

## SCHEDULE 2 – THE SERVICES

### A. Service Specifications

<b>Service Specification No.</b>	A06/S/e
<b>Service</b>	Assessment and Preparation for Renal Replacement Therapy (including establishing dialysis access)
<b>Commissioner Lead</b>	
<b>Provider Lead</b>	<i>The name of the individual leading on the service for the provider</i>
<b>Period</b>	<i>12 months</i>
<b>Date of Review</b>	

#### 1. Population Needs

##### 1.1 National/local context and evidence base

End stage renal failure (ESRF), also known as established renal failure (ERF), is an irreversible, long-term condition as a result of chronic kidney disease (CKD) (or less commonly acute kidney injury) for which regular dialysis treatment or transplantation is required if the individual is to survive. If the kidneys fail, the body is unable to excrete certain waste products, excess water, acid and salts resulting in increasing symptoms and eventually death. When ESRF is reached, renal replacement therapy (RRT), in the form of dialysis or transplantation, is required or the person may die within weeks or months. In 2011, 108 patients per million (ppm) population in the UK started renal replacement therapy (RRT) for established renal failure but the UK Renal Registry showed significant variation in the crude acceptance rate in England from 50 to 226 ppm. Some of this variation is explained by ethnicity and socioeconomic deprivation both of which influence the prevalence of kidney disease.

On average, 76% of incident RRT patients start treatment with haemodialysis, 18% peritoneal dialysis and 6% with a renal transplant but the percentage starting on each modality varies markedly between centres. The percentage of prevalent patients by dialysis modality (31/12/11) varies from 0 - 11.5% for home haemodialysis from 0 - 84% for satellite haemodialysis, 0 - 27% for continuous ambulatory peritoneal dialysis (CAPD) and 0 - 16% for automated peritoneal dialysis (APD) in England. The published (<http://www.rightcare.nhs.uk/index.php/atlas/kidneycare>) atlas of variation has shown that

the rate of pre-dialysis transplantation varies between 1 and 20 ppm in different parts of the UK.

Approximately 20% of patients start renal replacement therapy (by dialysis) without sufficient prior contact with renal services to allow optimal planning to take place. This may be because they present with an acute kidney problem (or acute on chronic kidney problem) and do not recover independent function or that the progression of their kidney problem is not recognised. Despite the introduction of chronic kidney disease registers in primary care, many patients are still not identified or the patients themselves may not be aware they have chronic kidney disease. These patients have poorer outcomes with increased hospitalisation and increased mortality. There is good evidence that patients who start RRT in a controlled manner with established vascular or peritoneal access have better outcomes. In addition, opportunities for pre-emptive transplantation or for patients to be able to choose not to have RRT are missed. Therefore an important part of the pathway of care for patients with chronic kidney disease is the planning of further treatment as renal function declines. This would include making a timely informed decision about treatment options and locations which covers renal transplantation, haemodialysis, peritoneal dialysis and **conservative** care.

The Renal National Service Framework (NSF) part 1 (2004) and clinical practice guidelines from the UK Renal Association

(<http://www.renal.org/Clinical/GuidelinesSection/RenalReplacementTherapy.aspx>)

emphasise the importance of counselling and education of patients with progressive chronic kidney disease to allow an informed choice about options for renal replacement therapy (including dialysis and transplantation) or, for some patients, **conservative** care.

## 2. Outcomes

### 2.1 NHS Outcomes Framework Domains & Indicators

<b>Domain 1</b>	<b>Preventing people from dying prematurely</b>	√
<b>Domain 2</b>	<b>Enhancing quality of life for people with long-term conditions</b>	√
<b>Domain 3</b>	<b>Helping people to recover from episodes of ill-health or following injury</b>	√
<b>Domain 4</b>	<b>Ensuring people have a positive experience of care</b>	√
<b>Domain 5</b>	<b>Treating and caring for people in safe environment and protecting them from avoidable harm</b>	√

The provider will have an IT system integrated into the hospital IT system for patients with

renal disease. This system will be able to provide information to the UK national Renal Registry.

