SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	A07/S/a
Service	Adult Kidney Transplant Service
Commissioner Lead	Jon Gulliver
Provider Lead	*The name of the individual leading on the service for the provider*
Period	*12 months*
Date of Review	

1. Population Needs

1.1 National/local context

Kidney transplants have been performed successfully in the UK since the 1960s. There have been major improvements in outcomes over time with significant advances associated with the advent of new immunosuppressive drugs, better patient management and developments in histocompatibility and immunogenetics (H&I). There is clear evidence of a survival benefit for those transplanted compared to patients who are on the waiting list for transplantation but who remain on dialysis. Up to 30% of established renal failure patients are deemed medically suitable for transplantation. The risk adjusted 5 year graft and patient survival following a first deceased donation transplant are 86% and 89% respectively, and 92% and 95% for first living donor transplant (NHS Blood and Transplant (NHSBT) Activity Report 2014/15. (www.organdonation.nhs.uk/statistics/transplant_activity_report/) A transplant also offers the opportunity for an improved quality of life with greater social independence and worth. Transplantation is not only beneficial for the individual but also represents value to the greater health economy. The first year of care after a kidney transplant costs around £17,000 and £5,000 for every subsequent year; whereas the average cost of dialysis is £30,800 (data from 2009, and is likely to change with the introduction of a national tariff) In addition, many patients can return to work and therefore have a lower dependency on state support.

There are 19 adult kidney transplant centres in England. On 31 March 2015 5686 (2014: 5881) patients were on the active list for a kidney only transplant in the UK and in the

financial year 2014/15 2793 (2013/14: 2930) adult kidney only transplants were performed in the UK of which 961 (2013/14: 1050) were from living donors. In addition on 31 March 2015 there were 202 (2014: 201) patients waiting for a kidney and pancreas transplant; 173 (2013/14: 188) were performed in the last financial year. As a result of the 14 recommendations of the Organ Donation Taskforce, which were published in 2008, there are on-going improvements to the organ donation infrastructure which have resulted in a 64% increase in the number of deceased organ donors by April 2014, although numbers have been static in 2014/15. This has mainly been an increase in the number of Donation after Circulatory Death (DCD) donors, but with a small increase in the number of Donation after Brainstem Death (DBD) donors. Over the last decade there has also been a significant increase in living donor transplants from 400 to over 1000 per year, although numbers were down 2014/15, but there is scope for a further increase. As a consequence of these national changes, there have been significant increases in transplant activity in the UK over the last few years. These numbers are increasing further following the launch of a new UK strategy in July 2013, 'Taking Organ Transplantation to 2020' (www.nhsbt.nhs.uk/to2020/) ; and of Living Donor Kidney Transplantation 2020 (www.odt.nhs.uk/pdf/ldkt_2020_strategy.pdf)

The initial assessment and work up of potential transplant recipients takes place in one of the 52 specialist renal centres, some of which are co-located with a kidney transplant centre. The initial assessment and work up of potential living donors takes place in one of the specialist renal centres and/or the kidney transplant centre. The follow up of transplant recipients transfers from the transplant centre to the specialist renal centre at any time post transplant from the time of initial discharge onwards, at the agreement of the two centres. Long-term follow up continues at the specialist renal centre.

1.2 Evidence Base

Renal Association Guidelines – Assessment of the Potential Kidney Transplant Recipient (2011).

NHSBT/British Transplantation Society (BTS) Guidelines for Consent for Solid Organ Transplantation in Adults (2013)

UK Guidelines for Living Donor Kidney Transplantation (2011) and Addendum (2014)

Renal Association Guidelines – Post-operative care of the Kidney Transplant Recipient (2011)

Kidney Disease Improving Global Outcomes (KDIGO) Guideline for Care of the Kidney Transplant Recipient (2009)

British Transplantation Society Guidelines for the Prevention and Management of Cytomegalovirus Disease after Solid Organ Transplantation (2011)

European Best Practice Guidelines for Renal Transplantation (2002)

British Transplantation Society - Antibody Incompatible Transplant Guidelines (2016)

British Society for Histocompatibility and Immunogenetics (BSHI)/BTS Guidelines for the detection and characterisation of clinically relevant antibodies in allotransplantation (2014)

British Transplantation Society – Management of the Failing Kidney Transplant (2014)

