



The Royal College of Pathologists

Pathology: the science behind the cure

Guidelines on autopsy practice:

Guidance for pathologists conducting post-mortem examinations on individuals with implanted medical devices

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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 five years from 25 July 2017. More information on accreditation can be viewed at www.nice.org.uk/accreditation.

For full details on our accreditation visit: 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 specimen 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 stakeholders consulted for this document were:

- Human Tissue Authority
- Medicines and Healthcare Regulations Agency or equivalent body.

The information used to develop this document was derived from current medical literature and a previous version of this guideline. 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. The medical literature was searched for data on the relevant devices as indicated in the index above using PubMed and Google Scholar and dates searched were from September 2020 to December 2020 inclusive.

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

A formal revision cycle for all guidelines takes place on a five-yearly cycle. The College will ask the authors of the guideline, to consider whether 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, 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 short notice of change 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 has been reviewed by the Clinical Effectiveness team, Death Investigation Committee, Forensic Pathology Specialty Advisory Committee and Lay Advisory Group. It was placed on the College website for consultation with the membership from 23 May 2022 to 21 June 2022. All comments received from the membership were addressed by the author 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 Clinical Effectiveness Department and are available on request. The authors of this document have declared that there are no conflicts of interest.

1 Introduction

This document aims to provide advice to pathologists conducting standard medico-legal and consented post-mortem examinations regarding foreign objects and devices found within the body at autopsy.

Since the circumstances of each case will vary, it is recognised that the pathologist conducting the case must use his/her own clinical judgment to consider whether additional specialist investigation will be needed to derive a cause of death. The content does not constitute as legal advice, which should be obtained as necessary from relevant legal service sources or providers.

Special post mortems and other non-standard investigations are not specifically addressed in this document although this guidance may be of use in such situations. Particular attention in this document is drawn to the areas relating to safety, as these are relevant to all post-mortem studies.

It is accepted that the medical devices seen at autopsy are numerous. These include the common, in the form of vascular lines (venous and arterial lines, short and long), butterfly needles, airways and urinary catheters. There are complex and less common devices, a large and diverse group including intra-aortic balloon pumps, arterial/aortic stents, joint stabilisation devices or replacement metal prostheses, various tubes, post-operative and percutaneous drains (biliary, urostomy, gastro-enterostomy), artificial cardiac (metal and tissue) valves, electronic devices, drug delivery pumps, specialised orthopaedic implants (rods, nails, screws), cochlear implants, intra-uterine devices and tubal clips, mesh supports, and radioactive devices. However, one appreciates that this list is not exhaustive.

1.1 Target users and health benefits of this guideline

The target primary users of this guideline are autopsy pathologists (conducting consent, medico-legal and Home Office examinations). The recommendations will also be of value to hospital practitioners, the device manufacturers and other medico-legal parties.

1.2 General comments of the devices

When dealing with the post-mortem examination of an individual containing any device, a number of possibilities should always be considered:

- the cause of death is due to a disease process, for which the device has neither caused nor contributed to death, for example an individual who died as a result of a ruptured aortic aneurysm who incidentally has a cardiac pacemaker or hip joint prosthesis
- the death is directly due to the presence of the implanted medical device, for example an individual who develops infective endocarditis sepsis following insertion of a heart valve replacement, or perforation of the oesophagus after stent insertion for occlusive malignancy
- the death is due to a malfunction of an implanted medical device, such as a cardiac defibrillator failing to electrically discharge.

Knowledge of the type of device, its role in health and disease and the potential complications is important when conducting the autopsy. This ensures the pathologist can interact effectively

with the item, to evaluate its potential role in the case. The pathologist may come across a device unexpectedly at autopsy. Furthermore, since some devices may have health risks, a degree of caution is always advised if the pathologist is unfamiliar with the item.

If an adverse incident is suspected or proven, a report should be completed and sent to the Medicines and Healthcare Products Regulatory Agency (MHRA) or equivalent body.¹ The responsibility for so doing initially lies with the Coroner or equivalent, if the case is being conducted under medico-legal jurisdiction. It may fall to the pathologist or medical team responsible for the implantable device, outside medico-legal investigations. The pathologist conducting the case should highlight the need for such reports to be made, allowing maintenance of patient safety.²

One should be aware that many complex implantable devices have specific identifying data marked onto the unit. This may be of particular use in case identification, particularly if the body features are lost (e.g., fire deaths, decomposed bodies). However, it should be remembered that in some parts of the world such devices may be reused, which may have implications in identifying the deceased.

2 The role of the autopsy

The autopsy is taken to be a standard investigation to derive a cause of death and the pathology factors relevant to the deceased.

3 Pathology of encountered at autopsy

The pathology relevant to the autopsy often reflects the reasons for the device implantation and its long-term issues. These have to be considered alongside any pathology from the device(s) discussed below.

