NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION

PATIENT SELECTION AND ORGAN ALLOCATION
CONTENTS

Introduction ................................................................. 3
All organs: patient selection and organ allocation ...... 5
Living organ donors who require transplant as a direct result of donation
  Kidney
    Selection
    Allocation
  Liver
    Selection
    Allocation
  Pancreas
    Selection
    Allocation
  Heart
    Selection
    Allocation
  Lung
    Selection
    Allocation
  Bowel
    Selection
    Allocation
  Cornea
    Selection
    Allocation

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INTRODUCTION

This document is designed to provide a comprehensive set of policies for patient selection and organ allocation. It has been developed by National Health Service Blood and Transplant (NHSBT) and the Advisory Group Chairs for each individual organ.

This policy contains an "all organs" section, the guidelines for which covers all transplants and must be adhered to by all centres. In addition, each individual organ has separate policies for patient selection and organ allocation. Inappropriate noncompliance to the guidelines may result in NHSBT reporting the clinician to a professional body, or declining to offer organs to the centre in question.

This policy for selection and allocation applies to organs from deceased donors and from certain living altruistic non-directed donors in the National Health Service. This policy also includes a section covering living donors who require a transplant as a direct consequence of their donation.

All the selection policies will follow the structure below:
1. Conditions that are considered for transplantation
2. Assessment of patients
3. Selection criteria
   3.1 Rationale for choice of selection criteria
   3.2 Clinical criteria for selection
      3.2.1 Criteria for selection
         3.2.1.1 Rationale for ‘super-urgent’ and ‘urgent’ classification
         3.2.1.2 Criteria for ‘super-urgent’ and ‘urgent’
         3.2.1.3 Other classifications (e.g. sensitised)
      3.2.2 Process for selection of ‘variants’
   3.2.3 Multiple organ transplants
   3.3 Contraindications
      3.3.1 Absolute
      3.3.2 Relative
      3.3.3 De-selection criteria
   3.4 Selection for re-transplant
4. Appeals process
5. Follow-up on list
6. Audit
All the allocation policies will follow the structure below:
1. Allocation policy
   1.1 Rationale for allocation policy
   1.2 How allocation policy was developed
      1.2.1 Justification for sub-groups (such as donation after brain death [DBD] versus donation after cardiac death [DCD])
   1.3 Allocation policy
      1.3.1 Details of policy

3. Acceptance of offered organs

4. Allocation policies for multiple organs

Definitions to be used in this policy

- Child: a person is considered a child until he/she has reached the age of 16 years (unless specified otherwise)
- Living altruistic non-directed donor: a healthy individual who chooses to donate an organ anonymously to someone not known to them

For selection criteria

- Equity: a potential transplant recipient will have the same access to the National Transplant List, irrespective of the centre at which they are assessed

For allocation criteria

- Equity: all patients with similar clinical characteristics on the National Transplant Waiting list shall have equal probability of receiving a graft from a deceased donor
- Utility: allocation of an organ to the individual with the greatest number of life-years following the transplant
- Benefit: allocation of an organ to the individual who is clinically assessed as having the greatest increase in life-years gained (comparing survival with and without transplantation)
ALL ORGANS: PATIENT SELECTION AND ORGAN ALLOCATION

1. Introduction
Organ transplantation has become a highly successful form of therapy in selected patients either as a form of life-saving or life-enhancing treatment. However, despite the increase in resources provided and the many different approaches taken to increase the number of donated organs available for transplantation, in the UK, as in other countries, there is a major short-fall between the number of people who would benefit from an organ transplant and the availability of suitable organs.

All clinicians will act in the best interest of the patient. However, transplantation poses a particular problem as the clinician will usually be responsible for several patients all of whom might benefit from the use of the donated organ. Furthermore, because organs donated from deceased and living altruistic donors are considered as a national rather than a local resource, all nationally-listed patients have to be considered in the decision as to who will receive the donated organ.