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

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

The service will be expected to provide accurate timely data to the NHS BT and the Renal Registry. This will enable NHS England to monitor outcomes. These need to be considered in conjunction with the quality monitoring detailed within this contract:-

- Number of live donor transplants and % pre-emptive (Domain 1 & 2)
- Number of deceased donor transplants and % pre-emptive (Domain 1 & 2)
- Median waiting time for transplant (Domain 1 & 2)
- Cold ischaemic times (Domain 3 &4)
- Thirty day patient mortality and transplant outcome (Domain 1, 3, 4 & 5)
- One and 5 year graft and patient survival for living donor and deceased donor transplants (Domains 1 & 2)

The key patient and service outcome measures are:

Transplant recipients (domains 1, 2, 3, 4 and 5)
Patients are able to make an informed choice and shared decision making about transplantation

Medically suitable patients are placed on the transplant list in a timely manner as per the quality requirements in this contract.

To ensure that the waiting time for a transplant is kept to the minimum and that the

pathway and quality requirements as described in the service specification are adhered to.

Time in hospital is minimized

Complications, side effects and co-morbidity of kidney transplantation are minimised

Optimal long term function of the transplant

There is effective communication between the patient and the right health care professional throughout the pathway

Living donors (domains 1, 2, 3, 4 and 5)
Donors are able to make an informed choice and shared decision making about living donor nephrectomy

Living donors are worked up according to national guidelines in a timely manner; including antibody incompatible transplantation and recipient pre-conditioning where this is an option. It is expected that the time for referral to surgery for all living donors will be less than 18 weeks unless the pathway has been paused for valid reasons, and that units will have plans in place so that this is 12 weeks by April 2017.

To ensure that the waiting time to proceed to living donor nephrectomy is kept to the minimum, unless the donor or recipient wants to delay.

Time in hospital is minimized

Complications, side effects and co-morbidity of living donor nephrectomy are minimised

Long term follow-up takes place and is nationally reported

There is effective communication between the donor and the right health care professional throughout the pathway.

Guidelines and Standards

These principles are supported by the national standards and guidelines listed in section 1.2 and 4.1. Transplant centres will deliver outcomes which are not significantly inferior to the national average in terms of numbers of transplants expressed as a percentage of the number of patients receiving renal replacement therapy, mortality and graft survival, cold ischaemic time and waiting times. Measures for these principles are included within the quality requirement of this contract.

Patients are able to make an informed choice about transplantation (domain 4)
Kidney transplantation is the renal replacement therapy of choice for patients with stage 5 chronic kidney disease who are considered fit for major surgery and for chronic immunosuppression

Specialist kidney transplant centres will have written criteria based on the national specialist society guidelines for acceptance on to the waiting list. The benefits and potential risks associated with transplantation will be fully explained both verbally and in writing. Potential transplant recipients will be informed of all donor options including living donation (directed, paired exchange and altruistic), donation after brain death (DBD) and donation after circulatory death (DCD).

Early provision of culturally appropriate information; discussion with and counselling of patients, relatives and carers about the risks and benefits of transplantation with a clear explanation of tests, procedures and results.

Consent to transplantation will be obtained at the time the patient is accepted for inclusion on the National Transplant List, reviewed annually and reconfirmed prior to surgery.

Medically suitable patients are placed on the transplant list in a timely manner (domain 2 and 3)

Medically suitable patients are placed on the transplant list in a timely manner irrespective of when they present.

Patients with progressive deterioration in renal function and medically suitable for transplantation will be offered the option of being placed on the national transplant list within six months of their anticipated dialysis start date to optimise their chance of a pre-emptive deceased donor transplant. To facilitate living donor pre-emptive transplantation, information will be provided at an early stage and discussion with potential donors and recipients may be started when the recipient estimated glomerular filtration rate (eGFR) is approximately 20 ml/min, but there will be flexibility depending on the rate of decline of renal function.

Patients will undergo a surgical assessment prior to being placed on the transplant list.

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

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

Optimise the waiting time for a transplant (domain 1, 2, 3 and 4)

People with CKD are facilitated to receive a pre-emptive kidney transplant before they need dialysis, if that is their wish and they are medically suitable.

Pre-emptive transplantation is the treatment of choice for all suitable patients who choose this option whenever a living donor is prepared to donate.