4 Specific health and safety aspects

There are no specific issues relevant for most studies for the devices discussed. However, defibrillator units require deactivation before the autopsy starts. Radionuclide containing cases need consideration in terms of possible radiation exposure, as directed by the local medical physics department.

5 Clinical information relevant to the autopsy

Full clinical data should be available in all autopsies.

6 The autopsy procedure

The autopsy will need to follow standard Royal College of Pathologists guidelines and to be adapted against investigation of the devices discussed.

7 The devices seen at autopsy

One can debate how to present the devices in this document, whether by type, cavity/tissue sites, or complication. The devices are listed in this document in terms of general frequency of being encountered at autopsy, while recognising that other pathologists may have slightly different exposures to any or all of these devices.

7.1 Vascular lines (venous and arterial lines, short and long), including butterfly needles and intra-osseous lines

One can look at needles, standard venous and arterial vascular lines, and long lines within a broad group of metal and plastic tubes inserted into the body to deliver drugs, blood, or other fluids. There are also haemodialysis and haemofilter lines which both remove and return blood to the body. These tubes rarely are of significance in terms of the cause of death, but the pathological examination of the body does require one to be aware of potential pathology and problems associated with the device insertion.

Common issues reflect local infection from skin commensals and other pathogens making ingress into the body soft tissues and potentially into the blood stream. On occasion, there may be significant haemorrhage around the device and/or misplacement of the device such that any fluids are delivered to the wrong site (e.g. chemotherapy introduced into soft tissues, rather than the bloodstream). Very rarely, these devices may leak at a point along their length. Potential thrombotic changes along and around intravascular lines should be considered as possible points for sepsis. Rarely, pneumothorax can be associated with central vascular lines.

If there are any problems to be considered from these devices, then it is recommended that the line is cut flush with the skin and pushed inwards slightly. After this, the skin and soft tissues are reflected/dissected such that the course of the device, line or other may be followed into the body up to the end point. Samples for microbiology and histology may be taken at this point.

Intra-osseous lines need careful assessment to assess the position and efficacy of these devices. They can be bent during removal and potentially have a needlestick injury risk.

[Level of evidence – Good practice point (GPP).]

7.2 Arterial/venous stents and filters

These predominantly metal-based mesh tubes are placed into various blood vessels, which are then expanded using a pressurised balloon to fix them into place and to hold the vessel open. Some coronary artery stents may elute drugs after deployment to diminish restenosis risk. Stents are commonly used in atheromatous sites, such as coronary, carotid arteries and leg arterial tissues.³⁻⁵ More recently, some self-dissolving stents have been introduced in clinical practice, allowing the pathologist to consider histology in such cases. However, higher rates of restenosis have been described in early trial.⁶

Stents are generally a solution to arterial obstruction or significant narrowing, obviating the need for open interventional surgery. They generally do not produce immediate complications, although there is a risk of acute coronary rupture during the percutaneous angioplasty intervention. This complication often causes cardiac tamponade and death almost immediately. Such cases do not usually cause diagnostic difficulties, but photography and histology of the rupture or dissection sites are advised. In some cases, retention of the whole coronary artery intact, with fixation followed by decalcification allows sequential artery sectioning after removal of any metal device. This may assist evaluation of the background disease and any complication of the stenting site.

Arterial stents may also suffer with long-term progressive thrombosis and/or neo-intimal proliferation, which can narrow the lumen of the treated artery progressively. With time, significant stenosis can return and cause common pathology relevant to death (e.g. myocardial ischaemic damage).⁵

Venous stents (usually in the superior vena cava) are usually to maintain venous patency in the face of malignancy, best recognised in superior vena cava obstruction.

In general, the autopsy needs to address the nature of the background disease, the degree and nature of stenosis and whether there are any particular issues with regard to previous stent deployment and expansion.

The 'reverse' of a stent involves the placement of the inferior vena cava filter to trap embolic fragments of thrombus. These devices need to be confirmed as correctly placed and to be checked for thrombus fragments. There is a small risk of needlestick injuries during evisceration from the anchoring prongs.

[Level of evidence – Good practice point (GPP).]

7.3 Closure devices

There are some congenital heart cases that will have been treated, often in infancy, to close septal defects or to permit realignment of blood flow within/around the heart. The devices include metal occluders and mesh devices, with homograft materials sometimes being used. These items will need to be considered before the autopsy commences, ideally, with clinical notes review or treating clinician commentary. The dissection may need to be adapted to the device concerned with attention to the underlying disease, the effectiveness of the device and any complications (infective endocarditis, etc). Specialist cardiac pathology advice may be helpful, but the need for photographs of the autopsy examination is strongly advocated.

[Level of evidence – Good practice point (GPP).]