National Health Service Blood and Transplant (NHSBT) is required, amongst other duties, to ensure that, within the four nations of the UK, there is a fair, transparent and equitable approach to patient selection and organ allocation. This policy document outlines how patients are selected and organs allocated across the UK. The organs and tissues included in this policy are the heart, lung, kidney, liver, bowel, pancreas (including islets) and cornea.

Although corneal tissue and pancreatic islets cells are classified as tissues, selection and allocation policies for these tissues are also included here as the Organ Donation and Transplantation Directorate (ODT) is involved in allocation of these tissues.

Excluded from this policy are thymus, face and hand transplants, since there is, at present, no donor shortage and transplantation is performed purely on clinical need.

NHSBT covers all four nations of the UK and works under Directions from the Department of Health. NHSBT works within these Directions and does not have the authority to make exceptions, including the determination of eligibility to receive a donated organ under the NHS.

The criteria for selection and allocation must be objective, and the reasons evidence-based where possible. There should be clarification as to the balance of the rights of the competing individuals, and the focus of selection and allocation should be
on benefiting the patient, not the centre. The policies are consistent across organs where possible and appropriate.

This "All organs" section presents overall policies that should be adhered to across all organs. In addition, there may be further clarification in the organ-specific section where appropriate, such as alcohol use in liver recipients or smoking in heart or lung recipients, for example. Inappropriate noncompliance to the guidelines may result in NHSBT reporting the clinician to a professional body, or declining to offer organs to the centre in question.

2. Roles and responsibilities for approving policies
The responsibility for developing this policy lies with the Board of NHSBT. However, for policies to have credibility, there needs to be full support from all the healthcare professionals involved in transplantation, potential recipients and their families, donors (including potential donors) and their families, relevant patient groups and the general public.

To achieve these goals, Advisory Group is asked by NHSBT to propose the policies for patient selection and allocation for that organ. Each Advisory Group is chaired by a clinician who is independent of NHSBT, and consists of clinical representatives from designated centres and other relevant healthcare professionals and scientists. In addition, the Associate Medical Director for ODT and the Chair of the Advisory Group meet with patients and patient groups on an annual basis to discuss, amongst other issues, selection and allocation to ensure that patients are involved in developing these policies. The membership and minutes of each Advisory Group meeting are published on the NHSBT website (http://www.nhsbt.nhs.uk/).

Policies agreed by the Advisory Groups are considered by the Clinical Governance Medical Group (CGMG) and then referred to the Senior Management Team of the ODT. When approved, policies are referred to the Transplant Policy Review Committee (TPRC), a sub-group of the NHSBT Board for final approval and annual review.

3. Approaches to selection and allocation
Organs may be retrieved from deceased or living donors.

- Deceased donation may occur after circulatory death (DCD) or brain death (DBD).
- Living organ donation is usually directed, but non-directed altruistic donation also occurs. In practice, living donation mainly involves kidneys but donation of other organs such as liver and lung may occasionally occur.
- Domino transplants are where organs, removed to enable transplantation are used for another patient.
Living and altruistic donation is regulated by the Human Tissue Authority (HTA).

All donations from deceased donors must be unconditional although guidance does allow for requested allocation in some situations (www.dh.gov.uk).

Worldwide, different healthcare administrations have adopted different approaches to patient selection and organ allocation.

There are broadly two approaches to selection;
1. List everyone who might benefit from the transplant procedure.
2. Restrict the list so that those who are listed will have a reasonable expectation that they will receive a transplant.

The first approach allows all those who might benefit to have a chance of receiving an organ and will give a more accurate reflection of the need for transplantation. It will highlight the extent and impact of the organ shortage. However, with this approach many listed patients will have no realistic chance of receiving a transplant.

Eligibility to the list is usually controlled by minimum listing criteria. A large list may lead to problems in fair allocation. Restricting the list to reflect the availability of organs may lead to challenges in determining listing criteria. Discussions with patient groups have indicated that the great majority prefer the second approach of restricting access to the list.

Allocation policies will need to balance a number of factors, some of which may be conflicting. Factors to be considered include equity, utility, benefit and fairness.

In all cases, the recipient surgeon has the responsibility of deciding whether to accept the allocated organ for the recipient. If declined, the reasons should be documented.

