**Site visit inspection report on compliance with HTA licensing standards**

**Addenbrooke's Hospital**

**HTA licensing number 12318**

**Licensed under the Human Tissue Act 2004 for the**

- **making of a post mortem examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

**18 – 19 June 2019**

## Summary of inspection findings

The HTA found the Designated Individual (DI), the Licence Holder (LH), the premises and the practices to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Addenbrooke's Hospital (the establishment) had met the majority of the HTA's standards, four major and eleven minor shortfalls were found against standards relating to consent, governance and quality systems, traceability and premises, facilities and equipment.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

**The HTA's regulatory requirements**

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

## Background to the establishment

Addenbrooke's Hospital (the establishment) is part of Cambridge University Hospitals NHS Foundation Trust. The establishment has been licensed by the HTA since 2007. Addenbrooke's Hospital holds HTA licences for activities in the research, anatomy, human application, organ donation and transplant and post mortem (PM) sectors.

Since the last inspection of this establishment in 2016, the microsurgical skills laboratory transferred from the governance of the PM sector licence to the anatomy sector licence (in May 2016) and the molecular genetics laboratory has ceased licensed storage activity.

The DI is the HTA Compliance, Governance and Quality Lead. The Corporate Licence Holder (CLH) is the Trust, and the Director for Clinical Quality is the CLH named contact. There are Persons Designated (PDs) in all areas of the establishment where licensed activities take place, except for the mortuary (see *Advice*, item 4).

### *Mortuary*

The mortuary is located on the lower floor of the main hospital building. Security arrangements include the use of closed-circuit-television (CCTV), an audio-visual intercom system, swipe card access and key locks for doors (see shortfall against standard PFE1(d)).

The department admits approximately 2,000 bodies annually. Bodies are received from the hospital wards, the community and from other HTA-licensed establishments for PM examination. Out of hours, porters transfer bodies to the mortuary from the wards and funeral directors transfer bodies to the mortuary from the community. Anatomical Pathology Technologists (APTs) train the porters and funeral directors in mortuary procedures. Identification of bodies admitted to the mortuary is checked by APTs, using a minimum of three identifiers. During these checks an additional identifier (the date of death) is added to the wristband on the body to ensure that a minimum of three identifiers of the deceased can be checked against information brought by funeral directors for release of the body from the mortuary.

The body store comprises of a number of banks of fridges, including separate units for paediatric and perinatal bodies. There are 120 spaces for adult bodies, 30 of which can accommodate bariatric bodies and five dedicated freezer spaces (see *Advice,* item 6). A temporary refrigerated storage unit is located in a secured gated area external to the rear doors of the mortuary and can hold a further 12 bodies. There is a separate fridge for the storage of toxicology specimens taken at PM examination (see shortfall against standard PFE2(e)).

Temperature monitoring is completed manually and records of this are kept in the body storage area (see shortfall against standard PFE2(a)). Most of the refrigerated units are connected to temperature alarms that sound both internal and external to the mortuary. The

alarms and alarm response system are tested regularly (see shortfall against standard PFE2(e)).

The establishment performs approximately 900 PM examinations each year. This includes around 600 cases on behalf of HM Coroner for Cambridgeshire and 300 hospital consented paediatric and perinatal cases. Seven adult consented PM examinations and five forensic PM examinations were carried out at the establishment in 2018. There is a dedicated PM room for high-risk cases, which has one PM table, a paediatric and perinatal PM room with three PM tables and an adult PM room with five PM tables. The doors into the PM rooms can be locked to prevent unauthorised access and act as demarcation between the PM rooms and the body store area (see shortfall against standard PFE1(b)).

External examination of bodies for PM examinations under coronial authority usually takes place in the afternoon prior to the PM examination, with a further crosscheck of the identification of the deceased against the Coroner's paperwork on the day of the PM examination (see shortfall against standard T1(c)). A system is in place to prevent the mix-up of organs at PM examination, and tissue samples are sent to the histology laboratory at the hospital (see shortfall against standard T1(c)).

