NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Renal replacement therapy services

Date of Quality Standards Advisory Committee post-consultation meeting:
02 September 2014

2 Introduction

The draft quality standard for renal replacement therapy services was made available on the NICE website for a 4-week public consultation period between 12 June and 10 July 2014. 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 and 2.

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. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

3. For each quality statement what do you think could be done to support improvement and help overcome barriers?

Questions about the individual quality statements

4. For draft quality statement 7: Within what timeframe should the person who has a suspected acute rejection episode have a timely transplant kidney biopsy carried out and reported on before treating the episode. Please can you specify a timeframe to aid clarity and measurement to this statement?

5. For draft quality statement 8: What are the most important procedures and processes to ensure effective monitoring and maintenance of vascular access and to prevent complications?

4 General comments

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

- Overall, the quality standard was supported for its approach for reflecting the key areas of quality improvement to raise standards however concern was raised on the duplication of efforts between NICE and other organisations such as the UK Renal Registry data and NHS England’s policy documents on 5 service specifications.
- The inclusion of children in this quality standard was supported. However it was suggested that specific reference should be made to existing paediatric data sources or audits.
- A stakeholder suggested that the terms ‘support’ and ‘assessment’ could be better defined.
- A stakeholder queried the reference to conservative care and symptom control in the introduction with the suggestion to remove.
- A stakeholder requested including Multi-Disciplinary Team (MDT) involvement in the quality standard which was seen as vital in this patient group.
- A stakeholder suggested that the preferred current term in use is ‘deceased donor’ rather than ‘cadaveric donor’.
- The House of Care (adopted by NHS England for Long term condition management) was suggested for inclusion to identify the elements within each Quality Standard.
- Suggestion to amend the audience descriptor for Quality Statements 1, 2 and 7 as the whole transplant pathway is commissioned as a specialised service and therefore will not be commissioned by Clinical Commissioning Groups.

Consultation comments on data collection

- Concern raised that a diversion of resources to data collection can potentially obstruct service improvement.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

People with CKD requiring renal replacement therapy are supported to receive a pre-emptive kidney transplant before they need dialysis, if they are medically suitable.

Consultation comments

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

- General support raised for this quality statement with reported substantial current variation between centres in regards to adult pre-emptive listing rates and late presentations.
- Length of pathway of pre-emptive live donation needs to be shortened in terms of time from identification of need for transplant to actual surgery.
- Improved access to and investment in antibody removal services will aid incompatible transplantation.
- Support to sustain awareness of CKD and transplantation amongst Black, Asian and minority ethnicity (BAME) communities.
- The rationale section states pre-emptive transplantation is the optimal approach when there is a living donor but it was suggested that even patients without living kidney donors should be referred early for transplantation.
- Reported patient feedback from kidney patients suggests that the timeframe for being put on the national transplant list should be extended from the current six to nine months as the extra time period would help account for any unforeseen delays and complications.
- Agreement that data would be easy to collect with dialysis start time, wait-listing and transplantation dates already being collected by NHS Blood and Transplant (NHSBT) and the UK Renal Registry. However concern was raised on who will collect evidence that patients are ‘supported’?

5.2 Draft statement 2

People with CKD on dialysis are supported to receive a kidney transplant, if they are medically suitable.

Consultation comments

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

- Clarity requested on the statement wording and outcome measure- ‘CKD previously or currently on dialysis’.
- UK Renal Registry data has shown inter-centre variation existing in patients wait-listed (both pre-emptively and after commencing dialysis) across different ethnic, age and blood groups. Significant unexplained inter-centre variation was also reported in the proportion of highly sensitised listed patients.

5.3 Draft statement 3

People with established kidney failure start dialysis with a functioning arteriovenous fistula or peritoneal dialysis catheter in situ.

Consultation comments

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

- The need for planned arteriovenous fistula access (AVF) was agreed when possible. Physical and emotional support and guidance within the hospital setting in order to make an informed decision was reported as key.
- Suggestion that many children would also benefit from AVF. Clarity was requested on this even in the absence of metrics at this stage to support the statement.
- Amendment to the rationale requested as you can’t start peritoneal dialysis without a catheter being in situ.
- A National Service Specification was suggested to support this quality statement with arrangements for the peritoneal catheter placement to be made within 48 hours of patients choosing peritoneal dialysis if they are late presenters requiring urgent start dialysis.

- Organ Donation and Transplantation (ODT) at NHS Blood and Transplant was suggested as a more robust data source for the number of living donor transplants performed.
- Suggestion that live donor kidney screening is an outpatient activity and therefore will not be recorded in HES data, but as part of the development work for National Tariff outpatient currencies.

5.4 Draft statement 4

People on long-term dialysis receive the best possible therapy, incorporating regular and frequent application of dialysis and ideally home-based or self-care dialysis.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- Query raised on statement wording as arguably all dialysis patients should receive the ‘best possible’ care? Also it was argued that evidence needs to be considered on patients who are suitable for different RRT at different times during their life.
- Query raised on when short-term dialysis becomes long-term?
- Query raised on the assessment of suitability with evidence suggesting that 78% of people are suitable for peritoneal dialysis and with the advent of assisted services for home dialysis patents, this proportion could be increased.
- Suggestion to consider re-wording rationale to say that that peritoneal dialysis is the “preferred” option to keep in line with the NICE Peritoneal Dialysis Clinical Guideline 125.
- Suggestion to define the terms ‘self-care’ and ‘regular and frequent application of dialysis’.
- Clarification requested on this statement’s structure measure (b) on “people on long-term dialysis are reviewed regularly”. It was argued that this needs to be more explicit than the frequency of review. Also another query was raised on the appropriate person to deliver this review- should this be the nephrologist or a specialist treatment options education nurse?
- Clarification requested to explain the reason for the process measures relating to the number of people who have automated peritoneal dialysis (APD) relative to

continuous automated peritoneal dialysis (CAPD) as this was felt to not be a measure of quality of dialysis. An alternative suggestion was to add the proportion of people on peritoneal dialysis relative to those on dialysis as outlined in NICE Peritoneal Dialysis Clinical Guideline Costing report which states 39% as the optimal proportion of patients on peritoneal dialysis.

- Suggestion to widen the audience descriptors to include for new patients starting dialysis both in a planned way and as an emergency.
- Suggestion that the measure of regular and frequent application of dialysis should incorporate data relating to frequency of haemodialysis however UK Renal Registry reports data only on patients who have dialysis more than or less than 3 times a week and does not collect hours of treatment. Therefore this measure will not be applicable within current reporting methods.

5.5 Draft statement 5

People with CKD receiving haemodialysis or training for home therapies who are eligible for transport, have access to an effective and efficient transport service.

Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

- Good overall support for the importance of this statement on patient transport however clarification on transport eligibility was requested as arguably all dialysis patients should be eligible.
- Concern was raised on the statement terms of ‘effective and efficient’ transport service and the word ‘reliable’ in the patient audience descriptor. All were felt to be ambiguous terms for patient transport manager and the patient.
- Patient transport was supported as an important patient experience marker although recorded intermittently on a national basis due to its complexity.
- The need for a more universal assessment of experience was highlighted with the suggestion that every renal centre should undertake an annual patient experience survey with a national template developed to support this. Consideration should also be given to extending the Friends and Family test to renal centres, covering all modalities and outpatient settings.

- Suggestion to add ‘and escort if appropriate’ to this statement.
- Suggestion that this statement needs to cover all dialysis patients as people on peritoneal dialysis often have clinic appointments requiring hospital transport.
- Query raised on the structure measure (b) – ‘Evidence of local arrangements to act upon patient satisfaction results from the latest national kidney transport audit.’ Clarification requested on whether the transport survey is mandatory for all those receiving transport for dialysis?
- Query raised on whether there will be nationally set targets for each of the Quality Measures based on the 2012 Patient Transport Audit? Also, concern raised that the 2012 patient transport surveys are now out of date and may not be repeated as it was resource consuming.

