NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Renal replacement therapy including conservative care

Topic

NHS England has asked NICE to develop a guideline on renal replacement therapy (RRT), including conservative care and transplant.

This guideline will also be used to update the NICE quality standard for RRT.

The guideline will be developed using the methods and processes outlined in Developing NICE guidelines: the manual.

For more information about why this guideline is being developed, and how the guideline will fit into current practice, see the context section.

Who the guideline is for

- People using services, families and carers and the public.
- Healthcare professionals in primary care.
- Healthcare professionals in secondary / tertiary care.
- Providers of RRT.

It may also be relevant for:

- Private sector or voluntary organisations commissioned to provide services for the NHS or local authorities

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government, and Northern Ireland Executive.

Equality considerations

NICE has carried out an equality impact assessment during scoping. The assessment:

- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope.

The guideline will look at inequalities relating to access issues in rural areas, age, minority groups and social class.

1 What the guideline is about

1.1 Who is the focus?

Groups that will be covered

- Adults (18 and over) with chronic kidney disease (CKD) stages 4 and 5.
- Children (under 18) with CKD stages 4 & 5.
- The following groups have been identified as needing special consideration:

- Older people.

- Infants (under 2).

- People from Black, Asian and minority communities.

- People with type 1 and type 2 diabetes.

- People who have RRT without previous planning .

Groups that will not be covered

- People with CKD stages 1- 3.

1.2 Settings

Settings that will be covered

- All settings where NHS commissioned care is provided to people who might need renal replacement (including care at home)

1.3 Activities, services or aspects of care

We will look at evidence on the areas listed below when developing the guideline, but it may not be possible to make recommendations on all the areas.

Key areas that will be covered

1. Assessment and review for people with deteriorating renal function who appear likely to need RRT.
2. Information, education and support for people who may need RRT and their families or carers.
3. Decision-making for people who may need RRT and their families or carers, including the option of conservative management.
4. Renal replacement therapy or conservative management - which modality for which person and when.
5. Symptom management.
6. Diet and fluid management.
7. Ongoing care including transferring between forms of RRT (for example, follow-up and review, switching between in-centre and home dialysis).
8. Discontinuing RRT.
9. Coordination of care between different specialties involved in the care of patients (for example diabetes/cardiology/liver specialists/primary care/mental health teams).

Areas that will not be covered

1. Management of CKD.
2. Management of acute kidney injury.

3 Anaemia in CKD.
4 Bone mineral disorder.
5 Technical aspects of delivery of RRT.
6 Management of growth in children with CKD.

1.4 Economic aspects

We will take economic aspects into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses primarily using an NHS and Personal Social Services (PSS) perspective.

1.5 Key issues and questions

While writing this scope, we have identified the following key issues, and key questions related to them:

1 When should people with progression to later stages of CKD be assessed for RRT?
2 What assessment (for example history, examination, investigations) is needed for those people with deteriorating CKD being considered for RRT?
3 What information, education and support is useful for people and their families/ carers when considering RRT, when transitioning from one form of RRT to another or considering conservative management?
4 How should decision-making for people who may need RRT be supported?
5 What is the most clinical and cost effective way of preparing patients for RRT (for example planning, timeliness of access formation and transplant listing)?
6 What is the clinical and cost effectiveness of each form of RRT?
7 Are there factors which suggest that certain forms of RRT may be more appropriate for certain groups of people?

8 What are the indicators for initiating RRT?

9 Are there groups of people in which conservative management is more appropriate than RRT?

10 What are the most important symptoms to manage for people being prepared for RRT, undergoing RRT or receiving conservative management of end-stage CKD?

11 What is the clinical and cost effectiveness of diet, and fluid management in people being prepared for RRT, undergoing RRT or receiving conservative management of end-stage CKD?

12 What is the most clinical and cost effective way of delivering care during renal replacement therapy (for example co-ordination between specialties, follow-up, review)?

13 What is the clinical and cost effectiveness of different sequences of RRT in people with end stage CKD?

14 What are the indicators for transferring between the different forms of RRT?

15 What are the indicators for discontinuing RRT?

1.6 Main outcomes

The main outcomes that may be considered when searching for and assessing the evidence are:

1 Health-related quality of life (for example EQ-5D, SF-36)

2 Symptom scores and functional measures

3 Psychological distress and mental wellbeing

4 Patient, family and carer experience of care

5 Survival (mortality)

6 Growth

7 Malignancy

8 Adverse events

- infections
- vascular access issues
- dialysis access issues (for example peritoneal dialysis catheter)
- hospitalisation