The overall aim of the service is to prepare, educate and equip patients with ESRF in order to enable them to make an informed choice of their renal replacement therapy and to ensure that their therapy is started in a planned way.

Patient reported outcome and experience measures should be prioritised, and should be the principal barometer of success. Improved quality of life and experience for both patients and carers should be sought.

The following are outcomes expected.

Expected outcomes (Domain 1,2, 3, 4 and 5)

Outcome	Measurable output
<p>For the preparation of patients:- To ensure informed patient choice. For patients to be involved in shared decision making.</p>	<p>Patient survey including satisfaction with choice of RRT and patient reported health related quality of life. Percentage of patients starting dialysis known to the unit for &gt;3 months who complete education programme Percentage of patients known for &lt;3 months of starting dialysis Number and percentage of patients with access and instruction in use of Renal Patient View Number and percentage of patients utilising shared decision making aids/actively involved in decision making.</p>
<p>For the initiation of treatment:- For all suitable patients to have access to RRT. To increase the number of patients starting RRT electively with permanent access. To increase the number of patients starting RRT by transplantation.</p>	<p>Crude and corrected incidence rate of RRT (patients per million population). Percentage of patients on the electronic renal conservative care register, for who there is planned and collaborative care with palliative care specialists. Percentage of patients known &gt; 3 months starting haemodialysis with a usable arteriovenous fistula/graft or peritoneal dialysis (target &gt; 85%) Percentage of patients admitted to hospital to start RRT. Percentage of patients starting RRT who have pre-emptive transplants from living or deceased donors. eGFR at start of dialysis.</p>

<p>To ensure timely transplantation:- To meet the Renal Association guideline</p>	<p>Proportion of patients who have been assessed for suitability for transplantation or have a transplant status within a specified period.</p> <p>Proportion of patients starting RRT who receive a transplant prior to starting dialysis.</p>
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### 3. Scope

#### 3.1 Aims and objectives of service

The aim of the service will be to prepare, educate and equip patients with end stage renal failure to enable them to choose their preferred form of renal replacement therapy and to commence this treatment in a planned manner through the delivery of a seamless and comprehensive out-patient service.

The primary objectives will be :-

- Education and counselling of patients about progressive chronic kidney disease (CKD)
- Education and counselling of patients regarding renal transplantation (where medically appropriate), all forms of dialysis in all settings (home/hospital/satellite/shared care) and conservative care
- Shared decision-making by patients and health care professionals about treatment for ERF using evidence based aids
- Education about what people with ERF can do for themselves ('self-management'), where appropriate
- Access to both living and deceased donor kidney transplantation prior to dialysis where possible
- Timely establishment of vascular or peritoneal access
- Timely initiation of dialysis either by peritoneal dialysis or haemodialysis in the setting chosen by patient
- Ensure patients vaccinated against hepatitis B virus, in primary care.

This specification sets out what is required of a clinically safe and effective organisation that is providing care for adults being prepared for renal replacement therapy. It describes the interventions and actions required along the patient pathway, as well as entry and exit points. It is based upon evidence-based care and treatment models.

#### 3.2 Service description/care pathway

The initiation of renal replacement therapy is a well established patient pathway in specialist

renal centres. The pathway has been described by the National Institute for Health and Care Excellence (NICE).

## Entry To The Pathway

Patients with progressive CKD will enter the pathway when it is clear that kidney function is declining and that without some form of renal support they will become increasingly symptomatic and kidney failure may become life limiting. This will include patients who may subsequently decide not to have RRT and have conservative care. Most patients will enter with an estimated glomerular filtration rate of less than 20 ml/min/1.73m<sup>2</sup> and evidence of a progressive decline. Although precise estimation of when RRT may be necessary is difficult, people approaching ERF within a year shall be referred to a multi-disciplinary team for education and advanced CKD management. For those patients who start dialysis without adequate prior contact with renal services, the provider will have an accelerated pathway to allow all options for renal replacement therapy to be discussed within 3 months of initiating dialysis.