7.4 Specialist devices in cardiac transplantation

There are some cardiac support devices used for treating patients during their approach to transplantation, or those with very severe cardiac failure. These may be encountered at autopsy only rarely. They include mechanical hearts and assist devices (right/left). Any autopsy examination with such device present will need to have knowledge of the underlying pathology and a modified dissection technique. Such cases are usually only found in transplant centres, where knowledge of the patient and the device is usually fully understood. However, should a case present for a general pathologist, it would be sensible to defer autopsy examination until advice for the dissection is garnered, or the case is returned to the transplant centre for examination.

[Level of evidence – Good practice point (GPP).]

7.5 Urinary catheters

These are generally seen patients of all ages with underlying urological and renal problems. They rarely have significant pathology associated with the device, although a minor degree of bladder trauma is often present. Confirmation of the correct catheter position is advised and sampling for histology may be required in cases of malignant obstruction. Rarely, samples of the catheter drain bags may be needed to consider drug levels, as the bladder will invariably be empty. One should be aware that catheters are linked with an increased risk of urinary tract infections, which may have bearing on the cause of death. One should also remember that if the catheter is misplaced then then drainage function may be lost, resulting in post-renal renal failure.

[Level of evidence – Good practice point (GPP).]

7.6 Nasopharynx/oropharynx – gastric tubes

These tubes, entering via the nose or mouth pass along the naso/oropharynx, through the oesophagus and into the stomach.^{7,8} They are used to decompress stomach tissues, or to

introduce fluids or medicine. Their position should be maintained by cutting the tube around the entry point and pushing it marginally inwards to avoid displacement during neck tissue dissection and organ removal from the body. Any drainage bag should be checked for content and the tube end position in the stomach should be confirmed. Clearly, if there is no drainage, owing to misplacement, then some pathological consequences may ensue. It is rare to see any significant trauma or malposition from these tubes, but trauma/perforation of the viscera is a possibility.

[Level of evidence – Good practice point (GPP).]

7.7 Laryngeal masks, endotracheal tubes and tracheostomies

These devices act to maintain the airway, being normally connected to gas delivery/ventilation devices (ambu-bags, hospital oxygen/anaesthetic supplies, etc). Together they allow positive pressure lung ventilation for use in intensive care and/or ward settings. Their position in terms of the upper airway should be checked, particularly with regard to any obstruction. Rather than removing them before starting the autopsy, it may be necessary to firstly cut across the tube device at the mouth, so that it is not moved during upper respiratory tract/throat tissue dissection. On occasion, with respect to endotracheal tubes (ETT) it may be beneficial to transversely incise the trachea (below the cricoid) early during neck dissection, so that the distal end of the tube can be confirmed as correctly positioned. Cases with an ETT within the oesophagus are clearly of medico-legal significance, ideally requiring photography in case of medico-legal inquisition or challenge. Structural issues (e.g. break, cracks, etc) with any of these devices need to be documented and ideally photographed, with a report to the MHRA or equivalent body. Tracheostomies need similar attention along with checks for correct placement and inflation.

[Level of evidence – Good practice point (GPP).]

7.8 Contraceptive and female genital tract devices

Aside from injected depot drug preparations, contraceptive devices can be seen in two main forms. The first comprise uterine tubal clips, usually set by surgical intervention.⁹ Pathological issues potentially relevant to autopsy practice include unwanted/ectopic pregnancy and pelvic inflammatory disease. Photography, histology and microbiology sampling are advisable for these cases if there are complications.

Next most frequent are intrauterine contraceptive devices.⁹ These exist as various types, often comprising plastic and copper, being positioned within the endometrial cavity. These rarely have significant pathology found adjacent.

Additional gynaecological devices seen at autopsy include ring pessaries and menstrual cup items. These are incidental items normally but should be noted as present in the autopsy record.

[Level of evidence – Good practice point (GPP).]

7.9 Percutaneous and post-operative drains and tubes

These can be positioned in the gall bladder, biliary tract, renal pelvis, pericardium, chest or peritoneal cavities. These may serve to drain excess fluid secretions from the biliary system, kidney and peritoneal cavity, respectively. The first two drainage devices act to offload production of bile and urine, and thus preserve liver and kidney function, respectively.

The peritoneal drainage devices, placed into the peritoneal cavity, are used to allow drainage of blood and/or other fluids commonly following surgery. This is particularly important with large bowel surgery where any potentially infected proteinaceous fluid could provide a nidus for

peritonitis without prompt drainage of the material. Patency of the drain(s) and appropriate drain positioning need to be confirmed at autopsy. If the drainage has not occurred, then the reason behind this failure needs to be defined. Any loculated septic collection may require microbiology sampling and/or photography. Chest drains need confirmation of correct siting alongside specification of the rib space used. Similar considerations apply to these devices.

[Level of evidence – Good practice point (GPP).]

