Site visit inspection report on compliance with HTA licensing standards

Leighton Hospital

HTA licensing number 12145

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**

5 & 6 November 2018

Summary of inspection findings

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

Although the HTA found that Leighton Hospital had met the majority of the HTA's standards, one cumulative major, three major and eight minor shortfalls were found against the Consent, Governance and Quality Systems, Traceability and Premises, Facilities and Equipment standards. These related to the Trust consent policy and standard operating procedure (SOP) for post-mortem (PM) consent seeking, PM consent training, SOPs, audits, the use of three identifiers, traceability of tissues taken during PM examination, fridge temperature ranges, mortuary equipment, Personal Protective Equipment (PPE) and the condition of the PM suite.

Particular areas of strength 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

Leighton Hospital (the establishment) has been licensed by the HTA since May 2007. This report refers to the activities carried out at the establishment. The establishment is licensed for the making of a post-mortem (PM) examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes. The Designated Individual (DI) is the Medical Director and the Corporate Licence Holder contact is the Chief Executive for Mid Cheshire Hospitals NHS Foundation Trust. The mortuary is staffed by two Anatomical Pathology Technologist (APTs). The mortuary enlist support from Medical Laboratory Assistants (MLAs) when there is only one APT on duty. The pathology departments at this establishment and Macclesfield General Hospital (HTA licence number 12411) have formed a working partnership for the provision of services across both sites. One senior APT and one full-time APT are based at Macclesfield mortuary and work cross-site at both establishments.

The establishment receives approximately 1650 bodies each year from the hospital and community and perform around 410 PM examinations annually, all carried out under Coronial authority. The mortuary conducts high-risk PM examinations; forensic cases are transferred to a nearby HTA licensed establishment. Adult hospital (consented) PM examinations are rarely carried out at this establishment (see shortfalls against standards C1(a)-(f) and C2(a)-(d)).

PM examinations for perinatal and paediatric cases are undertaken by another HTA licensed establishment, however, consultant obstetricians and senior registrars seek consent for these cases, which is recorded using consent forms from the referring establishment (see shortfall against C2(a)-(d)). The consent form and information leaflet used for paediatric/perinatal PM cases is based on the Stillbirth and Neonatal Death (Sands) charity documentation.

Removal of tissue from deceased children in cases of sudden unexpected death in infancy (SUDI) is not performed in the Accident & Emergency (A&E) department. Staff will notify the police who will invoke the SUDI protocol and refer such cases to another licensed establishment, where all samples will be taken at PM examination.

The mortuary has 45 refrigerated body storage spaces, five bariatric spaces and a bank of five spaces that can be converted to a freezer for long-term storage of bodies. The mortuary has additional cold room storage, which provides 20 additional body storage spaces as contingency; these were not in use at the time of inspection. There is a separate fridge for the storage of perinatal and paediatric cases. All fridges including the cold room, are connected to a remote monitoring system and have audible alarms, which are connected to the hospital switchboard who notify mortuary staff of temperature fluctuations during and outside of working hours (see shortfall against PFE2(a)).

The Senior APT reviews the fridge temperature records for trends and carries out monthly fridge alarm testing which is documented. There is no fridge on the maternity ward for the temporary storage of foetuses as cold-cots are used before transfer to the mortuary.

Entrance to the mortuary from the hospital is covered by CCTV and secured by swipe card access, which is limited to mortuary, trained portering and MLA staff only. Funeral directors have their own entrance, which is under cover and discreetly located. This entrance is key locked and CCTV cameras allow staff to see who is requesting access.

Portering staff are responsible for the transfer of bodies from hospital wards to the mortuary. On arrival to the mortuary, porters place bodies in an available refrigerated body space and update the mortuary register and whiteboard with information of bodies brought into the mortuary, they also complete their section of the 'Body Acceptance Form' and leave this form in a designated tray for mortuary staff to check. The Coroner's contracted funeral directors transfer all community bodies to the mortuary and porters admit these bodies out-of-hours. All community bodies arrive with a wristband, which is attached to the body by the police before arrival at the mortuary. All community bodies are logged in the mortuary register and on the mortuary whiteboard.

