Changes in this version

Minor regulatory clarification.

Policy

Policies are developed and reviewed annually by the relevant Advisory Group and reviewed and approved by the *Organ and Tissue Donation and Transplantation Clinical Audit Risk and Effectiveness Group (OTDT CARE)* on behalf of the Board of NHSBT before being implemented by NHSBT and partners.

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INTRODUCTION

This document provides a summary of the legislation surrounding organ donation and transplantation and a comprehensive set of policies for patient selection and organ allocation. It has been developed by NHS Blood and Transplant (NHSBT) and the Advisory Group Chairs for each individual organ.

NHSBT, a Special Health Authority, has responsibilities across the United Kingdom with regard to organ donation and transplantation. Transplant centres in the UK are designated by the commissioners and are required to meet agreed clinical standards, including these patient selection and organ allocation policies, which apply to organs from deceased donors and from certain living altruistic non-directed donors in the National Health Service. ***POL198*** -The *Non-compliance with Selection and Allocation policy* sets out the process that will be followed where individuals fail to comply with these agreed policies.

This policy contains an "all organs" overview section, which contains the general principles that cover all organ transplants; the separate policies for patient selection and organ allocation for each individual organ; and a section covering living donors who require a transplant as a direct consequence of their donation.

The **selection** policies will mostly follow the structure below:
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The **allocation** policies will mostly follow the structure below:
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Definitions to be used in this policy

- Child: a person is considered a child for the purposes of these policies until he/she has reached the age of 18 years (unless specified otherwise) as the potential for growth may remain until he/she has reached this age
- Living altruistic non-directed donor: a healthy individual who chooses to donate an organ anonymously to someone not known to them
- Domino donor (only applies to kidney): an individual who requires or requests a nephrectomy for therapeutic reasons and the kidney is then available for transplantation.

For selection criteria

- Selection: the criteria that is applied to determine if an individual is to be placed on the waiting list for an organ
- 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

- Allocation: the process that is applied when an organ becomes available for transplantation
- 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 is a highly successful form of therapy in selected patients either as a form of lifesaving or life-enhancing treatment. The last decade has seen significant progress in organ donation and transplantation in the UK, during which deceased organ donation rates have increased by 56%. There remains a short-fall between the number of people who would benefit from an organ transplant and the availability of suitable organs. An estimated 3 people die each day because of organ shortage and up to 1 in 6 of those listed for a heart, lung or liver transplant die or become too sick to receive a graft.

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 same 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.

NHSBT is required, amongst other duties, to ensure that within 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.

NHSBT supports the principles on organ donation and transplantation from the World Health Organisation outlined in the Resolution on Human Organ and Tissue Transplantation of May 2010 (http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R22-en.pdf?ua=1) and is a signatory to the Declaration of Istanbul on Organ Trafficking and Transplant Tourism (http://www.declarationofistanbul.org).

The Organ and Tissue Donation and Transplantation (OTDT) Directorate also oversees the selection and allocation of corneal tissue, pancreatic islets and liver hepatocyte cells.

Excluded from this policy are composite tissue allografts (such as face, hand transplants and uterine) and thymus transplants since there is, at present, no donor shortage and transplantation is performed purely on clinical need.

Legislation (see Section 2 below) sets out who is eligible to receive a donated organ in the UK, such as those persons who are ordinarily resident in the UK. Neither NHSBT nor the Transplant Centres have the authority to make exceptions to this.

The criteria for selection and allocation of a donated organ 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. The *Non-compliance with Selection and Allocation policy* ***POL198*** - sets out the process that will be followed where individuals fail to comply with the agreed current policies.

2. Legislation surrounding organ donation and transplantation

NHSBT is a Special Health Authority for England and Wales and part of its remit is to facilitate, provide and secure the provision of services to assist tissue and organ transplantation, which it does across the UK[1]. NHSBT's accountabilities for providing organ donation and transplantation services in Scotland and Northern Ireland are governed via its Board arrangements and through Income Generation Agreements with the Scottish Government and the Department of Health, Social Services and Public Safety in Northern Ireland.

NHSBT is directed by the NHS Blood and Transplant (England) Directions 2005, and the NHS Blood and Transplant (Wales) Directions 2005[2], as amended (the Directions) which govern the arrangements relation to organ donation and transplantation services. [1] Both sets of Directions are identical regarding who is eligible to receive a donated organ in the UK.

