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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Author: Dr Alan Fletcher, National Medical Examiner

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The Royal College of Pathologists
6 Alie Street
London E1 8QT
T: 020 7451 6700
F: 020 7451 6701
www.rcpath.org
Registered charity in England and Wales, no. 261035

About the National Medical Examiner's Good Practice Series

Medical examiners are senior doctors providing independent scrutiny of non-coronial deaths in England and Wales, with the role now a statutory requirement since 9 September 2024.

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

It is important that medical examiners carry out their statutory responsibilities in ways that support organ and tissue donation as far as possible. There are 2 particular areas where medical examiners can focus their attention.

First, considering ways of working in the medical examiner office and ensuring 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 and tissue donation) and their availability through the working week.

Second, establishing good links with staff involved in organ and tissue donation and ensuring there are effective processes in place. Clinical leads for organ donation (CLODs) can be helpful in establishing relationships between the medical examiner office and other medical leaders. The specialist nurses and the organ donation committees of the trust/health board can support these close working relationships. Giving advance notice to specialist nurses for organ donation (SNODs) and other staff leading on organ donation can help ensure organ and tissue donation is not delayed unnecessarily. For example, where a death is expected or imminent, it will help specialist nurses, in both organ and tissue donation, and senior clinical leaders to identify circumstances that may cause delay or complication, such as cases which potentially require coroner notification. This is explored in the following section.

Impact of the Death Certification Reforms

The Death Certification Reforms from 9 September 2024 introduced statutory duties for medical examiners and rights to access records of deceased patients. These rights and duties do not commence in relation to a deceased person until an attending practitioner sends the medical certificate of cause of death (MCCD) to the medical examiner. Medical examiner scrutiny is not possible before death, as medical examiners are not entitled to access medical notes for patients that are still alive.

However, medical examiners can act in an advisory capacity to the senior clinician responsible for care (usually the intensive care unit [ICU] consultant for organ donation or another clinician for tissue donation). Medical examiners can assist senior clinicians and specialist nurses in deciding whether a case needs referral to the coroner or whether

organ and tissue retrievals can proceed without coroner referral. Such discussions will need to consider any reasons the senior clinician is aware of that may require coroner referral under the *Notification of Deaths Regulations 2019*, whether there are any clinical or family concerns about care, the causes of death that are likely to be recorded, and the circumstances leading to hospital/hospice admission. This risk-based approach reduces the occurrence of an unnatural element being discovered after organ and/or tissue retrieval has taken place and subsequent coroner referral being required. However, this advisory medical examiner process is not mandatory and is unlikely to be available 24/7; the organ and tissue donation team may proceed without medical examiner advice if the team judges this to be required and appropriate.

The medical examiner's input at this time is limited to providing an opinion on the likelihood of the donation process being able to proceed without coroner referral, based on the information available at the time. Through independent scrutiny after death, further information may emerge indicating that coroner referral is required, but this does not prevent medical examiners providing the earlier opinion. The organ and tissue donation team is responsible for any organ and/or tissue donation that proceeds despite coroner referral being required. Discussions should be documented by the clinician or specialist nurse and included in the clinical notes (in a manner similar to coroner's discussions), not in medical examiner scrutiny. Medical examiners should keep a personal record of the discussion, which can be made and stored confidentially and added to the record of scrutiny after the death has been notified to the medical examiner office. Medical examiners should note that their usual legal basis for accessing patient records in their medical examiner role does not apply while the patient is still living.

Such a discussion regarding coroner notification prior to organ and/or tissue donation does not replace full scrutiny. Full scrutiny must occur in the usual way after death, with completion of an MCCD as required in the *Medical Certificate of Cause of Death Regulations 2024*. There is no requirement for the same medical examiner who undertook the discussion to provide independent scrutiny after death.

Finally, the *Medical Certificate of Cause of Death Regulations 2024* include a provision for medical examiners to examine a body or instruct another individual to do so on their behalf. Such examination could impact organ and tissue donation. In practice, it is extremely rare for medical examiners to consider this a necessary part of their enquiries.

