Site visit inspection report on compliance with HTA licensing standards

Macclesfield District General Hospital

HTA licensing number 12411

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**

12 February 2019

Summary of inspection findings

This is the first inspection of this establishment against the HTA's revised licensing standards, which came into force on 3 April 2017.

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

Although the HTA found that Macclesfield District General Hospital had met the majority of the HTA's standards, four major and seven minor shortfalls were found against standards for Consent, Governance and Quality, Traceability and Premises, Facilities and Equipment.

The shortfalls relate to post-mortem (PM) examination consent training and PM consent seeking procedures; standard operating procedures (SOPs); records management; training; traceability; maintenance of premises and equipment; and body store alarms.

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

Macclesfield District General Hospital (MDGH) (the establishment) has been licensed by the HTA since February 2007, this report describes the third routine inspection with the previous inspection occurring in June 2015. The current DI has been in post since October 2014 and this is their second HTA site visit inspection.

Access to the mortuary from the hospital is via a hospital corridor and the mortuary is secured by a proximity card system and CCTV. The portering staff transfer all hospital bodies to the mortuary through the main hospital using a concealment trolley located in a lobby area adjacent to the mortuary. Upon arrival at the ward the porters conduct an identification check of the body using the information on the wristbands and compare this to the information on the notification of death (NOD) form attached to the shroud/body bag. Bodies from the hospital are brought into the mortuary via the lobby area adjacent to the mortuary body store. Community bodies and funeral directors enter the mortuary via a concealed rear entrance to the lobby area, to which local funeral directors have keys. Out-of-hours, the porters are responsible for opening the mortuary doors adjoining the lobby area, receiving bodies from the community by the Coroner's contracted funeral director, identifying a fridge location and transferring the body into refrigerated storage. The name of the body is written on the wipe board for the relevant fridge location and a door card is completed and put into the holder on the corresponding fridge door. All bodies admitted out-of-hours are recorded in the mortuary register by the porters. During working hours, the mortuary staff review the mortuary register and complete body identity checks of bodies.

Release of bodies is only conducted by the Anatomical Pathology Technologists (APTs) via the mortuary and is restricted to between certain times, within working hours. On occasion, out-of-hours releases are conducted by the on-call APT (see shortfall against T1(c)).

The establishment runs a PM examination service. There is one fully qualified part-time pathologist and two full-time APTs, one of which is a Senior APT. The pathology services at this establishment have merged with those of another HTA licensed establishment to form Cheshire Pathology Services. Pathologists and staff involved in quality management of the mortuary work across both sites. The APTs from each hospital occasionally work across sites. Mortuary processes and documentation are site-specific, as local practices vary.

The establishment receives approximately 1000 bodies per year from both the hospital and community, performing around 250 coronial PM examinations per year, including high-risk cases (up to biological hazard group 3). No forensic PM examinations are undertaken and no material is held under the Police And Criminal Evidence Act 1984 (PACE). Adult hospital consented PM examinations are no longer offered by the Trust. Perinatal and paediatric cases are transferred to another HTA-licensed establishment for PM examination. However, consent is sought for these PM examinations on site by clinicians using the SANDs documentation (see shortfall against C2(a)).

The body store consists of 45 refrigerated spaces, three of which are suitable for bariatric cases and there are three freezer spaces. There is no dedicated fridge for babies or fetuses, but the top spaces of the main body store fridges are used where possible.

All fridges and freezers are alarmed with upper and lower trigger points which, when triggered sound in the mortuary and alerts the hospital switchboard staff who contact the on-call APT, out-of-hours (see *Advice,* items 8 and 9). Bodystore temperatures are recorded continuously by the monitoring system and are reviewed via computer based software for trends to help identify any potential issues with the equipment.