NHSBT, and the Transplant Centres, must comply with the following legislation:

England and Northern Ireland
Human Tissue Act 2004 (HT Act)
Also, for England the Organ Donation (Deemed Consent) Act (2019), which amends for the Human Tissue (2004) Act

Wales
Human Tissue Act 2004 (HT Act)
Human Transplantation (Wales) Act (2013). (HT (W) Act), which amends the Human Tissue (2004) Act.

Jersey
Human Transplantation and Anatomy (Jersey) Law 2018.
Note: Jersey work within their own Act, however they refer to the English HTA CoP F for guidance.

Scotland
Human Tissue (Scotland) Act 2006
Human Tissue (Authorisation) (Scotland) Act 2019 amends the prior Act (2006) and provides a system of 'deemed authorisation' for organ and tissue donation for transplantation purposes.

NHSBT and the Transplant Centres are regulated by the Human Tissue Authority (HTA). NHSBT is designated by the HTA as the body in the UK that can lawfully allocate and supply organs to NHS hospitals.

In addition, NHSBT and the Transplant Centres in England are regulated by the Care Quality Commission.

3. Roles and responsibilities for approving policies

The responsibility for the development, review and dissemination of 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, each Advisory Group is asked by NHSBT to propose the policies for patient selection and organ allocation for that organ. Each Advisory Group consists of clinical representatives from designated centres and other relevant healthcare professionals, scientists and lay members and is chaired by a clinician who is independent of NHSBT. In addition, the Medical Director for OTDT and the Chair of each 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 ODT website (http://www.odt.nhs.uk/transplantation/advisory-groups/).

Policies are agreed following the process outlined in POL223 with final approval provided by the Organ and Tissue Donation and Transplantation Clinical Audit, Risk and Effectiveness Group (ODT CARE).

3.1. Implementation of agreed changes to policies

Once approved by OTDT CARE, the Statistical Lead is informed who will work with operational leads to fully implement and operationalise the agreed changes. The implementation date for any changes will be decided following agreement with all relevant parties to ensure that all necessary processes are in place. **POL223** - Refers to Patient Selection and Organ Allocation Policies Review and Approval (Organs).

4. 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 of living-donor organs that are removed for clinical reasons but may be suitable for another patient.

Living and altruistic donation is regulated by the HTA. With the exception of domino kidney donation, as this arises from the patient's treatment, the HTA assess all cases of living donation prior to approving the removal of an organ.

All donations from deceased donors must be unconditional although donor families may request allocation to a close family member or friend (see Appendix 1).

Donor contraindications to organ donation are reviewed regularly and revised as needed. These criteria define those potential deceased donors where no organ would be accepted for transplantation and so the families would not be approached. **POL188** Policies and guidance - ODT Clinical - NHS Blood and Transplant

It should be noted that these guidelines detail the contraindications to approaching a family for consent/authorisation as no organ or tissue from such donors would be used for transplantation or research.

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. The selection policies for each organ have therefore been developed balancing equal access to the waiting list with the benefit that donation of a scarce resource will provide to individual patients.

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

The recipient surgeon, sometimes in conjunction with the physician, has the responsibility of deciding whether to accept the allocated organ for the recipient. If declined, the reasons should be documented.

4.1. 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, and 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 maximum acceptable cold ischaemic time varies from 4 hours for heart to up to 20 hours or more 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.

4.2. Requested allocation of a deceased donor organ

The fundamental principle of all deceased organ donation is that donation must be unconditional and free of financial reward. However, there are circumstances where a deceased organ donor has a relative or friend of long standing who is in need of an organ to whom they would have wished to allocate their organ. In these cases, it is possible for the family to request allocation of an organ to a named individual although the consent for organ donation must be unconditional (refer to **Appendix 1**).

5. Patient selection

5.1. Referral to transplant centres

Patients are referred to transplant centres from many sources but usually from specialist centres. Referral to a transplant centre is usually undertaken so that clinicians can assess the patient's suitability for transplantation 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 centre are primarily within the remit of the professional bodies (such as the British Transplantation Society (BTS), 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.

5.2. Transplant centres

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

5.3. Transplant assessment

Transplant assessment may be undertaken as an outpatient 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 or parent/advocate fully understands the transplantation process and the implications for transplantation as well as the implications for not proceeding with a transplant.

Assessment is carried out by the transplant multi-disciplinary team. It is usually desirable for the patient's family to be involved in the assessment process. These initial assessment procedures often follow outpatient review and consultation and are undertaken over several days. Patients remaining on the transplant list will be re-assessed at intervals during their wait for a donor organ (see section 6).

The decision whether or not to register a patient on the transplant list will be made after discussion with the patient and other relevant healthcare professionals, including surgeons, physicians, anaesthetists, and transplant co-ordinators and, in some cases, psychiatrists. The patient's family and partner usually will be involved as patients find it helpful, and the family's support is likely to improve the eventual outcome.