7.10 Bowel and urinary stents, as well as flatus tubes

These have similarity to vascular stents, being mostly seen in the oesophagus and rectum (as synthetic polymer and metal framework tubes),¹⁰ as well as in biliary tract and around the proximal urethra and ureters. These devices dilate or prevent collapse of stenosed and/or malignant tissues. Careful dissection should be undertaken in order to check the device position and to exclude blockage, perforation, local sepsis and/or bleeding.^{10,11} Any flatus tubes and rings should be carefully handled as pressurised devices might become projectiles by injudicious handling.

[Level of evidence – Good practice point (GPP).]

7.11 Joint stabilisation (orthopaedic) devices or replacement metalwork, including rods, screws and nails

Bone fixation implants and fracture reduction devices are most common in the elderly, perhaps most commonly as hip replacements but can be found at any age.¹² The devices include needles, passed along bones, to stabilise thin and fragile bones. They also include external fixators, large rods and plates for large and weight-bearing long bones. In addition, screws, wire tensioning bands and large metal replacement implants (e.g. hip and knee replacements) may be found in autopsy practice. Some may have ceramic and/or plastic components.

They may be long-standing devices and not implicated in the death of the individual. However, they may have been positioned shortly before death, with this raising the possibility of a direct complication. Any of these implants may be associated with problems of loosening and instability, prosthesis structural failure, local bleeding, infection, misalignment, bone fracture adjacent to the prosthesis and leaching of metals into the local tissues. Most of these problems are infrequent, but exclusion of these pathologies should be considered in all cases if the orthopaedic device and the bone operation site are being explored. If issues are encountered during the course of the surgery itself, then cement reaction syndrome and fat embolism (requiring frozen section Oil-Red-O lung sections) are issues to be considered.

If pathology associated with the devices is deemed likely or pertinent to the death, then review of ante-mortem radiology may help. Likewise, post-mortem CT scan (with rendered images) may also be particularly valuable. If open autopsy is needed then appropriate incision(s) may be made down, onto the prosthesis, to permit understanding of its position and its interaction with the bone and soft tissue structure. Rarely extracting the joint or bone completely may be needed for full appreciation of the anatomy and any pathology. Within open inspection, the pathologist may be able to assess the prosthesis/device just by macroscopic review. However, there should be a low threshold for microbiology and/or histology sampling. Photographs may be of use, particularly in cases of device failure. Such cases may require notification to the MHRA or equivalent body.

Most orthopaedic devices are inert, solid metal and/or plastic. However, the Fixion device should be considered as a special item in the mortuary and autopsy practice.¹³ This closed unit metallic implant has a fluid reservoir to permit hydraulic adjustment after insertion. It has a potential explosion risk during cremation and should be routinely extracted after death.¹⁴

[Level of evidence – Grade D.]

7.12 Cardiac pacemakers

These are commonly encountered at autopsy.¹⁵ Temporary pacemakers (positioned to deal with an immediate issue, such as complete heart block) comprise a lead and electrode (often blunt/round) fed through central veins, attached to an external generator unit. The electrode is placed against the endocardium of the right ventricle. Temporary units are not often seen at autopsy, with the permanent pacemaker (PPM) being the mainstay of post-mortem experience.

The PPM is usually surgically implanted in the left upper chest commonly, comprising the generator unit (battery unit and electrical circuitry housed within a metal casing) attached to (one/two/three) plastic coated lead(s) and the electrode(s) (that interact with the heart tissues, often with a corkscrew metal end).⁹ The leads enter the subclavian vein and ultimately pass into the right side of the heart. Some have separate leads for the right atrium, the right ventricle and the coronary vein to optimise control of cardiac rhythm and/or resynchronisation. Recently developed small intracardiac or endocardial-based pacemakers, inserted via the endoluminal route, may be encountered.^{16,17}

All standard pacemakers should be removed prior to cremation to eliminate any explosion risk on heating. This can be accomplished during the autopsy. Alternatively, it is possible to simply make an incision over the generator unit and cut the lead(s) in cases not being subject to autopsy. Perhaps the most important data for these autopsies is knowledge of the background pathology requiring a PPM, such as ischaemic heart disease or heart block. This may guide the overall approach to the case. One should be aware of possible complications surrounding the generator unit, including systemic sepsis and battery failure may also be relevant to case analysis. Some of the transcatheter PPM devices may be cremation safe, although this may need checking with the manufacturer.

One must be aware of the type of pacemaker (standard, defibrillator, resynchronisation, etc) as these have an electrical discharge risk for the mortuary staff or pathologist, when handling or extracting the pacemaker.¹⁸⁻²¹ It is therefore essential to ensure that any defibrillator device (i.e. capable of delivering a shock) is fully deactivated before any autopsy is started.