The mortuary has one PM suite with three fixed height, downdraught PM tables (see shortfall against PFE1(a)) and three dissection areas. The pathologist completes each PM examination prior to commencing the next to help mitigate the risk of mixing up organs and tissue samples. Any high-risk cases are conducted at the end of a PM session. The Coroner's Office email authorisation for a PM examination to the mortuary. The pathologist and APT check the identity of the body before the external examination and evisceration of the body (see shortfall against T1(c)).

Material retained at PM examination for histological analysis is labelled, documented and transferred by porters to the histopathology reception with a histology request form. Specimens are packaged and taken by hospital contracted transport to the other HTA licensed establishment in the network for analysis. Whole organs and toxicology samples requiring specialist analysis are sent to other HTA-licensed establishments. A fax receipt is sent to the mortuary for toxicology samples by the receiving establishment, however, no acknowledgement of receipt for wet tissue samples is requested from establishments outside of the network (see shortfall against T1(g)). Relatives' wishes with regards to the fate of any tissue retained following PM examination is managed by the Coroner's office who inform the mortuary and histology laboratory staff of the families wishes both prior to the PM examination and verifies these wishes with the family following the PM examination. Where appropriate consent has been given, blocks and slides are stored for use for scheduled purposes at the other HTA licenced establishment after analysis is completed.

Stillbirths and perinatal deaths are transferred to the mortuary within a few hours by porters. The establishment uses the Stillbirth and Neonatal Death charity (SANDs) consent documentation for these PM examination cases. Consent is sought by obstetrics and gynaecology clinicians (see shortfalls against C1(b) and C2(a)). No removal of relevant material takes place in A&E from sudden and unexpected deaths in infants or children (SUDIC) cases. There is no storage of relevant material for use for research or other scheduled purposed under this licence.

Description of inspection activities undertaken

Traceability audits of body identifiers, storage locations and mortuary register details were conducted for three adult bodies and one baby, these included both hospital and community cases, from refrigerated storage only. The names of the bodies were written on the mortuary location wipe board in the body store. There was a white card in each of the fridge doors which also stated the name, age and address of each body. Discrepancies were found for two of the bodies audited:

- date of birth on the wrist band on the body did not match the date in the mortuary register for a community body and a hospital body

(see shortfall against T1(c)).

In addition, tissue removed during PM examinations for four cases between 2017 and 2018 were audited for traceability. Material removed is recorded in the PM specimen register and the mortuary register. The histology number is added to the mortuary register from a list generated by the histology laboratory at the referring establishment once a month. No discrepancies in records for retained tissue held at this establishment were found.

Interviews were conducted on the day of the site visit inspection with the Medical Director (the DI); Cellular Pathology Lead (Mortuary Manager); Senior APT; Pathology Governance Lead; Porter and Coroner's Officer (by telephone). An interview was conducted with a Consultant Obstetrician and Gynaecologist as a perinatal PM consent seeker the day following the inspection as they were not contactable at the time of the inspection.

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		
b) There is a documented standard operating procedure (SOP) detailing the consent process	Consent for paediatric/perinatal PM examinations is sought by clinicians at the establishment. However, there is no SOP detailing the process for staff to refer to. Without this, the DI cannot be assured that there is a robust and consistent approach to seeking consent for these cases.	**Major**

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 perinatal/paediatric PM examination, have undertaken basic clinical consent training. However, there is no formal training which addresses the requirements of the HT Act or the HTA's Codes of Practice. *Standards C2(b), C2(c) and C2(d) could not therefore be assessed.*	**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.	While the establishment has a number of the required SOPs in place, they lack sufficient detail or attention to wording, these include but are not limited to: • SOP MO.SPA 039 – Viewing of bodies by relatives: lacks sufficient detail of the procedure. It does not state that three identifiers should be obtained from those wishing to view a body and that this information should be cross referenced with the information on the wristband of the body prior to viewing.	**Major**