Patients will need to be given extensive information about the reason for their assessment for transplantation, the risks associated with the procedure as well as the perceived benefits in their clinical context. That information must be in an easily understandable format commensurate with their ability to assimilate and understand the information given.[1]

A number of factors are used to inform decisions around the appropriateness of transplantation in each patient context and these must all be made explicit to the patients.

5.4. 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 will ask NHSBT to add the patient to the National Transplant List.

5.4.1. Requesting listing: Requests for adding patients to the national transplant list must be done by a named individual who will be personally accountable for the accuracy of the data and will confirm whether the patient is entitled to receive an organ from a deceased donor under the NHS. OTDT Senior Management Team (SMT) has considered the need for routine audit of compliance with listing criteria and has agreed not to undertake routine audits of the accuracy of the data (including the patient's eligibility for NHS treatment) at this time but

reserves the right to audit the accuracy of the source data and will ensure that appropriate action is taken in the event of any discrepancy.

5.4.2. 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 centres should follow a common policy to ensure equity of access.

5.4.3. 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 transplantation (or not) should be recorded in the patient's medical records, together with the names of those who made the decision and the rationale.

5.4.4. Second opinion: all patients not accepted for transplantation do have the right to request a second opinion from another designated UK transplant centre (this may not necessarily include a full reassessment of the patient). Patients who ask for a second review should discuss this request with their consultant and agree to which centre the patient should be referred but may seek referral from another clinician. Those providing a second opinion must be independent of the clinicians making the initial decision.

5.4.5. Access to the NHS Transplant list: The Directions (available at https://www.odt.nhs.uk/odt-structures-and-standards/regulation/) set out who is eligible to receive a donated organ in the UK, categorised as Group 1 and Group 2 patients. Eligibility status should be determined by the transplant centre before NHSBT is asked to list the potential recipient on the NHS Transplant list. If in doubt, hospitals should seek advice on a patient's eligibility status from the relevant National Health Department.

5.4.5.1. Group 1 *includes* those who are ordinarily resident in the UK; members of UK HM Forces serving abroad, their spouse, civil partner and children under the age of 19 years; persons entitled under EU Regulations and reciprocal health agreements. Group 2 patients are all those who are not included as Group 1(Full details of the categories can be found within the Directions and in the accompanying guidance, available on the website www.odt.nhs.uk).

5.4.5.2. As set out in the Directions, organs donated by deceased donors should first be allocated to Group 1 patients and then only to Group 2 patients if there is no suitable Group 1 patient in the UK.

5.4.5.3. As set out in Section 1, neither NHSBT nor the Appeals and Arbitration panels have the authority to determine whether a potential transplant candidate can be listed as either Group 1 or Group 2.

5.4.5.4. NHSBT does not have the authority to allocate organs from deceased donors to transplant centres in the private sector.

5.4.6. Concerning transplant candidates who are eligible for NHS treatment but elect to receive their transplant as a private patient: NHSBT will follow the principles below:

5.4.6.1. Selection and allocation will be on the basis of clinical need and relevant criteria (such as matching) but not on the ability to pay.

5.4.6.2. The principles will apply equally across the UK.

5.4.6.3. Once an organ from a deceased UK donor has been allocated and accepted for a patient on the National Transplant Waiting list as a Group 1 patient, that patient may elect to have their transplant procedure and/or their aftercare as a private patient.

5.4.6.4. NHSBT reserves the right to recover the costs for donor characterisation, retrieval and transport of an organ accepted for a private patient.

5.4.6.5. It is illegal to ask for or make any payment for a donated organ.

5.4.6.6. A transplant candidate registered on the active UK National Transplant List may not simultaneously be on the active transplant list in another jurisdiction. However, a candidate may be on the active list in another jurisdiction but suspended from the UK National Transplant List. If the suspension is for longer than six months, the patient must re-register.

5.5. Review while on the transplant 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. Any decision around suspension or removal will be taken using the criteria laid down in the selection policy current at that time and following discussion with the patient and their family/advocate.

5.6. Consent

5.6.1. 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.

5.6.2. Centres should follow the Guidelines on Consent for Solid Organ Transplantation in Adults **POL191** https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/4378/guidelines_consent_for_solid_organ_transplantation_adults.pdf issued by NHSBT and the BTS[1].

5.6.2.1. Patients may decide not to accept organs from donors with specific risks: in such cases, these restrictions should be made at the time of listing rather than when the organ becomes available.