3.1 Different approaches for different organs
Factors associated with both selection and allocation will, in part, be organ specific. Considerations that will affect the approach will include alternative treatments to transplantation, the ability to stratify risk, the different factors that affect patient and/or graft survival, differences in the interactions between donor graft and recipients on outcomes, amongst many others.

Furthermore, different organs have different lengths of time after which they become unusable (the cold ischaemic time varies from 4 hours for heart to up to 20 hours for the kidney although for hearts, every hour beyond the first reduces its likely function).
Therefore, allocation policies have to reflect the need for as short a time as possible between retrieval and implantation.

4. Patient selection

4.1 Referral to transplant units

Patients are referred to transplant units from many sources but usually from specialist units. Referral to a transplant unit is usually undertaken so that clinicians can assess the patient’s suitability for transplant and other therapeutic options, and the patient can gain an understanding of the implications of the procedure and other therapies. Guidelines for referral to a designated transplant unit are primarily within the remit of the professional bodies (such as the Renal Association, the British Association for the Study of the Liver, etc.) but NHSBT is supporting on-going dialogue for the development, revision and promulgation of referral guidelines.

4.2 Transplant units

Transplant units are designated by the Departments of Health, either directly or through appointed bodies. These units work as multi-disciplinary teams, involving surgeons, physicians, anaesthetists, nurses, physiotherapists, radiologists, pharmacists, recipient coordinators, psychiatrists, social workers, dieticians, healthcare scientists and many other healthcare professionals.

4.3 Transplant assessment

Transplant assessment may be undertaken as an out-patient or in-patient process, and involves detailed discussion with the patient and their families. The questions that will be addressed during the assessment include whether transplantation is appropriate for that individual at the time, whether the potential candidate meets the eligibility criteria and whether the patient fully understands the transplantation process and the implications for transplant as well as the implications for not proceeding to transplantation.

4.4 Listing

The decision to list a patient for transplantation is usually taken at a Multi-disciplinary Team (MDT) meeting. It is good practice for records to be kept, including the names of those present and the reasons for the decision made (listing, refusal, deferring). If the patient meets the criteria for transplantation and if the clinicians and the patient agree that transplantation is appropriate at that time, and if fully informed consent is given, then the transplant centre will confirm the patient meets the current criteria and ask NHSBT to add the patient to the National Transplant List.

4.4.1 Because of the organ shortage (for most organs) patients are, in effect, competing for life-saving (or life-enhancing) organs. Therefore, a decision to offer one patient a
transplant may deny another a life-saving procedure. Thus, all units should follow a common policy to ensure equity of access.

4.4.2 In some cases (see section 5.2), the clinical needs of the patient may require a decision to be taken as an emergency and there will be insufficient time to seek the views of the whole team. In such emergency situations, it is advisable that the decision to offer transplantation is made by more than one senior clinician and the decision to offer transplant (or not) should be recorded in the patient’s medical records, together with the names of those who made the decision and the rationale.

4.4.3 Second opinion: all patients not accepted for transplantation do have the right to request a second opinion from another designated transplant unit (this may not necessarily include a full reassessment of the patient).

4.4.4 Eligibility to the National Transplant List is determined by the Departments of Health according to national and international criteria. Eligibility status should be determined by the transplant unit before NHSBT is asked to list the potential recipient.

4.5 Review while on the waiting list
The transplant candidate will normally remain under clinical review; this is for many reasons, including the need to ensure that transplantation is still indicated. Rarely, some patients may unexpectedly improve to such an extent that transplantation is no longer indicated, but, more commonly, the disease may progress so that transplantation becomes futile and the patient should be suspended or removed from the transplant list.

4.6 Consent
4.6.1 While it is the responsibility of the operating surgeon that the patient gives properly informed consent wherever possible (exceptions such as mental incapacity are covered by appropriate legislation and guidance), ensuring the patient has all the information required to give informed consent is a team effort involving clinicians, nurses, pharmacists and other members of the MDT, and usually takes place over a period of time.