Many patients will already be known to nephrology services and be managed in CKD clinics. However, others may be referred directly from other hospital departments, from hospitals that do not have nephrology services and from primary care.

## Staffing

Patients with progressive CKD shall have access to a multidisciplinary team which will include:-

- Trained nephrologists
- Specialist renal nurses
- Specialist renal dieticians
- Renal pharmacist
- The provider shall also provide access to other support including (but not limited to) clinical psychology, counsellors and social workers/welfare officers with specific expertise in the problems encountered by patients with kidney disease
- Surgical teams (or other suitably trained operators) with expertise in creating vascular and peritoneal access
- Interventional radiology
- Transplant surgical teams and transplant co-ordinators
- Where these services are not available at the provider's facility, information should be provided about how, and/or arrangements made to, access them

Specialist support, that is patient centred and enables patient choice, will be provided for young adults (age 18-25). This will include those who are in the process of transferring from paediatrics, those who have transferred from paediatrics or those who have come straight into adult services at a young age. Transition will involve a period of joint care from paediatric and adult services and it is important for multi-disciplinary teams (MDTs) to be aware that this group may have additional developmental needs, including educational and employment.

## Key Care deliverables

### **Preparation for renal replacement therapy will be based on Renal NSF part 1 standard 2**

All adults approaching established renal failure are to receive timely preparation for renal replacement therapy so the complications and progression of their disease are minimised, and their choice of clinically appropriate treatment options is maximised.

#### **Markers of good practice**

Referral to a multi-skilled renal team, where possible at least one year before the anticipated start of dialysis treatment, for appropriate clinical and psychological preparation. This principle should also be followed for people with a failing transplant.

Accelerated process with intensive input from the renal team for those who present late to renal units or as acute uraemic emergencies.

People with ERF are provided with information about all forms of treatment so that an informed choice can be made.

**Proportion of** patients placed on the national transplant list within six months of their actual dialysis start date where clinically appropriate.

The provider will offer all patients, together with their families and carers, an appropriate education programme aimed at improving their knowledge and understanding of their condition, and of the options for treatment. This will include, where medically suitable, renal transplantation, all forms of dialysis including home dialysis and **conservative** care without dialysis. The education programme will be multidisciplinary, multifaceted and tailored to the needs of the individual. A variety of approaches will be available including individual conversations, group work, written materials, DVD/CDs and access to expert patients. This will be delivered in an appropriate setting and using lay language. Where necessary, interpreters and information in other languages will be provided to assure understanding. The process will be based on the principles of shared decision making with access to evidence based shared decision making aids. Providers shall make patients aware of local and national kidney patient support groups (e.g. local kidney patients' associations, National Kidney Federation, **British Kidney Patients Association**).

Patients will be enabled to change their initial treatment of choice over time (subject to clinical considerations) to reflect personal choice or change in personal circumstances.

Patients who present late or as uraemic emergencies will be able to access an accelerated pathway to provide the same information about treatment choices within 3 months of presentation to the provider. The provider will also ensure they liaise with referrers regarding late presentation to try to reduce this over time.

### **Establishing suitable access for dialysis will be based on Renal NSF part 1 standard 3**



Adults with established renal failure are to have timely and appropriate surgery for permanent vascular or peritoneal dialysis access, which is monitored and maintained to achieve its maximum longevity.

### **Markers of good practice**

Early referral for assessment and investigation for the best means of access, and timely surgery (current best practice being six months before haemodialysis, four weeks before peritoneal dialysis) which enables patients to begin dialysis with their vascular or peritoneal dialysis access established and functioning.

Monitoring and early intervention to minimise complications of the access.