Most mortuary staff and pathologists extract PPMs by cutting the pacemaker leads close to the generator unit as the chest tissues are reflected from the sternum and ribs. It is also possible to keep the generator, leads and electrodes intact during the autopsy extraction by careful dissection of the upper chest ribs and clavicle. Alternatively, one might choose to unscrew the leads from the generator unit. The removal of a PPM from the body should be recorded in the case notes and/or autopsy report. It is possible to send the device back to the local cardiology clinic, to check the battery status and performance of the device. Ideally, this should include at least 3 cm or the whole lead attached to the generator unit. The integrity of the wire(s) should be checked during autopsy dissection, with clues pointing to insulation failure in the form of local soft tissue (black/brown) discoloration.²² During the autopsy, the generator unit implantation site should also be carefully examined. Any features of local bleeding and/or infection should be documented, with microbiology and histology sampling of the tissues.²³

It is evident that standard cardiac tissue dissection is not possible if there are one/more PPM leads passing into the heart. So, thinking ahead to the heart examination, one may elect to locate the pacemaker leads in the superior vena cava, via small incision, to check their position. The leads may now be cut at this point. This means that cardiac tissue extraction can take place while keeping the distal leads/electrodes in position. The back of the right atrium and ventricle are then opened cautiously to confirm the leads and electrodes are correctly positioned, bearing in mind that vigorous tugging on tissues may cause electrode displacement. Clearly, any displaced electrode or lost connection may be relevant to the

pacemaker function overall. This staged protocol assists photography. Furthermore, once the leads and electrodes are removed, resumption of the standard cardiac dissection can continue.

Given the pivotal functionality of a pacemaker in terms of health, there may need to be a statement made as to whether or not it was felt that the device may have contributed to the death.²² Certainly, gross pathology, such as perforation of the right ventricle and tamponade following insertion of the device, is likely to be directly relevant. Vegetations around the insertion point of the electrodes are also almost invariably significant as acute and chronic disease processes, requiring microbiology and histology.²³

Many modern PPMs have a rhythm capture potential. This data can be interrogated or downloaded to assess the final cardiac rhythm.^{24–27} The necessity for pacemaker retention and interrogation will depend on the type of post-mortem being conducted, as well as on the burden of proof required in the case. Indeed, one might make an argument that all devices should be explanted, reviewed by the local cardiology departments and returned to the manufacturer for functional analysis. This would assist the industry and the regulatory authorities to monitor the reliability of the different models.²⁷ Such detailed analysis is rarely needed, meaning the pathologist should select such cases with diligence. Given that most autopsy studies are medico-legal, any such retention and/or investigations should be coordinated by the relevant office.

In some cases, interrogation of the device can give useful information, such as an accurate time of death and information regarding the pre-terminal rhythm of an individual's heart prior to a fatal road traffic collision.²⁶

However, there may be limitations for the interpretation of events stored by these devices around the time of death. It should not be assumed that ventricular arrhythmias or an observation of loss of pacing capture are the direct cause of death. Cardiac electrical activity may persist for variable periods (many minutes) after cardiopulmonary death has been pronounced by a medical professional. Such signals may be recorded by these devices.²⁸ For those with significant heart or cerebrovascular disease, any abnormal terminal cardiac rhythm record probably reflects the agonal electrical consequences (i.e. while dying) and not the primary pathology. Examples may include features of the pulseless electrical activity arrest, coarse ventricular fibrillation, broadening of the QRS complexes, separation of the electrocardiogram (ECG) into multiple components (fractionation) and dissociation of right and left ventricular activation. All may indicate likely structural pathology, and not electrophysiological dysfunction.

[Level of evidence – Grade D.]

7.13 Loop recorders

These implanted recording devices record cardiac electrical activity, with episodic data downloads being possible. They have dramatically reduced in size over the last two decades, being barely thicker and longer than a matchstick. Without knowledge of the precise implantation site, or identification from ante-mortem radiology or post-mortem computerised tomography (PMCT), they can be difficult to find at autopsy. As with pacemakers, the devices may provide information on the pre-terminal ECG, with the limitations of interpretation as above.^{29–31}

[Level of evidence – Grade D.]

7.14 Cardiac valves and annuloplasties

Replacement cardiac valves are frequently seen at autopsy.⁹ They may be directly implicated in the cause of death or relevant to background pathologies that are drivers for disease and

progressive debility. They are also potentially incidental findings that have no bearing upon the cause of death.

The majority of valve replacement surgical interventions are for aortic and mitral valve disease with degenerative valve disease now being more common than for rheumatic fever. The valve replacements are generally grouped into two broad categories.

The first are tissue valves, comprising animal or human valve tissue, generally mounted on a plastic and cloth frame to mimic the normal valve structure and function. These valves do not normally require anticoagulation but do degrade with time. They suffer progressive fibrosis, calcification and potentially valve failure after ten years. They are particularly useful in the elderly who might be at risk of complications from prolonged anticoagulation. The second group comprises the metal valve replacements. These have twin tilting leaflets, mounted on a metal frame with a cloth matrix adjacent. This type of valve requires ongoing anticoagulation therapy.