5.7. Re-transplantation

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

6. 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. Allocation of organs will differ for Group 1 and Group 2 patients.

6.1. 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 may be allocated to a centre where the receiving clinician will select the most appropriate recipient on the transplant list of that centre. Where there is centre-based allocation, transplant centres are recommended to develop and publish their own policies and processes.

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.

Once an organ has been accepted for a named patient and the patient contacted, the organ should not be re-allocated, (unless offering has paused see 6.5) except in rare instances and following discussion and agreement by the surgeons looking after the two potential recipients.

6.2. 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 that 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. The advent of machine perfusion may alter the impact of CIT.

Where such fast-track schemes are in place, the rationale and criteria require defining and justifying.

6.3. 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. NHSBT will offer organs that cannot be used for UK patients only to recognised transplant organisations and will ensure that no charge is made for the organ.

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.

6.4. Centre-based allocation

In some cases, organs are allocated to a centre and the recipient surgeon, with appropriate advice from colleagues where appropriate, will select the most appropriate recipient. In other cases, organs may be transplanted into a recipient other than the nationally allocated one. Centres should keep written records outlining the decision-making process. NHSBT reserves the right to investigate and seek external reassurance that due process is followed.

6.5. Pauses in Offering

On occasion, unforeseen circumstances at the donating centre may result in an unexpected pause to the donation process. Dependent on the circumstances and associated timeline this may on occasion impact on organ offers. Where the pause is less than twenty-four hours these offers made and accepted should be honoured. Centre to centre discussion continues to apply where a super-urgent patient is listed within this timeframe

Any pauses lasting over twenty-four hours would require a review of the allocation scheme. At the point of the identified pause, all centres where an organ has been accepted will be advised that the process has been paused and if greater than twenty-four hours the allocation of organs will be reviewed with the potential that the organs maybe re-allocated depending on the status of the patients at the time of reactivation.

The above only applies to Cardiothoracic and Liver (Renal – Kidney, Pancreas original offers will stand).

7. 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 specified in each individual organ policy. 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 cases, 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 centres will have in place processes for review and, where appropriate, re-assessment.

7.1. Age

Legislation precludes disadvantaging any group on the grounds of age. However, in some instances, there are objective clinical reasons why one age group should be prioritised over another for receipt of an organ. For example, organ failure can be associated with growth retardation, and this can be corrected by transplantation (although often requires subsequent treatment).[2] 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 proportionate and justified on clinical grounds.

Children are usually managed within specialist Children's Hospitals or Centres. 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.[3] 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.

7.2. Alcohol use

Allocation of donated organs to those who have organ damage as a consequence of excess alcohol use 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[4] 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 who are 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.

7.3. 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 who are 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.

7.4. Adherence and non-adherence (also termed compliance/non-compliance and concordance/non-concordance)

7.4.1. 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 who are expert in the field of transplantation and management of immunosuppression. Non-adherence 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 adherence 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-adherence is difficult to predict.[5] All potential recipients will need to understand the need for follow-up and adherence, and where there is concern, arrangements should be put in place to maximise the likelihood of adherence with treatment and follow-up.

In exceptional cases, the MDT may consider that the potential recipient will not follow treatment regimens, so that there is a 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.

7.4.2. Difficult considerations apply when non-adherence has resulted in graft failure and the patient is being assessed for a re-transplant. The rights and needs of the patient need to be balanced against other potential recipients who might otherwise not gain access to a transplant. This is a particular problem for young people where non-adherence can be common.[6] The MDT will need to consider the reasons for non-adherence, what support is required to prevent a recurrence should the patient undergo a re- transplant, and the likely outcome.

7.5. Co-morbidity: medical

Many potential transplant candidates have associated co-morbidities. Such co-morbidities 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 co-morbidity and determination of contraindications for transplantation. As always, involvement by appropriate experts, discussion in the MDT and documentation of decisions is the key to ensuring the optimal outcome for all patients.

7.6. 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-adherence (section 6.4).

7.7. 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 are 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, the interval between treatment and transplant assessment and potential impact of the immunosuppressive regimen.

7.8. Quality of life

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

7.8.1. In most cases, a poor quality of life if due to organ failure will be corrected by transplantation. However, in some cases, the poor quality of life may be due to other factors (such as other medical co-morbidities) or may not be corrected by transplantation.

7.8.2. In some cases the MDT in collaboration with the patient or the patient's parent/advocate 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.

7.9. 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.

7.10. 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, where agreed, published policies exist, these should be followed.

7.10.1. *Patients not meeting listing criteria for organs*
Where patients are considered for multi-organ transplants, they should be accepted for all organs by the appropriate MDT in the hospital.

