# REQUESTED  ALLOCATION OF A DECEASED DONOR ORGAN

**March 2010**

**This policy has been agreed by all UK Health Administrations**

## EXECUTIVE SUMMARY

1. This framework document provides advice about the circumstances in which a request for an allocation of a deceased donor organ to a close relative or friend could be considered in exceptional circumstances and when the needs of other patients should take precedence over that request for the allocation. This document has been developed by UK health administrations together with the Human Tissue Authority (HTA) and NHS Blood and Transplant (NHSBT).

2. This document outlines a change to allocation policy which must be implemented consistently across the whole of the UK and must comply with law including the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006. The new allocation policy needs to be clear and simply expressed if it is to be readily understood by families and friends who are making requests at a time of huge emotional stress.

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 exceptional cases, where all the following principles apply:

    - that there is appropriate consent, or authorisation in Scotland, to 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 not others in desperately urgent clinical need of the organ (as defined below in paragraph 4) who may be harmed by a request for the organ to be allocated to a named individual going ahead;
    - that in life the deceased had indicated a wish 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 deceased's family expresses such a wish;
    - 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 2005 Directions to NHS Blood and Transplant as amended or subsequent 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 Urgent Heart Scheme or 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 will also take priority.

**INTRODUCTION**

5. Over the last two 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. NHSBT, HTA and the UK Health Administrations acknowledge that they each have a role in determining a framework for a request to allocate a deceased donor organ:

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

   - The HTA's general functions, as set out in the Human Tissue Act 2004, include giving guidance on the Act's consent requirements for the deceased donation of organs. In Scotland, the requirements for the authorisation of the use of organs from deceased donors for transplantation are set out in the Human Tissue (Scotland) Act 2006.

   - UK Health Administrations are responsible for legislation and overall policy direction, and provide the link between Arm's Length Bodies (such as NHSBT and HTA) and their Ministers. Ministers remain ultimately accountable to their Parliament or Assembly for the deceased donation system. This change of policy has been approved by them.

**BACKGROUND**

7. There are likely to be very few cases of requested allocation of deceased donor organs each year. 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 should not, therefore, have any significant impact on the UK-wide organ allocation scheme nor on the individuals on the transplant list waiting for a transplant.

8. The Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 give 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 voluntarily and freely 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**: The UK-wide allocation procedures are designed to ensure that patients are treated equitably. Donated organs are allocated in a fair and unbiased way according to agreed criteria. These are 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 requested allocation case is considered, 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 it is clinically appropriate for the liver to be split, then the request may be considered. However, this is providing the organ 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
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b) in cases where a potential live kidney donor dies unexpectedly, prior to the procedure being carried out, a request to allocate the deceased's donor kidney to the intended recipient should generally be allowed to proceed after their death. However, 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 2005 Directions to NHS Blood and Transplant as amended or subsequent directions.

When considering such requests, 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 or friends that they wished to be assessed as a living donor.

13. There may be circumstances, where the potential donor was not far enough into the process for there to be evidence of their intent to be considered as a living 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 have started the process to be considered as a living donor, but was then found to be unsuitable – for example as a result of a medical condition - which may have been 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 people most in need of a transplant to save their life get priority on the transplant list. Consequently, NHSBT has two categories of patient for whom the need for an organ is desperately urgent:

    - people on the Super Urgent Liver list; and
    - people on the Urgent Heart Scheme.

17. Patients on the Super Urgent Liver list are unlikely to live for more than 72 hours without transplantation. Patients on the Urgent Heart scheme are expected to die within days without a transplant. Patients on either of these lists take precedence over **<u>any</u>** request for requested donation 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 2005 Directions to NHS Blood and Transplant as amended and any subsequent 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 (eg 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 Donor Transplant Co-ordinator (DTC) 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 DTC 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 DTC 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 (eg organ incompatibility, organ transplanted to someone on the Super Urgent Liver List or Urgent Heart Scheme or organ unsuitable for use when examined) the reason should be documented and notified to NHSBT, either by the donor transplant coordinator 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 allocation policy. The protocol will follow the steps outlined below:

    - As in all cases of potential donation, the DTC must first establish whether the deceased wished to donate their organs. This is greatly simplified where the deceased has given consent/authorisation by joining the organ donor register.
    - If the deceased has 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 deceased's views are not known, then the DTC should establish whether the family is prepared to give consent or authorisation in line with existing legislation.
    - Once consent or authorisation to unconditional donation has been established, the DTC should confirm as part of the donation procedures, that the deceased donor and/or the family do not wish to request the allocation of a deceased donor organ.

- If the deceased, or their family, has given unconditional consent or authorisation to donation and has indicated a wish to donate to a specified named relative or friend in need of an organ, the DTC must confirm with the duty office in the Organ Donation and Transplantation (ODT) 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 DTC must notify the on-call ODT Regional Manager prior to donation.
- The on-call Regional Manager must contact the ODT Associate Medical Director (AMD), or their deputy in their absence, for further advice if the circumstances of the requested donation do not clearly fall within this policy framework.
- If the circumstances are not clearly within this policy framework, the DTC should tell the family and inform them that advice is being sought.

**SEEKING ADVICE**

25. A group will be established by NHSBT to provide advice at any time. This group will be known as the Requested Allocation Oversight Group and will act on behalf of, and report to, all relevant interested parties including NHSBT, HTA, and the UK Health Administrations The group will be chaired and organised by the Associate Medical Director (AMD) for Organ Donation and Transplantation and will consist of up to 15 people well versed in the clinical and ethical implications of requested allocation of deceased donor organs.

26. The members of the group will be drawn from the following three groups:
    - transplant clinicians (including surgeons, physicians and Regional Managers for Donation)
    - relevant patient groups
    - other relevant parties (such as NHSBT's Director of Organ Donation and Transplantation)

    These members will agree to be consulted at any time by the AMD. Many of the organisations listed above already have 24-hour on-call arrangements.

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

28. Considering the tight timescales necessary for organ transplantation, it will not be possible to consult all members of the committee for any given case. Furthermore, given the expected rarity of this process, it would be cumbersome to arrange a rota that would cover every day.

29. The AMD will therefore contact three members from the Requested Allocation Oversight Group, drawn, where practicable, from one representative in each group mentioned above, taking account of any national jurisdictions and any potential conflict of interest.

30. A decision will then be made by the individuals involved and advice given to the clinician and DTC involved in the case. The request for a directed allocation will proceed if the majority of the group agree.

31. In exceptional circumstances, for example if other members cannot be contacted and to delay would jeopardise the donation, a decision as to whether a requested allocation can proceed may be taken by the Associate Medical Director and another senior member of the Organ Donation and Transplantation Directorate. They will report back to the Oversight Group at the earliest opportunity.

**MONITORING**

32. NHSBT will establish a systematic process to record and monitor:
    - all requests for an allocation of a deceased donor organ;
    - all cases where advice is sought;
    - all cases where requested allocation proceeds; and
    - all cases where requested allocation does not proceed and the reasons why (eg precedence of an urgent patient, intended recipient not clinically suitable etc).

33. 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; and
    - consistency of application for example whether the guidance needs to be reviewed.

34. The findings of the monitoring will be considered by NHSBT and the UK Donation Ethics Committee. Statistics will be published annually as part of NHSBT's Transplant Activity Report and disseminated more widely as appropriate

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