To facilitate pre-emptive living donor transplantation, donor evaluation will start sufficiently early by the specialist renal unit to allow time for more than one donor to be assessed if necessary. Information will be provided at an early stage and discussion with potential donors and recipients may be started when the recipient eGFR is approximately 20 ml/min, but there will be flexibility depending on the rate of decline in renal function.

Thereafter, recipient and donor assessment will be tailored according to the rate of decline in recipient renal function to prevent unnecessary investigations, taking into account disease specific considerations and individual circumstances. Ideally transplantation will take place when the patient is within six months of their anticipated dialysis start date. Genetic screening of potential living related donors for polycystic kidney disease (PKD) recipients is now available, and professional guidelines are required in this area to clarify indications and limitations.

When antibody incompatible transplantation is being considered, units will have a written protocol based on best published practice. This will include the recommendations on prevention, diagnosis and treatment of antibody mediated rejection from the British Transplantation Society – Antibody Incompatible Transplant Guidelines (2011)

Consent to transplantation will be obtained at the time the patient is accepted for inclusion on the National Transplant List reviewed annually and reconfirmed prior to surgery. Whilst awaiting transplantation, patients will be formally reminded every 12 months, or whenever a change in their condition warrants, of the risks and benefits of the transplant and this will be recorded in the patient records. Consent will be re-affirmed at least every 12 months and immediately prior to the transplant; this will be done by an appropriately experienced and trained health care professional.

Any patient suspended long term from the national transplant waiting list will be reviewed as a minimum every 6 months and the outcome of the review communicated to the patient verbally and in writing.

All patients on the waiting list will have an annual review focussing on their suitability to receive a renal transplant (see section 3.2 for what this will include)..

Minimise time in hospital (domain 3 and 5)
Timely operating theatre availability to ensure optimal cold ischemia times and there will be 24/7 availability of an emergency theatre. Patients having a deceased donor transplant will be given priority in the emergency operating theatre. Once a clinical decision has been made to proceed induction of anaesthesia will normally start within 2 hours, or if theatre is occupied they will be allocated the next theatre slot after the current operation is finished. There will be a recording of exceptions.

Detailed guidelines available covering all aspects of post-transplant care including immunosuppression

Minimise complications, side effects and co-morbidity (domain 5)
Effective preventive therapy to control infections (Cytomegalovirus (CMV), Pneumocystis, Tuberculosis, influenza vaccination as a minimum).

Appropriate immunosuppression in accordance with NICE guidance and effective monitoring and treatment to minimize the risks of adverse effects of immunosuppressive treatment.

Detailed guidelines available covering all aspects of post-transplant care including immunosuppression, prevention and treatment of cardiovascular disease and prevention

and screening for malignancy.

Optimise long term function of the transplant (domain 1 and 2)
Detailed guidelines available covering all aspects of post-transplant care including immunosuppression and monitoring of the transplant.

NICE Renal replacement therapy services Quality Statement 7: Transplantation – rapid access to a specialist histopathology service states 'Adults who have a suspected acute rejection episode have a transplant kidney biopsy carried out and reported on within 24 hours.'

Effective communication between the patient and the right health care professional throughout the pathway (domain 4)
Clear explanation for patients of tests, procedures and results. This applies especially for information and education about immunosuppressive therapy and when patients are called in for a potential transplant that does not happen.

To aid effective communication, transplanted patients or patients registered on the transplant pathway will be offered access to Renal Patient View.

Specialist advice from the transplant team available for patients with a kidney transplant admitted to hospital, whatever the clinical setting

Communication and care will be based upon the NICE quality standard on 'Patient experience in adult NHS services'. This includes establishing, respecting and reviewing the patients' preferences for sharing information with partners, family members and/or carers.

Ensure that the patient's' General Practitioner is kept informed throughout the transplant pathway.

Living donor (domain 4)
The welfare of the donor remains paramount, and vigilance in donor care and management is essential to ensure that appropriate safeguards are in place to protect individuals and to inspire public confidence.

Reimbursement of the expenses incurred by the living donor will be as per the national policy [www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2014/01/a07-pa-policy.pdf].

The donor and recipient will be assessed using a protocol based upon British Transplantation Society / Renal Association guidelines (UK Guidelines for Living Donor Kidney Transplantation).

