The Royal College of Pathologists
Pathology: the science behind the cure

National Medical Examiner's Good Practice Series No. 4

Organ and tissue donation

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Contents

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About the National Medical Examiner's Good Practice Series

Medical examiners – senior doctors providing independent scrutiny of non-coronial deaths in England and Wales – are a relatively recent development.

While there is extensive guidance available on a wide range of topics for NHS and public sector staff, the National Medical Examiner's Good Practice Series highlights how medical examiners and medical examiner officers can better meet the needs of local communities and work more effectively with colleagues and partners.

The Good Practice Series is a topical collection of focused summary documents, designed to be easily read and digested by busy front-line staff, with links to further reading, guidance and support.

Introduction

As medical examiners become more widely established, it will be increasingly important that they assist with processes to enable organ and tissue donation. There are two particular areas where medical examiners can focus their attention.

Firstly, medical examiners should establish good links with staff involved in organ and tissue donation and ensure there are effective processes in place. For example, where a death is expected or imminent, it will help Specialist Nurses for Organ Donation (SNODs) and other staff leading organ donation work if multidisciplinary discussions can take place before the SNOD explores consent for donation with the family. Medical examiners should also be alert to circumstances which may cause delay or complication, such as cases which potentially require coroner notification. Giving advance notice to SNODs and other staff leading on organ donation can help ensure organ and tissue donation is not delayed unnecessarily.

Secondly, they should consider ways of working in the medical examiner office and ensure these do not create obstacles to efficient organ and tissue donation. This can include arrangements for out-of-hours cover. There are many opportunities presented by medical examiner officers' skills and knowledge of processes (for example, coroners, intensive care units and organ donation), and their availability through the working week.

The next section sets out a full list of recommendations.

Recommendations for medical examiners – organ and tissue donation

Medical examiners should:

1. actively seek and build positive relationships with SNODs and other staff leading organ donation work

2. discuss with SNODs, and other staff leading organ donation work, how contact with the family of donors/potential donors should occur. This should clarify who would make first contact, when the SNOD will approach for organ donation and what messages will be given to avoid duplication and distress to the family. It is important that the discussion with an independent medical examiner, or the medical examiner officer acting on their behalf, is maintained as this is a key element of medical examiner scrutiny.

3. actively consider and encourage the opportunities for medical examiner officers to support organ and tissue donation, through their skills and knowledge of processes (for example, coroners, intensive care units and organ donation), and availability through the working week

4. in cases where death of a potential donor is known in advance or the death is imminent, hold pre-emptive discussions with SNODs and other staff leading organ donation work, so that processes can be expedited after death. Medical examiners should positively encourage such arrangements. This could include medical examiners carrying out limited aspects of their work in a preliminary manner before death is verified, without detracting from the importance of full scrutiny after death.

5. give SNODs and other staff leading on organ donation notice as early as possible of cases which potentially require coroner notification, so that organ and tissue donation is not delayed unnecessarily

6. consider arrangements outside normal office hours.[1] These arrangements, where appropriate for the locality, should also provide for discussions with colleagues working on organ and tissue donation. This will normally be enough to facilitate the overwhelming majority of organ and tissue donation to proceed in a timely manner.

7. liaise with local coroners to ensure there is a clear mutual understanding of expectations and constraints. Of course, the Notification of Deaths Regulations apply to deaths where there is a possibility of organ and tissue donation in the same way as they do for all cases. There is no additional requirement to notify coroners of deaths where organ and tissue donation is anticipated. However, in cases where the death is to be notified to the coroner, medical examiners can play a key role in reducing the risk of delays, including cases where post-mortem examination may be required, but donation of organs or tissue could take place without jeopardising the coroner's investigation.

[1] It is not a requirement that medical examiner offices operate 24/7, nor that medical examiners are available at all times for organ donation staff, but many medical examiner offices will have considered arrangements outside office hours (e.g. evenings and weekends).