5.6 Draft statement 6

Specialist renal centres have ongoing individualised education programmes for people preparing for or receiving renal replacement therapy with their families or carers.

Consultation comments

Stakeholders made the following comments in relation to draft statement 6:

- Good overall support; fundamental for both patients and carer to manage this complex care pathway. Suggestion for this to be the first quality statement based on its importance.
- Concern raised on the structure measure for its measurability value.
- Suggestion for patients to visit transplant units including access to laboratory services or laboratory professionals involved in their care.
- Suggestion that education programmes should have multidisciplinary team involvement.
- Suggestion that shared decision making should be mentioned in the rationale. Also, the need for a specialist pre-dialysis service was also highlighted to allow the space and organisational infrastructure for shared and informed decision making to happen.

- Tools such as Renal Patient View, Kidney Research UK Decision Aids and a DVD were all suggested to help empower patients in their condition management and to also help older people to research informed choices.
- Suggestion that each centre should have dedicated patient education with a specific audit mechanism to measure access of late presenting patients to educational resources.
- In terms of self-care, it was highlighted that measuring tasks that patients undertake in their own dialysis care is important and has formed the basis of a Commissioning Quality and Innovation (CQUIN). A suggested suitable target was 10% of patients undertaking at least 5 out of 14 tasks. The metrics according to unit are reported in http://www.shareddialysis-care.org.uk

5.7 Draft statement 7

People who have a suspected acute rejection episode have a timely transplant renal biopsy carried out and reported on before treating the episode.

Consultation comments

Stakeholders made the following comments in relation to draft statement 7:

- Overall support on the importance of this statement with variation reported in current practice with major transplant units biopsies processed on a rapid schedule however in other centres this rapid service is not available at weekends. In this case treatment for transplant rejection is often started without a biopsy.
- Suggestion that the management of acute rejection should follow the principle of 7 day equity. Irrespective of which day of the week, biopsy, diagnosis and treatment this should be within 24 hours.
- In order to achieve a 7 day national service increased service provision is required with significant financial investment and potential cross cover between regional histopathology departments. Advice should be sought from the Royal College of Pathologists on this issue.
- Other suggested factors that may result in delay include:

  -medical unsuitability (e.g. hypertension, bleeding tendency)
  -lack of beds for outpatients requiring biopsy
  -delay in other investigations and unavailability of medical staff.

-patient refusal.

- In regards to Question 4, it was suggested that this timeframe will depend on the time post-transplant. Ideally, however, any acute deterioration of transplant function where acute rejection is suspected should have an ultrasound scan and biopsy within 24 hours especially in the first two months when patients are being seen regularly.
- In regards to Question 4, the biopsy timeframe would be as soon as possible after the blood test result and no later than 4 hours. This answer is however specific to a blood test being carried out on a recently transplanted patient whilst an in-patient, and the test taken early morning.
- Request for the title and the rationale to be clarified as to which aspect(s) of timeliness are being measured?
- Reported patient feedback highlights the importance of a shared decision-making approach to this issue with one feedback comment suggesting that healthcare staff may be too quick to follow ‘the book’, leading to unnecessary and potentially dangerous biopsies. This further highlights the importance of shared decision-making.
- Suggestion to broaden this statement on access to specialist laboratory services - to include Histopathology and Histocompatibility and Immunogenetics. This would highlight the need that antibody testing should be being requested at the time of any biopsy for transplant dysfunction. This would synchronise the availability of results and better inform clinical judgements.

5.8 Draft statement 8

People receiving haemodialysis have their vascular access monitored and maintained in line with local protocols.

Consultation comments

Stakeholders made the following comments in relation to draft statement 8:

- Maintaining and monitoring vascular access was supported as being essential; ensuring that it works well for as long as possible and to help prevent infection and other complications.
- Support for statement wording for being as much as can be currently said until it becomes clearer what the cost effective monitoring strategies are.
- Clarification requested on rupture of vascular access (fistula and graft) as a data source with the suggestion to remove this as a safety measure. Venous needle disconnection was recommended as an alternative safety measure.
- Outcomes for access such as explicitly, primary and secondary catheter patency rates (with definition needed on the latter) were also suggested.

6 Suggestions for additional statements

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

- Transition from paediatric to adult services.
- End of life planning
- Regular monitoring and timely referral to a vascular surgeon to prevent loss of access through clotting or stenosis
- Regular monitoring of peritoneal dialysis access and early referral for revision if appropriate
- Benefits of promoting healthy lifestyle ie exercise
- Adequate preparation of failing transplant patients to enable them to start dialysis in a timely manner

Appendix 1: Quality standard consultation comments table

ID	Stakeholder	Statement No	Comment on	Comments[1]
1	NHS England	General	Domain 1 Reducing premature mortality	The two quality standards around transplantation (QS1 & 2) and QS 4 (delivery of dialysis) aspects cover this area very well. For those patients who can have a renal transplant this offers the best outcomes. For those who cannot, improving the overall quality of their dialysis is important.
2	NHS England	General	Domain 2 Long term conditions	The elements of QS4 around home based dialysis therapies reflect Domain 4. This domain is strongly supported by the suggested Patient Participation QS above
3	Clinical Reference Group: Renal Dialysis	General	General	I do not know why renal replacement therapy was designated as a "high-priority areas for quality improvement". For 16 years the UK Renal Registry has collected mostly biochemical data as proxy measures of some aspects of quality of care, the atlas of variation also gives comprehensive comparisons of outcome measures, to have explored those vast data sets to attempt reduce variation in care may have been a more efficient approach.
4	Clinical Reference Group: Renal Dialysis	General	General	As there is a separate CRG for renal transplantation we have agreed the renal dialysis CRG will not comment on issues that are peculiar to that modality, but will comment on standards where there is overlap.
5	Clinical Reference Group: Renal Dialysis	General	General	You say "the quality standard is considered alongside current policy documents," it is important these NICE quality standards are cross checked against the "Quality standards specific to the service" which are listed in the five service specifications that are the NHS England policy documents guiding commissioners and dialysis providers. They are published as below but note a public consultation exercise has just finished and so the web published documents will change:

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[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 No	Comment on	Comments[1]
				http://www.england.nhs.uk/wp-content/uploads/2013/06/a06-renal-dia-hosp-sat-ad.pdf http://www.england.nhs.uk/wp-content/uploads/2013/06/a06-renal-dial-hm-ad.pdf http://www.england.nhs.uk/wp-content/uploads/2013/06/a06-renal-dial-peri-ad.pdf http://www.england.nhs.uk/wp-content/uploads/2013/06/a06-acu-kidney-inj-ad.pdf http://www.england.nhs.uk/wp-content/uploads/2013/06/a06-renal-asses-ad.pdf There is a lot of duplication of effort. The renal transplantation CRG will make the same point.
6	Clinical Reference Group: Renal Dialysis	General	General	"NICE quality standards are a concise set of prioritised statements designed to drive measurable quality improvements" I do not think all the standards you have indicated reach that threshold as several are too vague to be meaningfully measured.
7	Clinical Reference Group: Renal Dialysis	General	General	"The Health and Social Care Act 2012 sets out a clear expectation that the care system should consider NICE quality standards in planning and delivering services" although no one would argue against "general duty to secure continuous improvement in quality" there should be some recognition of the opportunity and financial cost of measuring and collecting data to demonstrate improvement, it may be the case that diversion of resources to data collection obstructs improvement in service.
8	Royal College of Paediatrics and Child Health	General	General	No comments submitted
9	British association for paediatric nephrology	General	General	We are pleased to note the inclusion of children in this important area. We note that further information could be included relating to children as follows
10	Renal Nutrition	General	General	Document written in a way that it's about supporting patients about to start renal replacement