Recording and regular auditing of the type of access in use at the start of dialysis, time from referral to surgery, and complication rates for each procedure.

Temporary access replaced by permanent access as early as possible.

Proper training for patients, carers and members of the renal team in the care of the access.

The provider will have a system to allow timely referral for vascular access surgery and should ensure there is adequate follow up and checking that vascular access has developed, remains patent and is suitable for use. The use of haemodialysis catheters should be discouraged to minimise the risk of health care associated infections.

The provider will have a system for peritoneal dialysis catheter insertion in appropriate settings, including operating theatre, radiology departments and clean areas on renal wards. 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.

### **Work up for renal transplantation**

Pre-emptive transplantation (i.e. transplantation before dialysis starts) is the optimal form of renal replacement therapy for medically suitable patients. It is associated with better outcomes compared to patients transplanted after starting dialysis.

The provider will have a structured system to ensure all medically suitable patients have explored all the options of living kidney donation (related/unrelated/paired exchange/blood group incompatible (ABOi) and antibody incompatible) and deceased donor transplant listing. The chance of a deceased donor renal transplant will be determined by the national allocation policy but patients should be activated on the transplant list where it is anticipated they will require RRT within six months.

Living donor transplantation should be explored for all medically suitable patients, where there is a potential live donor. The provider will plan to achieve renal transplantation before the need to initiate dialysis treatment with the process starting at least a year before RRT will be needed. If the provider does not have direct access to facilities for assessment of transplant recipients and donors, they must ensure they have a robust link and timely referral pathway with another provider to ensure equity of access to these treatments.

### **Initiation of Treatment**

The decision to initiate RRT should be based on the guidelines laid out in section 5 of the

Renal Association clinical practice guideline on Planning, Initiating and Withdrawal of Renal Replacement Therapy (see below).

- Guideline 5.2 - RRT: Initiating renal replacement therapy  
**It is** recommended that the decision to start RRT in patients with CKD stage 5 (estimated glomerular filtration rate (eGFR) < 15ml/min/1.73m<sup>2</sup>) should be based on a careful discussion with the patient of the risks and benefits of RRT taking into account the patient's symptoms and signs of renal failure, nutritional status, co-morbidity, functional status, and the physical, psychological and social consequences of starting dialysis in that individual
- Guideline 5.3 - RRT: Initiating renal replacement therapy  
Serious consideration should be given to starting renal replacement therapy in patients with an eGFR <6ml/min/1.73m<sup>2</sup>, even if the patient is asymptomatic
- Guideline 5.4 - RRT: Initiating renal replacement therapy  
It is recommend that once a decision has been made to start dialysis in a patient with established access there should be no delay in starting treatment i.e. no waiting list to start dialysis
- Guideline 5.5 - RRT: Initiating renal replacement therapy  
It is recommend that urgent dialysis via a haemodialysis catheter should only be initiated where there is a clear clinical indication
- Guideline 5.6 - RRT: Initiating renal replacement therapy  
Where dialysis is started via an established access (vascular or peritoneal) which fails to work effectively urgent corrective action should be taken and dialysis via a haemodialysis catheter avoided if possible

### **Exit from the pathway**

A proportion of patients being prepared for renal replacement therapy will die before renal replacement therapy is clinically indicated. The majority of patients will progress to renal replacement therapy at which point they come off this care pathway.