Context and background

Numbers of donors per individual hospitals can vary considerably, with some hospitals having few or no donors and others having 40−50 per year. Most hospitals will have between six and 12 donors per year. The number of potential donors is higher than actual donors.[2]

UK population	= 66,000,000
UK deaths	= 620,000
Deaths in hospitals	= 280,000
Potential donors	= 7,415
Referred potential donors	= 6,898
Donation requests	= 3,276
Consented donors	= 2,303
Actual donors	= 1,580

As can be seen from the figures above, a significant number of families do not feel able to support donation and a small proportion of families will change their mind after initially supporting donation.

Donation may not proceed for several reasons. A significant proportion will have medical conditions that mean that organs will not be of suitable quality for transplantation. This exclusion generally occurs before families are approached to consent for donation but may occur if further information comes to light during the more in-depth screening that occurs post consent.

Around 4% of consented donors do not proceed due to coroner or procurator fiscal refusal. This percentage varies between jurisdictions. The refusal is due to the potential or perceived potential for the donation of organs to interfere with future investigations. In practical terms these tend to be traumatic or suspicious deaths as those patients with no clear cause of death are unlikely to be deemed medically suitable to donate. There is the possibility of registrars notifying deaths to coroners, although numbers should be very low or zero for deaths where there has been medical examiner scrutiny.

Ethical considerations and confirmation of death

Deceased organ and tissue donation is an element of an individual patient's end of life decisions and should be facilitated where ethically and legally possible.

- Ethically, donation must not cause death, so the patient has to be deceased before organ and tissue donation can proceed (the dead donor rule).
- Death can be confirmed in two ways: neurological criteria (brainstem death) and circulatory criteria as per the Academy of Medical Royal Colleges' Code of Practice.
- Donation after brainstem death (DBD) is possible from patients whose death has been confirmed using neurological criteria (also known as brainstem death or brain death).

[2] Latest information is available at www.odt.nhs.uk/statistics-and-reports/.

Deceased organ donation

A patient has a potential to be an organ donor if there is an intention to withdraw life sustaining treatment or an intention to test for brain stem death.

Neurological criteria for the diagnosis and confirmation of death apply in circumstances where brain injury is suspected to have caused irreversible loss of the capacity for consciousness and irreversible loss of the capacity to breathe before terminal apnoea has resulted in hypoxic cardiac arrest and circulatory standstill. This diagnosis is only possible in patients who are on mechanical ventilation.

Donation after circulatory death (DCD) refers to the retrieval of organs for the purpose of transplantation from patients whose death is diagnosed and confirmed using cardio-respiratory criteria.

There are two principal types of DCD: controlled and uncontrolled. Uncontrolled DCD refers to organ retrieval after a cardiac arrest (in the community or in the Emergency Department [ED]) that is unexpected and from which the patient cannot or should not be resuscitated. This is currently not practiced in the UK.

By contrast, controlled DCD takes place after death which follows the planned withdrawal of life-sustaining treatments that have been considered of no overall benefit to a critically ill patient on ICU or in the ED.

For DCD organ donation to proceed, patients must die and be confirmed deceased within four hours after withdrawal of life sustaining treatment. This means a proportion of consented donors will not die and will generally follow an end-of-life pathway. The potential for tissue donation when these patients eventually die persists. A very small number of patients may survive longer term.

Deceased tissue donation

Deceased tissue donation can be considered after any death. It often occurs in conjunction with organ donation but is more frequently independent of organ donation. Tissue donation can take place in a mortuary setting, hospice or funeral home. The retrieval of corneal tissue must take place within 24 hours, but other tissues can be retrieved up to 48 hours.

Organ donor register

The organ donor register is a confidential record of people's organ donation decisions. It allows members of the public to register if they would like NHS staff to speak to their family or another appropriate person about how or whether organ donation can go ahead in line with faith or beliefs.

Organ donation and the law

The Human Tissue Act 2004 contains the legislative framework around organ donation and transplantation in England, Wales and Northern Ireland. Equivalent legislation in Scotland is The Human Tissue (Scotland) Act 2006.