ID	Stakeholder	Statement No	Comment on	Comments[1]
	Group (RNG) of the British Dietetic Association			therapy – what about those already established and expectations for what constitutes a good service for them?
11	Renal Nutrition Group (RNG) of the British Dietetic Association	General	General	What about benefits of promoting health lifestyle, exercise? Could this fit into this quality standard
12	Renal Nutrition Group (RNG) of the British Dietetic Association	General	General	Very little about MDT involvement which is vital in this patient group
13	NHS England	General	General	This is a difficult area to provide quality standards on, with the need to reflect a patient pathway, with the need to integrate the use of different renal replacement modalities into the patient journey. All of the quality standards presented have validity, but may not give a measure of integration.
14	NHS England	General	General	Statement 1 is incorrect in its phrasing – a pre-emptive transplant takes place before dialysis commences.
15	NHS England	General	General	The quality standards should be grouped around the Outcomes Framework.
16	NHS England	General	General	The House of Care (adopted by NHS England for Long term condition management) could be used to identify the elements within each QS.
17	NHS England	General	General	QS 7 maps to this domain, enhancing recovery from a renal transplant. There are no measures around hospitalisation of the RRT population as a whole. Measuring rates of admission across all modalities, with a view to improving rates, might be useful
18	Baxter Healthcare Ltd	General	General	We would like to thank NICE for the opportunity to comment on these quality standards and hope that they will be used to improve the standard of care for kidney patients. We hope you find our comments and feedback useful.
19	Polycystic Kidney Disease Charity	General	General	The ‘definitions’ in each quality statement are inadequate, compared with other NICE quality standards.
20	Polycystic Kidney Disease Charity	General	General	The ‘assessment’ explanations in each quality statement are inadequate, compared with other NICE quality standards.

ID	Stakeholder	Statement No	Comment on	Comments[1]
21	Polycystic Kidney Disease Charity	General	General	The standard applies to children as well as adults. Should specific reference be made to paediatric data sources or audits, where they exist?
22	Royal College of Nursing	General	General	This is to inform you that the Royal College of Nursing have no comments to submit to inform on the above quality standards consultation at this time. Thank you for the opportunity to review this document.
23	British Kidney Patient Association	General	General	There is a significant level of detail on issues covered in these quality standards which is replicated in the NHS England dialysis specifications – please can you confirm that these have been considered alongside other guidelines. http://www.england.nhs.uk/ourwork/commissioning/spec-services/npc-crg/group-a/a06/
24	British Kidney Patient Association	General	General	We cannot see reference in these standards to the concept of sharing a decision with the healthcare professional about the choices of treatment.
25	Department of Health	General	General	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.
26	Clinical Reference Group: Renal Dialysis	Introduction	Introduction	You say: "The links between this quality standard and the chronic kidney disease quality standard will be considered following the consultation with consideration given to have a single amalgamated quality standard." This makes sense as the majority of patients who develop established renal failure will be known to have chronic kidney disease and prior management in that part of the pathway influences the quality of renal replacement therapy services.
27	Renal Transplant Clinical Reference Group	Introduction	Introduction	Attention is drawn to the Renal Transplant Service Specification with the associated quality standards which is available to view at http://www.england.nhs.uk/wp-content/uploads/2014/04/a07-renal-transpl-ad-0414.pdf
28	Baxter Healthcare Ltd	Introduction	Introduction	Please could the reference to conservative care and symptom control be removed from the introduction? We made a comment to the engagement process held earlier this year "It should also be acknowledged that conservative management does not replace renal function and is therefore not a Renal Replacement Therapy. This option should be more highly regulated, well defined and patients should be accurately informed before opting out of active treatment regimes." This was discussed during the advisory committee meeting on 3rd April and it was agreed that conservative care and symptom control are not treatments. This issue is not discussed in the document at any other point.

ID	Stakeholder	Statement No	Comment on	Comments[1]
29	Baxter Healthcare Ltd	Introduction	Introduction	We agree that a person centred, integrated approach to providing services is fundamental to delivering high quality care to people receiving renal replacement therapy service.
30	British Kidney Patient Association	Introduction	Introduction	The statement 'there are two main types of dialysis' would be more accurate if it said 'there are two types of dialysis'
31	British Kidney Patient Association	Introduction	Introduction	It would have been an easier read to see the full set of standards, including both the new and earlier ones as that is how we suggest a patient might want to see it.
32	Renal Transplant Clinical Reference Group	Introduction & general	Introduction & general	The preferred term that is in current use is 'deceased donor' rather than 'cadaveric donor' – and this should be used throughout the document.
33	NHS England	New quality standard	New quality standard	All of the above measures are relevant to children, young adults and adults. However, there is no mention of transition services – when a person moves from a paediatric to adults service – or when an adolescent/ young adult presents de novo to an adult unit. This is a gap in service provision in many centres and needs a quality standard to support change.
34	National Kidney Federation	Question 1	Question 1	Whilst largely reflecting key areas there are some omissions and if included it is felt would reflect more roundly the needs of the population this standard serves. Notably these are: • Provision of capacity for Dialysis Away From Base • Timely access to Psychological Therapy • Access to a Renal Social Worker or Welfare Officer
35	NHS England	Question 1	Question 1	In part, although there will be a suggested framework for the QS given below
36	Baxter Healthcare Ltd	Question 1	Question 1	No, however we have outlined where we believe that additions can be included above
37	NHS England	Question 2	Question 2	Not all the quality standards have identified metrics to measure performance. The UK Renal Registry is able to provide some data, some data are in development and some are available elsewhere.
38	Baxter Healthcare Ltd	Question 2	Question 2	Yes, however there are some instances where there may be issues and we have detailed these in our responses above
39	National Kidney Federation	Question 3	Question 3	Within QS 1 & 2 there is an equality/diversity issue which does not appear to have been stated which is that of live donation for individuals from BAME communities, which includes both the prevalence of CKD amongst these communities and the lack of forthcoming donors.
40	NHS England	Question 3	Question 3	To support improvement, there is a need for a generic improvement network across Renal units,

ID	Stakeholder	Statement No	Comment on	Comments[1]
				clear metrics and potentially change packages.
41	National Kidney Federation	Question 4	Question 4	Timeframe for a biopsy would be as soon as possible after the blood test result, no later than 4 hours. This answer is specific to a blood test being carried out on a recently transplanted patient whilst an in-patient, and the test taken early morning. For individuals seen as an outpatient it would depend on whether the blood request was initially urgent or standard, with a standard blood request usually returning mid-late afternoon depending on the laboratory. In these circumstances the urgency for a biopsy may be hampered by communication of this result to the patient and/or person responsible for communicating action after the result, never-the-less a similar response time to an in-patient is suggested/wanted.
42	NHS England	Question 4	Question 4	The management of acute rejection should follow the principle of 7 day equity. Irrespective of day of the week, biopsy, diagnosis and treatment should be within 24 hours.
43	Baxter Healthcare Ltd	Question 4	Question 4	No comment
44	National Kidney Federation	Question 5	Question 5	• Identifying to a patient what a ‘buzz’ & ‘thrill’ are i.e. sound and feel of the fistula, and understanding what is happening if those are not present • Helping a [patient to understand the impact of low blood pressure, hot weather, lifting heavy objects and dehydration on the fistula • Helping a patient to understand the needling process of a fistula • Helping a patient to understand the benefit of skin care/site surveillance i.e. keeping skin moisturised and being vigilant for infection • Listening to patient concerns and acting in a timely and sensitive way • Use of technology to aid maturation and/or identify early signs of complication
45	Clinical Reference Group: Renal Dialysis	Question 5	Question 5	I do not think that this has been established.
46	NHS England	Question 5	Question 5	There is no proven set of diagnostic and interventional procedures to maintain vascular access. All centres should have agreed protocols to manage suspected access dysfunction – including examination, imaging and agreed intervention pathways. This is summarised in Guidelines 4.3 and 4.4 of the Renal Association Vascular Access guideline. This is summarised in Guidelines 4.3 and 4.4 of the Renal Association Vascular Access guideline.

