



**Guidelines on autopsy practice:  
Autopsies after tissue and organ donation**

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**Series authors:** Dr Michael Osborn, Imperial College Healthcare NHS Trust

**Specialist authors:** Dr Patrick J Gallagher, Bristol Medical School  
Dr Akila Chandrasekar, NHS Blood and Transplant, Liverpool  
Professor John Forsythe, NHS Blood and Transplant, Edinburgh  
Dr Paul G Murphy, NHS Blood and Transplant, Leeds  
Dr Kathryn Urankar, North Bristol NHS Trust  
Dr Ines Ushiro-Lumb, NHS Blood and Transplant, Colindale

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Produced by	Dr Patrick J Gallagher (specialist in autopsy and cardiovascular pathology), Dr Akila Chandrasekar (consultant in transfusion medicine), Professor John Forsythe (Medical Director for Organ Donation and Transplant for NHS Blood and Transplant), Dr Paul G Murphy (consultant in neuroanaesthesia and critical care, and National Clinical Lead for Organ Donation for NHS Blood and Transplant), Dr Kathryn Urankar (consultant neuropathologist) and Dr Ines Ushiro-Lamb (consultant virologist, Clinical Microbiology Lead for Organ Donation and Transplantation).
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The Royal College of Pathologists  
6 Alie Street, London E1 8QT  
Tel: 020 7451 6700  
Fax: 020 7451 6701  
Web: [www.rcpath.org](http://www.rcpath.org)

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NICE has accredited the process used by the Royal College of Pathologists to produce its autopsy guidelines. Accreditation is valid for 5 years from 25 July 2017. More information on accreditation can be viewed at [www.nice.org.uk/accreditation](http://www.nice.org.uk/accreditation).

For full details on our accreditation visit: [www.nice.org.uk/accreditation](http://www.nice.org.uk/accreditation).

## Foreword

The autopsy guidelines published by the Royal College of Pathologists (RCPATH) are benchmark guidelines for pathologists to deal with non-forensic consent and coroner's 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 one-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 specimen type and clinical scenario. Occasional variation from the practice recommended in this guideline may therefore be required to report a case in a way that maximises benefit to the coroner and the deceased's family.

There is a general requirement from the General Medical Council (GMC) to have continuing professional development 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 scheme.

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

The following stakeholders were contacted to consult on this document: NHS Blood and Transplant (NHSBT), the Forensic Science Regulator, and the Human Tissue Authority and its Histopathology Working Group, which includes representatives from the Association of Anatomical Pathology Technology, Institute of Biomedical Science, The Coroners' Society of England and Wales, the Home Office Forensic Science Regulation Unit and Forensic Pathology Unit, and the British Medical Association.

The information used to develop this document was derived from current medical literature. Much of the content of the document represents custom and practice, and is based on the substantial clinical experience of the authors. All evidence included in this guideline has been graded using modified SIGN guidance (see Appendix A). The sections of this autopsy guideline 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 the autopsy guidelines

A formal revision cycle for all guidelines takes place on a five-year cycle. The College will ask the authors of the guideline to consider whether or not the guideline needs to be revised. A full consultation process will be undertaken if major revisions are required. If minor revisions or changes are required, an abridged consultation process will be undertaken whereby a short note of the proposed changes will be placed on the College website for two weeks for members' attention. If members do not object to the changes, the changes will be incorporated into the guideline and the full revised version (incorporating the changes) will replace the existing version on the College website.

The guideline was reviewed by the Death Investigation Group, Lay Governance Group and the Clinical Effectiveness department, and it was placed on the College website for consultation with the membership from 14 February to 14 March 2019. All comments received from the membership were addressed by the authors to the satisfaction of the Clinical Lead for Guideline Review.

The 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 Clinical Effectiveness department and are available on request. The authors of this document have declared that there are no conflicts of interest.

## 1 Introduction

Many different organs and tissues can be transplanted. While some organs 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. At present in England organ and tissue donation requires the consent of relatives, or an appropriate qualifying adult, if the patient's donation decision is not registered on the Organ Donor Register. In some cases, a lack of objection is also required from the responsible coroner. A system of presumed consent has been implemented in Wales and discussions are in progress in other parts of the UK. The requirement for a coroner's autopsy is not usual after organ donation but is even less common after donation of tissues such as corneas. If a coroner 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 recovery, 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 this reason, Home Office-registered pathologists may perform some of these examinations. However, most are performed by non-forensically trained coroner's pathologists.

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.<sup>1</sup> Despite this practice, there are reports of donor-derived tumours<sup>2</sup> (including melanoma, lymphoma, ovarian carcinoma and central nervous system tumours) and infective processes<sup>3-10</sup> (including viruses such herpes simplex virus, human herpes virus 8 and rabies virus, as well as bacterial, parasitic and fungal infections) that have developed in recipients, probably or certainly as a result of transplantation. 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 investigated post-mortem (see section 6 below).

### 1.1 Target users of these guidelines

The target primary users of these guidelines are consultant pathologists performing autopsies on the instruction of a medicolegal authority 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. 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 technicians, and coroners and their officers.