To facilitate effective use of the shared living donor pool, theatre capacity at different Trusts will need to be aligned to ensure such surgery are able to take place on the same day. For patients in the National Living Donor Kidney Sharing Schemes (LDKSS) there will be a maximum eight week standard from transplant centre notification of the outcome of a kidney donor matching run to the date of surgery, which is facilitated by the national

sharing weeks.

There will be the opportunity for the preparation and work up of living donors to be undertaken as near to the donor's home as possible when this is requested. It is therefore expected that such work may be undertaken by a different specialist transplant nephrologist or transplant centres from that of the actual recipient and the planned transplant. This activity will be funded as per local agreement pending instigation of national tariff.

Follow up of the living donor will be in accordance with national guidance and EUODD requirements.

Antibody incompatible transplants (domain 1)

There are two types of antibody incompatible transplants:

- ABOi transplants: these are defined as transplants where the recipient has a blood group incompatibility with the donor*
- HLAi transplants: these are defined as transplants where the baseline flow cytometric crossmatch, or complement dependent cytotoxic crossmatch, is positive. Transplants where the recipient has donor specific antibody, but a negative crossmatch, do not fall into this category.

The number of antibody incompatible transplants performed over the last four years had remained reasonably stable, although there has been a modest reduction in the number of ABOi transplants with the success of the NKDSS. It is not recommended that AIT is performed on an 'ad hoc' basis, but units performing this type of transplant should have appropriate clinical guidelines, resource allocation, and established working with the laboratories. Laboratories must be able to define antibodies to the standard defined in the BSHI/BTS document 'Guidelines for the Detection and Characterisation of Clinically Relevant Antibodies in Allotransplantation'.

Some transplant units may choose not to perform AIT, or may perform just ABO or just HLA AIT. If this is the case, patients should be informed of their choices in respect of AIT and be offered appropriate referral to another transplant unit if they wish.

Service specifications for each of these types of transplants are considered separately.

ABOi transplants

Prior to undertaking these complex transplants, specialist kidney transplant centres will be required to adhere to the best practice guidance for such transplants. Assurance by commissioners will be sought that there is:-

- Access to robust, validated haemagglutinin assays, within the range of variation accepted in the UK. Although it is not necessary to provide a 24 hour service, a 7 day per week service with same day turn-around time is required.
- Dedicated clinical expertise across the multidisciplinary team. Specifically, this will include clinical consultants and haematologist/MLSOs with an interest and expertise in ABOi transplantation, to ensure consistency in titre results.

- A critical mass of patients to develop clinical expertise, ameliorate the learning curve effect and streamline services more economically. Where a centre typically performs <5 ABOi transplants a year, there will be an established link with a larger centre for advice and guidance. Access to a continuously available antibody removal service (using either immunoabsorption or plasmapheresis).
- Flexibility in the availability of theatres and surgical expertise, so that transplants can be rescheduled at short notice where necessary.
- Outcome monitoring through all participating centres contributing data to the NHSBT Antibody Incompatible Transplant Registry.

*The following donor-recipient blood group pairs would be considered to indicate blood-group incompatibility:

$A_1$to O, A_2 to O, B to O, B to A, A_1 to B, A_2 to B, AB to O, AB to A, AB to B.

HLAi transplants

Prior to undertaking these complex transplants, specialist kidney transplant centres will be required to adhere to the best practice guidance for such transplants. Assurance by commissioners will be sought that there is:-

- Access to solid phase donor specific antibody assays, and a quantitative cross-match. Although it is not necessary to provide a 24 hour service, a 7 day per week service with same day turn-around time is required.
- Dedicated clinical expertise across the multi-disciplinary team. Specifically, this will include clinical consultants and H&I staff with an interest and expertise in HLAi transplantation.
- A critical mass of patients to develop clinical expertise, ameliorate the learning curve effect and streamline services more economically. Where a centre typically performs <5 HLAi transplants a year, there will be an established link with a larger centre for advice and guidance.
- Access to a continuously available antibody removal service (using either immunoabsorption or plasmapheresis).
- Flexibility in the availability of theatres and surgical expertise, so that transplants can be rescheduled at short notice where necessary.
- Access to emergency renal histopathology 6 days a week, recognising that the ideal is 7 days a week.
- Access to onsite postoperative intensive care.
- Outcome monitoring through all participating centres contributing data to the NHSBT Antibody Incompatible Transplant Registry.
- Use of eculizumab: this new and costly drug has been used by some centres to treat severe acute rejection after HLAi, and is currently the focus of studies concerning use as prophylaxis against rejection. Further data on efficacy are therefore awaited, along with a policy on funding.