Viewing of bodies is undertaken by appointment only and is facilitated both in and out of hours by APTs. Identification of bodies for viewing is checked at the point of preparation of the body and matched against identifiers of the deceased provided by the relatives at the time of booking. These identifiers are then requested from the relatives at the point of their arrival for the viewing. However, only two identifiers of the deceased are requested (see shortfall against standard T1(c)).

***Maternity Department (The Rosie Hospital)***

The maternity department has a fridge for the storage of perinatal cases, which is located in a secured area. The fridge is temperature monitored and has a temperature alarm that sounds locally (see shortfall against standard PFE2(e)). Records are kept of all cases transferred to the mortuary and information on the process is available to all staff.

There are two designated bereavement midwives involved in the consent seeking process for PM examination and a core team of midwives trained in seeking consent for PM examination. Clinicians may also be involved in the consent seeking process (see shortfall against standard C2(a)). The PM examination consent forms are based on the Stillbirth and Neonatal Death (Sands) charity documentation for paediatric/perinatal cases, and families receive information booklets detailing the consent process.

***Accident & Emergency (A&E) and Neonatal Intensive Care Unit (NICU)***

Removal of tissue from bodies being investigated under the Sudden Unexplained Death in Infancy and Childhood (SUDIC) protocols may occur in both A&E and NICU departments. Blanket approval for the removal of tissue in SUDIC cases has been given by the Coroner

(see shortfall against standard GQ1(a)). Samples are labelled with identifiers of the deceased and are transferred directly to the relevant pathology laboratories.

***Histology Department***

The establishment has a tissue coordinator who works across both the mortuary and histology laboratory. The tissue coordinator regularly reviews all organs and tissue samples taken at PM examination to ensure that traceability is maintained and the wishes of relatives for the fate of the samples are complied with once the Coroner's jurisdiction has ended. Samples are transferred from the mortuary directly to the histology laboratory in numbered cassettes and are processed accordingly (see shortfall against standard T1(c)). The department has a tissue block and slide storage area, which is secured by key pad entry, well ventilated and uses a date order filing system. Larger wet tissue specimens are stored externally to the laboratory in a room secured by a key code pad.

***Clinical Science Museum***

The Clinical Science Museum holds 784 potted specimens, which were all obtained prior to 1 September 2006 and so are 'existing holdings' under the HT Act. All potted specimens are stored in a locked room in the medical school. There is a comprehensive catalogue of the pots that details storage location and specimen type. Each pot has a unique identification number. The specimens have not been accessed for approximately two years and standard operating procedures (SOPs) relating to procedures in the museum have not been reviewed recently (see *Advice*, item 3). The establishment plans to close the museum and transfer of all of the specimens to another HTA-licensed establishment.

***Theatres***

Removal of tissue from the deceased for both transplantation and research purposes is undertaken in the main theatres. Organs and tissue for transplantation and samples for research are stored in separate designated fridges. The fridges are electronically temperature monitored and alarmed. Comprehensive traceability records are kept and researchers removing tissue for research purposes must provide the Recognised Ethics Committee (REC) number for the research study before accessing the tissue.

***Brain Bank***

Consent for brain donations is sought by a core team of trained individuals. A brain bank reference number is allocated to each specimen upon receipt at the brain bank (see shortfall against standard T1(c)). The brains are divided with one half fixed in formalin and stored in the laboratory and one half frozen and stored in -80°C freezers. Freezers are temperature monitored and connected to an external alarm system. There is also contingency freezer storage available on site and via a contracted company.

## Description of inspection activities undertaken

This was the fourth HTA inspection of this establishment; the last inspection of this licence was in 2016. The site visit included a visual inspection of the mortuary, laboratories, brain bank, main theatres, Clinical Science Museum, A&E department and a visit to the maternity ward to review the storage fridge. Formal interviews were conducted with staff.

