Changes in this version

New policy entitled Exceptional Donation Requests Policy utilising previous POL200 Introduction to Patient Selection and Organ Allocation Policies (Appendix 1) which has been further reviewed and expanded here.

Change of title from RM on call to ODMT on call.

Policy

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 of long standing.

2. This policy should be read in conjunction with POL200 Introduction to Patient Selection and Organ Allocation Policies and only applies to patients currently listed on the UK transplant waiting list or could be considered to be placed on the UK waiting list as per paragraph 4 below. The document has been developed by UK health administrations together with the Human Tissue Authority (HTA) and NHS Blood and Transplant (NHSBT).

3. 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.

4. The fundamental principle of all deceased organ donation is that the offer to donate 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 organ donation;
- that the consent or authorisation for organ donation is not conditional on the acceptance of request for the allocation of a donor organ to the specified relative or friend of long standing;
- that there are no others in urgent clinical need of the organ (as defined below in paragraph 5) 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 or intention.
- that the specific named relative or friend of long standing is on the UK transplant waiting list or could be considered to be placed on the UK 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.

5. Priority must be given to a patient in 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. This principle is in keeping with core NHS principles of prioritising life-saving clinical need over all other non-clinical considerations.

INTRODUCTION

6. 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.

7. 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 and Northern Irish 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. Codes: (https://www.gov.scot/binaries/content/documents/govscot/publications/advice-and-guidance/2021/03/guidance-deceased-organ-tissue-donation-scotland-authorisation-requirements-donation-pre-death-procedures-1st-edition-published-march-2021-1st-ed/documents/g

Guernsey
The Human Tissue and Transplantation (Bailiwick of Guernsey) Law 2020 which replaces the Human Tissue (Bailiwick of Guernsey) Law (1981). Codes:
https://www.gov.gg/CHttpHandler.ashx?id=162761&p=0

Northern Ireland
Human Tissue Act (2004)
Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022, which amends the Human Tissue (2004) Act

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.

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.

BACKGROUND

8. 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, is likely to happen very infrequently.

9. 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

10. 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

11. 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 deceased 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 clinical 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.

12. 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 legality 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

13. 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. 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 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.

b) 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. Where possible, the clear indication of intent could be corroborated by more than one family member or third party, with the intended recipient not being one of these due to the conflict of interest.

13. There may be circumstances, however, where the potential donor has not progressed 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, confirmation of such intent, if available, can be provided by relatives. Previous discussion could be considered as a statement of 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 very 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
- Clinically urgent paediatric patients prioritised for kidney transplantation (as per POL186)

17. Patients on Super Urgent Liver, heart and urgent heart require an organ transplant within days to save life. Patients on the Super-Urgent or Urgent Lung lists are expected to survive for no longer than 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. In relation to Tier A kidney transplant wait-listed patients the guidance for possible scenarios are as below:

Scenario One;

a. If the donor had two transplantable kidneys at retrieval, one kidney would go through requested allocation pathway and the second kidney would be allocated according to POL186.

Scenario Two;

b. If the donor at retrieval is found to only have one kidney this would go through the requested allocation pathway. If there were two kidneys and one was damaged, the non-damaged kidney would go through the requested allocation pathway.

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. Establishing this should involve a conversation between the SN and the family and may include requesting further proof of the attachment/relationship 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 or clinical team to confirm that transplantation is clinically indicated and that the clinical team conclude the recipient would qualify and are ready to be placed on the transplant waiting list.

- If the multidisciplinary team caring for the intended recipient are assured that the patient has satisfied the requirements to be placed on the transplant waiting list and are medically suitable to receive an organ on the day in question.
- In all circumstances, the SN must notify the OTDT Manager on call prior to donation.
- The OTDT Manager on call 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
- Record on HTA Form so that statistical team can monitor cases.