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

Guidelines on autopsy practice

Autopsies on donors following tissue and organ donation

July 2025

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Unique document number	G176
Document name	Guidelines on autopsy practice: Autopsies on donors following tissue and organ donation
Version number	2
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Date active	July 2025 **(to be implemented within 3 months)**
Date for review	July 2030
Comments	This edition supersedes the 1st edition of *Autopsies after tissue and organ donation*, published in 2019.

	In accordance with the College's pre-publications policy, this document was on the Royal College of Pathologists' website for consultation with the membership from 22 April to 20 May. Responses and authors' comments are available to view at https://www.rcpath.org/profession/publications/documents-in-development.html. **Dr Brian Rous** **Clinical Lead for Guideline Review**

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Registered charity in England and Wales, no. 261035

Contents

Foreword

The autopsy guidelines published by the Royal College of Pathologists (RCPath) are guidelines that enable pathologists to deal with non-forensic consent and coroner's/procurator fiscal post-mortem examinations in a consistent manner and to a high standard. The guidelines are systematically developed statements to assist the decisions of practitioners and are based on the best available evidence at the time the document was prepared. Given that much autopsy work is single observer and 1-time only in reality, it has to be recognised that there is no reviewable standard that is mandated beyond that of the FRCPath Part 2 exam or the Certificate of Higher Autopsy Training (CHAT). Nevertheless, much of this can be reviewed against ante-mortem imaging and other data. This guideline has been developed to cover most common circumstances. However, we recognise that guidelines cannot anticipate every pathological case type and clinical scenario. Occasional variation from the practice recommended in this guideline may therefore be required to report an autopsy in a way that maximises benefit to the pathologist, coroner/procurator fiscal and the deceased's family.

There is a general requirement from the General Medical Council (GMC) to have continuing professional development (CPD) in all practice areas, and this will naturally encompass autopsy practice. Those wishing to develop expertise/specialise in pathology are encouraged to seek appropriate educational opportunities and participate in the relevant external quality assurance (EQA) scheme.

The guidelines themselves constitute the tools for implementation and dissemination of good practice.

The following stakeholders were consulted for this document:

- Organ and Tissue Donation and Transplantation (OTDT) Clinical Team, NHS Blood and Transplant (NHSBT)
- Human Tissue Authority
- Crown Office and Procurator Fiscal Service
- Coroner's Service, England and Wales
- Northern Ireland Coroner's Service
- Home Office Forensic Science Regulation Unit and Forensic Pathology Unit
- British Medical Association.

The information used to develop this document was derived from current medical literature and they previous version of the guideline. Much of the content of the document represents custom and practice, and is based on collective substantial clinical experience among the consultant authors. All evidence included in this guideline has been graded using modified SIGN guidance (see Appendix A). The sections of this document that indicate compliance with each of the AGREE II standards are indicated in Appendix B.

No major organisational changes or cost implications have been identified that would hinder the implementation of these guidelines.

A formal revision cycle for all guidelines takes place on a 5-yearly cycle and the full revised version (incorporating the changes) will replace the existing version on the College website.

The guideline has been reviewed by the Professional Guidelines team, Death Investigation Committee, Cellular Pathology and Forensic Specialty Advisory Committees, and Lay Advisory Group. It was placed on the College website for consultation with the membership from 22 April to 20 May. All comments received from the membership were addressed by the authors to the satisfaction of the Clinical Lead for Guideline Review.

This guideline was developed without external funding to the writing group. The College requires the authors of guidelines to provide a list of potential conflicts of interest; these are monitored by the Professional Guidelines team and are available on request. The authors have declared no conflicts of interest.

1 Introduction

Many different organs and tissues can be transplanted. While over 1,000 organs per year are donated from living donors, organ donation mostly occurs in patients who have either met the criteria for brainstem death or had life-sustaining treatment withdrawn on an intensive care unit (ICU).