A traceability audit of bodies being stored in the mortuary was undertaken for four bodies (two adult cases admitted from the hospital and two perinatal cases transferred from other HTA-licensed establishments). Body identifiers, storage locations, mortuary register details and associated documentation were reviewed and cross-referenced. Although full traceability of bodies was demonstrated for these cases, numerous discrepancies were identified in the mortuary register (see shortfall against standard T1(b)).

Four specimens stored in the brain bank were audited for traceability. Storage location, specimen identifiers and the electronic database records were crosschecked. No discrepancies were found in traceability; however, many pots did not have the required minimum number of identifiers and the allocated identifier used was inconsistent (see shortfall against standard T1(c)).

Two museum specimen pots were audited for traceability. Storage location and specimen details were crosschecked against information in the specimen catalogue. No discrepancies were found.

The log of samples removed in the theatres for research purposes was reviewed. Two cases were audited to ensure that REC numbers had been provided by researchers accessing the samples and that sample transfer details had been recorded. No anomalies were found.

The process and documentation for removal of relevant material in SUDIC cases in the A&E and NICU departments were reviewed.

## Material held for the police

Home Office PM examinations are conducted at the establishment. Under section 39 of HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority contained a recommendation that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process. Therefore, procedures for Home Office PM examinations and management of tissues and organs taken for criminal justice purposes were reviewed by the HTA at this site visit inspection.

## Inspection findings

The HTA found the LH, the DI and the premises to be suitable in accordance with the requirements of the legislation.

## Compliance with HTA standards

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| **C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice** | | |
| b) There is a documented standard operating procedure (SOP) detailing the consent process | There is no SOP covering the process for seeking consent for paediatric and perinatal PM examinations. | **Minor** |
| c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice | The information provided to those giving consent for PM examination does not reflect the requirements of the HT Act 2004. For example, it states that tissue will be routinely taken at PM examination and does not further explain that consent must be given for this to happen. | **Minor** |

| | | |
|---|---|---|
| **C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent** | | |
| a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice | Clinicians who seek consent for paediatric/perinatal PM examination may have received PM consent training as part of their medical training, but there is no evidence that refresher training has been completed. | **Minor** |

| **GQ1 All aspects of the establishment's work are governed by documented policies and procedures** | | |
|---|---|---|
| a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath. | i) Mortuary SOPs do not always contain sufficient details of procedures. Some practices have been updated but this has not been reflected in the SOPs. For example, this includes but is not limited to:<br>• MORT.SOP.ADM.31638 – The SOP for preparing for PM examination states that the identification check of the body is completed on the morning of the PM examination. In practice, preparation for PM examination usually occurs the day before and there is no detail in this SOP of what identification check is completed at this stage.<br>• The department have introduced a system for crosschecking the identification of the body upon arrival of visitors coming for viewings however, this practice is not detailed in the SOP for viewing of bodies (MORT.SOP.ADM.32220).<br>• SOPs reference the term 'next of kin' and do not provide information about the hierarchy of qualifying relationships in the HT Act.<br>ii) The SUDIC protocol in the A&E and NICU departments does not reference that the Coroner has given blanket approval for tissues to be taken. | **Major** |

| **GQ4 There is a systematic and planned approach to the management of records** | | |
|---|---|---|
| b) There are documented SOPs for record management which include how errors in written records should be corrected | The records management SOP does not detail how errors in written mortuary records should be corrected. The inspection team observed inconsistent approaches to written amendments in the mortuary register. | **Minor** |

| **GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored** | | |
|---|---|---|
| b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed | i) Whilst risk assessments cover most risks of undertaking licensed activities, the risk of accidental damage to bodies is not covered in the sharps risk assessment.<br>ii) Risk assessments relating to HTA Reportable Incident (HTARI) categories are not reviewed or updated following incidents. | **Minor** |