Some patients needing multi-organ transplants may not meet the agreed selection criteria for all organs (for example, a patient who needs a heart transplant and with impaired renal function may need both heart and kidney transplants as the impact of surgery and medication will result in irreversible loss of kidney function). In such situations where the individual organ-specific indications are not met, the listing should be approved through the relevant Appeals/Arbitration panel.

7.10.2. *Exclusion from multi-organ allocation*

- Heart accepted for patient listed as super-urgent or urgent
- Lung accepted for patient listed as super-urgent or urgent
- Liver accepted for super-urgent liver recipient or accepted for splitting
- One kidney already accepted for multi-organ recipient (excluding kidney and pancreas)

7.10.3. *Prioritisation*

The following scheme is a guide. Where the guidance does not meet clinical need, the decision should be discussed by the Chairs of the relevant solid organ Advisory Groups and reported at the next meeting.

7.10.3.1. Where patients are listed for multi-organ transplants, organs should be offered in the following order:

Heart
Liver
Lung
Bowel
Kidney
Pancreas

Only one kidney per donor can be allocated to multi-organ patients (excluding kidney and pancreas patients). If more than one multi organ patient requires a kidney then one kidney should be allocated in the following order:

Multi-visceral
Urgent heart
Routine heart
Lung
Liver

7.11. 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.

7.11.1. Service Development and Innovations: It is important that when clinicians wish to develop new indications for transplantation, 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.

7.11.2. Research: NHSBT is keen to support research and development. This includes both new indications and use of organs and tissues for approved research. These are covered in the appropriate policies.

7.11.3. The Research, Innovations and Novel Technologies Advisory Group (RINTAG) has been set up to support research, service developments and innovations.

7.12. Patients disadvantaged because of administration errors

There have been rare occasions when, because of an administrative error, a patient on the National Transplant Waiting List, has missed an offer of an organ (or organs) or has inaccurate waiting time recorded.

7.12.1. As soon as such a situation is recognised, and identified as an ODT error, it should be reported to ODT through the Incident Reporting process (www.odt.nhs.uk) and managed according to the agreed process to identify the cause and institute remedial action. If not identified as an ODT error, the occurrence would be reported to OTDT CARE via existing mechanisms.

7.12.2. If a patient was not (re)activated on the list when it is documented that they should have been and where the relevant allocation system includes waiting time as a factor, the waiting times should be amended. This should be approved by the relevant Chair of the Advisory Group (or Deputy when appropriate).

7.12.3. If it is shown that organ offer(s) were missed, then compensatory action is required unless the organ(s) missed were not accepted for any patient. If the patient did miss offer(s) of organ(s) used for other recipient(s), then the Chair of the Advisory Group (or Deputy when appropriate), the Associate Medical Director and the relevant Statistical Lead should agree how best to provide appropriate compensation to the patient, balancing the needs of all potential recipients. This decision should be reported to OTDT CARE and recorded in the minutes

7.12.3.1. Kidney: It should be noted that the practice for patients awaiting a kidney transplant and who had missed an offer of a kidney that was used for another, would be to prioritise to the top of the kidney matching run tier in which they appeared until a similar offer was made; if the offer was not accepted but transplanted into another patient, then the patient would lose that prioritisation.

7.12.3.2. Pancreas and islets: The practice for a recipient, who has missed the offer of a pancreas or islets as a result of an administrative error, would be to offer compensatory points in subsequent matching runs until they receive an offer of a pancreas or islets. Where a recipient is awarded such prioritisation, they will be ranked above all other recipients in the pancreas matching run. If they are offered a pancreas/islets but the offer is not accepted and the pancreas/islets are used in a different patient, then the patient would lose that prioritisation.

8. 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.

8.1. Therefore, each Advisory Group will have an Appeals or Arbitration Panel that will, according to agreed and published protocols, respond quickly to requests for NHSBT to list patients who do not fulfil the agreed criteria outlined in this document.

8.2. Decisions must be based on clinical criteria

8.3. Decisions and the reasons underlying them will be recorded and reported at each Advisory Group meeting.

8.4. Appeals and Arbitration Panels do not have the authority to determine whether a potential transplant candidate is included as Group 1 or Group 2.

References

1. NHS Blood and Transplant and British Transplantation Society. Guidelines for consent for solid organ transplantation in adults **POL191** https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/4378/guidelines_consent_for_solid_organ_transplantation_adults.pdf

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Appendix 1

REQUESTED ALLOCATION OF A DECEASED DONOR ORGAN

EXECUTIVE SUMMARY

1. This policy describes the response to a request for allocation of a deceased donor organ to a close relative or friend. The document has been developed by UK health administrations together with the Human Tissue Authority (HTA) and NHS Blood and Transplant (NHSBT).