ID	Stakeholder	Statement No	Comment on	Comments[1]
47	Baxter Healthcare Ltd	Question 5	Question 5	As stated above; monitoring venous and arterial pressures during treatment.
48	NHS England	Safety	Safety	There are a number of important safety markers within the suggested QS. However, the focus is largely on haemodialysis. Infection is an important risk for patients requiring all forms of RRT. Suggest that QS 8 is expanded/altered to 1) A statement about vaccination of the RRT population (influenza, pneumococcus and Hepatitis B) 2) Reducing the risk of infection – provision and maintenance (using QS3) of vascular access, PD access, clear protocols for CMV/PCP prophylaxis in renal transplant recipients 3) Measure bacteraemia rates in all populations, plus PD peritonitis plus CMV/PCP rates in transplant populations 4) The Quality standard is titles 'Safety' and is QS3
49	National Kidney Federation	1	1	• In terms of pre-emptive live donation the length of the pathway needs to be shortened in terms of time from identification of need for transplant to actual surgery. • Reduce the number of late presenters through improved identification and management in Primary Care. • Sustain the awareness of CKD & Transplantation amongst BAME communities • Improve access to & investment in antibody removal services to aid incompatible transplantation • Align standard to the work of the Renal CRG, NHS BT & BTS
50	Kidney Research UK	1	1	People with CKD requiring renal replacement therapy are supported to receive a pre-emptive kidney transplant before they need dialysis, if they are medically suitable
51	Kidney Research UK	1	1	We broadly support this. Pre-emptive transplantation confers a substantial benefit in terms of patient and graft survival, which improves and persists during long-term follow-up. There is a graded, stepwise decline in post-transplant graft and patient survival for each year spent on dialysis, and this effect is highly significant even after adjusting for other plausible factors. There is currently substantial variation between centres with respect to adult pre-emptive listing rates. The availability of this procedure can be hampered by late referral from Primary to Secondary Care. The standard can only be met if CKD patients are referred promptly to a renal specialist at the appropriate point in the progression of the disease. The Renal Registry reports wide variation in late

ID	Stakeholder	Statement No	Comment on	Comments[1]
				referrals by centre, the lowest being 7% and the highest, 32%. It follows that better diagnosis of CKD at Stage 3a/3b will support this. Physician awareness of the condition is crucial. Kidney Research UK has produced a training package for practices that introduces a care bundle approach to CKD management. Deployment of the tool increased CKD diagnosis in the study group of practices. A full explanation of benefits and drawbacks of transplant needs to be given to the patient who can then make informed decisions about transplant and dialysis in advance of treatment.
52	Polycystic Kidney Disease Charity	1	1	Process flowcharts with an outline of each step should be produced to accompany the text.
53	Polycystic Kidney Disease Charity	1	1	Quality Measures Structure a) Data source: The UKRR collects the data but who will collect the evidence that patients are 'supported'? The 'support' should be defined in this and every quality statement where referenced.
54	Renal Transplant Clinical Reference Group	1	Audience descriptors	All of the transplant pathway is commissioned as a specialised service and therefore will not be commissioned by Clinical Commissioning Groups.
55	Renal Transplant Clinical Reference Group	1	Data source	• Can we suggest that ODT at NHS Blood and Transplant is a more robust source of data for the number of living donor transplants that are performed? • Live donor kidney screening is an outpatient activity and therefore will not get picked up by HES data, but as part of the development work for a National Tariff outpatient currencies for live donor screening, live donor assessment, recipient workup and recipient should now be being collected
56	Kidney Research UK	1	Data source	This data is easy to collect. Indeed dialysis start time, date of wait-listing and date of transplantation are already collected by NHSBT.
57	Kidney Research UK	1	Question 3	US studies show that pre-emptive recipients are more likely to be white than black, able to work, covered by private insurance, college-educated, and with higher levels of HLA mismatching. It would therefore be important to demonstrate that the benefits of preemptive transplantation are made available equally among all patient demographics. Most pre-emptive transplants are from a living donor, but it is critically important for patients to have early access to the transplant list whether or not they have a living donor. Hence for a patient with GFR < 20, preemptive kidney transplantation should be a main focus of efforts, including workup and referral to a transplant centre. Pre-emptive transplant with a living donor is the optimal

ID	Stakeholder	Statement No	Comment on	Comments[1]
				approach, but even patients without living kidney donors should be referred early for transplantation. Feedback from kidney patients themselves also suggests it would be preferable if the timeframe from being put on the national transplant list be extended to nine months from the current six. Patients have described coming 'too close [to dialysis] for comfort' and feel the extra time period would help account for any unforeseen delays and complications.
58	Clinical Reference Group: Renal Dialysis	2	2	I think "CKD on dialysis are supported to receive a kidney transplant" is too vague to be useful
59	Kidney Research UK	2	2	People with CKD on dialysis are supported to receive a kidney transplant, if they are medically suitable
60	Baxter Healthcare Ltd	2	2	Would NICE consider reviewing the evidence to support PD prior to transplant as the best possible therapy for patients? A study by Molnar (Clin J Am Soc Nephrol 7: 332–341, February, 2012) showed that in 14,508 kidney transplant recipients with comprehensive pre-transplant data during dialysis treatment who were followed for up to 6 years post-transplantation, pre-transplant treatment with PD was associated with lower all-cause and cardiovascular mortality. This evidence is further supported in the following papers Schwenger et al Nephrol Dial Transplant (2011) 26: 3761–3766 and Goldfarb-Rumyantzev et al. American Journal of Kidney Diseases, Vol 46, No 3 (September), 2005: pp 537-549 537
61	British Kidney Patient Association	2	2	'CKD on dialysis'. I assume this is to differentiate between CKD & AKI. Should this say established on dialysis i.e. not on temporarily when recovering from AKI?
62	British Kidney Patient Association	2	2	'Proportion of people with CKD previously or currently on dialysis' If they have CKD and are heading towards kidney failure would they not be covered by standard 1?
63	Renal Transplant Clinical Reference Group	2	Data source	• Can we suggest that ODT at NHS Blood and Transplant is a more robust source of data for the number of living donor transplants that are performed? • Live donor kidney screening is an outpatient activity and therefore will not get picked up by HES data, but as part of the development work for a National Tariff outpatient currencies for live donor screening, live donor assessment, recipient workup and recipient should now be being collected
64	Clinical Reference Group: Renal Dialysis	2	Process measure	"with documented valid clinical reasons for the need for non-fistula access." Presumably what is meant is excluded from numerator or denominator is people with valid reasons for non-fistula

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				access.
65	Renal Transplant Clinical Reference Group	2	Audience descriptors	All of the transplant pathway is commissioned as a specialised service and therefore will not be commissioned by Clinical Commissioning Groups
66	Kidney Research UK	2	Question 1	Yes. UK Renal Registry data shows that inter-centre variation exists in the number of patients wait-listed (both pre-emptively and after commencing dialysis) and in the proportion listed across different ethnic, age and blood groups. This may reflect differences in geography, local population density, age distribution, ethnic composition, prevalence of diseases predisposing to kidney disease and the social deprivation index of that population as well as individual centre practice patterns. Significant unexplained inter-centre variation is also seen in the proportion of patients listed that are highly sensitised.
67	Kidney Research UK	2	Question 2	Data regarding wait-listing is easy to collect. Data regarding medical suitability is less easy to collect and there will be substantial inter-centre variability in practice. In the interests of equity all centres should work to the same selection criteria
68	Kidney Research UK	2	Question 3	The Kidney Advisory Group of NHSBT has agreed a policy for the selection of adult and paediatric patients on to the UK national transplant list and, where necessary, criteria for their de-selection. These criteria apply to all proposed recipients of organs from deceased donors. Broad acceptance and implementation of these guidelines should reduce inter-centre variation in practice. Patients should also feel empowered to make their own decisions about treatment. Staff at centres should help patients have the knowledge and confidence needed to self-manage their treatment.
69	National Kidney Federation	3	3	The need for planned access is supported and agreed, and there is obvious merit for AVF access, however the emphasis for the individual should be ‘whenever this is possible’ and understanding that physically and/or emotionally it might not be a viable option. Individuals have reported to us either they don’t want a fistula or have a reluctance to have a fistula. Such reports often suggest a lack of support or guidance within the hospital setting to make an informed decision or that when decisions have been made they may be ignored.
70	British association for paediatric	3	3	This largely refers to adults. AVF creation may not be appropriate in infants and very small children, but many children would also benefit from AVF and this could be made clear, even in the absence of metrics at this stage to support the statement