All autopsy cases with valve prostheses need a modulation of the normal cardiac dissection, such that the valve is seen in position from the upper and lower aspect. The normal incisions to open the heart are rarely possible, given the valves are made of metal, plastic and related materials which are resistant to knife or scissor dissection.

For mitral (and tricuspid) devices, the atrial and ventricular tissues require a large and circumferential sweeping cut around the base of the atrium and also around the upper ventricle to expose the tissues adjacent to the valve and to permit exclusion of thrombotic material, infective endocarditis, paravalvular leakage, fibrosis, distortion, calcification or misalignment.

For aortic (and pulmonary) valve replacements, the superior cut needs to be made transversely around the low aorta (or pulmonary artery). The aortic cut should allow inspection of intact coronary ostia. A circumferential cut around upper ventricle allows inspection of the under-surface of the valve. Appropriate microbiology for suspected vegetations alongside histology is important.

The recent introduction of endoluminal placed valve prostheses is seen mainly as metal stent-like outer casing, supporting the tissue valve centrepiece. These should be approached in a similar manner to the standard prosthetic valves with careful inspection from above and below.

Photography serves a particular benefit in allowing later review of any pathologies. Retention of the valve and local tissues is occasionally needed, particularly if the device is deemed to have mechanically failed. Histopathology of the tissue valves is rarely needed, although it can highlight the dystrophic calcification and distortion of the tissues in chronic degenerative changes.

Annuloplasties occasionally cause trouble in terms of interpretation, comprising a partial ring of plastic, covered by cloth-type matrix.⁹ These are sutured around the atrio-ventricular valve annulus, to allow a reduction in the circumference of the valve tissues. This allows normal valve cusp apposition and thereby prevention of incompetence. Annuloplasty devices are potentially prone to thrombosis and infection, akin to valve replacements, meaning they should be considered in exactly the same manner, with sampling as above.

[Level of evidence – Grade D.]

7.15 Balloon pumps

The intra-aortic balloon pump is used to maintain blood pressure after significant cardiac dysfunction, with the repetitively inflated balloon being placed in the descending aorta, allowing blood to be diverted towards the brain and vital organs.^{32,33} The pump is placed endoluminally, via the groin. It is rare that the balloon is left in position for a prolonged period of time, whereby

it might cause thrombosis, infection or aortic wall damage. As usual, with endovascular devices, at autopsy, the device should be cut flush with the skin at the start of the examination and pushed slightly inwards with careful dissection so that the device stays where originally deployed. The position of the balloon and the local aorta can thus be checked.

[Level of evidence – Good practice point (GPP).]

7.16 Mesh devices

These plastic mesh devices are commonly used for support of lower abdominal wall hernias but can also be seen in other sites. They are designed to be placed/sewn into an anatomical site where there is a weakness of the tissue. The subsequent fibrosis and the mesh itself allow restoration of the wall integrity and a reduction in the risk of bowel obstruction, or ischaemia of any herniated content. There is a finite risk of infection with these devices, which should be considered macroscopically, photographed and sampled for microbiology, if present.³⁴ Rare complications include the mesh device having the fibrosis extend into local structures or erode into other tissues. Histology is rarely needed but may add to the diagnostic evaluation.

[Level of evidence – Good practice point (GPP).]

7.17 Cerebrospinal fluid drainage devices

There are a variety of drainage tubes aimed at offsetting raised intracranial pressure and hydrocephalus, being used across all ages. In most ways their considerations parallel other drainage devices. Commonly, a plastic cerebrospinal fluid (CSF) drainage tube passes from the lateral ventricular cavities through the brain tissue, out through the skull, underneath the scalp tissues and down towards the pleural or peritoneal space.⁹

Preceding autopsy radiology (PMCT) may assist the autopsy strategy and will guide how to remove the drains. However, the autopsy approach to the head usually requires transection of the tube immediately parallel to the external skull surface, after scalp tissue incision and reflection. One must avoid movement of the tube as the calvarium is removed. Careful subsequent brain sectioning permits one to confirm the tip of the drainage tube within the ventricle. As always, consideration of brain tissue overall (sometimes after brain fixation) and particularly the brainstem tissues should follow. The course of the extra-cranial drainage tube should also be considered, potentially with photography. It is always important to consider the possibility of sepsis and to take microbiology samples as dissection progresses.

There is one group of CSF devices deserving special attention, often being described as 'programmable hydrocephalus shunts'. These have a spring tensioned ball valve to regulate CSF flow. These devices may be adjusted by an external magnet. As such, they have no battery or electronic components and may be cremated with the body, rather than being removed after death.