Mortuary staff perform body checks of all bodies the next working day, verifying the identification band details on the bodies against the mortuary register, whiteboard and 'Body Acceptance Form' for hospital bodies and make sure all bodies are appropriately shrouded. Mortuary staff carry out daily visual checks of the fridges, noting details of any bodies with same and/or similar names and write a red asterix on the whiteboard and place a red sticker in the mortuary register to alert staff of these bodies.

The mortuary only release bodies during normal working hours and have devised a 'Body Release Request Form', which undertakers must present to mortuary staff before a hospital body can be released. For Coroner's cases, the Coroner will email authorisation to the mortuary for release (see shortfall against T1(c)).

Babies over 12 weeks and 6 days gestation are transferred to the mortuary by a member of the portering staff and are always released from the mortuary. Babies under 13 weeks gestation for hospital cremation, burial or sensitive incineration are transferred to the histopathology laboratory or, if the family are making their own funeral arrangements, the laboratory liaise with the mortuary and maternity unit regarding release of these bodies.

The mortuary operates an appointment system for viewings, which generally takes place during working hours. Although viewings are discouraged outside of working hours, mortuary staff will accommodate viewings out-of-hours if there is a particular requirement (see shortfall against T1(c)).

The PM suite at the establishment has three downdraft PM tables and there is a dissection bench for the preparation of tissue samples. PM examinations take place one at a time to help minimise the risk of organ and tissue mix-up between cases. The external examination and identification of bodies is always checked by the pathologist and an APT prior to evisceration.

Mortuary staff have access to PPE within the PM room and body store area (see shortfall against PFE3(d)) and there is demarcation of clean and dirty areas within the mortuary. Material retained at PM examination for histological examination is placed into formalin-filled containers and the identifying information is handwritten on the container label by mortuary staff.

Tissue samples may be kept, if appropriate consent has been given for retention or for use for scheduled purposes, but the establishment does not routinely store samples for use for research.

Description of inspection activities undertaken

This was the third site visit inspection of the establishment; the previous inspection took place in 2015. The inspection team reviewed governance and quality system documentation, carried out interviews with key members of staff, a visual inspection of the mortuary body store areas, PM room, viewing area and conducted traceability audits of bodies and tissue blocks and slides in storage.

Audits were conducted for five bodies in refrigerated storage; three from the community and two from the hospital. Body location and identification details on identification bands were cross-checked against the information recorded in the mortuary register and relevant documentation. No discrepancies were found.

In addition, three Coroner's cases where tissue was retained following the PM examination and two hospital consented cases where tissue was retained were audited. The audit included details of tissue type, number of tissue blocks and slides retained, consent forms, and other associated paperwork. There were issues locating one tissue block from one of the cases and tissue slides from a two further cases; establishment staff were able to locate all of these the following day (see shortfall against T1(g)).

Inspection findings

The HTA found the Licence Holder and the Designated Individual 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		
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	The Trust 'Consent Policy' uses the term 'next of kin' throughout, which could imply that a person not ranked highest in the hierarchy of qualifying relationships could give consent to a PM examination or retention and future use of tissues. In addition, the policy states that consent should be sought by a healthcare professional trained in seeking consent There is currently no training for those responsible for seeking consent for PM examination (see shortfall against C2(a)).	**Major (cumulative)**
b) There is a documented standard operating procedure (SOP) detailing the consent process	There is no documented procedure in place, which details the process, which should be followed by staff involved in seeking consent for adult or perinatal/paediatric consented PM examinations. This presents a risk that there may be an inconsistent or incorrect approach taken when seeking consent.	
c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	There is no written information for those giving consent for adult consented PM examinations. They only receive a copy of the consent form, which contains minimal information. As result standards C1(d) and (e) cannot be met.	
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	PM adult consent forms audited by the inspection team were found to be incomplete. Several of the consent form sections, which required initials were ticked, and the 'changing your mind' sections were not completed, even though it states clearly that the section 'must be completed'. For perinatal PM examinations, it was not clear that families are being provided with appropriate contact information for changing their mind, as it is hoped that parents will make a firm decision before they leave the hospital.	