The National Medical Examiner provides guidance and expected standards for medical examiners. It is issued under the *National Medical Examiner (Additional Functions) Regulations 2024*. This guidance notes that, "… cover for weekends and public holidays is likely to be required in most areas, though a continuous 'on call' service is not necessary. Arrangements at each office should reflect local health priorities and the needs of communities, particularly if there is regular demand for urgent release of bodies at weekends and public holidays. Urgent release may be required to facilitate organ and tissue donation, or to fulfil religious practices and other needs of local communities."

Recommendations for medical examiners – organ and tissue donation

Medical examiner offices should:

1. actively seek and build positive relationships with SNODs, CLODs and other staff leading organ and tissue donation work and agree how contact with the medical examiner office (during office hours) or individual medical examiner (outside office hours) will occur.
2. ensure processes have been agreed with SNODs/CLODs and other staff leading organ and tissue donation, setting out how contact with the family of donors/potential donors should take place. These will need to consider the interests of the bereaved, so that the SNOD can discuss organ and tissue donation with the family. The family should also be given the opportunity to discuss causes of death or raise concerns with a medical examiner or officer acting on their behalf in accordance with MCCD regulations.
3. be cognisant that organ and tissue donation timeframes are constrained and require donation in a timely manner to best support the potential donor and for organ and tissue retrieval. In cases where the death of a potential donor is known in advance or the death is imminent, holding pre-emptive discussions with specialist nurses in both organ and tissue donation and other staff leading organ donation work may enable processes to be expedited after death. Medical examiners should note their right of access to records of deceased patients under the *Access to Health Records Act 1990* only applies to deceased patients where the medical examiner is providing independent scrutiny.
4. 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.
5. give specialist nurses and other staff leading on organ and/or tissue donation notice as early as possible of cases that potentially require coroner notification, so that 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.

7. liaise with local coroners to ensure there is a clear mutual understanding of expectations and constraints. 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 others. There is no additional requirement to notify coroners of deaths where organ and tissue donation is anticipated.

Medical examiners should:

1. help to identify whether there are any requirements to refer the case to the coroner, ideally through discussion with the senior clinician responsible for care (usually the ICU consultant for organ donation or another clinician for tissue donation). This discussion can take place prior to completing full scrutiny.

2. ensure discussions occur in a timely manner and do not unnecessarily delay the donation process.

3. assist the coroner, if required, in determining whether organ/tissue donation will interfere with their investigations.

[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 all medical examiner offices are required to consider arrangements outside office hours (e.g. evenings and weekends) – see Good Practice Series No. 8.

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 6 and 12 donors per year. The number of potential donors is higher than actual donors.

UK potential deceased organ donor population between April 2023 and March 2024.[2] Corneas were retrieved from 2,154 cornea only donors and from 435 organ donors.

UK population	= 67,600,000
UK deaths	= 662,000
Deaths in hospitals	= 290,000
Potential organ donors	= 6,794
Referred potential organ donors	= 6,421
Donation requests	= 3,107
Consented organ donors	= 1,180
Actual donors	= 1,510
Patients transplanted	= 3,713

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

Around 8% of potential donors do not proceed due to coroner/procurator fiscal objection. This percentage varies between jurisdictions. The full objection is due to the perceived potential for the donation of organs or tissues to interfere with future investigations.

The Chief Coroner has issued guidance (number 26) to coroners regarding organ and tissue donation.

Information on the professional, ethical and legal aspects on organ donation is contained in the 2022 *Donation Actions Framework*. A summary of key considerations is included below.

[2] NHSBT. *Organ and tissue donation and transplantation activity report 2023/2024*. Available at: https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/33778/activity-report-2023-2024.pdf

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 3 ways: circulatory criteria, neurological criteria (brainstem death) and somatic criteria, as per the Academy of Medical Royal Colleges' 2025 Code of Practice.
- Donation after brainstem death (DBD) is possible from patients whose death has been confirmed using neurological criteria.
- Organ donation laws vary across different countries in the United Kingdom. In general terms, all adults are now considered to have agreed to be an organ or tissue donor when they die unless they made a decision not to donate or are in an excluded group.