Patients opting for **conservative** care should receive similar medical treatment and support as those opting for dialysis with the exception of formation of vascular or peritoneal access. Links with local community health providers shall be established to provide comprehensive care. Their exit point would be when their symptom burden exceeds medical management (i.e. the point at which they would have started dialysis if they had chosen that option). At that time they would be referred on for 'End of Life' care. The provider will have an electronic renal **conservative** care register in place which includes all patients who have chosen not to start dialysis, those with a failing transplant who decide not to return to dialysis or those who are deteriorating despite dialysis and are thought to be in the last year of life. **This register to be shared with primary care and palliative care specialists to ensure co-ordinated care of the patient.**

### **Supporting Technology**

The provider will have an IT system integrated into the hospital IT system for patients with renal disease. This system will be able to provide information to the UK National Renal



Registry and link with the national Renal Patient View (RPV) - a web based system which gives patients direct access their blood test results and, in many units, clinic letters. The IT system shall provide information for monitoring the quality of care for commissioners. All people with ERF (or their families/carers) shall be offered access to RPV **and encouraged to advise their GP if they register with RPV.**

### **3.3 Population covered**

The service outlined in this specification is for patients ordinarily resident in England or are otherwise the commissioning responsibility of the NHS in England (for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England).

Specifically this service is for adult patients (18 years and over) with progressive chronic kidney disease with an eGFR  $<20\text{ml}/\text{min}/1.73\text{m}^2$  and evidence of declining renal function where it is anticipated that kidney failure will become increasingly symptomatic and/or life limiting. Special arrangements will be required for young adults (age 18-25 years) to ensure their smooth transition from paediatric services or deal with the additional care needs, **including employment and education**, for patients newly presenting at this age. **Additional support will be patient centred and enable patient choice.**

### **3.4 Any acceptance and exclusion criteria and thresholds**

#### **Acceptance criteria**

This service will accept referrals from within nephrology departments, from other hospital departments, from hospitals that do not have nephrology services and from primary care.

The service will accept patients who meet one of the following criteria:-

- progressive chronic kidney disease with an eGFR  $<20\text{ml}/\text{min}/1.73\text{m}^2$  and evidence of declining renal function where it is anticipated that kidney failure will become increasingly symptomatic and/or life limiting
- acute kidney injury where renal function does not recover (e.g. vasculitis, anti glomerular basement membrane disease)
- acute uraemic emergencies where it transpires that the patient had chronic kidney disease and remains on renal replacement therapy

#### **Exclusions**

This service specification excludes young people under the age of 18 years.

The general care of patients with CKD including management of blood pressure, fluid balance, anaemia, renal bone disease, acidosis and cardiovascular risk is not included in this specification. These aspects of care for patients approaching ESRF will be commissioned locally.

### **3.5 Interdependencies with other services/providers**

The care of patients with progressive CKD is multidisciplinary and often involves interaction with other specialities. The members of the multidisciplinary team may vary but the minimum will as specified in section 3.2.

In addition the provider shall be able to provide rapid access to other specialities.

### **Co-located services**

#### **Surgical services**

There will be timely access to surgical out patient review to assess for vascular and peritoneal access

There will be timely access to theatre time for vascular and peritoneal access surgery

There will be access to transplant surgical expertise for assessment of suitability for transplant listing.

#### **Radiology**

There will be access to ultrasound or other imaging for assessment of vascular access.

There will be access to interventional radiology to treat failed or sub-optimal peripheral vascular access.

There will be access to radiology investigations to allow assessment of both donors and recipients for renal transplantation (full details of this are given in the service specification for renal transplantation).

#### **Anaesthetics/ITU**

There will be access to specialist opinion, intensive care support for surgical interventions and to non-invasive tests for cardiac and respiratory reserve.

### **Interdependent services**

#### **Cardiology**

There will be access to specialist opinion and investigations to assess suitability for transplantation given the high rate of cardiovascular morbidity in this group.

#### **Related Services**

- Renal Dieticians
- Specialist Pharmacy
- Clinical psychology
- Counsellors and social workers
- **Benefits advisors**
- Transplant services and transplant co-ordinators
- Primary care

All these services should be readily available and easily accessible but there is no absolute requirement for these to be on the same site.

## **4. Applicable Service Standards**

#### **4.1 Applicable national standards e.g. NICE**

The following national guidelines, service frameworks and registries are applicable to this service specification.