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	There is no formal consent training for clinicians and other staff in seeking PM consent for paediatric/perinatal or adult consented cases, which addresses the requirements of the HT Act and the HTA's codes of practice for adult or paediatric post mortems. As a result, the consent standards C2(b), (c) and (d) cannot be met.	**Major**

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.	Some of the SOPs do not accurately reflect current practice and do not contain sufficient detail for staff regarding the procedures that must be followed. Particular examples include but are not limited to: - SOP MO.SPA045 'Releasing of bodies to funeral directors' does not state that three identifiers (one being unique) are being requested from funeral directors. - SOP MO.SPA039 'Viewing of bodies by relatives' does not state that three points of identification are being requested from the family visiting the mortuary. - SOP MO.SPA046 'Releasing foetuses/stillbirths to funeral directors' does not fully describe the process of releasing bodies if no PM examination is due to take place. - SOP MO.SPA001 'Protocol for performing PM examinations' references the term 'next of kin' regarding the seeking of consent for hospital PM examinations. To fully address this shortfall, the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail of the procedures. In addition, the mortuary have many SOPs some of which could be amalgamated for clarity. This is particularly important as the mortuary share SOPs with Macclesfield General Hospital and request regular support from on-site MLAs. If procedures are not clear, this could lead to issues with staff not following correct practice.	**Minor**
e) There is a system for recording that staff have read and understood the latest versions of these documents	The distribution lists for SOPs in the Q-pulse system do not always include all the relevant staff or do not have a distribution list at all; therefore, there is no record that staff have read and understood SOPs that govern their work.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Although the establishment have a documented schedule of audits, they do not cover all areas of mortuary activities, for example: - Horizontal audits of bodies in storage and PM procedures; - Vertical audits of bodies in storage and long stay bodies. In addition, completed audits reviewed by the inspection team on Q-Pulse, showed that there were incomplete audit summaries for some of them, which had also been closed off by the auditor.	**Minor**
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	The establishment carried out a tissue audit prior to the inspection, which highlighted issues with tissue traceability. Existing tissue audits only include a small number of samples and are only undertaken yearly. The DI cannot be assured that traceability processes are adequate and confirm that appropriate consent is in place for the continued storage and use of tissue.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
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) Community bodies are not consistently identified with three identifiers when admitted to the mortuary. In addition, the mortuary register details are not always fully completed, for example, the address may be missing. Although the Coroner's release form contains three points of identification, which can be checked against the wristband of the body, this is currently being emailed directly to the mortuary. The funeral directors do not bring paperwork with them for release, so the mortuary are releasing on a verbal request from them and are not checking the identifiers on the body against any paperwork. ii) Families are not being asked to provide three identifiers when attending the establishment to undertake viewings and often, only the name of the deceased is requested. (see *Advice,* item 3) The use of less than three separate identifiers (one being unique) when identifying bodies, presents a risk of releasing and viewing of the wrong body.	**Major**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The establishment's current procedures do not provide for full traceability of PM tissue blocks and slides, as there are no processes to ensure sample location is appropriately recorded. This means that when slides are not stored in the laboratory, the establishment does not know whether the slides are being stored by the pathologist, are lost or have been disposed of. The establishment could not demonstrate full traceability of tissue blocks and slides for three of the five cases audited at the time of the inspection. Although the establishment later located these samples to demonstrate traceability, the weaknesses in the establishment's procedures for traceability of blocks and slides mean that full traceability cannot be assured. Further to the above, a record of the quantity and type of tissue blocks retained after the PM examination is recorded only on the 'tissue retention form' that is sent with the tissue to the laboratory. This is the only record of the tissue taken at PM examination; the mortuary do not keep any other records. This means that records of tissue retained at PM examination cannot be fully audited from the mortuary to the laboratory.	