

PATIENT SELECTION FOR DECEASED DONOR KIDNEY ONLY TRANSPLANTATION

This policy has been created by the Kidney Advisory Group on behalf of NHSBT.

The policy has been considered and approved by the Organ Donation and Transplantation Clinical Audit, Risk and Effectiveness Group (ODT CARE), formerly Clinical Governance Monitoring Group (CGMG) and the Senior Management Team of the Organ Donation and Transplantation Directorate (ODT). It has also received final approval from the Transplant Policy Review Committee (TPRC), who act on behalf of the NHSBT Board, and who will be responsible for annual review of the guidance herein.

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Next review: January 2013

The aim of this document is to provide 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.

In the interests of equity and justice all centres should work to the same selection criteria.

Non-compliance to these guidelines will be handled directly by NHSBT, in accordance with the *NHS Blood and Transplant Organ Donation and Transplantation: Policy on Non-compliance with Selection and Allocation policy (May 2011)*.

It is acknowledged that these guidelines will require regular review and refreshment. Where they do not cover specific individual cases, mechanisms are in place for selection of exceptional cases.

This policy provides clinicians with evidence-based criteria by which to assess patients, based on guideline principles from the Renal Association¹, which have been endorsed by the British Transplantation Society (BTS).

This policy predominantly covers kidney only transplantation. Multiple organ transplantations are covered in section 3.2.2.

1. Conditions that are considered for transplantation

All patients with end-stage renal failure, who might benefit from transplantation, should be assessed for transplantation. Listing for transplantation may be limited by contraindications (see section 3.3).

1.1 Pre-emptive listing

Pre-emptive listing refers to the listing of patients for transplantation within 6 months of their anticipated need for renal replacement therapy.

Pre-emptive transplantation from either living or deceased donors offers the potential for better patient and graft survival than transplantation performed after the start of dialysis.

Pre-emptive renal transplantation should be encouraged for all patients whenever a living donor is available. To facilitate pre-emptive transplantation, donor evaluation should start sufficiently early to allow time for more than one donor to be assessed if necessary. Information should be provided at an early stage and discussion with potential donors and recipients should be started when the recipient's estimated Glomerular Filtration Rate (eGFR) is approximately 20 ml/min. Thereafter, recipient and donor assessment should be tailored according to the rate of decline in recipient renal function, taking into account disease specific considerations and individual circumstances.

Pre-emptive transplantation from a deceased donor may ideally be offered to all transplantation candidates but is of particular importance for children where dialysis affects growth and development. It is worth noting that the average wait for a kidney from a deceased donor is over 2 years after listing. Suitable patients should be eligible for the transplant list if it is predicted that renal replacement therapy will be needed within 6 months – typically those patients with a GFR of <15 ml/min.

2. Assessment of patients

The assessment of patients for transplantation should be undertaken in a timely way without unnecessary delay.

Comprehensive information on renal transplantation should be given to all potential candidates with end-stage renal failure, including the likely mortality and morbidity associated with transplantation, compared with that of dialysis, and also data concerning the different sources of kidneys, including higher risk organs.

The specific transplant evaluation should only be performed after this information is delivered and clear acceptance is given by the patient (and/or guardian if the patient is <18 years old). Inclusion on the transplant list is the final step of the procedure and requires formal informed consent from the prospective recipient² (and/or guardian if the patient is <18 years old).

All critical aspects concerning kidney donor selection for transplantation, including the use of higher-risk organs, need clear informed consent from the prospective candidate, both in advance, whenever possible, and at the time of an offer.²

Assignment to the transplant list is a crucial step for the patient and should follow objective scientific principles after careful evaluation of their medical history.

2.1 Information required for listing a patient

Patients should be formally assessed before being placed on the transplant list. The information required to be able to list a patient for transplantation includes:

- Blood group
- HLA typing according to minimum resolution specification agreed by the NHSBT Kidney Advisory Group
- Antibody screening should be performed according to BTS guidelines³
 - Unacceptable donor HLA mismatches are registered with NHSBT, along with the reason
- Any minimum HLA match requirements
- Date of birth
- Results of virological screening
- Height and weight
- Requirements for dialysis

2.2 Screening for cardiovascular risk

Full assessment of cardiovascular risk should be performed – this is a key component of patient assessment.

In end-stage renal disease there is no compelling evidence that pre-transplantation screening tests for coronary artery disease in asymptomatic patients are effective in preventing future cardiac events or reducing mortality after transplantation; however, they may be used to identify high-risk patients for exclusion from the transplant list, and in those listed, may help to inform consent for transplantation.