| **T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail** | | |
|---|---|---|
| b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records) | i) The written mortuary register has numerous duplicate entries of bodies admitted to the mortuary. In most instances the duplicate record has been created at a later date and used to sign the body out of the mortuary by the funeral director on release from the mortuary. In these cases, the release section of the original entry in the mortuary register is left blank and is not linked to the duplicate record. This could lead to confusion and a loss of traceability.<br>ii) The physical location of bodies stored in the bariatric fridges does not correlate with the numbering system on the body store whiteboard due to a change to the internal fridge racking. | **Minor** |

| | | |
|---|---|---|
| c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier | i) Bodies admitted from the community are not always labelled with a minimum of three identifiers that can be crosschecked prior to the start of a PM examination.<br><br>ii) Tissues taken at PM examination are placed into individual cassettes that have one printed unique PM identifier. However, cassettes from all PM cases undertaken during a session are placed together in one pot for fixing and transfer to the histology laboratory. This practice could lead to a loss of traceability of tissue because sufficient checks cannot be made of the tissue retained for each case when the tissue is transferred and received in the laboratory.<br><br>iii) Only two identifiers of the deceased are used to prepare bodies for viewing and provided by visitors prior to the viewing taking place.<br><br>iv) Specimens in the brain bank are not labelled using a standardised and agreed traceability system. Most pots audited by the inspection team were labelled with only one or two identifiers.<br><br>The use of less than three identifiers of the deceased for identification of bodies and tissues presents a risk of misidentification. | **Major** |

| **PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.** | | |
|---|---|---|
| a) The premises are clean and well maintained | Whilst the premises were clean at the time of inspection, some areas of the body store are showing signs of wear and require maintenance:<br><br>• The seal between the flooring and the walls has failed in several areas;<br><br>• There are several areas of damage to walls and flaking paint exposing porous plaster, meaning that the walls cannot be sufficiently cleaned or disinfected; and<br><br>• Corners of walls are damaged in several areas.<br><br>In addition, the frame holding body measurement tools is constructed from unsealed wood meaning that the surface is porous and is difficult to clean and disinfect adequately. | **Minor** |

| | | |
|---|---|---|
| b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors | Following PM examination, bodies are transferred on trolleys from the PM rooms, including the high-risk PM room, through the body store area by staff still attired in PM room personal protective equipment (PPE).<br><br>This poses a risk of cross-contamination because the body store is considered to be a clean area and is accessed at the same time by funeral directors, porters and other hospital staff, such as doctors. The body store is only cleaned routinely once per week and this does not address the risk of cross-contamination sufficiently. | **Major** |
| d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access) | The entrance door to the body store reception area from the main hospital has no visual system in place to allow mortuary staff to determine if there is a risk to security and/or personal safety prior to opening the door. This risk has not been formally assessed. | **Minor** |

| **PFE2 There are appropriate facilities for the storage of bodies and human tissue.** | | |
|---|---|---|
| a) Storage arrangements ensure the dignity of the deceased | The temperature monitoring chart shows that one bank of fridges had been running at temperatures up to 10°C for extended periods in the week prior to the inspection. There is no evidence that action had been taken in response to this or that the temperature alarms had been triggered. The monitoring chart states action must be taken if the temperature is noted to be in excess of 8°C and that the action taken should be recorded on the monitoring chart. These temperatures will not optimally maintain the condition of bodies stored. | **Minor** |
| e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range | i) The fridge in the mortuary used for the storage of toxicology samples is not temperature monitored or connected to the external temperature alarm system.<br><br>ii) The upper temperature trigger point for fridge alarms in the main body store is set too high to ensure that the storage temperatures are appropriate.<br><br>ii) The temporary body store unit located in the external yard of the mortuary is not connected to the external alarm system.<br><br>iii) The fridge in the maternity department is located in an area where the local temperature alarm may not be heard. This fridge is not connected to an external temperature alarm system. | **Major** |

| PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored | | |
|---|---|---|
| a) Items of equipment in the mortuary are in good condition and appropriate for use | Hydraulic body trolleys in the mortuary have areas of damage and rusting making effective decontamination difficult. | **Minor** |
| c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually | The paediatric PM room ventilation system does not provide the minimum air flow required. Whilst the air flow is just below the minimum recommended level, action is required to prevent the system function reducing any further. | **Minor** |