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	nephrology			
71	Kidney Research UK	3	3	People with established kidney failure start dialysis with a functioning arteriovenous fistula or peritoneal dialysis catheter in situ.
72	NHS England	3	3	A peritoneal dialysis catheter should be in situ, whenever possible, before starting peritoneal dialysis. Is a redundant statement – you cannot do PD without a PD catheter.
73	Baxter Healthcare Ltd	3	3	Please could the following sentence be amended? "A peritoneal dialysis catheter should be in situ, wherever possible, before starting peritoneal dialysis" It is not possible to start PD without a catheter in situ and so we suggest that this is changed to reflect best practice and be in line with the Service Specifications which state that "There shall be sufficient flexibility in the provision to allow a routine catheter insertion to be performed within two weeks and for an urgent catheter insertion within 24 hours."
74	Baxter Healthcare Ltd	3	3	We agree that temporary vascular access should be avoided where possible and converted to permanent as soon as possible for the numerous reasons stated. However an alternative option that also avoids the use of temporary vascular access is to use PD for unplanned start patients who do not have AV fistula in situ. Increasing the use of PD in unplanned patients would ensure that more patents start treatment with a permanent access. There are a number of studies and clinical papers that support this approach. These include Johan V. Povlsen and Per Ivarsen Nephrol Dial Transplant (2006) 21 [Suppl 2]: ii56–ii59 doi:10.1093/ndt/gfl192 Lobbedez et al. Nephrol Dial Transplant (2008) 23: 3290–3294 doi: 10.1093/ndt/gfn213 and Jo et al. Peritoneal Dialysis International, Vol. 27, pp. 179–183 In addition to the advantages of avoiding the use of temporary vascular access, there are the additional clinical advantages of using PD as a first treatment modality in that it preserves vascular access for use later in the patients' life, and preserves residual renal function (Marron et al Kidney International (2008) 73, S42–S51; doi:10.1038/sj.ki.5002600)
75	NHS England	3	3	The measure of a PD catheter in situ 2 weeks before use should be removed. There is no evidence base to support it and was based on open surgical placement.
	Baxter Healthcare	3	3	We agree that a measure of success for vascular access is the percentage of patients who use

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76	Ltd			temporary access for dialysis. However would NICE please consider bringing this quality standard in line with the Renal Association recommendation that 65% of all incident haemodialysis patients should commence dialysis with an arteriovenous fistula and that 85% of all prevalent patients on haemodialysis should receive dialysis via a functioning arterio-venous fistula
77	Baxter Healthcare Ltd	3	3	We support the use of infections as a measure of access success, in particular the rate of MRSA and MSSA in all renal patients. However PD peritonitis is not an appropriate measure in this instance as peritonitis is not often directly linked to PD access. PD peritonitis can be attributed to a range of issues including the level of patient education and training, dialysis technique, the environment where dialysis is performed, depression and co-morbidities rate in people receiving peritoneal dialysis.
78	Baxter Healthcare Ltd	3	3	Would NICE consider clarifying “other dialysis-associated infection rates”? This term is very broad as people undergoing dialysis may have a broad range of infectious that may or may not be linked to their dialysis access. These include blood borne viruses and pericarditis which can be present with or without central venous catheters.
79	British Kidney Patient Association	3	3	‘A peritoneal dialysis catheter should be in situ, whenever possible, before starting peritoneal dialysis.’ This statement does not make sense as a catheter is needed to commence PD. However a PD catheter does need to be in place in time if a patient has chosen to use this method of dialysis. If not in place the patient may lose their choice and that is what a quality standard should aim to avoid.
80	British Kidney Patient Association	3	3	This statement also misses out something about teaching patients to look after their catheter to avoid infection and the education needed for that.
81	Clinical Reference Group: Renal Dialysis	3	Rationale	“A peritoneal dialysis catheter should be in situ, whenever possible, before starting peritoneal dialysis” is tautological; you can’t start peritoneal dialysis without a catheter being in situ!
82	Renal Transplant Clinical Reference Group	3	Rationale	The final sentence should be reworded as peritoneal dialysis cannot be started without a peritoneal dialysis catheter in situ. Can we suggest this reads, ‘A peritoneal dialysis catheter should be in situ, whenever possible, before dialysis is required (in those patients where peritoneal dialysis is the intended form of dialysis).’
	Baxter Healthcare Ltd	3	Process measure	Please could a correction be made to the sentence… Denominator – the number of people starting long-term haemodialysis within 90 days of referral

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83				with intravenous vascular access. Please could the word intravenous be replaced by arterio-venous to complement the numerator above?
84	Baxter Healthcare Ltd	3	Process measure	Please could the measure for PD catheter insertion timeliness be in-line with the dialysis service specifications (as above) which state that "… routine catheter insertion be performed within two weeks and for an urgent catheter insertion within 24 hours."
85	British Kidney Patient Association	3	Process measure	'documented valid clinical reasons for the need for non-fistula access' We think that people do retain the right to not have fistula access – documenting the reasons is sensible and could catch poor practice but there could be other reasons than clinical ones for not having an a/v fistula
86	Kidney Research UK	3	Question 1	The measure used on PD access is not quite right. The focus on the two weeks is a mistake, as that is a disincentive for patients to have PD catheters for dialysis if they are late presenters. A better metric could be the one adopted with the National Service Specification, which is that arrangements should be made for the placement of a PD catheter within 48 hours of patients choosing PD if they are late presenters requiring urgent start dialysis. An alternative measure is around catheter survival. More than 80 % of first PD catheters should be functioning at one year (censored for elective transfer to HD, death and transplantation). It would be brave to have a metric around percent of patients who start on PD – currently about 12% for late presenters. If patients start with a PD catheter then it avoids a tunnelled line and the risk of bacteraemia is dramatically reduced.
87	Kidney Research UK	3	Question 2	We have been able to do so through the UK Renal Registry and continue to do so. The data that is being collected via that route includes percentage of patients starting dialysis on PD stratified by presentation (known to the service for less than 90 days; between 90 days and one year; and more than one year). We have data on one year first catheter survival stratified as described above – and this is an important metric. The average UK one- year catheter survival is just under 80% with considerable variation. The report can be accessed here: http://renalreg.com/Report-Area/Report%202013/14-Chap-14.pdf
88	Kidney Research UK	3	Question 3	Improvement will be achieved through local audits, with results being presented to teams as well as national publication of data via the UK RR, with centres being identified. The UK Peritoneal Dialysis Outcomes and Practice Patterns Study, 2013-2016 (PDOPPS) 'Incorporating – Optimising early

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				catheter function - NIHR RFPB Reference: PB-PG-0613-31028 intends to explore these questions further and in particular identify the best approach to catheter placement in the UK.
89	National Kidney Federation	4	4	We find the phrase 'long-term' in appropriate and confusing, it suggests a difference in treatment – all dialysis patients should receive the best possible care. When does short-term become long-term? In terms of barriers to overcome for this QS: • The introduction of a clear standard rate and process for HHD reimbursement; which means a fair market rate for utility costs to service the treatment of HHD, paid on a regular basis reflecting the needs of the individual to pay their service provider. • Access to a supportive & dedicated environment in which to self-care or take part in shared care • Important to engage staff 'buy-in' to the philosophy of shared care to avoid the risk of staff fearing for their job. • Improve access to intra-dialetic exercise or access/advice to exercise in the community • Access to psychological therapy in a timely manner, without the need to wait six months, as so often is reported by patients.
90	Clinical Reference Group: Renal Dialysis	4	4	"People on long-term dialysis receive the best possible therapy" I read this to imply that we know what the best possible therapy for a population. The "best possible renal replacement therapy" is of course a renal transplant. The best possible dialysis therapy for a patient would be peritoneal dialysis if they greatly value the fact that this treatment makes travel easier, but for dialysis efficiency as measured by some biochemical indices frequent short haemodialysis and for fluid and blood pressure control less frequent long dialysis sessions may be the "best possible therapy". Throughout this section the implication is that home treatment is the best possible therapy and although that is the case for many what should be changed is that patients (where suitable) have a choice of dialysis therapies.
91	Renal Nutrition Group (RNG) of the British Dietetic Association	4	4	Agree that home based therapies should be the default option – is it worthwhile mention that the Multidisciplinary team will aim to try and facilitate home based therapies as an option for all and challenge and support barriers– e.g. of you have someone that is unable to perform themselves but the carer could do it
92	Kidney Research UK	4	4	People on long-term dialysis receive the best possible therapy, incorporating regular and frequent