Renal Association Clinical Practice Guidelines:

- Planning, Initiating and Withdrawal of Renal Replacement Therapy (<http://www.renal.org/Clinical/GuidelinesSection/RenalReplacementTherapy.aspx>)
- Assessment of the potential kidney transplant recipient
- Vascular access for haemodialysis
- Peritoneal access (<http://www.renal.org/Clinical/GuidelinesSection/PeritonealAccess.aspx>)

The National Service Framework for Renal Services. Part One: Dialysis and Transplantation 2004

NICE pathway on management of CKD stage 5

(<http://pathways.nice.org.uk/pathways/chronic-kidney-disease/management-of-stage-5-ckd>)

End of Life Care in Advanced Kidney Disease: A Framework for Implementation. NHS Kidney Care National End of Life Care Programme Jun 2009

(<http://www.endoflifecareforadults.nhs.uk/publications/eolcadvancedkidneydisease>)

Renal Registry (<http://www.renalreg.com/index.html>)

The provider shall ensure that data is recorded accurately on a local IT system and all required data is uploaded electronically to the national Renal Registry

Focus on: Preparing for End Stage Renal Disease. NHS Institute for Innovation and Improvement. Feb 2008

[http://www.institute.nhs.uk/option,com\\_joomcart/Itemid,26/main\\_page,document\\_product\\_info/products\\_id,367.html](http://www.institute.nhs.uk/option,com_joomcart/Itemid,26/main_page,document_product_info/products_id,367.html))

Guidance on home compared with hospital haemodialysis for patients with end-stage renal failure. <http://publications.nice.org.uk/guidance-on-home-compared-with-hospital-haemodialysis-for-patients-with-end-stage-renal-failure-ta48>

Peritoneal dialysis: Peritoneal dialysis in the treatment of stage 5 chronic kidney disease.

<http://publications.nice.org.uk/peritoneal-dialysis-cg125>

#### **4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)**

**5. Applicable quality requirements and CQUIN goals**

**5.1 Applicable quality requirements (See Schedule 4 Parts A-D)**

**5.2 Applicable CQUIN goals (See Schedule 4 Part E)**

**6. Location of Provider Premises**

**The Provider's Premises are located at:**

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## Appendix 1

Quality standards specific to the service using the following template

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
<b>Domain 1: Preventing people dying prematurely</b>			
For all suitable patients to have timely access to RRT	Service to comply with national standards.  Less than 2% of patients admitted to hospital solely to allow start of RRT	Crude and corrected incidence rate of RRT (patients per million population).  % of patients admitted to hospital to start RRT.	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
<b>Domain 2: Enhancing the quality of life of people with long-term conditions</b>			
To increase the number of patients starting RRT by transplantation.	Benchmark followed by action plans for improvements.  5% more patients receive pre-emptive renal transplant compared to last	% of pre-emptive transplants.  Annual audit	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
	twelve months. Exempt if already in top quartile of UK performance		

**Domain 3: Helping people to recover from episodes of ill-health or following injury**

To ensure patients are informed and involved in their care.	Benchmark followed by action plans for improvement.	Number and % of patients utilising shared decision making aids/actively involved in shared decision making.	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
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**Domain 4: Ensuring that people have a positive experience of care**

To ensure informed patient choice and to be involved in shared decision making	Benchmark to be followed by evidence of improvement.	Annual Audit: 1. Patient survey including satisfaction with choice of RRT and patient reported health related quality of life.  2. Number and % of patients with access and instruction in the use of Renal Patient View.	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
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**Domain 5: Treating and caring for people in a safe environment and**



Quality Requirement	Threshold	Method of Measurement	Consequence of breach
<b>protecting them from avoidable harm</b>			
To increase the number of patients starting RRT electively with permanent access.	85%	% of patients known >3 months starting haemodialysis with a usable arteriovenous fistula/graft or peritoneal dialysis.  Annual audit.	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan

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