### Advice

The HTA advises the DI to consider the following to further improve practice:

| No. | Standard | Advice |
|---|---|---|
| 1. | C1(d) | The DI may wish to consider updating the consent form for adult hospital PM examinations to separate the scheduled purpose options for tissues in case those consenting do not wish for material to be used for all of the purposes currently grouped together. (See the HTA model consent form: www.hta.gov.uk/policies/post-mortem-model-consent-forms). |
| 2. | C1(f) | Whilst those consenting to PM examination are given a minimum of 12 hours in which to change their minds to withdraw or alter the consent given, the DI is advised that the HTA recommends that a minimum of 24 hours are provided for this purpose. |
| 3. | GQ1(d) | The DI is advised that if the current plans do not progress to close the Clinical Science Museum and transfer all of the specimens in this collection to other HTA-licensed premises, then the SOPs governing the storage of these samples should be reviewed. |
| 4. | GQ1(g) | The DI is advised to consider appointing a PD from staff working permanently in the mortuary to help ensure oversight of licensed activities. |
| 5. | GQ2(a) | While tissue audits in the mortuary and brain bank are well constructed, these audits focus only on one sample per audit. The DI is advised to audit a representative number of samples per audit in order to help identify trends in non-conformances. |
| 6. | PFE2(b) | The DI is advised to keep under review the progress in relation to the acquisition of freezer storage for bariatric cases, which is currently on the Trust risk register. |
| 7. | PFE2(g) | The DI is advised to develop a process to ensure that shrouding of bodies is replaced and body bags are used where required. This will help to ensure that the dignity of the deceased is preserved and the risk of cross-contamination is reduced. |

## Concluding comments

Whilst shortfalls were found against the overarching standards, a number of good practices were identified during the inspection.

- The use of colour-coded body measures to help porters to select an appropriately sized body storage space when they admit bodies to the mortuary.
- The training and competency package for the core team of PM examination consent seekers includes six monthly competency quizzes to help maintain competency and awareness of the consent process.
- Competency assessments undertaken within the mortuary require staff to provide objective evidence of how they have achieved competency in tasks relating to licensed activities.

There are a number of areas of practice that require improvement, including four major shortfalls and eleven minor shortfalls.

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

**Report sent to DI for factual accuracy: 16 July 2019**

**Report returned from DI: 30 July 2019**

**Final report issued: 31 July 2019**

## Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

**Date: 14 April 2020**

## Appendix 1: HTA licensing standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Standards that are not applicable have been excluded.

**Consent**

**C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice**

a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.

b) There is a documented standard operating procedure (SOP) detailing the consent process.

*Guidance*

*This should include who is able to seek consent, what training they should receive, and what information should be provided to those giving consent for post-mortem examination. It should make reference to the use of scanning as an alternative or adjunct to post-mortem examination.*

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.

*Guidance*

*Information on consent should be available in different languages and formats, or there is access to interpreters/translators. Family members should be given the opportunity to ask questions.*

d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.

e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained.

f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds.

g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.

*Guidance*

*This may be based on the HTA's model consent form for adult post-mortem examinations available on the HTA website, or in relation to infants, the resources pack developed by the*

*Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.*

**C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent**

a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice.

*Guidance*

*Refresher training should be available (for example annually).*

b) Records demonstrate up-to-date staff training.

c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.

d) Competency is assessed and maintained.

