Site visit inspection report on compliance with HTA licensing standards

Kingston Hospital

HTA licensing number 12023

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**

17 & 18 October 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 Kingston Hospital had met the majority of the HTA's standards, five major and fourteen 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 consent seeking procedures; standard operating procedures (SOPs); records management; storage of bodies; risks assessments for licensable activities; audits; traceability; maintenance of premises and equipment; security and body store alarms. The current DI has been in post since the end of June 2018.

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

Kingston Hospital (the establishment) is licensed under the Human Tissue Act 2004 (HT Act) for: carrying out post-mortem (PM) examinations; removal from the body of a deceased person of relevant material (for scheduled purposes) and storage of the body of a deceased person or relevant material which has come from a human body for use for scheduled purposes. The establishment has been licensed by the HTA since March 2007 and this report describes the fifth routine inspection, with the previous inspection occurring in July 2015.

The mortuary is a stand-alone, purpose-built building located within the grounds of the hospital. The entrance to the mortuary is via a shutter door leading from a public and loading bay area, with offices located at the rear. Community and hospital bodies are both brought to the mortuary via the shuttered door entrance. The doors leading to the body store are clear plastic allowing visibility into the body store area from the loading bay and public areas when the shutter doors are left open, which happens on occasion (see shortfall against PFE1(d)). At the time of inspection, proximity access door locks were being introduced to the mortuary to replace the existing door lock systems. Out-of-hours, Funeral Directors (FDs) and porters contact security, who unlock the shutter door to allow delivery of bodies from the community and the hospital to the mortuary.

Hospital bodies are transferred to the mortuary by porters. The bodies have an identification wrist band with name, date of birth (DOB), and hospital number. A notification of death form is also attached to the shroud of the body with name, DOB, date of death (DOD) and ward. For community deaths, the body is brought in by FDs or by ambulance staff accompanied by security (see *Advice*, Item 1). The bodies also have a wrist band with name (or unknown male/unknown female), DOB (or date of death (DOD)), address or place of death. In addition, a FD's admission sheet is completed for each body admitted to the mortuary. In normal working hours, the mortuary staff receive the body and check the wrist band details and enter them into the mortuary register and a unique mortuary number is generated for every body admitted to the mortuary. All bodies are checked and entered into the mortuary register the next working day by mortuary staff.

Release of bodies occurs in normal working hours only and is undertaken by two members of mortuary staff. The FDs arrive with paperwork detailing the name, DOB and address of the deceased. This paperwork is cross checked against the details on the identity wrist band and the mortuary register.

The establishment operates a PM examination service. There are three pathologists, one of which is employed directly by the Coroner and three full time Anatomical Pathology Technologists (APTs); one of whom fulfils the role as Mortuary Manager. The establishment receives approximately 1200 bodies each year. They perform approximately 325 coronial PM examinations including, on average, five forensic PM examinations and two defence PM

examinations per year. Adult hospital consented PM examinations are conducted on rare occasions; on average five per year. 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 and midwives using the Stillbirth and Neonatal Death (SANDs) documentation (see shortfall against C2(b)).

The body store consists of 78 refrigerated body spaces, three of which are suitable for bariatric cases and six are dedicated for use for babies/paediatric cases. There is an additional temporary unit that can be erected in peak periods which gives an additional twelve refrigerated spaces. There are six freezer spaces, all of which were occupied at the time of inspection (see shortfall against PFE2(c)). There is also a standalone fridge for perinatal cases.

All permanent fridges and freezers are alarmed with upper and lower trigger points which, when triggered, sound in the mortuary. Out-of-hours, the alarm system alerts the hospital switchboard staff who in turn contact the on-call APT (see shortfall against PFE2(e)). Temperatures are recorded continuously by the monitoring system and are reviewed for trends via computer based software to help identify any potential issues with the equipment.

The mortuary has one PM suite with six sets of metal stands, onto which fridge trays are secured for PM examination (see shortfall against PFE1(a)). Only five stands are useable due to placement of the temporary body store within the PM suite. Dissection areas are located at the end of each stand. The Coroner's Officer faxes authorisation for a PM examination to the pathologist and the mortuary. The pathologist and APT check the identity of the body before evisceration (see shortfall against GQ1(b)). Since mid-2017, material retained at PM examination for histological analysis is placed into unlabelled cassettes, documented and packaged in the mortuary before being sent to the histopathology laboratory with a histology request form. Once received into the histology laboratory, samples are transferred to new cassettes labelled with a unique number generated in the laboratory. Samples are then entered into the histology computer database (see shortfall against T1(g)). Relatives' wishes with regards to the fate of any tissue retained following PM examination is managed by the establishment's Cellular Pathology Service Manager (see shortfall against T2(b)).

Stillbirths and perinatal deaths are transferred to the mortuary within a few hours by porters in a dedicated transfer bag. The establishment removes relevant material from deceased infants/children brought into A&E under pre-emptive authorisation of HM Coroner following the Sudden Unexpected Death in Infants/Children (SUDIC) protocol.