Deemed consent was introduced in Wales in 2015, in England in 2020 and in Northern Ireland in 2023. This ‘opt-out’ system for organ and tissue donation means individuals are presumed (or considered willing) to consent to organ and tissue donation for the purpose of transplantation. The exceptions to this are listed in the relevant Human Tissue Authority Codes of Practice. Where consent may be deemed, a specialist nurse should explain this

to the family and have a sensitive discussion to best support their needs and to facilitate donation. In these circumstances, deemed consent legislation allows for someone in a qualifying relationship to provide information that would lead a reasonable person to conclude that the person did not want to be a donor. When deemed consent does not apply, appropriate consent may be given by someone who was in a qualifying relationship with the potential donor immediately before their death. Further information is available in the Human Tissue Authority *Code of practice for deceased organ and tissue donation*.[1]

In Scotland, a system of 'deemed authorisation' for organ and tissue donation for transplantation purposes came into effect in 2021, which assumes a patient is willing to donate organs and tissues for transplantation unless they have decided to opt out.

If the coroner or procurator fiscal is not involved in the investigation of a death, an autopsy may be performed with the consent of the relatives. However, very few so-called 'consented' autopsies are currently performed in the UK. Autopsies occur at a variable interval after organ retrieval, but this may be up to and can exceed a week. The primary purpose of the autopsy is to establish an accurate cause of death, to identify and document patterns of injury, and to address potential medicolegal implications. For these reasons, consultant forensic pathologists may perform some of these examinations. However, most are performed by non-forensically trained pathologists, and the identification or confirmation of other pathological processes may be of particular importance to the transplantation recipient.

When a potential donor is identified, there are established ante-mortem protocols for the identification of infective or neoplastic processes that have the potential to be transmitted from the donor to a recipient.[2–4] Despite this practice, there are reports of donor-derived pathologies that have developed in recipients, probably or certainly as a result of transplantation.[5,6] Reported donor-derived tumours include lung cancer, renal cancer, prostate cancer, pancreatic cancer, ovarian cancer, melanoma and lymphoma.[7–11] Reported donor-derived infective processes include viruses, such as herpes simplex virus, human T-lymphotropic virus and rabies virus; bacterial infections, such as tuberculosis; parasitic infections, such as *Strongyloides stercoralis*; and fungal infections, such as cryptococcosis.[12–15] It is, therefore, important that all pathologists are aware of this possibility and adjust their approach to the autopsy accordingly. Of note, owing to the significant impact on the clinical management of recipients, relevant donor processes that could not be diagnosed intra vitam must be promptly reported to allow for investigation post mortem (see section 6 below).[5,16]

1.1 Target users of these guidelines

The target primary users of these guidelines are pathologists performing autopsies on the instruction of a medicolegal authority (coroner or procurator fiscal) or with the consent of the relatives of the deceased. The recommendations will also be of value to pathologists in training, particularly those preparing for the CHAT examination. The guidelines may form part of appraisal by demonstration of personal good practice case reviews.

The recommendations should also be of value to forensic pathologists, specialist nurses (organ donation), microbiologists, anatomical pathology technologists and coroners/procurators fiscal and their officers.

These guidelines are not aimed at and do not claim to cover the investigation of deaths that are deemed suspicious by the relevant investigating authorities. Such cases should be conducted as a forensic post-mortem examination by a suitably trained forensic pathologist working to the guidelines developed for such suspicious scenarios.

2 The role of the autopsy

The role of the autopsy is to determine various aspects related to the death, including:

- to establish an accurate cause of death, where necessary in collaboration with relevant clinical teams. In some deaths, information provided by the coroner, procurator fiscal or police officers will be important (see section 4 below)
- to identify any pathological processes which may have an impact on the management of the recipients of the donated organs, and thus potentially preventing future deaths
- to exclude neoplastic, infective, systemic inflammatory or congenital abnormalities that were not identified during life, and that may have implications for transplant recipients.

