Site visit inspection report on compliance with HTA licensing standards

York Teaching Hospital NHS Foundation Trust

HTA licensing number 12093

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**

9 & 10 April 2019

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 York Teaching Hospital NHS Foundation Trust had met the majority of the HTA's standards, one major and twelve minor shortfalls were found against the Consent, Governance and Quality systems, Traceability and Premises, Facilities and Equipment standards. These related to the policy and Standing Operating Procedure (SOP) for seeking consent for post-mortem (PM) examination; training for seeking of consent for adult PM examination; the consent form used for adult PM examination; SOPs; risk assessments; the use of three identifiers; premises, equipment and body store alarm testing.

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

York Teaching Hospital (the establishment) is part of the York Teaching Hospital NHS Foundation Trust. This report describes the activities carried out in the mortuaries located at York Teaching Hospital (the hub site) and Scarborough Hospital (the satellite site). The mortuary is managed by Cellular Pathology, part of the Laboratory Medicine directorate. The DI is a Head Biomedical Scientist and the Corporate Licence Holder contact is the Medical Director of the Trust.

The establishment receives approximately 2,000 bodies each year from deaths in the hospital and the community. The establishment performs around 400 PM examinations annually, the majority of which are conducted for HM Coroner for the Western District of North Yorkshire. These PM examinations include high-risk (up to category three) and around four adult hospital (consented) PM examinations. Bodies requiring PM examination from Scarborough Hospital are transferred to another HTA-licenced establishment. Forensic PM examinations are also performed at the hub site and material is held under the Police And Criminal Evidence Act 1984 (PACE) at the establishment. Paediatric/perinatal PM cases are transferred to another HTA-licensed establishment.

There is an overarching consent policy which details the requirements for seeking consent (see shortfall against C1(a)). Consent for paediatric/perinatal PM examinations is sought at the establishment by clinicians and midwives, including a bereavement midwife who have received training in seeking consent for PM examination. Consent for adult hospital PM examinations is sought by senior hospital clinicians with direct support from consent trained Bereavement Service or Anatomical Pathology Technologists (APTs) (see shortfall against C2(a)).

The establishment has 90 permanent refrigerated body spaces, 10 of which are semi-bariatric. A temporary refrigerated unit is available for the storage of bariatric bodies which can be erected as required. There are two freezer spaces available for the storage of long-term bodies which are utilised for both sites. At the time of the inspection these spaces were unoccupied (see shortfall against GQ1(a)). There is additional temporary refrigerated storage available which can be erected during busy periods which increases the total capacity to 100 spaces (see shortfall against PFE2(c)).

All fridges and freezers are monitored by an electronic monitoring system and alarmed with upper and lower trigger points, which when triggered sound locally and also externally to switchboard. An engineer is called and the on-call APT if the alarm is triggered out-of-hours (see shortfall against PFE2(e)).

Swipe card access is required for all external doors to the mortuary, which are covered by CCTV. CCTV can be monitored by staff internal to the mortuary and is also monitored by the security department. An intercom system is also in place for staff to identify visitors to the

department prior to granting access. Funeral Director (FD) access is at the rear of the premises and consists of a roller shutter door which is lowered during the transfer of bodies to and from FD vehicles. All visitors to the mortuary are required to sign in upon arrival and detailed records are kept.

Across both sites, porters transfer and admit all hospital bodies. They are also responsible for admitting community bodies during out-of-hours periods. Hospital bodies are transferred from the wards using a concealment trolley. The route taken to transfer bodies at Scarborough Hospital from wards requires the use of a lift down to the mortuary. This lift is unable to accommodate bariatric bodies so an alternative route has been identified. However, this route and the methods used for transfer have not been risk assessed (see shortfall against GQ6(a)). Upon admission, the mortuary register and body store location whiteboard are completed by the porters using the information on the body label transferred and kept with each body (see *Advice,* item 5). At Scarborough Hospital a 'fridge card' is also completed and placed on to the corresponding fridge door.

The mortuary staff complete body identification checks as soon as possible on the day, or the next working day if the body was admitted out-of-hours using the body labels and wristbands for bodies received from hospital wards, and the wristband only for community bodies. Bodies are labelled with three identifiers and a unique reference number generated from the mortuary register is added to the body label. Documentation brought by FDs at the time of release is inconsistent, meaning bodies are predominantly released from the mortuary using only one or two identifiers (see shortfall against T1(c)). Release of bodies is completed by APT staff within normal working hours.

Training in mortuary practices and procedures has been provided to porters by the APTs and records of training are maintained and refresher training is provided annually.

The PM suite contains three PM stands, each with an associated dissection area. When removing bodies from refrigerated storage, APTs carry out initial identification checks against Coronial or consent documentation and again with the pathologist prior to the external examination and evisceration commencing. Pathologists complete each PM examination before commencing the next case to help mitigate the risk of a mix-up of organs and tissue samples between cases. All PM cases are assigned a unique reference number which is recorded within the mortuary paperwork along with a record of all specimens taken during PM examination. All retained PM histology specimens are labelled with the unique reference number and are taken and processed at the histopathology laboratory on site. High-risk PM examinations are completed at the end of the routine PM session.

Two Consultant Histopathologists based at the establishment fulfil the PM service.

A Mortuary Manager and two other APTs routinely staff the mortuary at York Teaching Hospital with a further APT staffing Scarborough Hospital as a lone worker. Consideration

has been given to this staff member working alone with the provision of a personal alarm and is part of regular mortuary meetings. The APT also attends the hub site at least four times per year to maintain competency of key skills. During annual leave periods, APT staff from the hub site cover the satellite site. Mortuary staff work on-call and provide cover for the hub and satellite site during out-of-hours periods.