## 2 The role of the autopsy

- To establish an accurate cause of death, where necessary in collaboration with relevant clinical teams. In some deaths, information provided by coroners or police officers will be important (see section 5 below).
- 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 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,<sup>11</sup> including acute lung injury, small bowel necrosis and hepatic fatty change.
- Changes associated with medical interventions and organ recovery surgery.

*[Level of evidence – GPP.]*

### **4 Specific health and safety aspects**

None beyond the standard health and safety considerations. For full guidelines, please consult relevant health and safety publications.<sup>12</sup>

### **5 Clinical information relevant to the autopsy**

The donor typically will have been an inpatient in a hospital prior to tissue donation and will always be in the base of 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 prior to 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 transplant surgeons or other relevant parties and pathologists may be helpful in these cases.

Forensic pathologists and police officers may be involved in medicolegal discussions prior to organ donation. General pathologists are unlikely to be involved in this way.

The following clinical information is also relevant:

- details of circumstances of initial presentation, including events occurring prior to 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
- 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 or a Home Office-registered pathologist. If, having done so, they cannot

satisfy themselves that the case is not suspicious then they should not proceed with the case.

*[Level of evidence – GPP.]*

## **6 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; however, it is recognised that this may not be possible.
- Documentation of external injuries and abnormalities, including ante-mortem injuries and signs of medical intervention before death. Specifically, the surgical incisions and procedures associated with organ recovery should be described.
- Full autopsy according to standard clinical practice:
  - this should include a search for occult malignancy (thyroid, colon, breast, pancreatic, lymphoma) and lymphadenopathy
  - examination of the brain is essential. Spontaneous haemorrhage and hypoxic-ischaemic encephalopathy are the commonest causes of death diagnosed using neurological criteria (54% and 24%, respectively).
- Sampling for histology, toxicology, bacteriology, virology and biochemistry (see sections 9–11).

Ideally, admission bloods should be retained by the hospital laboratory in potential coronial cases and not disposed of prior to death. In practice this may not occur, especially if there is no local arrangement between the coroner and the relevant hospitals.

*[Level of evidence – GPP.]*

## **7 Specific organ systems to be considered**

- Careful examination of common sites of occult malignancy, including breast, colon, kidneys and lung (where present), mediastinum, ovaries or testis, and thyroid.
- Examination of lymph node groups for lymphadenopathy or involvement by malignancy (lymphoma or metastatic).
- Evidence of previous or active pulmonary disease, especially tuberculosis (when lungs present).
- 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 (when heart present).
- 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, retention and fixation of brain after head injury or death determined using neurological criteria (brainstem death).

*[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. **Where necessary, the consent of relatives must be obtained.**

- 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 regarding microbiological advice and sampling).
- In unexplained sudden cardiac deaths such as hypertrophic cardiomyopathy, sudden death with a structurally normal heart, myocarditis, etc., histological sampling should follow established guidelines.<sup>13,14</sup>
- Ideally, the brain should be fixed 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 as to the samples that 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 prior to their death and screened according to established protocols. If necessary, results should be discussed with the relevant toxicologist. As indicated in section 6, residual samples of admission bloods 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 prior to 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.

*[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.<sup>15</sup> 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 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 at  $-80^{\circ}\text{C}$  or in RNA later at  $4^{\circ}\text{C}$ . Current College and European guidelines<sup>13,14</sup> suggest samples of the spleen (if not removed during surgery for tissue typing), heart and EDTA 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**

Photographic imaging is now increasingly used and may be of value. There is a clear role for imaging in cases of trauma where it may be superior to a traditional invasive post mortem.<sup>16</sup>

*[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 prior to 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. This call should be followed by submitting the information through the Incident Portal (<https://safe.nhsbt.nhs.uk/IncidentSubmission/Pages/IncidentSubmissionForm.aspx>). ODT HUB Operations 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)

or

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

or

1a Raised intracranial pressure  
1b Head injuries

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

([https://www.ncepod.org.uk/2006Report/Downloads/ncepod\\_2006\\_report.pdf](https://www.ncepod.org.uk/2006Report/Downloads/ncepod_2006_report.pdf)):

- 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, for example corneas, are transplanted 2–4 weeks after retrieval. Therefore, a timely communication of any findings of concern, even 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 ([www.rcpath.org/profession/quality-improvement/conducting-a-clinical-audit/clinical-audit-templates.html](http://www.rcpath.org/profession/quality-improvement/conducting-a-clinical-audit/clinical-audit-templates.html)).

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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	<p>At least one 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</p> <p>or</p> <p>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.</p>
Grade B	<p>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</p> <p>or</p> <p>Extrapolation evidence from studies described in A.</p>
Grade C	<p>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</p> <p>or</p> <p>Extrapolation evidence from studies described in B.</p>
Grade D	<p>Non-analytic studies such as case reports, case series or expert opinion</p> <p>or</p> <p>Extrapolation evidence from studies described in C.</p>
Good practice point (GPP)	<p>Recommended best practice based on the clinical experience of the authors of the writing group.</p>

## 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.

<b>AGREE II standard</b>	<b>Section of guideline</b>
<b>Scope and purpose</b>	
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
<b>Stakeholder involvement</b>	
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
<b>Rigour of development</b>	
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
<b>Clarity of presentation</b>	
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
<b>Applicability</b>	
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
<b>Editorial independence</b>	
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