  It is important to notify NHSBT urgently of such findings (see section 13 below for contact details).

- to document traumatic injuries that may have contributed or led to death determined using neurological criteria (brainstem death) to aid in the medicolegal investigation of the case.

[Level of evidence – GPP.]

3 Specific health and safety aspects

None beyond the standard health and safety considerations. For full guidelines, please consult relevant health and safety publications.[17]

4 Clinical information relevant to the autopsy

Before undertaking a post-mortem examination, the pathologist should be briefed by the coroner's officer/procurator fiscal, or other relevant parties involved in the investigations, or by the clinical team in the case of a consented hospital post mortem.

The donor typically will have been an inpatient in a hospital before tissue donation and will typically be at the base hospital for organ donation. It is, therefore, of great importance that the medical records pertaining to the current admission of the patient (including ambulance records) are provided before autopsy. It is, however, recognised that this may not be possible in all cases. Occasionally, an accurate clinical diagnosis will not have been established before organ retrieval. Discussions between the OTDT Clinical Team or other relevant parties and pathologists may be helpful in these cases.

Forensic pathologists, coroner's officers, procurators fiscal and police officers may be involved in medicolegal discussions before organ donation. General pathologists are unlikely to be involved in this way but may be approached by coroner's officers and procurators fiscal seeking advice on whether organ donation is appropriate.

The following information aids any post-mortem examination and, when available, should be provided to the pathologist by the coroner's officer or procurator fiscal, or should be sought in the available medical records before the post-mortem examination commences:

- details of circumstances of initial presentation, including events occurring before admission (outside the hospital) and those surrounding admission
- past medical history, including alcohol and drug abuse
- recent clinical history, specifically symptoms or signs suggesting systemic disease
- surgical operative notes, including details of organs removed and additional tissue sampling
- results of in-hospital toxicological or other biochemical testing.

Many cases will have had radiological imaging prior to organ donation and reports should be reviewed, particularly when there is a history of trauma.

If any of the information provided raises the possibility that the death may in any way be suspicious, non-forensically trained pathologists should carefully consider whether they should proceed with the case and, at the very least, should discuss the case with the relevant coroner/procurator fiscal or a consultant forensic pathologist. If, having done so, they cannot be certain that the case is not suspicious, then they should not proceed.

[Level of evidence – GPP.]

5 The autopsy procedure

Because of the clinical importance of occult infection or malignancy, we recommend that the autopsy is performed at the earliest opportunity, and ideally on the first working day after authority for autopsy has been given. Timely examination increases the likelihood of good quality sampling for microbiology and histology; however, it is recognised that this may not be possible.

Documentation of external injuries and abnormalities should be made, including ante-mortem injuries and signs of medical intervention before death. Specifically, the surgical incisions and procedures associated with organ recovery should be described.

Complete evisceration and examination of the organ systems where present should be conducted in all cases; post-mortem computed tomography (PMCT) could be considered as an adjunct investigation (see section 12).

- This should include a search for occult malignancy (e.g. thyroid, colon, breast, pancreatic, lymphoma) and lymphadenopathy.
- Examination of the brain is highly recommended to look for or confirm evidence of trauma, hypoxic-ischaemic encephalopathy and spontaneous haemorrhage.
- Sampling for histology, toxicology, bacteriology, virology and biochemistry should be considered (see sections 9–11).

Ideally, admission bloods or samples obtained in hospital pre-mortem (if admission bloods are no longer available) should be retained by the hospital laboratory, seized in potential forensic cases and should not be disposed of before death. In practice, this may not occur and there may be regional variation in how long a clinical laboratory will

hold a sample before disposal. If toxicological analyses may be required as part of the coronial/procurator fiscal case, consideration should be given to obtaining blood samples before transplantation, as ante-mortem samples are always preferential to post-mortem samples and post-mortem samples may not be attainable after transplantation surgery has taken place.

[Level of evidence – GPP.]