3. Scope

3.1 Aims and objectives of service

The aim of this service is to provide comprehensive care to patients who either require or who have received a kidney transplant. This is underpinned by the National Institute for Health and Care Excellence (NICE) Renal replacement therapy services Quality Standards [QS72] (November 2014) 2, 3 and 7 (http://www.nice.org.uk/guidance/qs72)

Providers of kidney transplant services will ensure that as a minimum the following care is provided:

- Equity of access to transplantation regardless of point of referral and location
- Clear and unambiguous care pathways, supported by the provision of culturally appropriate information; specifically in relation to:
    - The counselling of patients and relatives/carers regarding the risks and benefits of transplantation
    - Explanation of tests, procedures and results
    - Outcome of assessment and review to be documented in a letter to the patient detailing discussions and agreed shared decision reached, including those patients who are not suitable
    - Information and education about immunosuppressive therapy

- Safe, effective, evidence-based care, delivered through effective pathways of care, in particular through the provision of:
    - Detailed recipient assessment (including cardiac assessment) and annual transplant focussed review whilst on transplant list, including patients with a failing transplant where suitable for further transplantation
    - A surgical assessment of each patient prior to being placed on the national kidney transplant list.
    - Detailed H&I assessment
    - Detailed living donor assessment when an appropriate option; and offering all options including paired/pooled exchange or blood group incompatible (ABOi)/HLA antibody incompatible transplantation (recognising that in some units patients may need to be referred elsewhere for these treatments)
    - Referral of suitable patients for pancreas and kidney transplantation.
    - Timely operating theatre and relevant staffing availability (surgeon, anaesthetist and H&I) to ensure optimal cold ischaemia times.(<18 hours for DBD donor and <12 hours for DCD donor transplantation)
    - Effective immunosuppressive therapy
    - Effective preventive therapy to control infections
    - Prevention/management of long term complications and co-morbidities, particularly with respect to cardiovascular disease, infection and cancer.
    - Additional support to the post transplant patient transitioning from paediatric services that is centred on the patient and their choice. Such support is to take into account employment and education needs of the patient.

Specialist advice from the transplant team available for patients with a renal transplant admitted to hospital, whatever the setting.

Specialist transplant centres will have a process/system to ensure patients are added to the national transplant list, and that the list is regularly reviewed and updated; kidney offers are received and assessed from NHS Blood and Transplant (NHS BT) in a timely manner, and ensuring the requirements of the European Union (EU) Organ Donation Directive are met. In accordance with the EU Organ Donation Directive, written information relating to organ offers should be reviewed prior to the acceptance or decline of offers; this can be achieved through the use of EOS Mobile (NHS Blood and Transplant Organ Donation and Transplantation online system). There will be 24/7 availability of a recipient point of contact and NHSBT standards in accepting or rejecting an organ within one hour will be met.

3.2 Service description/care pathway

This specification relates specifically to transplantation and in terms of this specification begins when the patient undergoes surgical assessment for transplantation prior to joining the transplant list. This specification pathway stops, either when the transplant fails and the patient returns to dialysis, or with the death of the patient. The actual patient pathway for transplantation begins with the work up and this is covered in the A6e Renal Assessment service specification. Other forms of RRT are described in the Renal Dialysis Service Specifications A06/S/a, A06/S/b and A06/S/c.

The transplant pathway will be delivered by specialist kidney transplant centres and referring specialist renal units with the necessary infrastructure. This infrastructure will include the necessary resources of staffing, beds, 24 hour access to theatres, access to H&I services, and the interdependencies described in section 2.5; supported by a multi-disciplinary team (MDT) style process where indicated; and a robust clinical governance structure including clinical audit.

Care Pathway
The transplanting centre is based at *[insert names(s)]*. The referring renal units are based at *[insert name(s)] [or other description of local set up]*

All patients with CKD 5 and CKD 4 with progressive disease will be considered for transplantation and reasons for not being considered documented. Patients with progressive deterioration in renal function and medically suitable for transplantation will be offered the option of being placed on the national transplant list within six months of their anticipated dialysis start date. It is expected that timely investigation and written referral by the nephrologist to the transplant surgeon, for surgical assessment, together with appropriate information to the patient is provided during the transplant pathway. Patients will attend a patient information session, ideally with expert patients. It is expected that for non-complex patients the referral to listing process will take under 18 weeks.