4.6.2 Units should follow the Guidelines on Consent issued by NHSBT (www.organdonation.nhs.uk) and the British Transplantation Society (http://bts.demo.eibs.co.uk/).

4.7 Re-transplantation
Grafts may fail for several reasons, including primary non-function, technical problems, recurrent diseases and rejection. Criteria for listing for re-grafts may vary from those for the primary graft. For some organs in some circumstances, outcomes after re-graft are
worse than after primary grafts. Selection policies will clearly indicate agreed policies for re-graft.

5. Allocation of organs
Organs from DCD and DBD donors may require different processes for allocation as these organs are associated with different factors that predict outcome.

5.1 National and local allocation.
Allocation may be on a national basis where there is a defined evidence base for the allocation process (as seen with kidney transplantation, for example).

Alternatively, for the liver or heart, for example, organs are allocated to a centre where the receiving clinician will select the most appropriate recipient on the waiting list of that unit.

The individual organ policies will outline the preferred method and put robust measures in place to ensure that local allocation does not result in inequity of access.

Whichever method is adopted, regular review and audit is needed to ensure the allocation model delivers its objective and, where necessary, adjustment made in light of new data, changing donor availability and characteristics and the case-mix.

5.2 Super-urgent and fast-track schemes
For some patients, in the absence of transplantation, organ failure may lead to death within a few days. This applies to some cases of liver or heart failure, for example. In such cases, it may be appropriate to list these patients as ‘super-urgent’ so that the potential candidate receives the next nationally available and clinically appropriate donor organ. Such schemes require clear justification for allocation, with defined criteria for listing.

Cold ischaemic time (CIT) may be broadly considered as the time between cooling of the retrieved organ and implantation. The acceptable CIT varies between and within organs. In some situations, the CIT which an organ can withstand is very short meaning that it should be allocated to the team that can transplant that organ the quickest. In this case, or when a prolonged CIT had already accrued, allocation is dependent in part on the centre and associated logistics rather than the recipient. Once the centre is decided, the organ will then be prioritised among the patients listed at that centre.

Where such fast-track schemes are in place, the rationale and criteria require defining and justifying
5.3 Sharing organs internationally

In very few cases, there is no suitable recipient for a donated organ within the UK. In such cases, that organ may be offered for use internationally. This is a bilateral arrangement. In some cases, there are agreements between two nations that allow a potential recipient in one jurisdiction to receive an organ donated in the other. Such arrangements need to be clearly defined and regularly reviewed to demonstrate that such a process results in the most effective use of donated organs in both jurisdictions.

6. Contraindications to transplantation

There are many considerations to be taken into account as to whether a patient should be listed for transplantation, some of which are controversial.

Contraindications may be absolute or relative. Absolute contraindications will completely exclude a potential candidate from being listed. Such contraindications are usually specified as the procedure would be futile. Some absolute contraindications will be common to all organs transplanted (such as valid refusal to consent, an agreed view by the MDT that the candidate will not survive the procedure or an agreed view that the quality of life after the transplant will be unacceptable to the patient), or specific to the organ (for example, severe and refractory pulmonary hypertension may contraindicate liver-only transplantation).

Relative contraindications constitute those conditions or circumstances where the successful outcome of the transplant as defined by the selection criteria for that organ or organs are not certain. In some instances, such relative contraindications may constitute an absolute contraindication. In other circumstances, however, these circumstances may not preclude meeting the agreed criteria. For example, a history of previous malignancy may preclude transplantation if, in the view of the MDT, following expert advice, the malignancy may recur rapidly after transplantation, whereas if the likelihood is low (because of complete excision or response to treatment), the risk of recurrence may be felt to be low and so not preclude transplantation. Often, there is only a limited evidence base to make informed decisions, so while clear guidance cannot be given for all circumstances in all cases, the MDT has to make the best decision that will balance the rights of the recipient with other potential recipients. Decisions can be made only in the light of best evidence and clinical judgment. It is important that the basis of decisions and the names of those making the decisions are clearly documented.