6 Pathology typically encountered at autopsy

Evidence of trauma, especially head injuries, rib and spinal fractures, and multiple long bone fractures.

Features of multi-organ injury,[18] including acute lung injury, small bowel necrosis and hepatic fatty degeneration.

Changes associated with medical interventions and organ recovery surgery, including the absence of retrieved organs.

[Level of evidence – GPP.]

7 Specific organ systems to be considered (where present)

- Careful examination of common sites of occult malignancy, including breast, colon, kidneys, lung, pancreas, mediastinum, ovaries or testis, and thyroid.
- Examination of lymph node groups for lymphadenopathy or involvement by malignancy (lymphoma or metastatic disease).
- Evidence of previous or active pulmonary disease, especially tuberculosis.
- Evidence of systemic inflammatory or autoimmune disease, especially if there is ante-mortem clinical or laboratory evidence of this.
- Evidence of cardiac disease, including myocarditis.
- Examination of the brain, to document, where possible, changes resulting in brain death and/or to assess traumatic injuries that may have caused brainstem death. This should be undertaken to a suitable level of detail. This examination will also exclude other pathology leading to death, such as meningitis, encephalitis or tumour.

[Level of evidence – GPP.]

8 Organ retention

Where possible and relevant, temporary retention and fixation of the brain for examination by the primary pathologist or specialist neuropathologist may be considered, particularly after head injury or death determined using neurological criteria (brainstem death).

It is important to be mindful of family, religious and cultural feelings on this matter. Temporary retention, followed by localised or targeted sampling, can often remove the need for prolonged whole organ retention, thus allowing the brain to be returned rapidly to the body and avoiding delays to funeral arrangements.

[Level of evidence – GPP.]

9 Histological examination

The primary role of autopsies after organ and tissue donation is to establish the cause of death. Notwithstanding this, histology has particular importance in identifying the presence of other pathological processes. Where additional samples are deemed necessary, careful discussion should be had with the coroner/procurator fiscal and the consent of relatives must be obtained, where necessary.

- Detailed histological sampling (including fresh frozen, unfixed tissue) of any lesion that could be a tumour or demonstrate evidence/suspicion of an infective process (see section 11 on microbiological advice and sampling).
- In unexplained sudden cardiac deaths, such as hypertrophic cardiomyopathy, sudden death with a structurally normal heart or myocarditis, histological sampling should follow established guidelines.[19]
- In appropriate cases, it is recommended the brain be fixed temporarily, and brain blocks taken and reported by a neuropathologist, but it is recognised that this may not be possible in many cases. If the brain cannot be retained but formal expert histological assessment is desirable, consideration should be given to which samples should be taken from the fresh brain.
- Pathologists should be aware that transplanted organs may have been sampled at the time of transplantation for ‘time-zero’ assessment of the allograft structure. These

biopsies may, therefore, be of value if unexpected findings are recognised in post-mortem histological samples.

[Level of evidence – D.]

10 Toxicology

If required as part of the clinical care, blood will have been taken from the patient before their death and screened according to established protocols. If necessary, results should be discussed with the relevant toxicologist. As indicated in section 5, residual samples of admission bloods/samples obtained in hospital pre-mortem are valuable for alcohol estimation and screening for drugs of abuse. It is not infrequent for organ donors to have received massive transfusions of blood components and products before their death, and a haemodilution calculation is performed as part of donor assessment.

This information should ideally be available for pathologists and toxicologists to consider when performing and interpreting such blood results. Consideration should be given to obtaining blood samples before transplantation in these cases.

[Level of evidence – GPP.]