2. This policy should be interpreted in conjunction with the NHSBT policy for allocation of organs from deceased donors therefore applies throughout the UK and must comply with all current legislation across the UK.

3. The fundamental principle of all deceased organ donation is that it must be **unconditional.** Having first established that the consent or authorisation to organ donation is unconditional, a request for the allocation of a donor organ can be considered in those cases, where all the following principles apply:

   - that there is appropriate consent/authorisation to deceased donor organ donation;
   - that the consent or authorisation for organ donation is not conditional on the request for the allocation of a donor organ to the specified relative or friend of long standing going ahead;
   - that there are no others in desperately urgent clinical need of the organ (as defined below in paragraph 4) who may be harmed by the organ being allocated to a named individual;
   - that in life the deceased had indicated a decision to donate to a specific named relative or friend of long standing in need of an organ; or, in the absence of that indication, the family of the deceased expresses such a decision;
   - that the specific named relative or friend of long standing is on the transplant waiting list or could be considered to be placed on the waiting list in line with the NHS Blood and Transplant (England) Directions 2005 or the NHS Blood and Transplant (Wales) Directions 2005, as amended (the Directions).
   - that the need for a transplant is clinically indicated for the intended recipient.

4. Priority must be given to a patient in desperately urgent clinical need over any requested allocation of deceased donor organ. Patients registered on the NHSBT Super-Urgent or Urgent Heart lists, Super-Urgent or Urgent Lung lists, Super Urgent Liver list will always take priority, if the organ is clinically suitable for them. If other urgent organ schemes are developed over time, then these patients should also take priority.

INTRODUCTION

5. Over the last few years, NHSBT, HTA and the UK Health Administrations have been asked on several occasions to clarify whether, if a living donor dies before their intended living donation can be carried out, the requested allocation of their organ can still be assured. Additionally, families have asked whether it is possible to request the allocation of a deceased donor organ to a family member or close friend.

6. All three organisations – NHSBT, HTA and UK Health Administrations – acknowledge that they each have a role in determining a framework for a request to direct the allocation of a deceased donor organ:

- NHSBT is required to consider and advise the Secretary of State and NHS bodies on ethical, legal and clinical issues which arise out of the organ and tissue donation and transplantation service. NHSBT is also responsible for the allocation or overseeing the allocation of donated organs across the UK.

- The HTA's general functions include giving guidance on the Act's consent requirement for the deceased donation of organs. Legislation applicable as below:

  England and Northern Ireland
  Human Tissue Act 2004 (HT Act)
  Also, for England the Organ Donation (Deemed Consent) Act (2019), which amends for the Human Tissue (2004) Act

  Wales
  Human Tissue Act 2004 (HT Act)
  Human Transplantation (Wales) Act (2013). (HT (W) Act), which amends the Human Tissue (2004) Act.

  Jersey
  Human Transplantation and Anatomy (Jersey) Law 2018.
  Note: Jersey work within their own Act, however they refer to the English HTA CoP F for guidance.

  Scotland
  Human Tissue (Scotland) Act 2006
  Human Tissue (Authorisation) (Scotland) Act 2019 amends the prior Act (2006) and provides a system of 'deemed authorisation' for organ and tissue donation for transplantation purposes.

NHSBT and the Transplant Centres are regulated by the Human Tissue Authority (HTA). NHSBT is designated by the HTA as the body in the UK that can lawfully allocate and supply organs to NHS hospitals. UK Health Administrations are responsible for legislation and overall policy direction, and provide the link between arm's length bodies and their Ministers. Ministers remain ultimately accountable to their Parliament or Assembly for the deceased donation system and this change of policy has been approved by them.

BACKGROUND

7. Cases of requested allocation of deceased donor organs are likely to be very few in number. Circumstances where an individual dies, is a potential donor, and has a relative or friend of long standing in need of an organ to whom they would wish to allocate their organ, will happen infrequently. Such cases have not had any significant impact on the UK-wide organ allocation scheme or on the individuals on the transplant list waiting for a transplant.

8. The law gives precedence to the wishes of the deceased in the consent or authorisation for organ donation. In line with this principle and bearing in mind such cases should not impact on the allocation system in any adverse way, the relevant organisations (UK Health Administrations, NHSBT and the HTA) are agreed that in certain exceptional circumstances, the requested allocation of an organ to a specified relative or friend may be permissible.