It must also be recognised that an absolute contraindication for one organ may be a relative contraindication for another. For example, ongoing alcohol use is an absolute contraindication for liver transplantation when the liver disease was caused by excess alcohol use, whereas excess alcohol use would be a relative contraindication for transplantation of a kidney or ocular tissue.
It should also be noted that some absolute contraindications may be overcome (for example, significant active bacterial infection would exclude a transplant but once effectively treated would no longer be a bar): transplant units will have in place processes for review and, where appropriate, re-assessment.

### 6.1 Age

Legislation precludes disadvantaging any group on the grounds of age. However, in some instances, there are valid reasons why one age group should be prioritised over another for receipt of an organ. For example, organ failure is associated with growth retardation, and this can be corrected by transplantation (although often requires subsequent treatment). Once growth has ceased, it may not be possible to catch up, so growth failure may be a valid reason to prioritise those for a transplant who are still growing. However, any preference to any group has to be justified on clinical grounds.

Children are usually managed within specialist Children’s Hospitals or Units. It is important that clinicians working with adults and with children liaise closely so that selection and allocation is fair to all.

Conversely, older age is associated with less favourable outcomes after solid organ (not corneal) transplantation. The extent to which this will affect the decision to offer transplantation will vary between patients and will depend on many factors. The concept of biological age rather than chronological age is useful but difficult to define. It is not acceptable to exclude a patient from transplantation solely on the basis of age without consideration of other factors such as the benefit of transplantation to that patient.

### 6.2 Alcohol use

Allocation of donated organs to those who have organ damage as a consequence of excess alcohol is controversial and, in general, not supported by the public (as evidenced by public opinion surveys). However, outcomes of selected patients with alcohol-induced liver damage are at least as good as for other indications so it is important that these patients are treated fairly.

Different conditions may apply when alcohol use has contributed significantly to the organ failure, compared with concerns about alcohol use without organ damage. Where the MDT has concerns that the potential candidate is either abusing or dependent on alcohol, there should be a full assessment by clinicians expert in the field of alcohol abuse. The specialists should assess the background, treatments offered and accepted, the likely outcome after transplantation, and the support required to ensure the recipient complies with medical advice.
6.3 Illicit drug use
Use of illicit drugs may affect the appropriateness of the potential candidate for listing. For example, there may be a greater risk of infection from viruses (such as HIV and Hepatitis C virus) as well as bacterial infection if there is evidence of continued drug use with unsafe procedures.

The potential candidate should be assessed by healthcare professionals expert in the field of drug use who can advise the MDT as to the likely prognosis of the patient, and the degree and nature of support required. In light of this, the MDT will need to agree whether, with full support recommended and agreed, the patient will meet the nationally agreed criteria for transplantation.

6.4 Compliance and non-compliance
6.4.1 In nearly all cases, solid organ transplant recipients will be required to take immunosuppression for the rest of the life of the organ, and will need to be followed-up by clinicians expert in the field of transplantation and management of immunosuppression. Non-compliance, (also termed non-adherence or non-concordance) with the taking of medication and attending follow-up, may result in organ failure or drug toxicity.

Social support is usually very important in helping the potential transplant recipient cope with life after transplantation, including the recovery from surgery and compliance to immunosuppression. MDTs will assess the need for and availability of social support and develop plans with the patient for the provision of appropriate levels of support that will ensure the patient makes a sufficient recovery to become independent.

Non-compliance is difficult to predict. All potential recipients will need to understand the need for follow-up and compliance, and where there is concern, arrangements should be put in place to maximise the likelihood of compliance with treatment and follow-up.

In exceptional cases, the MDT may consider that the potential recipient will not follow treatment regimes, so that there is very high probability that graft or patient survival will be significantly impaired, despite the full provision of appropriate support. In such cases, it may be reasonable to deny the recipient access to transplantation.