11 Other relevant samples to consider

- Swabs/tissue samples of any potentially infective lesion for bacterial culture, staining or specific microbiological investigations.[20] It may be prudent to obtain advice from microbiologists on the types of samples that are required.
- Where indicated, samples of fresh brain and, if possible, cerebrospinal fluid for microbiological testing including viral culture, polymerase chain reaction or other specialist investigations, especially if the cause of brain death is uncertain. Note, this is of vital importance as testing may not be possible on formalin-fixed tissue.
- Samples of organs or tissues and blood in unexplained cardiac death (for future genetic screening). These should be stored frozen or in RNA later. Current College and European guidelines[19] suggest samples of the spleen (if not removed during surgery for tissue typing), heart and ethylenediaminetetraacetic acid blood should be taken. Skin and liver samples are also recommended for future fibroblast culture in the investigation of metabolic diseases.

[Level of evidence – C.]

12 Photographic and radiological imaging

Imaging may be indicated to determine the possibility, and for the documentation, of trauma, or for other reasons particular to a given case. If such imaging studies are deemed necessary, access to local services should be sought before commencing the autopsy. The role of PMCT is expanding and there is growing evidence to support its use in cases of trauma.[21] However, PMCT without invasive autopsy and sampling is not advised in these cases because many infections and malignancies, which could inform transplant recipient management, cannot be identified from this imaging alone.

[Level of evidence – C.]

13 Clinicopathological summary

- Summarise circumstances of death, ante-mortem surgical interventions, surgical procedures for organ retrieval and other signs of medical intervention at autopsy.
- Summarise all traumatic injuries, including those treated before death and those evident at autopsy.
- Make appropriate comments in unnatural deaths. Organ retrieval or ante-mortem surgical intervention may occasionally obscure or modify the pattern of injuries. If this is relevant, discuss this possibility.
- List all abnormal additional findings, indicating whether histology was performed.
- Summarise macroscopic and histological findings and discuss any implications on donation.
- Indicate whether and when abnormal findings were reported to NHSBT. If the finding/incident could affect the quality and safety of an organ for transplantation, or the treatment of recipients, urgently call the Organ Donation and Transplant (ODT) Hub Operations on 0117 975 7580 or 0117 931 4777. This call should be followed by submitting the information through the Incident Portal. The ODT Hub Operations team is available 24 hours per day, 365 days a year.

  [Level of evidence – GPP.]

14 Examples of cause of death opinions/statements

In the majority of cases this should be straightforward, for example:

1a Multiple blunt force injuries
(with comments about probable causation in the clinicopathological summary if not stated in part 1b (i.e. road traffic collision, fall from height))

or

1a Hypoxic-ischaemic encephalopathy
1b Cardiac arrhythmia
1c Hypertrophic cardiomyopathy

or

1a Raised intracranial pressure
1b Head injuries
(with comments about probable causation in the clinicopathological summary if not stated in part 1c (i.e. road traffic collision, fall from height))

or

1a Status epilepticus

or

1a Subarachnoid haemorrhage
1b Ruptured berry aneurysm

The retrieval of organs should be included in the clinicopathological comments section, not in the statement of cause of death.

[Level of evidence – GPP.]

15 Criteria for audit

The following standards are suggested criteria that might be used in periodic reviews to ensure a post-mortem report for coronial autopsies conducted at an institution comply with the national recommendations provided by the 2006 National Confidential Enquiry into Patient Outcome and Death (NCEPOD) study.

- supporting documentation:

  - standards: 95% of supporting documentation was available at the time of the autopsy
  - standards: 95% of autopsy reports documented are satisfactory, good or excellent.
- reporting internal examination:
  - standards: 100% of the autopsy reports must explain the description of internal appearance
  - standards: 100% of autopsy reports documented are satisfactory, good or excellent.
- reporting external examination:
  - standards: 100% of the autopsy reports must explain the description of external appearance
  - standards: 100% of autopsy reports documented are satisfactory, good or excellent.
- reporting relevant findings:
  - standards: 100% of autopsy reports should indicate that either no infective or neoplastic lesions were discovered or, if any were, the histological findings are recorded in detail
  - standards: when the brain has been retained, in 100% of cases it should have been referred to a neuropathologist who should have reported the findings promptly. If the brain was not retained but brain tissue was sampled instead, a neuropathologist should have received and reported on those histological blocks in 100% of cases.
- communicating with colleagues:
  - standards: in 100% of cases, all unexpected findings should be reported to both the clinical team that treated the deceased and NHSBT as soon as they are identified and confirmed (see section 13 for contact details). Some tissues, such as corneas, are transplanted 2–4 weeks after retrieval. Therefore, a timely communication of any findings of concern, though they may not have been confirmed at that point, is crucial to prevent release of potentially unsuitable tissues for transplantation. Any new or confirmed finding in the