PURPOSE

9. This framework aims to provide clinical staff with the necessary information to make confident decisions at a local level or where appropriate to refer the case for a decision to be taken at a national level.

UNDERLYING PRINCIPLES

10. In addition to the requirement for consent or authorisation, there are two key principles which underpin the UK organ donation programme - the absence of conditionality and the requirement that patients are treated equitably:

Absence of conditionality: It is a fundamental principle of the UK donation programme that organs are freely and unconditionally given. Consent or authorisation for organ donation must not be conditional on their request for the allocation of a donor organ to the donor's specified relative or friend going ahead. Conditionality offends against the fundamental principle that organs are donated altruistically and should go to patients according to the agreed criteria. Furthermore, in Scotland, attaching conditions to an authorisation for transplantation is prohibited by the terms of section 49 of the Human Tissue (Scotland) Act 2006
It is therefore not acceptable to attach any conditions to the donation of organs, other than by specifying the organ/s for which consent/ authorisation has been given.

Equitable Treatment: Organs are allocated to patients according to agreed criteria. The UK-wide allocation procedures are designed to ensure that patients are treated equitably and the donated organs are allocated in a fair and unbiased way based on the patient's clinical need and the importance of a range of factors, one of which may be achieving the closest possible match between donor and recipient.

11. These two overarching principles also underpin the framework where a request is made to allocate an organ to a relative or close friend. It is vital that whenever a potential requested allocation case is considered, that these two principles are respected to ensure that the integrity of the UK donation and allocation programme is not compromised.

Circumstances when a request to allocate a deceased donor organ to a named individual may be considered

Death of an intended living donor

12. If a living donor dies before their intended living donation can be carried out, the acceptability of a requested allocation of the deceased donor organ to the intended recipient depends upon what organ is being donated and to whom:

a) In cases where a potential live liver donor dies unexpectedly before donating part of their liver, patients on the Super Urgent Liver list will take precedence over the requested allocation patient if the organ is clinically appropriate. However, if there is no super-urgent patient, or where it is clinically appropriate for the liver to be split, then the request may still be considered providing it is still clinically indicated for the intended recipient and that they are on the transplant waiting list or could be considered to be placed on the waiting list, in line with 2005 Directions to NHS Blood and Transplant as amended or subsequent Directions.

b) where a person being considered as a living kidney donor dies unexpectedly prior to the procedure being carried out, a request to allocate a deceased donor kidney to the intended recipient should generally be allowed to proceed after their death providing as above, that it is still clinically indicated for the intended recipient and that they are on the transplant waiting list or could be considered to be placed on the waiting list in line with the Directions.

For these purposes, evidence that there was a willingness to be a living donor can be considered to start from the point at which an individual expressed a wish to family and/or friends that they wished to be assessed as a living donor.

13. There may be circumstances, however, where the potential donor is not far enough into the process for there to be documentary evidence of their intent to be considered as a potential live donor. In such cases, relatives should be asked to provide confirmation of this intent. The type of confirmation to be provided should, in each case, be at the discretion of those dealing with the family (see also paragraph 22)

14. In some cases, a potential living donor might start workup but then be found to be unsuitable to complete the process – for example as a result of a medical condition which may be detrimental to them in later life. In such cases the requested allocation should be considered after their death providing all the principles set out in paragraph 3 apply.

Other exceptional cases

15. Ideally valid consent or authorisation for use of the organ for transplantation after death should be provided by the individual and documented. For consent or authorisation to be valid, it must be given voluntarily by a person who has the capacity to agree to the activity in question. In law, if an individual has expressed a wish in life to be an organ donor, this consent or authorisation should be respected and not overruled by relatives. Ideally, the wish to allocate an organ to a specific named relative or friend in need of an organ should also have been provided by the individual during life. However, it is more likely that the potential donor did not provide any evidence of their intent to donate or to direct an organ during their lifetime. In such cases, relatives may request the allocation of a deceased donor organ to a specific relative or close friend. This request can be considered, where all the principles set out in paragraph 3 apply.

DEFINING URGENT CLINICAL NEED

16. Organ allocation rules seek to ensure that the people most in need of a transplant to save their life get priority on the transplant list. Consequently, NHSBT has some categories of patient for whom the need for an organ is desperately urgent:

- people on the Super Urgent Liver list
- people on the Super-Urgent or Urgent Heart lists
- people on the Super-Urgent or Urgent Lung lists.