Deceased organ donation

A patient has the potential to be an organ donor if there is an intention to withdraw life sustaining treatment or an intention to diagnose death using neurological criteria.

Neurological criteria for the diagnosis and confirmation of death apply in circumstances where brain injury is suspected to have caused permanent loss of the capacity for consciousness and permanent 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 circulatory criteria.

There are 2 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) that is unexpected and from which the patient cannot or should not be resuscitated. This is currently not routinely practiced in the UK.

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

For DCD organ donation to proceed, patients must die and be confirmed deceased within 3 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.

Discussion between organ and tissue donation teams and medical examiner offices will need to occur in a timely manner to support the potential donor and tissue retrieval. Contact initiated during regular medical examiner office opening hours may begin after some of the limited hours of the window of opportunity have passed. Tissue donation services can advise on necessary time frames to identify any requirement of coroner referral. NHSBT care of tissue donors operates seven days a week, between 8am and 8pm.

Organ donor register

The NHS organ donor register is a confidential and secure 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. It also allows people to register their decision not to donate.

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 that introduced deemed consent:

- England: *Organ Donation (Deemed Consent) Act 2019*
- Wales: *Human Transplantation (Wales) Act 2013*
- Scotland: *Human Tissue (Authorisation) (Scotland) Act 2019*
- Northern Ireland: *Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022*.

Donation glossary and structures

National

- **Human Tissue Authority (HTA)** – the HTA is the national regulator for organ and tissue donation and transplantation. It is a non-departmental ('arms-length') public body of the Department of Health and Social Care that regulates organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and public display. They also give approval for organ and bone marrow donations from living people.
- **National Organ Retrieval Service (NORS)** – a commissioned service of abdominal and cardiothoracic surgical teams that perform organ retrieval or organ recovery in a donor hospital. The team usually includes the following members: lead surgeon, surgical assistant, organ preservation practitioner, theatre practitioner and a scrub practitioner.
- **NHS Blood and Transplant (NHSBT)** – a special health authority that manages organ and tissue donation and transplantation nationally.
- **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.
- **Organ Donation Register (ODR)** – a confidential, computerised national database managed by NHSBT that holds details of people who have signed up to become organ donors in the event of their death. It also holds details of people who have stated they

do not want to donate their organs after their death. The register is used after a person has died to help establish whether they wanted to donate and, if so, which organs.

- **Specialist nurse, tissue donation (SNTD)** – a senior nurse based at NHSBT's tissue banking facility in Liverpool. Responsible for coordination of tissue donation after death at a national level and providing support and assistance to the newly bereaved families of tissue donors.
- **Tissue and eye services** – a national referral centre staffed by specialist nurses for tissue donation and tissue donation teams who travel to hospitals, hospices or funeral homes to facilitate tissue donation.

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

Regional and local teams

- **Organ donation service team (ODST)** – NHSBT has 12 regional organ donation teams.
- **Specialist nurse, organ donation (SNOD)** – a senior nurse responsible for facilitating the entire donation process from initial donor referral to completion of organ retrieval, by working in close conjunction with all staff in critical care areas and donor family members. This includes ensuring that donation proceeds in line with appropriate legislation and national policies and procedures, supporting families of critical care patients, obtaining all relevant information enabling transplant centres and tissue establishments to assess the suitability of potential donors and provide expert advice to health care professionals.
- **Regional clinical lead for organ donation (RCLOD)** – clinician with sessional commitment to NHSBT. Responsible for providing medical leadership within a region.
- **Clinical lead for organ donation (CLOD)** – clinician from a trust/health board responsible for championing and removing barriers to donation.
- **Donation committee** – the role of the organ donation committee is to champion deceased donation processes and practice within hospital trusts and health boards. Additionally, organ donation committees have a duty to challenge and seek to overcome local barriers to donation and promote donation within the local community.