**Governance and quality systems**

**GQ1 All aspects of the establishment's work are governed by documented policies and procedures**

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath. These include:

i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk;

ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage;

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

vi. receipt and release of bodies, which reflect out of hours arrangements;

vii. lone working in the mortuary;

viii. viewing of bodies, including those in long-term storage, by family members and others such as the police;

ix. transfer of bodies internally, for example, for MRI scanning;

x. transfer of bodies and tissue (including blocks and slides) off site or to other establishments;

xi. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached;

xii. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family;

xiii. access to the mortuary by non-mortuary staff, contractors and visitors;

xiv. contingency storage arrangements.

*Guidance*

*SOPs should reflect guidance contained in the HSE's document: Managing the risks of infection in the mortuary, post mortem room, funeral premises and exhumation.*

*Individual SOPs for each activity are not required. Some SOPs will cover more than one activity.*

b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed.

c) Procedures on body storage prevent practices that disregard the dignity of the deceased.

*Guidance*

*For example, placing more than one body on a tray, placing bodies unshrouded on trays, or storing bodies in unrefrigerated storage should not take place.*

*The family's permission should be obtained for any 'cosmetic' adjustments or other invasive procedures prior to release of bodies, for example, sewing the deceased's mouth to close it or the removal of a pacemaker. It is also good practice to discuss with the family any condition that may cause them distress, for example when viewing or preparing the body for burial, such as oedema, skin slippage of signs of decomposition.*

*If identification of the body is to take place before a post-mortem examination, if available, a Police Family Liaison or Coroner's Officer should have a discussion with the family about the injures and let them know that reconstruction may be required.*

*However, the Pathologist should see the body without any changes being made, so if there is a need to reconstruct or clean a body before the post-mortem examination, it should be with the agreement of both the Pathologist and the Coroner. In Home Office cases, a viewing cannot normally take place until after the post-mortem examination.*

d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.

e) There is a system for recording that staff have read and understood the latest versions of these documents.

f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.

g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.

*Guidance*

*These areas include maternity wards where storage of fetuses and still born babies takes place, areas where material is stored for research, the Accident and Emergency Department where removal of samples may take place in cases of sudden unexpected death in infancy. There should be an identified Person Designated in areas of the establishment remote from the main premises.*

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.

*Guidance*

*Meeting minutes should be recorded and made available to staff.*

**GQ2 There is a documented system of audit**

a) There is a documented schedule of audits.

*Guidance*

*As a minimum, the schedule should include a range of vertical and horizontal audits*

*checking compliance with documented procedures, the completion of records and traceability.*

b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these.

*Guidance*

*Staff should be made aware of the outcomes of audits and where improvements have been identified.*

c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention.

*Guidance*

*Audits of stored tissue should include samples held under the authority of the police, where applicable.*

**GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks**

a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.

*Guidance*

*This includes portering staff, who have responsibility for bringing bodies to the mortuary out of hours and who may not be aware of the potential risks to the deceased during transfer into refrigerated storage, and unqualified mortuary 'assistant' staff.*

*APTs should be trained in reconstruction techniques to ensure that the appearance of the deceased is as natural as possible. APTs should be encouraged to work towards the achievement of the RSPH Level 3 Diploma in Anatomical Pathology Technology.*

b) There are clear reporting lines and accountability.

c) Staff are assessed as competent for the tasks they perform.

*Guidance*

*Assessment of competence should include the standard of APTs' reconstruction work.*

d) Staff have annual appraisals and personal development plans.

e) Staff are given opportunities to attend training courses, either internally or externally.

*Guidance: attendance by staff at training events should be recorded.*

f) There is a documented induction and training programme for new mortuary staff.

g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.

*Guidance*

*The qualifications of locum staff should be checked prior to them commencing work in the mortuary and their competency to undertake each task should be assessed.*

*Contractors, visiting and temporary staff and funeral service staff bringing bodies out of hours should be required to read relevant standard operating procedures and sign to confirm their understanding.*

**GQ4 There is a systematic and planned approach to the management of records**

a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.