	• SOP MO.SPA 045 – Releasing bodies to funeral directors: identifies forename and surname as two separate identifiers. However, forename and surname combined is classed as one identifier, meaning if the SOP was followed bodies would be released using only two identifiers (full name and DOB). However, staff are obtaining three identifiers to release a body; • SOP MO.SPA001 – Protocol for performing PM examinations: refers to checking of only two identifiers on the wristband of a body prior to PM examination. This SOP currently details the process for both Coronial and hospital consented PM examinations. The establishment have made a decision to no longer provide a service for adult hospital consented PM examinations, this section therefore needs to be removed; • SOP MO.SPA 020 – Fetuses, babies and placentas sent for examination at another establishment: no reference is made as to what records are kept by the mortuary or relevant hospital department when these cases are sent to the referring establishment. The procedure does not state what identifiers are checked on the identity band at the point of release to the funeral director; • BCP08a – Contingency: lacks sufficient detail as to who to contact when insufficient storage facilities are available and contingency arrangements need to be utilised. All SOPs require review to ensure they are robust and reflective of current practice.	
e) There is a system for recording that staff have read and understood the latest versions of these documents	The establishment uses a quality management computer software system, however, the distribution lists for appropriate staff were either absent or limited. Therefore updates to SOPs are not being circulated to staff for them to be made aware of or acknowledge changes.	**Minor**

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	Portering staff are unaware of the escalation procedure when the refrigerated storage facilities are at full capacity. It was reported that it had been suggested to store bodies in the PM room when the refrigerated body store reaches capacity. This practice does not provide dignified storage of bodies and shows a lack of awareness of the procedures in place when the body store is nearing capacity.	**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	Three identifiers are obtained for the release of hospital bodies by using a combination of the details on the wristband and the NOD form attached to the body. Funeral directors bring documentation that includes three identifiers, two of which can be crossed checked against the wristband on a body (full name and DOB). However, mortuary staff do not use a unique identifier to triangulate information on the wrist band of the body to the mortuary register to locate a third identifier for the release of community bodies. Three identifiers are not used to identify bodies that require PM examination prior to commencement of the examination. Establishment staff only use two identifiers which can be found on the wristband on the body and the Coroner's PM examination request form. In addition, bodies are viewed after staff are provided with only verbal communication of the identity of the deceased from those visiting the mortuary. No further identification check of the body is performed prior to the viewing. These practices pose a risk of releasing, conducting a PM examination or viewing of a wrong body. The establishment is required to review its current systems to ensure three identifiers are available to identify a body prior to release, PM examination and viewing.	**Major**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	While the establishment records tissue retained at PM examination for histological examination, no record of receipt is sent to the mortuary upon arrival at receiving establishments. This poses a risk of loss of traceability of retained tissue samples.	**Minor**

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	While the premises were found to be generally clean, some areas where maintenance was required were identified: • Damage, the size of a table tennis ball in a number of areas, to the floor; • seals have eroded around the bases of PM tables; • screws are missing in side access panels of the PM tables creating gaps, potentially allowing ingress of organic material and contaminated water. The body store area is a designated dirty area as bodies are transferred directly from the PM suite to the body store area. One wall in the body store area is not sealed and therefore porous. Corners of pillars in this area are also damaged exposing porous material underneath, making it difficult to clean and effectively decontaminated this area.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The current upper trigger point for the refrigerated body store alarm is 10^{o}C. This means that a temperature deviation from the advised storage temperature of around 4-6^{o}C may not trigger the alarm and therefore alert establishment staff to a deviation in temperature within an appropriate timescale, risking the condition of the bodies in storage.	**Minor**
g) Bodies are shrouded or in body bags whilst in storage	Bodies which have undergone a PM examination are not routinely fully shrouded afterwards; the heads are left exposed.	**Minor**