donor is valuable; while implementation of appropriate risk mitigation measures is usually best done in the early post-transplant period, pathogenesis of disease varies broadly, and disease manifestation can become apparent months after the transplant where the window for intervention can be extended.

A template for coronial autopsy audit can be found on the Royal College of Pathologists' website.

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Appendix A Summary table – Explanation of grades of evidence

(modified from Palmer K *et al. BMJ* 2008;337:1832)

Grade (level) of evidence	**Nature of evidence**
Grade A	At least 1 high-quality meta-analysis, systematic review of randomised controlled trials or a randomised controlled trial with a very low risk of bias and directly attributable to the target population or A body of evidence demonstrating consistency of results and comprising mainly well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias, directly applicable to the target population.
Grade B	A body of evidence demonstrating consistency of results and comprising mainly high-quality systematic reviews of case-control or cohort studies and high-quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relation is causal and which are directly applicable to the target population or Extrapolation evidence from studies described in A.
Grade C	A body of evidence demonstrating consistency of results and including well-conducted case-control or cohort studies and high-quality case-control or cohort studies with a low risk of confounding or bias and a moderate probability that the relation is causal and which are directly applicable to the target population or Extrapolation evidence from studies described in B.
Grade D	Non-analytic studies such as case reports, case series or expert opinion or Extrapolation evidence from studies described in C.
Good practice point (GPP)	Recommended best practice based on the clinical experience of the authors of the writing group.

Appendix B AGREE II compliance monitoring sheet

The autopsy guidelines of the Royal College of Pathologists comply with the AGREE II standards for good quality clinical guidelines. The sections of this guideline that indicate compliance with each of the AGREE II standards are indicated in the table below.

AGREE II standard	Section of guideline
Scope and purpose	
1 The overall objective(s) of the guideline is (are) specifically described	Foreword
2 The health question(s) covered by the guideline is (are) specifically described	Foreword, 1
3 The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described	Foreword, 1
Stakeholder involvement	
4 The guideline development group includes individuals from all the relevant professional groups	Foreword
5 The views and preferences of the target population (patients, public, etc.) have been sought	Foreword
6 The target users of the guideline are clearly defined	1
Rigour of development	
7 Systematic methods were used to search for evidence	Foreword
8 The criteria for selecting the evidence are clearly described	Foreword
9 The strengths and limitations of the body of evidence are clearly described	Foreword
10 The methods for formulating the recommendations are clearly described	Foreword
11 The health benefits, side effects and risks have been considered in formulating the recommendations	n/a
12 There is an explicit link between the recommendations and the supporting evidence	2–14
13 The guideline has been externally reviewed by experts prior to its publication	Foreword
14 A procedure for updating the guideline is provided	Foreword
Clarity of presentation	
15 The recommendations are specific and unambiguous	2–14
16 The different options for management of the condition or health issue are clearly presented	Foreword

17 Key recommendations are easily identifiable	2–14
Applicability	
18 The guideline describes facilitators and barriers to its application	Foreword
19 The guideline provides advice and/or tools on how the recommendations can be put into practice	Foreword
20 The potential resource implications of applying the recommendations have been considered	Foreword
21 The guideline presents monitoring and/or auditing criteria	15
Editorial independence	
22 The views of the funding body have not influenced the content of the guideline	Foreword
23 Competing interests of guideline development group members have been recorded and addressed	Foreword