All patients will undergo a surgical assessment prior to being placed on the transplant list. Patients will be placed on, or removed from the waiting list only after discussion and agreement with the nephrologist, transplant surgeon and the patient themselves according to local practice.

Complex or borderline patients require a MDT discussion to establish their suitability and/or to plan their management. Surgical issues may also provide insurmountable challenges and the patient will not be listed. Patients will be offered the option of having a second opinion from a transplant clinician in a different transplant centre.

The provider is required to copy all correspondence with patients and between consultants to the patient's General Practitioner.

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Transplant listing

When patients have completed their assessment and are considered suitable transplant candidates they will be entered onto the NHSBT kidney transplant list as soon as possible. This task, and the on-going maintenance of the local transplant list, will be the responsibility of the recipient transplant co-ordinator *[or other named person]*. Patients will be made aware of their activation status.

Maintenance on the list

All patients on the waiting list will have an annual review focussing on their suitability to receive a renal transplant. This review will incorporate a relevant history and examination including a cardiovascular assessment, lower limb pulses and any new clinical problems; requesting of additional investigations; a discussion of donor types, risks and confirmation of consent; and re-exploration of living donor options. Patients who are deemed to be at higher than average risk, such as for cardiovascular or surgical reasons, should be informed of their high risk status. In addition they will be reviewed by a transplant surgeon and/or nephrologist at the regional transplant centre at least annually to ensure their condition has not deteriorated.

All patients on the list will have antibody analysis performed at least every three months and after sensitising events

Transplant Episode

Transplant centres will have the necessary infrastructure to enable transplantation of organs from DBD and DCD donors and living donors (including the national kidney sharing schemes). It is expected that there will be 24/7 availability of an emergency theatre, to help ensure optimal cold ischaemia times (<18 hours for DBD donor and <12 hours for DCD donor transplantation). Outcomes are expected which are not significantly inferior to the national average.

Follow up Care

All transplant recipients require regular follow up as per the UK Renal Association guidelines on the Post-operative care of the kidney transplant recipient. Follow-up will be patient focussed and units will consider local blood tests and telephone follow-up in addition to clinic visits. This will initially be frequent (2-3 x per week) but will usually become less frequent as time proceeds – often 3-4 x per year. Early follow up is expected to be shared between the transplant surgical team and the transplant nephrologists; whilst later care will usually be the responsibility of a nephrologist. Where patients are repatriated to specialist centres at the time of post-transplant discharge it is expected that transplant surgical input will be available when required. In some centres transplant specialist nurses or a pharmacist will also be involved in early and long term follow-up.

The handover of patients post transplant will be at the mutual agreement of the patient, transplant centre and the main renal unit and will vary according to local circumstances. Best practice would indicate that this handover takes place within the first 12 months after the transplant.

NHS England will be the responsible commissioner for all immunosuppression prescribing related to kidney transplantation. The transplant centre or specialist renal centre remains responsible for all follow-up and changes in therapy, and will prescribe all immunosuppression required post transplant. Further national agreement is required for the funding of new agents such as Alemtuzumab, Belatacept and Eculizumab. Consideration needs to be given to the availability of generic immunosuppressives and the importance for transplant patients of maintaining consistent supply. To that end, immunosuppressives (both innovator brands and branded generics) will be prescribed by brand and referred to by that brand in all correspondence in tertiary, secondary and primary care, and with all patients themselves (see Medicines and Healthcare products Regulatory Agency guidance)

The long term care of transplant recipients will include a holistic assessment of the patient's progress along with pre-emptive strategies to minimise future health, physical and psychological problems. This will include a regular review of their immunosuppressive therapy which will be tailored to prolong the life of their transplant whilst minimising the risk of drug related side effects. In addition patients will have their risk of future cardiovascular disease and bone disease assessed with steps taken to minimise such risks. Patients will be made aware of their increased risk of malignancy, in particular skin cancer, and counselled about appropriate changes in their lifestyle. Close links should be established between the transplant centre, local physician and dermatologist for the management of transplant patients postoperatively. Post transplant patients will be encouraged to attend cancer screening programmes if appropriate.