- family and carer outcomes
- time to modality failure

2 Links with other NICE guidance, NICE quality standards, and NICE Pathways

2.1 NICE guidance

NICE guidance that will be updated by this guideline

- Chronic kidney disease (stage 5): peritoneal dialysis (2011) NICE guideline CG125
- Guidance on home compared with hospital haemodialysis for patients with end-stage renal failure (2002) NICE technology appraisal guidance TA48

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to renal replacement therapy:

- Patient experience in adult NHS services (2012) NICE guideline CG138
- Service user experience in adult mental health (2011) NICE guideline CG136
- Medicines adherence (2009) NICE guideline CG76
- Transition from children's to adults' services for young people using health or social care services (2016) NICE guideline NG43

NICE guidance that is closely related to this guideline

Published

NICE has published the following guidance that is closely related to this guideline:

- Chronic kidney disease in adults: assessment and management (2014) NICE guideline CG182
- Chronic kidney disease: managing anaemia (2015) NICE guideline NG8

- Acute kidney injury (2013) NICE guideline CG169
- Chronic kidney disease (stage 4 or 5): management of hyperphosphataemia (2013) NICE guideline CG157
- Tolvaptan for treating autosomal dominant polycystic kidney disease (2015) NICE technology appraisal guidance 358
- Machine perfusion systems and cold static storage of kidneys from deceased donors (2009) NICE technology appraisal guidance 165
- Cinacalcet for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy (2007) NICE technology appraisal guidance 117
- Immunosuppressive therapy for renal transplantation in adults (2004) NICE technology appraisal guidance 85
- Guidance on the use of ultrasound locating devices for placing central venous catheters (2002) NICE technology appraisal guidance 49
- Acute kidney injury (AKI): use of medicines in people with or at increased risk of AKI (2016) NICE advice KTT17

In development

NICE is currently developing the following guidance that is closely related to this guideline:

- Kidney transplantation (children, adolescents) - immunosuppressive regimens (review of TA99) NICE technology appraisal. Publication date to be confirmed.
- Kidney transplantation (rejection) - everolimus NICE technology appraisal. Publication date to be confirmed.
- Multiple frequency bioimpedance devices (BCM - Body Composition Monitor, BioScan 920-II, BioScan touch i8, InBody S10 and MultiScan 5000) for fluid management in people with chronic kidney disease having dialysis Diagnostics guidance. Publication expected June 2017.

2.2 NICE quality standards

NICE quality standards that may need to be revised or updated when this guideline is published

- Renal replacement therapy services for adults (2014) NICE quality standard 72
- Chronic kidney disease in adults (2011) NICE quality standard 5
- Acute kidney injury (2014) NICE quality standard 76

NICE quality standards that may use this guideline as an evidence source when they are being developed