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				application of dialysis and ideally home-based or self-care dialysis.
93	Baxter Healthcare Ltd	4	4	Please could NICE further define the term “best possible dialysis”? Could NICE consider the evidence that patients are suitable for different RRT at different times during their life. For example, PD can preserve residual renal function and vascular access and so is therefore most suitable for new patients who are new to dialysis, particularly if they have residual renal function. (Marron et al Kidney International (2008) 73, S42–S51; doi:10.1038/sj.ki.5002600). Would NICE also consider the evidence to support patients receiving high dose haemodialysis (most conveniently delivered at home) as this has shown to deliver improved outcomes in many domains? Honkanen et al. Haemodialysis International 2014; 18:3–6
94	Baxter Healthcare Ltd	4	4	We agree with the following statement… “All patients should be encouraged to perform home-based dialysis if possible. People who are not able to have home-based dialysis should be actively involved in their treatment and encouraged to perform as much self-care dialysis as possible. Research suggests that given appropriate education and choice, many people would choose home-based dialysis (peritoneal dialysis or home haemodialysis) in preference to hospital-based dialysis. However, this is not reflected in the actual number of patients receiving dialysis at home.” However, please could NICE comment on the assessment of suitability? Mendelssohn Nephrol Dial Transplant (2009) 24: 555–561 doi: 10.1093/ndt/gfn484 states that 78% of people are suitable for PD and with the advent of assisted services for home dialysis patents, this proportion could be increased.
95	Baxter Healthcare Ltd	4	4	Whilst we agree with the statement “…encouraged to perform as much self-care dialysis as possible” please could NICE define the term self-care as this has a range of meanings for patients and healthcare professionals alike?
96	Baxter Healthcare Ltd	4	4	Please could NICE consider re-wording the sentence “Decisions around best possible dialysis should be based on current evidence and give patients a choice of treatments, and where appropriate, peritoneal dialysis as the agreed option” to state that PD is the “preferred” option to keep in line with the NICE PD Short Clinical Guideline?

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97	Baxter Healthcare Ltd	4	4	Please could NICE define the phrase “regular and frequent application of dialysis? There is evidence to suggest that more frequent, longer duration haemodialysis has superior clinical and health related outcomes when compared to conventional haemodialysis that is typically performed 3 times a week. There is also some evidence that the two day gap between dialysis sessions often experienced by people who have thrice weekly dialysis in-centre has poor outcomes. The following reference may be useful. Pauly RP, Gill JS, Rose CL, et al. Survival among nocturnal home haemodialysis patients compared to kidney transplant recipients. Nephrol Dial Transplant. 2009;24:2915-2919. Chertow GM, Levin NW, Beck GJ, et al. In-centre haemodialysis six times per week versus three times per week. N Engl J Med. 2010;363:2287-2300. Culleton BF, Walsh M, Klarenbach SW, et al. Effect of frequent nocturnal haemodialysis vs conventional haemodialysis on left ventricular mass and quality of life: a randomized controlled trial. JAMA. 2007;298:1291-1299 Foley RN, Gilbertson DT, Murray T, Collins AJ. Long interdialytic interval and mortality among patients receiving haemodialysis. N Engl J Med. 2011;365:1099-1107. Nesrallah GE, Lindsay RM, Cuerden MS, et al. Intensive haemodialysis associates with improved survival compared with conventional haemodialysis. J Am Soc Nephrol. 2012;23:696-705. Johansen KL, Zhang R, Huang Y, et al. Survival and hospitalization among patients using nocturnal and short daily compared to conventional haemodialysis: a USRDS study. Kidney Int. 2009;76:984-990. Rocco MV, Lockridge RS, Jr., Beck GJ, et al. The effects of frequent nocturnal home haemodialysis: the Frequent Haemodialysis Network Nocturnal Trial. Kidney Int. 2011;80:1080-1091. Eloot S, van BW, Dhondt A, et al. Impact of increasing haemodialysis frequency versus haemodialysis duration on removal of urea and guanidino compounds: a kinetic analysis. Nephrol Dial Transplant. 2009;24:2225-2232. Suri R, Depner TA, Blake PG, Heidenheim AP, Lindsay RM. Adequacy of quotidian haemodialysis. Am J Kidney Dis. 2003;42(suppl 1):42-48. Williams AW, Chebrolu SB, Ing TS, et al. Early clinical, quality-of-life, and biochemical changes of “daily haemodialysis” (6 dialyses per week). Am J Kidney Dis. 2004;43:90-102.

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				Goldfarb-Rumyantzev AS, Leypoldt JK, Nelson N, Kutner NG, Cheung AK. A crossover study of short daily haemodialysis. Nephrol Dial Transplant. 2006;21:166-175. Lindsay RM, Heidenheim PA, Nesrallah G, Garg AX, Suri R. Minutes to recovery after a haemodialysis session: a simple health-related quality of life question that is reliable, valid, and sensitive to change. Clin J Am Soc Nephrol. 2006;1:952-959. Ipema KJ, van der Schans CP, Vonk N, et al. A difference between day and night: protein intake improves after the transition from conventional to frequent nocturnal home haemodialysis. J Ren Nutr. 2012;22:365-372. Unruh ML, Larive B, Chertow GM, et al. Effects of 6-Times-Weekly Versus 3-Times-Weekly Haemodialysis on Depressive Symptoms and Self-reported Mental Health: Frequent Haemodialysis Network (FHN) Trials. Am J Kidney Dis. 2013;61:748-758.
98	Baxter Healthcare Ltd	4	4	We agree that a good measure of regular and frequent application of dialysis should incorporate data relating to frequency of haemodialysis however the renal registry reports data only on those patients who have dialysis >3 times a week or <3 times a week and does not collect hours of treatment. Therefore this measure will not be applicable within current reporting methods.
99	Baxter Healthcare Ltd	4	4	It is very important that there is evidence of local arrangements to ensure that people on long-term dialysis are reviewed regularly for the best possible therapy. However, would NICE consider clarifying the term “regular review” so that it is more explicit as to the frequency of review? In addition we believe that there should be some guidance on the most appropriate person to deliver this review i.e. should this be the nephrologist or a specialist treatment options education nurse?
100	Baxter Healthcare Ltd	4	4	Please could NICE explain the reason for the measure suggested relating to the number of people who have APD relative to CAPD as this is not a measure of quality of dialysis. Would NICE consider adding the proportion of people on peritoneal dialysis relative to those on dialysis as the NICE PD clinical guideline costing report states 39% as the optimal proportion of patients on PD.
101	Baxter Healthcare Ltd	4	4	We agree with the summary for service providers, healthcare professionals and commissioners to ensure they review people on long-term dialysis, offer the best possible therapy, incorporating regular and frequent application of dialysis, and support them to receive home-based or self-care dialysis if possible. Would NICE consider widening this to include the same standard for new patient starting dialysis both in a planned way and for those who start as an emergency?