[Level of evidence – Good practice point (GPP).]

7.18 Insulin pumps and monitoring devices

These are uncommonly used in diabetics but might be encountered at autopsy. They may be implanted devices below the skin surface or in the soft tissues, but some monitoring devices may be placed on the skin surface. They are generally regarded as an effective treatment for individuals with poorly controlled diabetes.^{35–38} They are mainly placed around the abdomen with direct infusion of insulin into the soft tissues and blood stream. If properly set, hypo/hyperglycaemic events should not occur. Autopsy considerations for such cases require appropriate toxicology assessment, with microbiology and histology often having a role. As with all implanted devices, but particularly for diabetics, local and systemic sepsis should be considered and excluded. Photography is pertinent if there is evidence of infection.

Complications rarely recorded include a risk of battery failure, electronic program dysfunction or pump machinery failure. These issues are rarely reported. It may be possible to download some data from the devices regarding peri-mortem glycaemic status. Any electronic or pump unit should be kept if there is a suspicion of device failure.

[Level of evidence – Good practice point (GPP).]

7.19 Baclofen pumps

These are uncommonly seen at autopsy, being inserted for neuromuscular problems, mostly in relation to spinal injuries.^{39,40} These pumps have a pressurised drug reservoir chamber, with a catheter to deliver the drug into the desired spinal site (usually by a long catheter). They are generally placed into the subcutaneous tissues around the upper abdomen with the catheter running towards the injured spinal cord and nerves. Top-up of the drugs is accomplished through the skin and via a silicone membrane. Sepsis should always be sought and excluded. Any issues with device function should be considered by explant and manufacturer review.

[Level of evidence – Good practice point (GPP).]

7.20 Breast (and other) implants

These devices are technically not medical devices, being inserted for breast reconstruction following mastectomy or for personal non-cancer augmentation or reconstruction reasons. Other sites that have occasionally had such implants include the penis, buttock and abdominal wall. The gel bags can be associated with significant scarring fibrosis and local nodal reactions owing to content leakage. Rare cases associated with anaplastic large cell lymphoma have been described with breast implants.⁴¹ Infections around these implants are less common than previously seen, but ‘cosmetic surgery tourism’ should be considered if there is no NHS record of such implants.

[Level of evidence – Good practice point (GPP).]

7.21 Implanted nerve stimulators

These are used for Parkinson's disease and drug-resistant epilepsy.^{42–47} They have a similar macroscopic structure to pacemakers, with a generator unit within the upper right or left chest. However, their leads pass upwards towards the cranium. The device position, integrity of the leads and ultimate positioning of the electrodes should be part of the autopsy and indeed the report.

Such devices may have downloadable time and date correlated memory functions. Post-mortem evaluation will need to consider, and exclude, device malfunction as linked to the cause of death. However, this will need specialist collaboration with clinical teams. As with permanent pacemakers, there is a conceivable risk of cremation explosion, which should prompt device removal after death.

[Level of evidence – Good practice point (GPP).]

7.22 Cochlear implants

Cochlear implants are auditory enhancement devices designed to pick up ambient sound and to relay it directly into the inner ear to allow auditory function. With any metal foreign material being inserted into bone and/or soft tissues there is a chance for infection, although this does not appear to be commonplace, given the number of devices used worldwide.⁴⁸ These devices rarely require detailed dissection, but may benefit from PMCT scan as a way of avoiding destructive dissection.

[Level of evidence – Good practice point (GPP).]

7.23 Radioisotopes

These isotopes are infused, or inserted as solid items, into the body principally for the treatment of cancers.⁴⁹ The isotopes currently used include:

- ¹³¹Iodine for benign thyroid disease and differentiated thyroid cancer
- ⁹⁰Yttrium, ¹⁶⁹Erbium and ¹⁸⁶Rhenium intra-articular therapy (radiation synovectomy)
- ¹³¹I-meta-Iodo-benzyl-guanidine and ¹⁷⁷Lutetium-oxodotreotide for neuro-endocrine tumours
- ²²³Radium dichloride for prostate carcinoma and other tumours with skeletal metastases
- ¹⁵³Samarium (lexidronam) for skeletal metastases
- ⁹⁰Yttrium (ibritumomab tiuxetan) for some lymphomas
- ¹⁷⁷Lutetium prostate-specific membrane antigen (PSMA) targeted molecular radiotherapy.

The pathologist should always be aware of how, when and where the isotope was introduced. Before the autopsy, there should also be data on the half-life of the radioisotope and the total amount of radioactive material inserted into the body. There should not be any issue with mis-dosage of the radionuclide, but it may be prudent to have the correct dose confirmed.