17. Patients on the Super Urgent Liver list are unlikely to live for more than 72 hours without transplantation. Patients on the Super-Urgent or Urgent Heart lists are expected to die within days without a transplant. Patients on the Super-Urgent or Urgent Lung lists are expected to die within 90 days without a transplant. Patients on any of these lists would take precedence over **any** request for allocation if the donated organ is clinically suitable for them. This precedence will apply even if the request is to allocate the donor organ to a child and/or if the deceased donor had indicated that they wanted to be a living donor.

18. At present there are no 'super urgent' schemes for other organs. Should comparable schemes be developed for kidney, pancreas or other organs in the future, then these too will take precedence over a request for an allocation to a relative or friend.

ORGAN RECIPIENTS - QUALIFYING FOR A REQUESTED ALLOCATION

19. An individual would qualify to be considered to receive a requested allocation of a deceased donor organ if they:

- are eligible to receive an organ in line with the Directions
- are clinically in need of a transplant (for example on the transplant list or being considered for a transplant by their consultant)
- had an attachment (e.g. family, friend) to the donor such as (this list is not exhaustive):
  - spouse or partner (including civil or same sex partner)
  - parent or child
  - brother or sister
  - grandparent or grandchild
  - niece or nephew
  - stepfather or stepmother
  - half-brother or half-sister
  - uncle or aunt
  - friend of long standing.

20. It will be the responsibility of the Specialist Nurse in Organ Donation (SN) to discuss any request to allocate a deceased donor organ with family members. It is vital that the family understands that although requests can be considered in certain circumstances, donation must never be conditional on the requested allocation going ahead.

21. The SN must also establish that the proposed recipient meets the criteria set out above in discussion with the family and others and should be satisfied as far as it is possible, that the request does not contravene the law. It may not be necessary to require documentary proof in these circumstances, but the SN should be alert to the possibility of requests that could fall outside the law and should seek advice if necessary. This may include requesting further proof of the attachment between the deceased and the potential recipient.

22. All discussions and decisions should be fully documented to inform any subsequent analysis or review, particularly where a requested allocation is refused.

23. In the event of a requested allocation not proceeding for any reason (e.g. organ incompatibility, or organ unsuitable for use when examined) the reason should be documented and notified to NHSBT, either by the SN or by a member of the transplant team at the receiving hospital. A record should be kept by NHSBT in all cases.

IMPLEMENTATION

24. NHSBT will be responsible for the implementation and monitoring of the policy. The protocol will follow the steps outlined below:

- As in all cases of potential donation, the SN must first establish whether the deceased wished to donate their organs. This is greatly simplified where the deceased had given consent/authorisation by joining the organ donor register.

- If the deceased had made a valid decision to refuse consent or authorisation before death and this decision is in force at the time of their death, then that decision must be respected.
- If the views of the deceased are not known, then the SN should establish whether the family is prepared to give consent or authorisation in line with existing legislation.
- If the deceased, or their family, has given unconditional consent or authorisation donation and has indicated a wish to donate to a specified named relative or friend in need of an organ, the SN must confirm with Hub Operations in the Organ and Tissue Donation and Transplantation (OTDT) Directorate of NHSBT whether there are any patients registered for a transplant that would take priority over the requested allocation (as detailed in this framework).
- There may be occasions when the potential requested recipient is not yet registered for a transplant; in these circumstances it will be necessary to seek further clarification from the potential recipient's consultant to confirm that transplantation is clinically indicated and that they would qualify to be placed on the transplant waiting list in line with 2005 Directions as amended.
- In all circumstances, the SN must notify the OTDT Regional Manager on call prior to donation.
- The on-call Regional Manager must contact the OTDT Medical Director or his/her deputy in their absence, for further advice if the circumstances of the requested allocation do not clearly fall within this policy framework.
- If the circumstances are not clearly within this policy framework, the SN should tell the family and inform them that advice is being sought.

SEEKING ADVICE

25. If this framework document does not cover the circumstances of the case, or the clinician/SN involved is not certain whether the circumstances apply, contact should be made with the Medical Director or their deputy immediately.

26. The Medical Director may seek advice from transplant clinicians, members of the HTA or a representative from the relevant UK Health Administrations.

MONITORING

27. NHSBT Hub Operations will record:

- all requests for an allocation of a deceased donor organ.
- all cases where advice is sought.
- all cases where requested allocation proceeds.
- all cases where requested allocation does not proceed and the reasons why (e.g. precedence of an urgent patient, intended recipient not clinically suitable)

28. This monitoring will enable peer review analysis to be undertaken, to establish:

- frequency.
- circumstances of the case – in particular whether requested deceased donation may inadvertently lead to discrimination or disadvantage to any group.
- consistency of application for example whether the guidance needs to be reviewed.