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102	Baxter Healthcare Ltd	4	4	Please could NICE consider adding a statement to ensure the quality of staff and level of training and education required that will enable them to deliver high quality unbiased information about treatment options?
103	Polycystic Kidney Disease Charity	4	4	Quality Measures Structure b) Data source: there is no definition of 'reviewed regularly'. What practical systems could be established to measure these reviews?
104	British Kidney Patient Association	4	4	This statement is very similar to that in the original & needs updating to reflect that the treatment therapy should be that which the patient and healthcare professional have agreed is the most suitable for the patient at that time from the full range of choices. While home therapies are a good choice for many, shared care dialysis is an approach which allows the patient to take some responsibility for care within a supported environment and may suit the person better.
105	Polycystic Kidney Disease Charity	4	Rationale	The wording of this section is confusing. Eg in paragraph 2, it is stated that 'peritoneal dialysis' is the agreed option.
106	Polycystic Kidney Disease Charity	4	Rationale	Paragraph 3 says that patients 'should be actively involved and their treatment and encouraged to perform as much self-care as possible'. This para suggests an either/or scenario. The use of the word 'should' sounds prescriptive particularly when stated alongside the directive of 'self-care'. These options may be infeasible in the elderly and very sick.
107	British Kidney Patient Association	4	Structure measure	"long-term dialysis are reviewed regularly for the best possible therapy" Could this be reworded as 'long-term treatment options' to allow for other treatments or indeed conservative care
108	Clinical Reference Group: Renal Dialysis	4	Process measure	"long-term dialysis are reviewed regularly for the best possible therapy" should spell out that this means reviewed for transplant listing status, live donor options, and choice of dialysis modality (where not dictated by clinical status).
109	British Kidney Patient Association	4	Patient audience descriptor	"or with the person's involvement (self-care dialysis) in a dialysis unit." Please can this be referred to as shared care?
110	Clinical Reference Group: Renal Dialysis	4	Audience descriptors	"or with the person's involvement (self-care dialysis) in a dialysis unit." I would much prefer the term "shared haemodialysis care" rather than this emphasis on self-care, in part because you cannot get to self-care dialysis (peritoneal of haemodialysis) without in practice sharing of the care until the patient has been trained.
	Kidney Research UK	4	Question 1	There is considerable scope for improvement, as most in-centre patients could be involved in at least one aspect of their own care. This should be part of a continuum from the beginning of the

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111				patient journey where renal patients are involved as equal partners in their own care. Home-based dialysis is not right for patients who may seek the social aspects of in-centre or may be afraid of dialysing at home. Staff enable patients to cope and adjust to their dialysis regime over time, including actively supporting decisions to increase self-care in hospitals and/or at home, and/or changes to dialysis regimes.
112	Kidney Research UK	4	Question 2	When it comes to self-care we believe that it is important to measure tasks that patients undertake and this has formed the basis of a CQUIN. We believe that a suitable target is that 10% of patients should be undertaking at least 5 out of 14 tasks involved in their own dialysis care. The metrics according to unit are reported in http://www.shareddialysis-care.org.uk
113	National Kidney Federation	5	5	The NKF fully support patient transport and believe all dialysis patients should be eligible. The key words of the statement are ‘efficient’ and ‘reliable’. At least one quarter of the issues the NKF Helpline & Advocacy Service handle are transport related. A key barrier to the success of this statement is the lack of enforcement on the failings of a transport service to meet the needs of kidney patients. Audits/surveys have previously been undertaken but are usually flawed by prior notification and a single day survey.
114	Clinical Reference Group: Renal Dialysis	5	5	Patient transport is not under the remit of specialised commissioning, and so no business of clinical reference group. The problem you have with this standard is that the patient transport surveys are now out of date (2012) and I think was so resource consuming it will not be repeated. I was surprised in fact at the generally positive assessment by patients of the service!
115	British association for paediatric nephrology	5	5	People with CKD receiving haemodialysis or training for home therapies who are eligible for transport, have access to an effective and efficient transport service. “and escort if appropriate” should be added here
116	Baxter Healthcare Ltd	5	5	The quality standard on patient transport is important and we agree that this can impact on the patient’s experience of dialysis treatment. Currently there are no national eligibility criteria and the criteria that do exist differ across the country. Should these standards therefore include a statement or standard that defines transport eligibility?
117	Baxter Healthcare Ltd	5	5	Would NICE consider rewording the statement “…people with CKD receiving haemodialysis or training for home therapies” so that is covers all dialysis patients as people on PD often have clinic appointments for which they require hospital transport?

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118	Baxter Healthcare Ltd	5	5	With reference to the following measure “Evidence of local arrangements to act upon patient satisfaction results from the latest national kidney transport audit.” Please could NICE confirm that the transport survey is mandatory for all those receiving transport for dialysis?
119	Polycystic Kidney Disease Charity	5	5	Use of the term ‘effective and efficient’. There is a tension caused by this term in the context of the current push in the NHS for increased ‘efficiency’, which has come to mean more generally cost cutting or higher productivity/throughput. Each of the words will have a different meaning to the patient transport manager and the patient. Will there be nationally set targets for each of the Quality Measures, based on the 2012 Patient Transport Audit?
120	National Kidney Federation	6	6	Please consider including in the rationale that ‘benefits of pre dialysis education help to empower patients to become equipped to engage in shared decision making and where possible shared care, contributing to better or improved outcomes.’
121	Renal Nutrition Group (RNG) of the British Dietetic Association	6	6	Education programmes should have multidisciplinary team involvement
122	Kidney Research UK	6	6	Specialist renal centres have ongoing individualised education programmes for people preparing for or receiving renal replacement therapy with their families or carers.
123	NHS England	6	6	This should be quality standard 1. The support and education of patients and carers is fundamental to managing this complex pathway. The current suggested metrics and scope need refining but it is accepted this can be a difficult area to measure. However, the quality standard needs to be broader than education – it is about shared decision making, access to information and dialogue. 1) As a metric, the use of Renal Patient View is a useful surrogate of patient engagement. Other patient facing information systems may be developed in the future but over 30000 patients with renal disease use the system, but there is variation between renal centres. Both sign up levels and usage statistics are available and could be used to formulate a metric, based on prevalent RRT patients. 2) This quality standards could be titled ‘Patient and Carer Participation’ and is QS1 3) The current suggested metric of ‘Evidence that specialist renal centres have ongoing

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				individualised education programmes for people preparing for or receiving renal replacement therapy and their families or carers.' may be too crude. 4) There is no statement on end of life planning. The presence of and universal access of patients to a multi-professional low clearance clinic may be a better surrogate.
124	Baxter Healthcare Ltd	6	6	To maintain consistency, please could NICE reword the sentence "The benefits of pre-dialysis education include improved well-being and physical functioning, as well as positively contributing to better planning and initiation of dialysis, improved vascular access, delaying the need for starting dialysis and an increased likelihood of patients choosing self-care" to include home dialysis as well?
125	Baxter Healthcare Ltd	6	6	Would NICE consider introducing a statement that measures the use of Renal Patient View and other web based technology as a measure of patient engagement and empowerment?
126	Baxter Healthcare Ltd	6	6	With reference to the statement that measures satisfaction "Patient satisfaction feedback from people preparing for or receiving renal replacement therapy (and their families or carers) about education programmes on renal replacement therapy in specialist renal centres, would NICE consider including a further question relating to the impact of the education on their ability to make the right choice of treatment. For example "Did the patient's choice match their expectation 6 months after dialysis initiation?
127	Baxter Healthcare Ltd	6	6	We wholeheartedly agree with the statement "The programme should also include provision of continuing education for people receiving dialysis, together with their families and carers, with the aims of reviewing the original choice made by the patient, optimising patient involvement in their own care, improving treatment adherence, and fostering good communication and collaborative relationships with caregivers."
128	Polycystic Kidney Disease Charity	6	6	Transition from paediatric to adult services is not mentioned in this section. Is there a separate quality standard and if so, this should be cross-referenced.
129	British Society for Histocompatibility and Immunogenetics (BSHI)	6	6	Should include amongst available approaches patient visits to transplant units including access to laboratory services/laboratory professionals involved in their care. This would assist with gaining consent to laboratory testing, ensuring patient compliance with three monthly screening schedules and in improving understanding of what is happening in the period of time from call-in for transplant to the moment they are informed of the transplant decision based on laboratory findings.