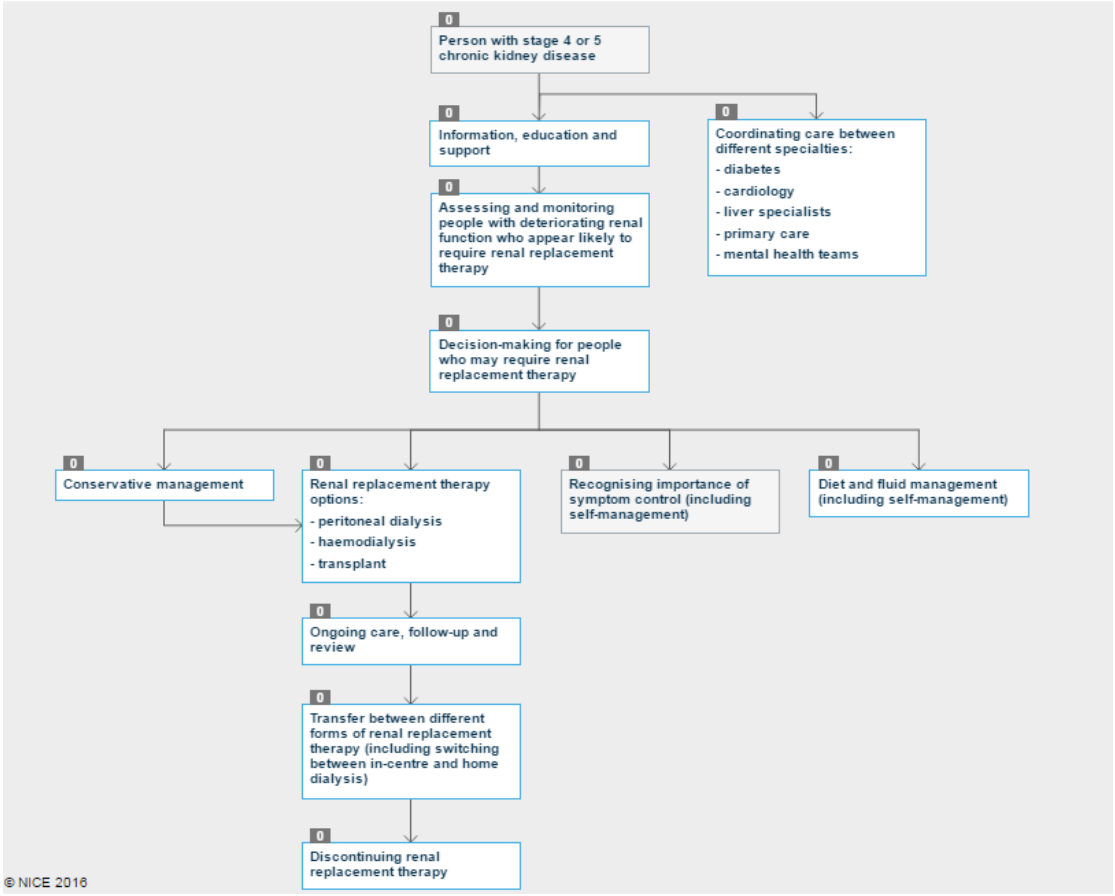
2.3 NICE Pathways

When this guideline is published, the recommendations will be added to NICE Pathways. NICE Pathways bring together all related NICE guidance and associated products on a topic in an interactive topic-based flow chart.

A draft pathway outline on renal replacement therapy, based on the draft scope, is included below. It will be adapted and more detail added as the recommendations are written during guideline development.

This pathway will be integrated into the NICE pathway on kidney conditions and is relevant to the NICE pathway on chronic kidney disease.

Renal replacement therapy overview



3 Context

3.1 Key facts and figures

The kidneys excrete certain waste products, excess water, acid and salts from the body. People with CKD have an irreversible and progressive decrease in kidney function. CKD may affect up to 4-5% of the adult UK population.

In 2% of people with CKD, the condition progresses to kidney failure, and RRT is needed for survival. RRT essentially comprises either transplantation or dialysis (artificially removing waste products and excess water from the blood). There are 2 main types of dialysis: haemodialysis (where the blood is filtered outside of the body using a dialysis machine) and peritoneal dialysis (where the person's abdominal lining is used to filter the blood).

In the UK approximately 60,000 adults and 1,000 children are on RRT, including transplant. The incidence of patients with renal failure requiring RRT

is approximately 115 per million population and in 2014, a total of 7,411 adults and children had RRT initiated. The median age of all people newly requiring RRT was 64.8 years, although this varied by ethnicity: 66.4 years for White people and 58.7 years for Asian people and people from minority ethnic groups.

According to the 18th annual report by the UK Renal Registry (2015), on 31 December 2014 there were 27,804 adults in the UK receiving dialysis. Of these, 86.9% had haemodialysis (44.0% in satellite units, 38.6% in hospitals, 4.3% at home), 5.8% had continuous ambulatory peritoneal dialysis and 7.0% had automated peritoneal dialysis. In addition, 190 children and young people under the age of 18 years were on dialysis (103 haemodialysis and 87 peritoneal dialysis). Reported 1- and 2- year survival rates for adult dialysis patients were 85.0% and 72.1%, respectively.

Approximately 5,500 adults and children are currently on the renal transplant waiting list (NHS Blood and Transplant), with about 3,000 renal transplants performed each year. The median time to transplantation for those on the national transplant list is around 1,000 days for adults and 300 days for children.

Some people with advanced CKD choose not to receive RRT and instead are treated conservatively, which will include management of anaemia and dietary modification as necessary.

RRT is an expensive treatment. The total cost of CKD in England in 2009-10 was estimated at £1.45 billion. Even though only 2% of people with CKD receive RRT, more than half of this sum was spent on RRT.

This guideline aims to improve the care of people who need RRT or conservative care.

3.2 Current practice

Most people who have RRT are treated with haemodialysis. Within 90 days of starting RRT 66.3% of people are on haemodialysis, 19.1% are on peritoneal dialysis, 9.7% have a functioning transplant and 4.8% have died or stopped treatment.

Access to transplantation demonstrates considerable inequality across racial groups. There are relatively fewer numbers of black, Asian and minority ethnic groups on the organ donor list. These populations, however, have a higher incidence and prevalence of CKD needing RRT and they tend to reach this stage at a younger age.

The number of people receiving conservative treatment varies between renal units and has been difficult to establish, but up to 40% of patients aged over 70 choose this treatment option. Most of these people still receive their care and treatment through renal services.

4 Further information

This is the draft scope for consultation with registered stakeholders. The consultation dates are 3 August to 7 September 2016.

The guideline is expected to be published in October 2018.

You can follow progress of the guideline.

Our website has information about how NICE guidelines are developed.