Provision for post transplant HLA specific antibody monitoring and investigations of humoral rejection episodes will be part of the transplant service.

Patients who have a failing transplant will be identified at an early stage as outlined in this specification to ensure they are prepared for another transplant or dialysis in a timely manner; or conservative care where patients opt for this. Patients requiring return to dialysis will require additional clinical, dietetic and psychological support to minimise the risks and optimise the outcomes for this patient group.

A consultant level health care professional will be available for every transplant clinic. Access to a renal dietician, a renal pharmacist and a clinical psychologist is considered essential. The routes to access social work and other support services will be offered to those patients requiring them.

Discharge criteria and planning

Transplant care will be continuous and extend for the life of the functioning transplant.. The care of the transplant recipient will normally transfer at some point within 12 months post transplant from the transplant centre to the care of the nephrologist at the main renal unit.

Any transfer of care must be supported by clear communication and documentation between the transplant unit and referring main renal unit. Patients will already be aware that their care will transfer back to the referring main renal unit (having been informed pre-transplant) but the exact timing of this transfer will be made clear to the patient with appropriate notice and agreement of the patient.

Governance and accountability will transfer to the local main renal unit at the point of repatriation.

3.3 Population covered

The service outlined in the specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in *Who Pays?: Establishing the responsible commissioner* and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

*Note for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP practice in Wales or Scotland, but INCLUDES patients resident in Wales or Scotland who are registered with a GP practice in England.

Specifically this service is for all adult CKD 5 patients and CKD 4 patients with progressive disease and those who already have a transplant

3.4 Any acceptance and exclusion criteria and thresholds

Acceptance Criteria

The service will accept inward referrals from nephrologists. Patients with CKD 5 and CKD 4 with progressive disease will generally be under the care of a nephrologist. The service will also accept referrals from other providers of kidney transplantation, particularly when the referring service does not undertake the specific transplant that the patient requires e.g. HLAi transplantation.

The service will accept referrals for all CKD 5 patients and CKD 4 patients with progressive disease who are medically suitable irrespective of gender, ethnicity, disability, faith or sexual orientation.

When a referral is received the patient will be seen in an assessment clinic by one of the transplant surgeons and if appropriate added to the national transplant list.

Exclusions

There are no absolute exclusion criteria for assessment except as implied by the listing criteria for transplantation. Patients under the age 18 are excluded from this service specification.

3.5 Interdependencies with other services/providers

In terms of the pathway, this service specification begins when the patients undergoes surgical assessment for transplantation prior to being added to the national transplant list and stops either when the transplant fails and the patient returns to dialysis or with the death of the patient. For this section the spell of care is defined at the inpatient episode for the actual transplant surgery. Optimum delivery of the agreed pathways requires effective working relationships with the following services and organisations, but not limited to:

Co-located services (need to be provided on the same site)

- Nephrology
- Intensive care
- Theatre and anaesthetic departments
- Radiology (including interventional radiology)
- Pharmacy
- Dietetics
- Allied Health Professionals (including physiotherapy)

Interdependent services (needed during the spell of care)

- Histocompatibility & Immunogenetics (H&I) laboratory (accredited by Clinical Pathology Accreditation (CPA) or equivalent)
- Histopathology/Haematology/Clinical Chemistry (accredited by Clinical Pathology Accreditation (CPA) or equivalent)
- Microbiology/infectious diseases
- The Blood Transfusion Service
- Cardiology – cardiopulmonary assessment and investigations

Related services (preceding or following the spell of care)

- Primary care
- Histocompatibility & Immunogenetics (H&I) laboratory
- Histopathology/Haematology/Clinical Chemistry
- Radiology (including interventional radiology)
- Microbiology/infectious diseases
- Dermatology
- Urology
- Haematology/oncology for management of patients with Post Transplant Lymphoproliferative Disorders
- Paediatric services (transition)
- Clinical Psychology
- Young person care workers
- NHS Blood and Transplant (NHSBT) – transplant listing, organ retrieval and allocation, paired exchange scheme
- Human Tissue Authority – regulatory approval of living donor transplants; and as the competent authority for EU Organ Donation Directive on the Quality and Safety of Organs
- Pancreas transplant centre for management of diabetic patients requiring kidney

and pancreas transplantation

- Medical genetics including laboratory genetics for patients with autosomal dominant polycystic kidney disease who have a potential related living donor who may need screening.

