

Changes in this version

Addition of final approval OTDT Clinical Audit, Risk and Effectiveness Group.

Policy

Executive Summary

1. Development and implementation of policies for allocation of organs from deceased donors is the responsibility of NHSBT.
2. Policies are developed by the Solid Organ Advisory Groups after consultation with stakeholders and reviewed by Advisory Group Chairs before final approval by OTDT Clinical Audit, Risk and Effectiveness Group on behalf of the Board of NHS Blood and Transplant (NHSBT).
3. This policy defines the criteria by which changes to allocation policies should be assessed before adoption and implementation.
4. The criteria (described in more detail below) that must be met include
 - patient focus
 - transparency
 - equity
 - patient benefit
 - compliance with current legislation
 - public support

1. Background

There is a significant imbalance between the number of people who would benefit from an organ transplant and the number of organs available for transplantation. Therefore, there needs to be some form of prioritisation to define how donated organs are allocated.

NHSBT has the statutory responsibility of developing and implementing allocation policies of organs from deceased donors. NHSBT is jointly responsible with stakeholders for developing and implementing selection policies enabling patients to receive organs from deceased donors.

Policies for patient selection and organ allocation are developed by the relevant Solid Organ Advisory Group after discussions with other stakeholders (including patients, patient groups and lay members) and are reviewed by the Associate Medical Director responsible for policies noting any other policy interdependencies before final approval by OTDT CARE on behalf of the Board of NHSBT. The processes by which the proposed policies are reached should be documented. When accepted, these will be implemented by NHSBT and other parties as appropriate.

Organs donated by deceased donors in the UK are a national resource and do not 'belong' to the donor hospital or retrieval team.

Selection and allocation policies have been in place over the last two decades and undergo regular review and modification in the light of clinical developments and patient needs. There will inevitably be significant policy differences between organs, and this occurs for many reasons, including the availability of alternative forms of organ support and logistical criteria such as ability of the retrieved organ to survive between retrieval and implantation. Furthermore, legal and ethical issues will also impact on both patient selection and organ allocation policies. To maintain public confidence in the donation and transplantation pathway, policies must be seen to be fair and equitable. Very occasionally there may be conflict between clinical, ethical, legal and public opinion. In these such circumstances key stakeholders such as Organ Advisory Group Chairs,

OTDT Clinical Audit, Risk and Effectiveness Group representatives and operational members will be convened to review and together reach a decision.

Transplantation of any organ is associated with risk and it remains the responsibility of the implanting surgeon to decide whether an offered organ is appropriate for the intended recipient and to ensure that the patient is appropriately consented. The responsibilities of the relevant parties are described in the *NHSBT/BTS Guidelines for consent for solid organ transplantation in adults*: <http://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/>.

Organs donated by living donors are subject to allocation as determined by the relevant authority (such as the Human Tissue Authority). The allocation of organs donated by altruistic living donors (non-directed) is outlined in the relevant organ allocation policy.

2. Aim of policy

The purpose of this document is to provide criteria by which both existing and changes to allocation policies can be assessed.

These criteria will be used initially for assessment of new policies and will also be used to review existing policies.

Some patients may decide not to accept organs from donors with certain characteristics therefore allocation policies will reflect the offering rather than the acceptance of a graft. Patient, in this context, implies a patient who meets the current criteria for inclusion on the UK National Organ Transplant List.

3. Criteria for assessing allocation policies

The aims of the allocation policy should be clearly outlined in the appropriate organ allocation policy and should include the following principles:

3.1. Patient Focus

Organs should be allocated to benefit patients and not to protect the interests of the transplant centre. The outcome desired should be defined for each organ after discussion with interested parties

3.2. Transparency

The basis and processes of organ allocation should be clear to all interested parties and made visible to all. Adherence to these policies should be audited by NHSBT through the Solid Organ Advisory Groups.

3.3. Equity of access

All patients with similar characteristics should have the same chance of being registered on the UK National Transplant List and of receiving an offered graft irrespective of where they are registered. Equity of access means that all patients with, for example, end stage kidney failure will have the same likelihood of being listed on the UK National Transplant List if they fulfil the listing criteria but patients who differ by blood group will not necessarily have the same likelihood of being offered a graft.

3.4. Geographical equity

The geographical location of the patient and the centre at which the patient is registered must have minimal impact on their chance of receiving an offered graft. It must be recognised that geographical equity will be impacted by clinical factors such as constraints of cold ischaemic times.

3.5. Patient Benefit

Donated organs should be distributed in a way that provides greatest good to the cohort of patients on the UK National Transplant List for that organ. In this regard:

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- 3.5.1.** Benefit should be estimated from the point of registration rather than transplantation.
- 3.5.2.** Where **clinically** indicated, donated livers will be split to benefit two recipients.
- 3.5.3.** There should be clear criteria that define when transplantation is no longer appropriate and when the patient should be removed from the list. Removal from the list may be permanent (such as might occur following the development of a new cancer) or temporary (such as with intercurrent illness). Where waiting time is a factor in the allocation model, the policy should indicate how such temporary removal (or suspension) is accounted for.
- It is recognised that, in some instances, the basis for allocation on benefit will not be supported by the level of evidence that is ideal (for example, there are few data collected on quality of life). Criteria for listing should be clear, evidence-based where possible, and objective.
- 3.6.** Compliance with legal requirements
Allocation policies must comply with current legal requirements and therefore, allocation must not be on, for example, the basis of ethnicity, age, gender, disability, lifestyle, and perceived value to society or ability to pay.
- 3.7.** Public support
Support from the public is essential to maintain confidence in the donation and transplant process. While clinicians and NHSBT have a clear responsibility to consult with interested parties, it is clear that in some instances, such as allocation of organs to prisoners or those with certain lifestyles, some do not support such a use of organs. In these situations, the ethical and legal issues will over-ride public concerns
- 3.8.** Research, innovation and flexibility
It is recognised that rigid policies for organ allocation may not always serve the patients' best interests. Such examples include service development, innovation and research and responses to individual cases not covered by the policies. Therefore, allocation policies should include transparent processes for responding in a fair and equitable way to such developments.
- Some patients do not meet agreed criteria for listing, but the centre's multi-disciplinary team meeting consider that transplantation is appropriate. Solid Organ Advisory Groups should have a timely process in place to respond to such requests for listing. The process should be transparent, accountable and ensure equity for all those on the UK National Transplant List.
- Policies should be explicit in the mechanisms for responding to situations where a transplant candidate has missed an offer, through no fault of their own. NHSBT expects that a transplant centre will inform patients in circumstances where a donated organ, allocated to them by the national scheme, has been declined by the clinical team at their transplant centre solely for reasons of resource (eg, theatre access, key staff availability, critical care beds). We will therefore be providing information to transplant units on every occasion when this occurs, with the expectation that they will use this to inform their discussions with the patient regarding the organ decline.
- Some patients may require simultaneous transplantation of more than one solid organ (such as kidney and pancreas or liver and lung). Selection and allocation policies should be consistent and transparent as to the selection of patients and allocation of organs for such recipients. The policies must be agreed by the relevant Solid Organ Advisory Groups and **approved by NHSBT OTDT CARE.**

3.9. Review

Policies should be reviewed on an agreed basis and there should be clear processes for revision.

3.10. Variation in policies

While the principles and processes underlying both selection and allocation policies will be the same for all solid organs, it is recognised that in practice there may be valid clinical and ethical reasons for variation.