Types of donation

- **Donation after brainstem death (DBD)** – donation of organs after a diagnosis of death using neurological criteria (DNC). In DBD, deceased donors have intensive care support continued after death is confirmed so that the heart, kidneys and other organs are supported, optimised and remain functioning up to the point that the donor's organs are retrieved. Organ retrieval can be planned for a time suitable to the retrieval team, intensive care and the donor's family.
- **Donation after circulatory death (DCD)** – donation of organs after the diagnosis of death using circulatory criteria. In controlled DCD, as currently practised in the UK, deceased donation follows a planned withdrawal of life sustaining treatment and the confirmation of the death. If a patient in these circumstances is believed to be willing to donate after death, treatment withdrawal is planned for a time and place that facilitates organ retrieval. Owing to the lack of circulation, organs must be retrieved within a few minutes of death to be suitable for transplantation.
- **Tissue donation** – donation of tissue, such as skin, bone, tendons, eyes, heart valves and arteries, after 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.

Typical processes

Deceased organ donation – example process

1. Criteria for potential donor identification (NICE Guidance). A mechanically ventilated patient where there is a plan to:
   - brainstem test
   - withdraw life sustaining treatment.
2. Potential donor identified by clinical team and SNOD is contacted to assess potential for donation.
   This involves consideration of medical history of patient, 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 may be applicable).

3. Medical examiner/coroner consideration:
    - the medical examiner may be approached at this point to act in an advisory capacity to the senior clinician responsible for care (usually the ICU consultant for organ donation or another clinician for tissue donation). Medical examiners can assist through a clinical discussion to help senior clinicians and specialist nurses decide whether a case needs referral to the coroner or whether organ and tissue retrievals can proceed without coroner referral.
    - if coroner referral is required, the treating clinician and/or SNOD will seek lack of objection from the coroner to organ and tissue donation occurring or if donation can proceed with restriction on what can be retrieved.
    - ideally, the discussion with the medical examiner/coroner will be held before donation is raised with a family to ensure the family is not offered donation which it later transpires cannot occur. This will also enable any discussions or investigations (e.g. police/pathologist) to be facilitated in daytime hours.
4. Family approached about intention to brainstem test or to discuss withdrawal of life sustaining treatment as part of end-of-life care.
5. SNODs explore with family consent for organ and tissue donation.
6. SNODs complete further assessment, which involves tissue typing, viral tests and offering the organs to the transplant centres. This can take up to 24 hours or more.
7. The NORS teams (surgeons and theatre staff from the transplant centre) are mobilised and arrive at the hospital with the potential donor.
8. From this point on, processes vary depending on whether the patient is a potential DBD or DCD.
    - In DBD, the patient has been confirmed deceased using neurological criteria (brainstem 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 with the retrieval team ready

in theatre. Organ donation does not proceed unless the patient dies and is confirmed deceased using circulatory criteria (absence of circulation and respiration). If the patient does not die within a few hours, they continue on an end-of-life pathway and are usually transferred to a ward. The possibility for tissue donation remains.

9. MCCD completion, medical examiner scrutiny and certification.

Deceased tissue donation – example process

1. Patient dies in a hospital, hospice, or community setting.
2. Referral for tissue donation is made to the National Referral Centre.
3. Specialist nurse for tissue donation (SNTD) assess potential for tissue donation:
   - this involves consideration of medical history of patient 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 may be applicable).
4. During the referral conversation with the National Referral Centre, the SNTD will ask if the case has been reviewed by the medical examiner and whether the death is reportable to the coroner.
5. SNTD explores with family consent for tissue donation.
6. Medical examiner/coroner consideration:
   - the medical examiner will be approached at this point to act in an advisory capacity to the senior clinician responsible for care. Medical examiners can assist through a clinical discussion to help senior clinicians and specialist nurses decide whether a case needs referral to the coroner or whether tissue retrievals can proceed without coroner referral.
   - if coroner referral is required, the SNTD will seek lack of objection to tissue donation occurring or if donation can proceed with restriction on what can be retrieved.
   - typically, the discussion with the medical examiner/coroner will be held after donation has been raised with the family and consent has been gained.

7. The tissue retrieval team are 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.
8. 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.
9. 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. 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. MCCD completion, 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
- NHSBT Clinical website for Organ donation and transplant: https://www.odt.nhs.uk/
- NHSBT Organ and tissue donation legislation and Donation Actions Framework
- 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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