherence to treatment. 2) External agencies and generic services in the community lack specialist knowledge of the complex and challenging issues that renal patients face on a day to day basis. 3) The long list of issues faced by renal patients currently fall outside of generic services criteria and remits which renal social workers help deal with and resolve.

ID	Stakeholder	Statement number	Comments[1]
			4) Gaps in already stretched generic services is evident across the country where renal patients do not always meet tighter eligibility criteria and or have long waiting lists up to 6 months – resulting in further health complications and more hospital admissions for renal patients. Therefore omitting quality statement 10 could only lead to increased hospital admissions and delayed discharges. Specialist psychosocial support has shown to improve medical compliance to treatment, improve patient's quality of life, reduces hospital admissions and improves renal treatment outcomes including kidney transplant. Furthermore and throughout the renal patients difficult journey Renal social workers are able to offer flexible and continuity of specialist care as part of a multi-disciplinary team that helps prevent renal patients from being passed from pillar to post. Therefore on behalf of renal patients and as with many other Nice guidelines for specific illness/conditions I strongly recommend that the quality statement should be included to state "People with established renal failure have access to each renal centre's specialist psychosocial practitioners including Renal Social Workers and Clinical Psychologists."
73	University Hospital Coventry & Warwickshire	Additional statement	I would like to comment on the omissions noted in the draft quality standard. Of particular importance, it is apparent that the statement 10 from the 2011 version is no longer considered a national priority for improvement. This previously stated "People with established renal failure have access to psychosocial support (which may include support with personal, family, financial, employment and/or social needs) appropriate to their circumstances." There is currently a shortage of this type of support across renal services up and down the country. It is negligent, not to actively include this in the new version. Further, the new version should in fact state that renal services should have specialist psychosocial support pertaining to renal challenges embedded as part of the multi-disciplinary team. The 2011 version is open to an interpretation that could leave people with established renal failure accessing generic local psychosocial support services which struggle to understand and treat the complex and unique challenges of this client group. Rather, as in other NICE guidelines about specific illnesses and conditions I strongly recommend the inclusion of a quality statement which states "People with established renal failure have access to each renal centre's specialist psychosocial practitioners including Clinical Psychologists and renal social workers."
			In reality, services who do not currently have such specialist psychosocial staff members amongst their teams note that often people with renal failure who are referred to local generic psychosocial services do not reach their specific remit and care criteria. They often fall between the cracks of services. The inclusion of specialist staff in the service, not only prevents this occurring, but has been actively shown to improve medical compliance to treatment, quality of life, reduced hospital admissions and successful kidney transplants where previously adherence to taking medication has been found to be problematic. Also, importantly, such services are able to provide flexible and adaptive support with a continuity of care throughout the renal journey.

Registered stakeholders who submitted comments at consultation

- Astellas Pharma Ltd
- British Kidney Patient Association
- British Medical Association
- British Renal Society
- Diabetes UK
- Elcena Jeffers Foundation
- Merck Sharpe & Dohme
- NHS England - Renal Services CRG
- Polycystic Kidney Disease Charity
- Renal Association
- Renal Psychologists Network (British Psychological Society)
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Physicians of Edinburgh
- University Hospital Coventry and Warwickshire