Description of inspection activities undertaken

Traceability audits of body identifiers, storage locations and mortuary register details were conducted for three adult bodies and one paediatric body, including both hospital and

community cases, and from both fridge and freezer storage. The names for the adult cases and mortuary identification number were written on the fridge door identity plate. Discrepancies for one adult body was found in the mortuary register.

In addition, tissue removed during PM examinations for four cases between 2017 and 2018 were audited for traceability. Discrepancies were identified with one sample. Reverse audits were performed for six cases and no discrepancies were found.

Interviews were conducted with: Cellular Pathology Service Manager (the DI) who oversees the histological processing of tissue retained at PM examination; Bereavement Midwife who oversees consent seeking for perinatal PM examinations; Consultant Paediatrician and Matron who are both involved in removal of material in A&E from SUDIC cases; Consultant Pathologist who is the lead for adult PM examination consent seeking; Porter; Coroner's Officer; Trainee APT based at an affiliated unlicensed body store. Discussions were undertaken with the Mortuary Manager and an APT based at the establishment.

Material held for the police

Under s39 of the Human Tissue Act 2004, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored at the establishment were reviewed by the HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

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	The SOP for seeking consent for a PM examination lacks sufficient detail for a user to follow the procedure.	**Minor**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training	Consent for perinatal/paediatric PM examinations is sought by trained clinicians and midwives. However, there is no refresher training which addresses the requirements of the HT Act or the HTA's codes of practice. *Standards C2(c) and C2(d) could not therefore be assessed.*	**Minor**

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	While the establishment has a number of the required SOPs in place, they lacked the required detail or attention to wording. These include but are not limited to: • MOR-19 Disposal of specimens taken at autopsy – no details of how a body is identified for repatriation of block and slides following a PM examination. • MOR-39 Hospital Consented PM examination – does not state an external examination of the body is conducted by the pathologist prior to evisceration. No details of the three points of identification used to identify the body prior to the PM examination.	**Minor**

	• MOR-46 Logging perinatal cases – does not detail three points of identification recorded when adding perinatal bodies to the mortuary systems. *See Advice, item 1*	
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	Although the pathologists are checking the identity of the bodies prior to evisceration, it was communicated to the inspection team that they are requesting mortuary staff eviscerate bodies prior to them conducting an external examination. The practice of evisceration prior to a thorough external examination by the pathologist is also contrary to Royal College of Pathologist's guidelines on the conduct of a PM examination.	**Major**
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The SOP MOR-29, refers to use of plastic trays on trestle tables in the corridor adjacent to the body store for contingency storage of bodies, if required. This practice does not ensure the dignity of bodies or that their condition will be suitably maintained.	**Major**
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	Many of the SOPs are authored and authorised by the same individual. This was given as advice and guidance by the previous inspection team.	**Minor**
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	No Persons Designated (PD) is identified for the A&E department where removal from SUDI cases occurs under the authority of the Coroner. This was identified as a shortfall by the inspection team during the previous site visit. While the shortfall was addressed by the establishment, the individual identified as a PD has since left the department. *See Advice, item 2*	**Minor**

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	Porters involved in licensable activities were unaware of HTA reportable incidents, who they would report them to or how to report the incidents.	**Minor**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	While risks were identified, risk assessments lacked details of all preventative actions to mitigate risks of HTA reportable incidents.	**Minor**
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	The mortuary had no unoccupied freezer or bariatric storage facilities at the time of inspection. A regular report is sent from the mortuary to the Trust detailing capacity status in the mortuary. However, at the time of inspection, the establishment were unable to demonstrate that the mortuary fridge and freezer capacity is on the Trust's organisational risk register.	**Minor**

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.	Bodies admitted to the mortuary with unknown identity are not adequately differentiated, for example, by using the unique mortuary register number; they are only identified as 'unknown male/female'; this includes 'unknown' forensic cases. There could potentially be more than one unidentified body in the mortuary at any one time and possibly from the same place of death. This increases the risk of mixing-up bodies. Forensic perinatal/paediatric and high-risk PM examinations are performed at other HTA licensed establishments but are returned to the establishment for release to FDs. Due to the nature of forensic cases, mortuary staff are not permitted to open the body bags in which the bodies are contained when they are admitted to the mortuary. However, the establishment do not have a system in place to indicate the identity of the body, or other information, to help maintain traceability of these bodies. See *Advice*, *item 10*	**Major**

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	Tissue taken during a PM examination is placed into unlabelled cassettes in the PM room. Often multiple pieces of tissue are placed into a single cassette. This tissue is transferred to the histology laboratory but it is not checked at the point of signing for receipt. Retained tissue is then transferred into cassettes labelled with a unique identifier generated by the histology database software. Tissue type is not identifiable until it has been processed and assessed macroscopically. Currently only two identifiers are entered onto the histology database for the tissue retained at PM examination.	**Minor**