2.3 Prior exposure to viral infections

All potential transplant recipients should be tested for prior exposure to viral infections including:

- Cytomegalovirus (CMV)
- Epstein-Barr virus (EBV)
- Varicella zoster virus (VZV)
- Hepatitis B and C
- Human immunodeficiency virus (HIV)

Immunisation should be offered to all hepatitis B (if not already immunised) and VZV antibody negative patients before transplantation. Patients otherwise suitable for renal transplantation with evidence of chronic hepatitis B and/or C or HIV infection

should be managed according to British Transplantation Society and European Best Practice Guidelines (EBPG)⁴ prior to transplantation.

Where necessary, appropriate advice should be sought from a virologist or hepatologist. Children should be checked particularly for measles, mumps and rubella and are vaccinated if appropriate. They should also be up to date with routine childhood vaccines.

2.4 Psychological evaluation

Transplantation and the subsequent management can be psychologically demanding. Consideration should be given to seeking advice from counsellors or appropriately trained healthcare professionals. There should be reasonable confidence that the patient will adhere to their post-transplant follow-up regime.

2.5 Assessment for malignancy

Renal transplantation should only be considered in potential recipients with previous malignancy (excluding non-melanoma skin cancer) if there is no evidence of persistent cancer. It is recommended that the waiting time between successful tumour treatment/remission and transplantation be at least 2 years.

For certain malignancies the waiting time may need to be extended to more than 5 years. The Israel Penn International Transplant Tumor Registry and other Registry reports should be consulted for tumour specific advice.⁵

2.6 Assessment for recurrent renal disease

Patients who are at risk of developing recurrence of original renal disease should be managed according to the EBPG.⁴

2.7 Assessment for comorbid conditions

There is no evidence that asymptomatic potential transplant recipients require screening for diverticular disease, peptic ulceration or gall bladder stones.

Obese patients (BMI >30 kg/m²) present technical difficulties and are at increased risk of peri-operative complications. They should be screened rigorously for cardiovascular disease and each case considered individually. Although obesity is not an absolute contraindication to transplantation, individuals with a BMI >40 kg/m² are less likely to benefit.

Smoking itself is not considered a comorbid condition, however, it may result in other comorbidities and may be associated with worse outcomes after transplantation. As such, potential transplant recipients should be strongly encouraged to stop smoking before and after transplantation. Formal smoking cessation programmes should be offered and accessed in primary care.

3. Selection criteria

All patients with end-stage renal failure should be considered for transplantation unless there are absolute contraindications, because renal transplantation in general offers better life expectancy and quality of life than dialysis.

3.1 Rationale for choice of selection criteria

The rationale behind the choice of selection criteria for kidney transplantation is the need to ensure patients are likely to tolerate the risks associated with major surgery and long-term immunosuppression and that there is a reasonable expectation that the transplant will improve their quality of life. The threshold for transplantation may differ for living donor and deceased donor transplantation.

3.2 Clinical criteria for selection

3.2.1 Criteria for selection

All patients within 6 months of initiation of renal replacement therapy should be considered as potential candidates for renal transplantation.

In older recipients, careful assessment of their cardiovascular status and tailored immunosuppression are both recommended after renal transplantation because cardiovascular disease and infections are frequent causes of death and older recipients usually have less rejection.

3.2.1.1 Rationale for 'super-urgent' and 'urgent' classification

Please see the *Living organ donors who require a transplant as a direct result of donation* policy for details on prioritising these patients.

3.2.1.2 Other classifications (e.g. sensitised)

Highly sensitised patients require special consideration because it is difficult to find cross-match negative kidneys for them. Such patients are prioritised in the allocation scheme for kidney donors whose death has been defined by brain-stem death criteria (please see the kidney allocation policy for details) and may be suitable for desensitisation followed by living donor kidney transplantation.

3.2.2 Multiple organ transplants

3.2.2.1 Kidney/liver

Transplant candidates with established cirrhosis should be considered for combined kidney and liver graft.

Patients with type I primary hyperoxaluria should generally be considered for combined kidney and liver transplantation because renal transplantation alone is associated with rapid deposition of oxalate and graft loss, and liver grafting corrects

the deficiency of the causative enzyme. Patients with pyridoxine-sensitive hyperoxaluria may be suitable for kidney transplantation alone, together with forced diuresis and early/prolonged pyridoxine administration.

Combined kidney and liver transplants should be offered to carefully selected recipients suffering from simultaneous renal and hepatic failure secondary to viral hepatitis, extensive polycystic liver disease and primary hyperoxaluria and also in children with portal hypertension secondary to autosomal recessive polycystic kidney disease.