**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	The following issues with the condition of the PM suite were identified: - There is flaking paint and exposed wood on the fire exit door of the PM suite, making the surface porous; - One of the PM tables is not completely sealed and requires re-sealing at the base of the table. These areas cannot be decontaminated effectively and may present a health and safety risk to staff. In addition, there are numerous small patches of black mould on the PM suite ceiling, making the surface porous. Due to the current staffing levels in the mortuary, the body store area does not get cleaned regularly, as the mortuary staff are busy with other operational activities. The mortuary have requested support from the management of the domestic cleaning staff to assist with this but this has not been granted.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The upper alarm trigger point for the fridges in the body store (15°C) will not ensure the alarms are triggered at appropriate temperatures to optimally maintain bodies stored in there. (see *Advice*, item 5)	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
b) Equipment is appropriate for the management of bariatric bodies	The body hoists in the PM room and body store are not suitable to support the weight of some bariatric bodies being received by the mortuary, meaning the equipment could fail and/or cause accidental damage to these bodies.	**Minor**
d) Staff have access to necessary PPE	The mortuary staff do not have any face-fitted FFP3 masks and access to only one respirator. As the mortuary conduct high-risk PM examinations, the lack of PPE presents a risk to the health and safety of pathologists and mortuary staff involved in undertaking PM examinations.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(g)	The DI is advised to identify a Persons Designated (PD) in the maternity unit, in order to help maintain oversight of relevant activities, for example, the seeking of consent for PM examination, which is taking place in this area.
2.	T1(a)	It was noticed that one of the hospital bodies had handwritten identification tags instead of the required printed labels as per Trust policy. Mortuary staff are advised to raise non-conformances and address these issues with ward staff to help ensure that bodies are labelled with the correct details and number of identifiers.
3.	T1(c)	In addressing the shortfall identified under this standard the DI is advised to consider ways to strengthen the procedure for undertaking viewings. The DI may wish to consider the introduction of a form to be completed by relatives when they attend for viewings. This form could include relevant identification information so that three identifiers can be checked on the body before the viewing takes place.
4.	T1(h)	The DI is advised to strengthen the 'Do Not Release' process where tissue sent for off-site analysis is awaiting repatriation before release of a body. Currently the mortuary staff update the mortuary register with a note 'awaiting repatriation of tissue' but could implement more visual cues on the body store doors and/or on the body to help mitigate the risk of a body being released prior to repatriation of tissue occurring.
5.	PFE2(a)	The DI is advised to ensure fridge temperatures in all areas are maintained between 4-6°C, with lower and upper triggers points of around 2°C and 7°C, respectively, with an appropriate time period before the alarm triggers. This will prevent the switchboard being unnecessarily alerted each time the fridge doors are left open when staff are working in the body store.
6.	PFE3(c)	The DI is advised to ensure that the 2018 ventilation system testing is completed as planned. This is especially important as although the 2017 tests were within acceptable range, the engineer at the time noted that the number of air changes per hour had decreased significantly and were only just meeting the required standard.

Concluding comments

All staff involved in the inspection demonstrated a sensitive and dedicated approach to their work. The mortuary staff are a cohesive, long-standing and experienced team, communicate well with each other and are open to accepting advice and guidance.

The mortuary risk assessments are a strength, particularly in relation to the risks associated to bodies.

The establishment have already taken a proactive approach to address some of the issues identified during the inspection. For example, they have recognised the issues in relation to the mortuary body trolley and have submitted a business case to replace it.

There are a number of areas of practice that require improvement, including one cumulative major, three major and eight minor shortfalls.

The HTA requires the Designated Individual 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: 3 December 2018

Report returned from DI: 17 December 2018

Final report issued: 21 December 2018

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: 06 August 2019

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 theyare 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.