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130	Kidney Research UK	6	Question 1	Shared decision-making is vital. Tools will be needed, and the consistent adoption of Renal Patient View will help empower patients in the management of their condition. Kidney Research UK is about to release two new tools to support this standard, the Kidney Research UK Dialysis Decision Aid and a DVD to help older people reach informed choices. A key resource to enable shared and informed decision making within the service is the provision of a specialist predialysis service. It allows the space and organisational infrastructure for shared and informed decision making to happen. This service model is unusual but key. Ensuring the communication that this service is as effective as possible, with evidence-based resources, is essential to patients' long-term experiences and management of their kidney disease as it changes from chronic to established to palliative. It is important that each centre should have a dedicated patient education. We also recommend that there should be a specific audit mechanism to measure access by late presenting patients to educational resources.
131	Kidney Research UK	6	Question 2	There are no resources available nationally to collect this data – but this can be subject to local audit, with patient flow evaluations. This will ensure that all patients are getting educational consultations and also at the same time to measure the choice patients make and whether they ultimately get the therapy they opted for.
132	Royal College of Pathologists	7	7	The recommendation for a timely kidney biopsy is based upon the Renal Association guidelines which state: 'We recommend that a transplant renal biopsy should be carried out before treating an acute rejection episode unless this will substantially delay treatment or pose a significant risk to the patient'. In many major transplant units biopsies taken for transplant dysfunction are processed on a rapid schedule that allows the examination of histological sections within 4-5 hours of the biopsy being taken. In practice this means that biopsies taken before 2 pm will be reported at the end of the day. This allows assessment of the cause of renal dysfunction and a decision on whether rejection is

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				present before institution of therapy. In some centres this rapid service is not available at weekends and, in that case, treatment for transplant rejection is often started without a biopsy. This pattern of clinical practice indicates that most clinicians caring for transplant patients consider that ‘a substantial delay’ would occur if it were not possible to obtain a biopsy within 24 hours of presentation with transplant dysfunction. Therefore the pattern of clinical practice indicates that ‘timely’ in this case should mean that a renal biopsy service is available every day. To achieve a 7 day a week service across the country would require an increase in service provision at those units that do not a present provide a weekend histopathology service and may require cross cover on a regional basis between histopathology departments providing renal biopsy services
133	Kidney Research UK	7	7	People who have who have a suspected acute rejection episode have a timely transplant renal biopsy carried out and reported on before treating the episode.
134	Baxter Healthcare Ltd	7	7	We agree with the importance being placed on people who have who have a suspected acute rejection episode having a timely transplant kidney biopsy carried out and reported on before treating the episode. Would NICE also consider adding in a standard that supports the adequate preparation of failing transplant patients to enable them to start dialysis in a timely manner?
135	British Society for Histocompatibility and Immunogenetics (BSHI)	7	7	Should be a broader statement - Access to specialist laboratory services - to include Histopathology and Histocompatibility and Immunogenetics, reflecting that antibody testing should be being requested at the time of any biopsy for transplant dysfunction to synchronise the availability of results and better inform clinical judgements.
136	Renal Transplant Clinical Reference Group	7	Rationale	The title of quality standard 7 refers to access to a specialist histopathology service. However in the subsequent rationale and in other sections the need for an appropriate and safe biopsy is also indicated and the non-histopathology factors highlighted above will result in a biopsy not being timely, as much as access to a specialised histopathology service. The title and the rationale need to be clearer as to which aspect(s) of timeliness are being measured. It is recognized that in many centres specialised renal histopathology services are not available seven days a week and in order to make them so would require significant financial investment. Advice should be sought from the Royal College of Pathologists on this issue.

ID	Stakeholder	Statement No	Comment on	Comments[1]
137	Renal Transplant Clinical Reference Group	7	Audience descriptors	All of the transplant pathway is commissioned as a specialised service and therefore will not be commissioned by Clinical Commissioning Groups
138	Renal Transplant Clinical Reference Group	7	Data source	There is a need for timely transplant biopsy when rejection is suspected and we support the need to encourage that. However we have a number of concerns. 1. There is the requirement for local data collection, when there is already much data that is provided nationally for transplantation. This will be a new area of data collection for many centres and there are a number of confounding factors that may make it difficult to ensure meaningful data capture. 2. There are a number of reasons for delay in performing a transplant biopsy of which access to histopathology is one. Other factors included medical unsuitability (e.g. hypertension, bleeding tendency), lack of beds for outpatients requiring biopsy, delay in other investigations, unavailability of medical staff. It may be that the whole pathway of transplant biopsy needs to be looked at, as histopathology isn’t the only factor that may result in a delay. We would suggest caution in using this as a quality measure unless clean data can be captured.
139	Kidney Research UK	7	Question 1	While timely access to a transplant biopsy is important to avoid the risks of delayed treatment for rejection or unnecessary empirical treatment for suspected rejection, there may be circumstances where a biopsy is unavoidably delayed, for example due to coagulation abnormalities, high blood pressure or patient refusal. Patient feedback has pointed out the importance of a shared approach to this issue. One comment suggested that healthcare staff may be too quick to follow ‘the book’, leading to unnecessary and potentially dangerous biopsies. This further highlights the importance of shared decision-making, which we have referred to elsewhere in this response.
140	Kidney Research UK	7	Question 2	These data would be difficult to collect as the time of onset of a suspected rejection episode may be difficult to define and, as stated above there may be sound clinical reasons why a biopsy may be delayed.

ID	Stakeholder	Statement No	Comment on	Comments[1]
141	Kidney Research UK	7	Question 3	Most transplant clinicians would suggest that a timely transplant kidney biopsy means a same day result. This obviously requires 7-day access to pathology services.
142	Kidney Research UK	7	Question 4	As above, most transplant clinicians would suggest that a timely transplant kidney biopsy means a same day result.
143	Renal Transplant Clinical Reference Group	7	Question 4	This will depend on the time post transplant but in reality any acute deterioration of transplant function where acute rejection is suspected should ideally have an ultrasound scan and biopsy within 24 hours. This is particularly the case in the first two months where patients are being seen regularly, but once patients are being seen less frequently then a biopsy within 48 hours would seem reasonable.
144	Clinical Reference Group: Renal Dialysis	8	8	“vascular access monitored and maintained in line with local protocols” this is probably as much as can be said at the moment until it becomes clearer what are cost effective monitoring strategies. As said on page 32 The Renal Association guidance (2011) is a good summary and standard.
145	NHS England	8	8	Defining a ruptured access is not clear. Suggest it is removed as a safety measure. A better safety measure is venous needle disconnection.
146	Baxter Healthcare Ltd	8	8	We agree that maintaining and monitoring vascular access is essential to ensure that it works well for as long as possible and to help prevent infection and other complications. Would NICE consider the inclusion of a standard to prevent loss of access through clotting or stenosis by regular monitoring and timely referral to a vascular surgeon. This can be done via monitoring access pressures during treatment for example.
147	Baxter Healthcare Ltd	8	8	Would NICE consider including a standard to for regular monitoring of PD access and early referral for revision if appropriate?
148	Renal Transplant Clinical Reference Group	8	Outcomes	Outcomes for access should include, explicitly, primary and secondary patency rates (with definition of latter
149	Kidney Research UK	8	8	No comments

Stakeholders who submitted comments at consultation

- Baxter Healthcare Ltd
- British association for paediatric nephrology
- British Kidney Patient Association
- British Society for Histocompatibility and Immunogenetics (BSHI)
- Clinical Reference Group: Renal Dialysis
- Department of Health
- Kidney Research UK
- National Kidney Federation
- NHS England
- Polycystic Kidney Disease Charity
- Renal Nutrition Group (RNG) of the British Dietetic Association
- Renal Transplant Clinical Reference Group
- Royal College of Nursing
- Royal College of Paediatrics and Child Health

- Royal College of Pathologists