*Guidance*

*Records include mortuary registers, PM examination records, tissue retention forms and*

*records of transfer and return of organs/tissue sent elsewhere for examination.*

b) There are documented SOPs for record management which include how errors in written records should be corrected.

c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

**GQ5 There are systems to ensure that all untoward incidents are investigated promptly**

a) Staff know how to identify and report incidents, including those that must be reported to the HTA.

*Guidance*

*HTA-reportable incidents must be reported within five days of the date of the incident or date of discovery.*

*Incidents that relate to a failure of hospital staff to carry out end of life care adequately should be reported internally and the incidence of these monitored.*

b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.

c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.

d) Information about incidents is shared with all staff to avoid repeat errors.

e) The establishment adopts a policy of candour when dealing with serious incidents.

**GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored**

a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis.

*Guidance*

*Risks to the dignity and integrity of bodies and stored tissue should be covered. The HTA's reportable incident categories provide a good basis for risk assessments. Risk assessments should be reviewed at regular intervals, for example every 1-3 years or when circumstances change. Staff should be involved in the risk assessment process.*

b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

*Guidance*

*Relevant staff should have knowledge of risks and the control measures that have been taken*

*to mitigate them.*

c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.

**Traceability**

**T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail**

a) Bodies are tagged/labelled upon arrival at the mortuary.

*Guidance*

*The condition and labelling of bodies received in body bags should always be checked and their identity confirmed. They should be labelled on the wrist and/or toe. Body bags should not be labelled in place of the body.*

b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records).

*Guidance*

*Body receipt and release details should be logged in the mortuary register, including the date and name of the person who received/released the body and, in the case of release, to whom it was released. This includes bodies sent to another establishment for PM examination or bodies which are sent off site for short-term storage which are subsequently returned before release to funeral service staff.*

c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier.

*Guidance*

*Identification details should not be written on bodies. Where bodies are moved off site for contingency storage the DI should ensure that suitable systems are in place to identify same or similar names.*

d) There is system for flagging up same or similar names of the deceased.

e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises.

*Guidance*

*Mortuary white boards containing the names of the deceased give potential for error if wiped clean (such as when visitors attend for reasons of confidentiality), and should not be relied upon as the sole source of information about the locations of bodies.*

*Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place*

*present a risk to traceability. Full identification checks should be made when they are placed back into normal storage.*

f) There are procedures for releasing a body that has been in long term storage and is therefore not in the current register.

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). The traceability system ensures that the following details are recorded:

i. material sent for analysis on or off-site, including confirmation of arrival

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

*Guidance*

*Consent information which covers retention/disposal of tissues should be made available to the other site, as appropriate.*

h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements.

*Guidance*

*Formal written agreements with funeral services are recommended. Coroners usually have their own agreements for transportation of bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment forthese cases.*

**T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.**

a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete.

b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.

c) Disposal is in line with the wishes of the deceased's family.

*Guidance*

*Organs and tissue returned to the body prior to its release should be contained in clear viscera bags, which prevent leakage, are biodegradable and pose no issues for crematoria in relation to emissions and pollution. Clinical waste bags or household bin bags should not be used for*

*this purpose.*

*Tissue blocks and glass slides should not be placed inside the body for the purpose of reuniting tissues with the deceased. Blocks and slides should be placed in a suitable container and transported with the body should the family wish to delay the funeral until the slides are returned.*

d) The method and date of disposal are recorded.

**Premises, facilities and equipment**

**PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue**

a) The premises are clean and well maintained.

*Guidance*

*Floors, walls and work surfaces should be of non-porous construction and free of cracks and chips. The premises should be subject to a programme of planned preventative maintenance, which ensures that the premises, facilities and equipment remain fit for purpose.*

b) There is demarcation of clear, dirty and transitional areas of the mortuary, which is observed by staff and visitors.

c) There are documented cleaning and decontamination procedures and a schedule of cleaning.