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

The Provider is expected to deliver in care in accordance with the following core standards and guidelines:-

Core standards

Assessment for transplantation
Patients with progressive deterioration in renal function medically suitable for transplantation will be offered the option of being placed on the national transplant list within six months of their anticipated dialysis start date to optimize their chance of a pre-emptive deceased donor transplant and/or be worked up for a pre-emptive living donor kidney transplant. Patients will be given written and verbal information about the benefits and potential risks associated with transplantation prior to listing.

Transplantation
Transplant centres will be licensed by the Human Tissue Authority in respect of the EU Organ Donation Directive.

Transplant centres will have the necessary infrastructure to enable transplantation of organs from DBD and DCD donors and living donors (including the national kidney sharing schemes), ensuring optimal cold ischaemia times and with outcomes which are not significantly inferior to the national average. When live donors are antibody incompatible the option of entry into the Paired Exchange scheme, local management or onward referral for direct transplantation must be discussed and offered where appropriate.

Transplant follow-up
Transplant centres and referring renal units will i) prescribe and monitor immunosuppressive therapy; ii) ensure all transplant recipients have regular follow up and holistic care as per national guidelines; iii) ensure the data return to NHSBT and Renal Registry is timely and complete and iv) have a robust clinical governance structure including clinical audit and review of NHSBT Renal Transplant Centre Specific Report..

Deceased donor organ acceptance

The National Standards for Organ Retrieval From Deceased Donors state that, following withdrawal of treatment in DCD donors, organ retrieval teams will wait for at least three hours for the onset of functional warm ischaemia.
Transplant Centres will consider accepting each individual organ offered, based on the suitability of the organ for their recipient, and undertake regular audit of deceased donor organs which are declined

Guidelines

NICE Quality Standards: Renal replacement therapy services Quality Standards (2014)

NICE Quality Standards: Patient Experience in Adult NHS services (2012)

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

Human Tissue Authority (HTA) Guidance for Transplant Teams and Independent Assessors

NHS England – Reimbursement of expenses for living kidney donors (2015)

National Standards for Organ Retrieval From Deceased Donors 2010

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

EU Organ Donation Directive
The Quality and Safety of Human Organs Intended for Transplantation

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:

ONLY LIST PROVIDERS IF THERE HAS BEEN A FORMAL DESIGNATION PROCESS.

Appendix 1

Quality standards specific to the service using the following template

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
Optimal long term function of the transplant. To ensure complications, side effects and co-morbidity of kidney transplantation are minimised	Below lower 99.8% confidence limit.	Patient and graft survival at 12 months, and 5 years. Annual [NHSBT audit data.]	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
Domain 2: Enhancing the quality of life of people with long-term conditions			
Medically suitable patients are placed on the national transplant list within 18 weeks of referral to transplant surgeon.	<85%	Number of medically suitable patients who are placed on the national transplant list within 18 weeks of referral to transplant surgeon. [Local annual audit]	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
To facilitate opportunity for pre-emptive transplants and to ensure timely listing of all	5% below national average	Number of pre-emptive living donor kidney transplants as a percentage of living donor	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
medically suitable patients on the transplant list prior to commencement of dialysis.		transplants. [Annual NHSBT data]	Action Plan
Domain 3: Helping people to recover from episodes of ill-health or following injury			
Cold ischaemic time to be as per national guidance.	>90% compliance	Cold ischaemic of <12 hours for DCD donor transplant and <18 hours for DBD donor transplant for first intended recipient where exceptions don't apply [Local audit data]	Conditions Clause 9 (GC9) Remedial Action Plan
Domain 4: Ensuring that people have a positive experience of care			
To ensure timely listing of all medically suitable patients on the transplant list prior to commencement of dialysis.	5% below national average	Percentage of patients on active national transplant list before start of dialysis [Annual NHSBT data]	Conditions Clause 9 (GC9) Remedial Action Plan
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm			
Complications,	Any signals	30 day graft and	Conditions Clause

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
side effects and co-morbidity of kidney transplantation are minimised	reported	patient survival [3 monthly NHSBT data]	9 (GC9) Remedial Action Plan