6.4.2 Difficult considerations apply when non-compliance has resulted in graft failure and the patient is being assessed for a re-graft. The rights and needs of the patient need to be balanced against other potential recipients. This is a particular problem for teenagers where non-compliance is not uncommon. The MDT will need to consider the reasons for non-compliance, what support is required to prevent a recurrence should the patient undergo a re-graft, and the likely outcome.
6.5 Comorbidity: medical

Many potential transplant candidates have associated comorbidities. Such comorbidities may affect the transplant procedure itself, the recovery, or short- or long-term patient or graft survival. There is usually insufficient data for specific advice to be given about the approaches to assessment for, say, heart disease, and to define criteria by which clear guidelines can be developed to determine which patient is considered eligible or ineligible for listing or transplantation. In such instances, policies must define the principles and, where possible, give guidance as to assessment of comorbidity and determination of contraindications for transplantation. As always, involvement by appropriate experts, discussion in the MDT and documentation of decisions is key to ensuring the optimal outcome for all patients.

6.6 Co-morbidity: psychiatric disease and psychological effects

Current or past psychiatric disease may be a contraindication to transplantation. Candidates will need to be assessed by suitably qualified clinicians who can determine whether the patient has received optimal therapy and the impact of the possible transplant on the patient. Whether the psychiatric disease will alter the decision to offer transplantation will depend on the nature of the disease, the impact of treatment and the availability of full support to mitigate any adverse impact.

In some cases, psychiatric illness may be associated with non-compliance (section 6.4).

6.7 Malignancy past/current

Some transplant candidates may have a history of malignancy. Immunosuppression may have the effect of allowing some cancers, which were previously in remission, to become active and adversely affect the patient’s survival.

Transplantation may be contraindicated if, in the view of the MDT and following expert oncological advice, there is a high probability that the cancer will recur or exacerbate on transplantation. While there is some data in the literature on which to base a prognosis, data are few and clinical judgment is necessary. The decision will depend on many factors, including the type of cancer, its natural history, the response to therapy, and the interval between treatment and transplant assessment.

6.8 Quality of life

Quality of life is a concept that can be measured by a variety of instruments but remains very subjective.

6.8.1 In most cases, a poor quality of life will be corrected by transplantation. However, in some cases, the poor quality of life may be due to other factors (such as other medical comorbidities) or may not be corrected by transplantation.
6.8.2 In some cases, the MDT may conclude that successful transplantation may not be associated with a return to a quality of life that is acceptable, even with the provision of full support from medical and social services. In this instance, transplantation may not be appropriate.

6.9 Malnutrition
Many patients with organ failure will have associated malnutrition. Most studies suggest that malnutrition will adversely affect the outcome after transplantation. All potential candidates should be assessed for malnutrition by the clinical team and those with significant malnutrition should be assessed by healthcare professionals and, where appropriate, nutritional support offered.

There is little literature on the most appropriate clinical tool to measure malnutrition in those with organ failure and what degree of malnutrition will contraindicate transplantation. Where the clinical team considers that the degree of malnutrition will make transplantation futile, the decision should be reviewed if the degree of malnutrition is corrected.

6.10 Multi-organ transplants
Some patients require simultaneous transplantation of more than one organ (such as liver and small bowel, kidney and pancreas or liver and kidney). In these cases, ideally there will be agreed, published policies in place, but where exceptional cases arise, these should be considered on an individual basis by the Head of the transplant unit and the Chairs of the relevant Advisory Group, with final agreement from the Associate Medical Director of ODT.

6.11 Research and innovation
It is important to balance the use of these organ policies to deliver transparency and equity with the need to encourage innovation and development. It is important that when clinicians wish to develop new indications for transplant, amend current indications or contraindications, proposals are discussed and agreed by the appropriate Advisory Group and then recommendations put to NHSBT for approval. The impact of any change will need to be reviewed at an agreed time to ensure the agreed changes have delivered their aims.

7. Process for ‘variant syndromes’ and for appeals from clinicians
It is accepted that no policy will cover every clinical eventuality, and sometimes rigid application of the policy will lead to inequity, so there needs to be a process for
introducing appropriate flexibility in the implementation of the policy. Therefore, each Advisory Group will have an Appeals Panel that will, according to agreed and published protocols, respond quickly to requests for NHSBT to list patients who do not fulfill the agreed criteria outlined in this document. Decisions and the reasons underlying them will be recorded and reported at each Advisory Group meeting.

References