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	Wooden instruments are used for measuring bodies in the mortuary. These are porous and therefore difficult to clean and decontaminate. These should be disposed of and replaced with non-porous replacements	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(a)	The HTA advises bodies should be moved into long term freezer storage after 30 days in refrigerated storage. While there is a system in place to identify when bodies have been in refrigerated storage for more than 30 days, the establishment do not initiate enquiries with the relevant parties until four weeks after the arrival of the body into the mortuary. The DI is advised to review this process to initiate enquiries at and earlier stage to help ensure that all bodies are transferred, when required, in to long-term freezer storage in line with the HTA's guidance.
2.	GQ1(g)	No Persons Designated (PDs) have been identified to oversee the seeking of consent for perinatal and paediatric PM examinations. The DI is advised to appoint PDs in the maternity unit to help with oversight and ensure only those suitably trained and assessed as being competent are seeking consent for PM examination.
3.	GQ6(a)	Not all the information contained within the mortuary register is stored electronically; only those bodies that require a PM examination are entered in to the electronic system. The DI is advised to risk assess not using the electronic system for all bodies entered in to the paper mortuary register and consider the benefits of storing this information electronically.
4.	GQ6a	The NOD forms were found to be attached to body bags using safety pins. The DI is advised to risk assess the use of pins to attach the NOD form to body bags of bodies that may be an infection risk.
5.	T1(c)	The DI is advised to ensure all clinicians are reminded that the identity wristband on the body should be used to directly verify the identity of the deceased when performing checks to complete cremation paperwork and not solely rely on memory for the identifiers. This will help to ensure they are completing cremation paperwork for the correct person.
6.	T1(c)	The DI may wish to consider using the unique mortuary number as an additional identifier for bodies while in the care of the mortuary. This number can be added to the wristbands and will help identify unknown bodies until they are formally identified or differentiate bodies with same and/or similar names.
7.	PFE1(d)	The door to the lobby area adjacent to the mortuary where both hospital and community bodies are taken prior to being transferred into the mortuary body store area, has the facility of a key lock in addition to a key code lock. The DI may wish to consider using both lock systems to increase the security to the mortuary.
8.	PFE2(e)	While the refrigerated body store alarm is tested for deviations above the upper limit temperature trigger point, the lower limit temperature trigger point is not challenged. The DI is therefore advised to challenge the lower temperature alarm trigger point to assure himself the alarm will activate if the temperature falls below the set trigger point.
9.	PFE2(e)	While regular manual challenges to the fridge and freezer alarms are conducted, those expected to respond to the activated alarm are informed in advance of testing. The DI is therefore advised to challenge the system without pre-warning those expected to respond to the activated alarm to assure himself an appropriate response will occur.

Concluding comments

Despite the number of shortfalls identified, areas of good practice were observed during the inspection. The establishment demonstrated a commitment to the continual improvement of practices and compliance with the HT Act. Areas of good practice include:

- All visitors to the mortuary are asked to add their initials to a wipe board inside the entrance to the mortuary, allowing staff to identify those who are in the mortuary as they enter;
- In addition to permanent records, wall checklists are present in the PM suite allowing staff to easily identify what has been cleaned, by whom and when, as well as those tasks outstanding;
- Wishes of the family are obtained by the Coroner's office and communicated to the mortuary prior to the PM examination. Any tissue retained during PM examination is then communicated to the family and their wishes with regards to the retained tissue are reconfirmed by the Coroner's office to ensure the family have not changed their minds;
- A variety of visual markers were used both on the wipe board and in the mortuary register, for example, to help identify same and/or similar names, long-term bodies, implanted devices and those ready for release.

All staff demonstrated a clear dedication to the role they undertake, a conscientious approach to the handling and traceability of relevant material and a compassionate approach to arranging viewings for families.

The Senior APT is a long serving member of staff who is very knowledgeable in his role. There is a good level of interaction and effective communication between the DI and those carrying out licensable activities.

There are a number of areas of practice that require improvement, including four major shortfalls and seven 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: 01 March 2019

Report returned from DI: 15 March 2019

Final report issued: 15 March 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: 05 July 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 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 for these 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.