These should be read in conjunction with the following Acts which introduced deemed consent:

- England: Organ Donation (Deemed Consent) Act 2019

- Wales: Human Transplantation (Wales) Act 2013
- Scotland: Human Tissue (Authorisation) (Scotland) Act 2019.

Legislation around consent for organ donation varies in the UK. For all UK organ and tissue donation legislations, a person can also record a decision to be or not to be a donor after death. Additionally, it is also possible to nominate up to two representatives to make the decision. These could be family members, friends or other trusted people, such as a faith leader.

Wales

The legislation for Wales is 'deemed consent'. This means that if a person has not registered an organ and tissue donation decision (opt in or opt out), they will be considered to have no objection to becoming a donor. This legislation was introduced in December 2015 and there is a code of practice.

England

Organ donation in England also moved to an opt out system on 20 May 2020. There is a code of practice.

Scotland

The Human Tissue (Authorisation) (Scotland) Act 2019 was passed by the Scottish Parliament in July 2019. The legislation provides for a 'deemed authorisation' or 'opt out' system of organs and tissue donation for transplantation. The system came into effect on 26 March 2021.

Northern Ireland

The current legislation for Northern Ireland is an opt-in system of organ and tissue donation;[3] it is unlawful to deem consent for organ and tissue donation and the requirements of the Human Tissue Act should be followed. This means that a person can express their decision by joining the NHS Organ Donor Register and sharing the decision with their family and friends.

Structures and organisations

National

- Human Tissue Authority – regulates organ donation and transplantation across the UK under The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended).[4]
- NHS Blood and Transplant (NHSBT) – manages organ and tissue donation and transplantation nationally.
- National Organ Retrieval Service (NORS) – responsible for organising national coverage and setting standards for organ retrieval teams.

[3] There are proposals to change to a deemed consent system – if agreed, this is unlikely to come into force until spring 2023.
[4] All hospitals where organ transplants take place are audited and must be licensed to be able to undertake certain donation and transplantation activities.

- Organ Advisory Groups – responsible for organ allocation policy.
- National Organ Donation Committee – forum of senior clinical leads and specialist nurses, with stakeholder representation, that helps advise national policy.

There are several charity organisations and support groups who promote organ and tissue donation and represent families of donors and those waiting for transplants.

Regions

- NHSBT has 12 regional organ donation teams.
- Each team will include SNODs who will assess potential donors and approach families for consent. They are embedded in acute hospitals but have an on-call role across the region.
- Regional Clinical Lead – clinician with sessional commitment to NHSBT. Responsible for providing medical leadership within a region.
- Retrieval teams – surgical teams based at transplant centres but travel to hospitals with potential donors to facilitate donation retrieval. Divided into abdominal organ retrieval and cardiothoracic organ retrieval specialist teams.
- Tissue and Eye Services operate a national referral centre staffed by Specialist Nurses for Tissue Donation (SNTDs) and four regional tissue donation teams who travel to hospitals, hospices or funeral homes to facilitate tissue donation.

Hospitals/healthcare providers

- Clinical Lead for Donation – clinician from a trust responsible for championing and removing barriers to donation.
- Donation Committee Chair – lay person responsible for championing and removing barriers to donation including promotion and chairs the local Organ Donation Committee.
- SNOD – embedded with honorary position in a trust.
- In some trusts SNTDs are embedded, and some trust Organ Donation Committees have a representative from tissue donation services.

Typical processes

Deceased organ donation – example process

1. Criteria for potential donor identification (NICE Guidance):
    - intention to brain stem test
    - in severe brain injury, one or more cranial nerves is absent or GCS <4 and not explained by sedation
    - intention to withdraw life sustaining treatment.
2. Potential donor identified by clinical team.
3. SNOD is contacted to assess potential for donation.