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).

*Guidance*

*Relatives who visit for a viewing should not be able to access the body store area. Security systems and lone working arrangements should take into account viewings which take place out of hours.*

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.

**PFE2 There are appropriate facilities for the storage of bodies and human tissue**

a) Storage arrangements ensure the dignity of the deceased.

*Guidance*

*Refrigeration of bodies should be at a temperature of approximately 4 degrees Celsius. The optimal operating temperature for freezer storage is around -20 Celsius, +/- 4 degrees.*

b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity.

*Guidance*

*Capacity should be regularly reviewed, particularly if contingency arrangements are used for an extended period.*

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.

*Guidance*

*There should be sufficient frozen storage for the long-term storage of bodies; the HTA advises that bodies should be moved into frozen storage after 30-days in refrigerated storage if there is no indication they are soon to be released or further examined, or before, depending on the condition of the body. Where there is insufficient freezer storage to meet needs, there should be arrangements with other establishments, or other contingency steps, to ensure that bodies can be stored appropriately.*

*Bodies in long-term storage should be checked regularly; this should include confirmation of their identity and the reason for their continued storage.*

*Where new fridges are installed, these should measure 24"-26" in width and consideration should be given to the proportion that should be larger to accommodate bariatric bodies.*

d) Fridge and freezer units are in good working condition and well maintained.

e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range.

f) Temperatures of fridges and freezers are monitored on a regular basis.

*Guidance*

*Temperature monitoring should enable the establishment to identify trends and may mitigate the risk of a possible fridge failure.*

g) Bodies are shrouded or in body bags whilst in storage.

h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.

*Guidance*

*Where contingency arrangements involve the transfer of bodies to other premises, these should be assessed to ensure that they are suitable and that traceability systems are of the required standard. Stacking bodies on the same fridge tray is not considered suitable practice.*

*Establishments should have documented agreements with any funeral services that they may use for contingency storage. Consideration should be given to whether the funeral service provides contingency storage for other mortuaries. SOPs should address issues such as risk*

*assessments and same/similar name systems.*

*The hire of temporary storage units should not be the sole contingency arrangement for an establishment. Establishments should put in place other formally agreed arrangements for contingency storage. Where the hire of temporary storage facilities*

*forms part of establishments' contingency arrangements, consideration should be given well in advance and steps taken to ensure availability of funds, and of units for hire.*

*Establishments should consider entering in to Mutual Aid Agreements*

*with neighbouring organisations in order that they can provide and obtain support during periods of capacity shortages.*

**PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored**

a) Items of equipment in the mortuary are in a good condition and appropriate for use:

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

   *Guidance*

   *Equipment should be made of material that is easy to clean, impervious, non-rusting, non-decaying and non-staining.*

b) Equipment is appropriate for the management of bariatric bodies.

c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.

   *Guidance*

   *COSHH requires a thorough examination of the ventilation system at 14-month intervals, and sets out what the examination should cover.*

d) Staff have access to necessary PPE.

   *Guidance*

   *Where face masks should be worn, they should be face fitted.*

e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation.

f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept.

*Guidance*

*This includes fridges in Maternity where fetuses or still born babies are stored prior to examination. Maintenance records may be held by the mortuary or centrally by the Trust, such as the Estates Department. They should be available for review during inspection by the HTA.*

## Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

**1. Critical shortfall:**

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

*or*

A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

(1) A notice of proposal being issued to revoke the licence

(2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

**2. Major shortfall:**

A non-critical shortfall that:

- poses a risk to human safety and/or dignity, or
- indicates a failure to carry out satisfactory procedures, or
- indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

*or*

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

**3. Minor shortfall:**

A shortfall which cannot be classified as either critical or major, but which indicates a

departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

## Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.