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	A number of blocks and slides retained at PM examinations in 2017 are being stored in the histology department with unknown consent wishes. While the DI was attempting to follow these up with the Coroner's office, a regular follow up schedule was not evident.	**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	There were issues identified with the cleanliness and maintenance of the establishment, including but not limited to: • Hair and tissue debris in the PM suite drains; • Small areas of rust (size of a fifty pence piece) are present on the PM table stands; • A number of cracks are present in the PM suite floor and in some areas, the flooring edge is coming away from the adjoining wall. The last two issues identified above make the equipment/surfaces porous, so they cannot be adequately cleaned or disinfected.	**Major**

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	At the time of inspection the establishment was awaiting the installation of CCTV. The door leading from the body store area to the PM suite was found to be unlocked by the inspection team. This meant that access from the loading bay area was not restricted. It was communicated to the inspection team that on occasion the shutter doors to the loading bay area are left open. This potentially would allow access to the mortuary by unauthorised persons and at least, visibility of the body store from the public area outside the mortuary.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	Due to the limited number of bariatric fridge spaces, a bariatric body was placed on a tray unsuitable in size, posing a risk of accidental damage to the body. Due to the limited freezer storage facilities, bodies were identified as being held in refrigerated storage for periods far in excess of the HTA's recommended 30-day time scale.	**Major**
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	The fridge alarm system is not manually challenged by the establishment staff. The system is only challenged once annually as part of the routine maintenance testing and may not necessarily provide the DI with sufficient assurance that the alarm will trigger when required. In addition, all alarm challenges should be recorded. *See Advice, item 6*	**Minor**
g) Bodies are shrouded or in body bags whilst in storage	During the inspection a body was observed to be in refrigerated storage without being shrouded. All bodies should be fully covered whilst in storage.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
b) Equipment is appropriate for the management of bariatric bodies	Due to the lack of availability of a bariatric concealment trolley, bariatric bodies are transferred to the mortuary using hospital beds and are covered over with blankets to disguise them whilst travelling through public areas of the hospital. This practice risks jeopardising the dignity of the deceased and could cause distress to other users of the hospital.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(a)	SOP MOR-31 describes the process by which bodies from the community are brought into the mortuary by ambulance staff. However, establishment practice is for ambulance staff to take the body to the A&E department, then transferred to the mortuary by porters. As ambulance staff are not trained in the procedures of the mortuary, the DI is advised to remove this process option from the SOP and continue with the current procedure.
2.	GQ1(g)	The DI is advised that staff involved in licensable activates in other departments are invited to HTA governance meetings to discuss matters relating to HTA-licensed activities.
3.	T1(d)	The DI may wish to consider strengthening the same and/or similar name procedure by using an another visual prompt, for example, a coloured wrist band on these bodies, in addition to the signs on the fridge doors.
4.	PFE1(d)	Currently there is no personal alarm system in the viewing room area, only in the waiting area outside the viewing room. The DI is advised to look at ways in which the safety of staff, the deceased and visitors are ensured during viewings.
5.	PFE2(d)	During the site visit the inspection team observed a large icicle hanging from the fan of the freezer on to the top body tray. The DI is advised to ensure regular checks of the freezer are performed to provide assurance it is working optimally.
6.	PFE2(e)	The current upper trigger point for the freezer is -5^{o}C. The DI is advised to reduce this trigger point to nearer to the set running temperature and the HTA's guideline of -20^{o}C. This will facilitate the correct storage temperature of long-term bodies and ensure staff are made aware of insufficient freezer function at a more appropriate temperature.
7.	PFE2(i)	The DI is advised to formalise any agreements with third parties as part of their contingency plan for storage of bodies. This will help ensure that in times of high demand, contingency storage will be available.
8.	PFE2(f)	The current temperature monitoring system produces reports for the fridges and freezer storage units. The DI is advised that these reports should be reviewed on a weekly basis in order to facilitate the prediction of storage facility failure.
9.	T1(c)	For viewings only the name of the deceased is verbally obtained from those wishing to view the body. The DI is advised to implement a system whereby three identifiers for the deceased is obtained from those wishing to view the body prior to commencement of the viewing.
10.	T1(c)	The DI is advised to develop a system that will help ensure traceability of 'unknown' and forensic bodies, including when they are transferred and subsequently returned to the mortuary. For example: • to include any identifying information or details that are known and the unique mortuary register number and other relevant information on the transfer form; • for forensic cases, placing an identification band through the zip loops of the body bag which states the identification details of the body, unique mortuary register number or any details that are known.

		It is expected that bodies returned from referring establishments are labelled to the required standard. NB: Identifiers should not be written on the external surface of body bags.

Concluding comments

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 of the deceased at the mortuary. The Mortuary Manager is a long serving member of staff and very knowledgeable in the role they undertake. 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, five major shortfalls and fourteen 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: 13 November 2018

Report returned from DI: [date]

Final report issued: 05 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: 01 November 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.