This involves consideration of medical history of patient, including infective status, to ensure that any organs donated will be of a sufficient quality and safety for the transplant recipient. The NHS Organ Donor Register is also checked to clarify previously expressed decisions (or if deemed consent would be applicable).

4. Family approached about intention to brain stem test or to discuss withdrawal of life sustaining treatment as part of end-of-life care.

5. SNOD explores with family consent for organ and tissue donation.

   If consent is gained,

6. Treating clinician considers if the case will require discussion with HM Coroner/medical examiner. If yes, treating clinician and/or SNOD seek lack of objection to organ and tissue donation occurring or if donation can proceed with restriction on what can be retrieved. Occasionally, this discussion may occur before donation is raised with a family.

7. SNODs do further screening, which involves tissue typing, viral tests and offering the organs to the transplant centres. This can take between six and 24 hours depending on the potential number of organs.

8. The NORS teams (surgeons and theatre staff from the transplant centre) are mobilised and arrive at the hospital with the potential donor.

9. From this point on processes vary depending on whether the patient is a potential DBD or DCD.

   In DBD, the patient has been confirmed dead using neurological criteria (brain stem tests). Ventilation and circulation are maintained when the patient is taken to theatre, and for part of the surgical procedure.

   In DCD, life sustaining treatment (ventilation and drug infusions supporting blood pressure) is withdrawn in the theatre complex or ICU/ED with the retrieval team ready in theatre. Organ donation does not proceed unless the patient dies and is confirmed dead using circulatory criteria (absence of circulation and respiration). If the patient does not die, they continue on an end-of-life pathway and are usually transferred to a ward. The possibility for tissue donation remains.

10. Medical examiner scrutiny and certification.

Deceased tissue donation – example process

1. Patient dies in a hospital, healthcare setting or community.

2. Referral for tissue donation is made to the National Referral Centre.

   - Some hospitals have automatic notification systems of all deaths therefore the family may not be expecting contact.

   - Referrals can be made by any individual.

3. SNTD assess potential for tissue donation.

This involves consideration of medical history of patient including infective status, to ensure that any tissues donated meet the requirements of the Tissue Donor Selection Guidelines – Deceased donors. The NHS Organ Donor Register is also checked to clarify previously expressed decisions (or if deemed consent would be applicable).

4. During the referral conversation, the SNTD will ask if the case is being referred to HM Coroner. If yes, the SNTD will seek lack of objection to tissue donation occurring or if donation can proceed with restriction on what can be retrieved. This discussion may occur after donation is raised with a family.

5. SNTD explores with family consent for tissue donation.

6. The tissue retrieval team is mobilised to facilitate the tissue donation, arrangements will be made with the hospital mortuary, hospice or funeral home to provide access to their facility to perform the tissue donation.

7. A blood sample for mandatory virology testing is secured during the donation process, either obtained by the retrieval team or provided by a healthcare professional or released from a hospital laboratory.

8. The donated tissue is quarantined within the NHSBT Tissue and Eye Banks until the consented donor has been reviewed by a clinician or senior nurse specialist to authorise the tissue suitable for transplantation. Donated corneas have to be transplanted within 28 days of donation, for all other tissues it is five to ten years after donation.

9. To enable this review, the donor's cause of death or, in the case of eye donation, provisional cause of death, must be confirmed by the Medical Examiner Office. In the event a post mortem has been undertaken, a copy of the report is obtained and reviewed to ensure there are no findings that may contraindicate donation.

10. Medical examiner scrutiny and certification.

Find out more

- Chief Coroner's guidance: https://www.judiciary.uk/publications/chief-coroner-guidance-no-26-organ-donation/
- NICE: Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation
- Human Tissue Authority (HTA) Codes of Practice: https://www.hta.gov.uk/guidance-professionals/codes-practice
- The organ donor register is a confidential record of people's organ donation decisions.
- Organ donation in Wales: https://gov.wales/organ-donation-guide
- Organ donation in England: https://www.organdonation.nhs.uk/

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