3.2.2.2 Kidney/pancreas

Simultaneous kidney/pancreas transplantation is the treatment of choice for carefully selected patients with end-stage renal failure with type 1 diabetes. Please see the pancreas policy for details.

3.2.2.3 Kidney/heart (lung)

Combined kidney and heart (lung) transplantation should be offered to carefully selected groups of recipients suffering from both chronic renal failure and severe heart failure irrespective of the cause (valvular, myocardial, coronary artery disease).

3.3 Contraindications

Age is not a contraindication to transplantation, but age-related comorbidity is an important limiting factor.

Previous chronic or recurrent infections, cancer, gastrointestinal complications, viral hepatitis, myocardial infarction and/or lower limb arteriopathy do not always represent an absolute contraindication to transplantation, but they indicate the need for a particularly careful work-up.

All contraindications may require modification in circumstances that change the balance of risks between dialysis and transplantation. For example, patients with severe vascular access problems could be considered for transplantation even if their overall prognosis for survival is less than 2 years.

3.3.1 Absolute contraindications

There are few absolute contraindications to renal transplantation. These include:

- Uncontrolled cancer
- Active systemic infections
- Any condition with a life expectancy <2 years

3.3.2 Relative contraindications

Patients may have a number of comorbidities that individually are not a contraindication to listing for transplantation, but when considered together may represent a clear contraindication to transplantation:

- Predicted patient survival of less than 5 years

- Malignant disease not amenable to curative treatment, or remission for greater than 5 years
- HIV infection not treated with Highly Active Anti-Retroviral Therapy (HAART) or already progressed to AIDS
- Cardiovascular disease – ischaemic heart disease, the prognosis of which cannot be improved by revascularisation and/or cardiac failure with a predicted risk of death greater than 50% at 5 years
- Predicted risk of graft loss greater than 50% at 1 year
- Patients unable or unlikely to adhere with immunosuppressant therapy requirements
- Immunosuppression predicted to cause life-threatening complications

Candidates for renal transplantation, particularly those older than 50 years of age, should undergo routine clinical assessment to exclude the presence of cancer and, where indicated, have participated in national cancer screening programmes (e.g. for breast and cervical cancer). In patients with previous cancer, renal transplantation should only be considered if there is no evidence of persistent cancer (see section 2.5).

3.3.3 De-selection criteria

It is assumed that while on the transplant list, patients will continue to fulfil criteria for selection.

Patients may be temporarily suspended from the list, for example if they contract flu, or other transient infections. In this instance, it is anticipated that the patient will be relisted. Reassessment of the patient will be dependent on the reason for their suspension.

Patients may be permanently de-selected if they no longer fulfil the then current criteria for selection.

3.4 Selection for re-transplant

The selection criteria for re-transplant are the same as those for the initial transplant (see section 3.2).

Re-transplants after early loss of a previous graft for technical reasons, or late graft loss for any reason give similar results to first grafts and do not require special precautions. For re-transplantation, nephrectomy of an asymptomatic earlier graft is not usually necessary.

Where the initial graft fails due to recurrent disease in the first 3 months after transplantation, the patient will not be suitable for a re-transplant unless the cause of the failure can be managed.

3.5 Decision

The final decision for listing a patient for initial or re-transplant should be made at an appropriately convened meeting of the multidisciplinary team (MDT) and the decision and reasons for it fully documented.

4. Appeals process

If a selection decision is appealed, it can be discussed and reconsidered at the next MDT meeting. If the decision is not altered following reconsideration by the MDT, the patient has the right to transfer to an alternative transplant centre for reassessment.

5. Follow-up on list

All patients should be reviewed at least annually. Those deemed to be at higher risk should be assessed more regularly.

Any significant change in the patient's condition while on the transplant list will require a re-evaluation of their suitability for transplantation.

6. Audit

NHSBT conducts regular audits on organ allocation and outcomes.

References

1. UK Renal Association. Clinical Practice Guidelines. <http://www.renal.org/Clinical/GuidelinesSection/AssessmentforRenalTransplantation.aspx> January 2011.
2. NHS Blood and Transplant and British Transplantation Society. Guidelines for consent for solid organ transplantation. March 2011.
3. British Society for Histocompatibility and Immunogenetics/British Transplantation Society document for guidelines on the detection and characterisation of HLA antibodies in renal transplantation. <http://www.bts.org.uk/transplantation/standards-and-guidelines/?locale=en> January 2011.
4. EBPG (European Expert Group on Renal Transplantation) *et al.* *Nephrol Dial Transplant* 2000;**15** (Suppl 7):1–85.
5. The Israel Penn International Transplant Tumor Registry. www.ipittr.uc.edu/Home.cfm