The general realities of safe practice prior to the autopsy include minimising radiation exposure to all mortuary staff, even while the body is just being stored in the mortuary. Any pregnant staff may need temporary redeployment. General risk minimisation of radiation risk also includes considered storage of the body, such that the distance is maximal from mortuary staff working and rest areas. The local medical physics and oncology service teams may be invaluable in providing guidance on radiation risk assessments before starting the procedure. Any autopsy interactions should be approved before starting the examination with the medical physics department. The autopsy practitioner should be aware of the need for specialist personal protective equipment (lead-lined aprons, appropriate masks, as well as disposable gowns and gloves).

The autopsy should be accomplished in as little time as possible in a safe fashion. Any needles and beads should be removed from the body, so that they may be isolated into a lead-lined container and stored/disposed appropriately. The thyroid in cases of ¹³¹Iodine treatment should be removed at the start of the examination and placed into a lead-lined container. Disposal of these tissues and the radionuclides should be coordinated by the medical physics department. Fixed tissue samples, ideally in cassettes, may benefit from a prolonged period of time in storage before processing.

One should be aware that cremation may not be possible until a safe level of radioactivity has been achieved. Again, discussion with medical physics specialists may be of help in this regard.

[Level of evidence – Good practice point (GPP).]

8 Ownership of implantable devices

Implantable medical devices are often expensive products, but mostly provided (free) by the health service in the UK, unless the device and its implantation are privately financed. It is reasonable to accept that, at the point of implantation, any device (property in law) passes from the hospital (or equivalent) to the patient.

On death, within UK probate law, such property passes into the deceased's estate, in the same way as clothing or jewellery. It follows that a pathologist cannot act in relation to a device, as though it were his or her property. However, aside from any value in retaining and testing some items (e.g. PPMs), it is probably inappropriate to ask the relatives, or the estate, about having devices returned. Nevertheless, the fate of any device taken from the body which is not being destroyed should be recorded in writing in the clinical record, within the autopsy report or as a report addendum.

9 Imaging

Imaging-based post-mortem examination should never be undertaken without an expert external examination of the body having first been performed by an appropriately trained and experienced pathologist. Yet, it may be valuable in considering the position and interaction of the device and the body. PMCT is preferable over post-mortem magnetic resonance imaging.

10 Clinicopathological summary

This will be guided by the autopsy and the data relevant to the device under consideration.

11 Examples of cause of death opinions/statements

- 1a. *Hypoglycaemic neurological injury*
- 1b. *Malfunctioning insulin pump inserted for type 1 diabetes mellitus*

- 1a. *Staphylococcus aureus bacteraemia*
- 1b. *Abscess around pacemaker inserted for bradycardia*
- 2. *Diabetes mellitus (Type 1)*

- 1a. *Aortic valve dysfunction*
- 1b. *Infective endocarditis*
- 1c. *Calcific aortic valve stenosis (operated)*

- 1a. *Cardiac tamponade*
- 1b. *Coronary artery dissection during stent placement*
- 1c. *Coronary atheroma*
- 2. *Previous myocardial infarction*

- 1a. *Ascending urosepsis or infection*
- 1b. *Urinary tract stent obstruction*
- 1c. *Benign prostate hypertrophy*

- 1a. *Fat embolism*
- 1b. *Periprosthetic fracture of hip replacement*
- 1c. *Osteoporotic hip fracture*

- 1a. *Status epilepticus*
- 1b. *Tumour obstructed (CSF) drainage device*
- 1c. *Meningioma (treated)*

- 1a. *Meningitis around intrathecal drug delivery device*
- 1b. *Spinal cord injury (treated)*
- 1c. *Multiple trauma*

12 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 complies with the national recommendations provided by the 2006 National Confidential Enquiry into Patient Outcome and Death (NCEPOD) study:⁵⁰

- supporting documentations:
 - 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 report 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 report must explain the description of external appearance
 - standards: 100% of autopsy reports documented are satisfactory, good or excellent.

A template for coronial autopsy audit can be found on The Royal College of Pathologists' website.⁵¹

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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 cancer type.</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 guideline 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 autopsy guideline that indicate compliance with each of the AGREE II standards are indicated in the table.

AGREE 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
3 The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described	Foreword
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	n/a
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	Throughout
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	Foreword
12 There is an explicit link between the recommendations and the supporting evidence	Throughout
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	2–11
16 The different options for management of the condition or health issue are clearly presented	Foreword
17 Key recommendations are easily identifiable	2–11
Applicability	
18 The guideline describes facilitators and barriers to its application	Throughout
19 The guideline provides advice and/or tools on how the recommendations can be put into practice	2–11
20 The potential resource implications of applying the recommendations have been considered	Foreword
21 The guideline presents monitoring and/or auditing criteria	12
Editorial independence	
22 The views of the funding body have not influenced the content of the guideline	Foreword
23 Competing interest of guideline development group members have been recorded and addressed	Foreword