The establishment has a maternity unit; there is no refrigerated facility for the storage of pregnancy remains, fetuses or stillbirths. However, there is a well-documented policy in place for the management of these cases. Cold and cuddle cots are used and bodies are transferred to the mortuary as soon as possible.

Removal of tissue may occur in the hospital's Accident and Emergency department in cases of sudden unexpected death of an infant or child (SUDIC). The process and documentation for these cases were reviewed as part of the inspection and found to be compliant with current guidelines.

Scarborough Hospital (satellite site)

Scarborough Hospital mortuary is a body storage facility only. Although there is a PM room, this has not been used for some time for PM examinations. It is however, routinely used for the removal of donated tissue for research and human application (see shortfall against PFE3(c)). Hospital bodies admitted to the mortuary that require a Coronial PM examination are transferred to another HTA licensed establishment as this hospital is situated within another Coronial district. The HTA licence is also maintained as removal of tissue may occur in the hospital's Accident and Emergency department for SUDIC cases.

The mortuary at the satellite site has a total of 23 refrigerated body spaces. There is additional temporary refrigerated storage available which was in use at the time of the visit increasing the total capacity to 35 spaces. This unit is also capable of storing two bariatric bodies. There is no freezer storage available, bodies requiring long-term storage are transferred to the hub site.

Scarborough mortuary can be used as contingency storage for the hub premises during busy periods and vice versa. There is also an unlicensed body store within the same Trust which can also be utilised.

There is an external access door to the mortuary, for the admission and release of all bodies, which is secured by swipe card access and monitored by departmental CCTV, which can be reviewed by staff to assess who is requesting access. Portering staff transfer and admit all hospital bodies using a concealment trolley (see shortfall against GQ6(a)).

Description of inspection activities undertaken

The establishment has been licensed by the HTA since June 2007. Previous routine site visit inspections took place in February 2011 and May 2015. This report describes the third routine site visit inspection in April 2019. Formal interviews were conducted with the DI, Quality Manager, Mortuary Manager, mortuary staff, hospital porters, Consultant Histopathologists and PM consent seekers (adult and perinatal). A visual inspection of the mortuaries was carried out, including body store areas, viewing rooms and the PM suites.

Visits to the maternity and A&E departments were undertaken at both sites.

Traceability audits of bodies being stored at the hub and satellite site was undertaken. Body identifiers, storage locations, mortuary register details and associated documentation were reviewed and cross referenced (three adult bodies, one perinatal body and three adult bodies, respectively). Although all bodies were labelled with at least three identifiers at both sites, the mortuary registers lack sufficient detail to check and confirm that the correct body is being released and signed for (see shortfall against T1(c)). In addition, an audit of three cases where tissue had been retained for histological analysis following PM examination was conducted at the hub site (one adult hospital consented case and two Coroner's cases). The inspection team visited the histopathology laboratory to review the stored tissue, associated traceability records and reviewed the relative's wishes regarding the fate of the tissue following its analysis. No anomalies were found.

Material held for the police

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

Inspection findings

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

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	The Trust policy detailing the procedure for hospital consented PM examinations does not accurately reflect the consent requirements of the HT Act 2004. The policy refers to the hierarchy of qualifying relationships however, it also refers to gaining consent of 'family' or 'those close to the deceased before death' in other sections. The policy should be consistent in detailing who the most appropriate person is to give consent. The HTA did not find evidence that the establishment has removed, used or stored relevant material without consent from the appropriate person under the HT Act. However, because the establishment's policy is not clear, consent could be sought from the incorrect person. Although the consent policy contains some detail of how consent is obtained, the process to be followed lacks sufficient detail. (see *Advice,* item 1)	**Minor**
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	The form used by the Coroner's office to record the relatives wishes for tissue gives the option of tissue to be used for research purposes. However, the establishment does not have any current research studies being undertaken. Therefore, tissue is routinely disposed of as soon as the instruction to use tissue for research purposes is received. Those giving consent are not aware of this practice, meaning they are not fully informed when they are making a decision regarding the fate of tissue.	**Minor**

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	Although it is documented on the adult consent forms that relatives can withdraw their consent, the date and time that consent was given and the time frame in which consent can be withdrawn is not recorded. This creates a risk that the family will not be offered the minimum 24 hour time period to withdraw consent.	**Minor**
g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	The form CPM/1 – 'Consent to a Hospital Post Mortem Examination on an Adult' references the HTA's old Codes of Practice (2006) and uses the term 'next of kin'.	**Minor**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	Consent forms reviewed during inspection did not always contain the signature of a consent trained witness. *As a result standards C2(b), (c) and (d) cannot be met.* (see *Advice,* item 2)	**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.	Although the establishment has a range of SOPs covering licensable activities, staff are not necessarily following them, some do not reflect current practice, or they require further detail or clarification. Examples include, but are not limited to: MO_SOP_AUTOPSIES – Although the SOP states that three points of identification (ID) on body labels must be checked against paperwork provided by the Coroner prior to PM examination, it also states that pathologists can decide whether to proceed if one of the identifiers is missing. This does not reflect current practice and does not comply with HTA standards or RCPath guidelines for conducting routine Coroner's PM examinations; MO-SOP-VIEWING – states that those visiting must provide three identifiers relating to the body however, it does not state these identifiers are then checked against the body label/wristbands prior to conducting the viewing. In addition, this SOP contains information regarding 'bodies for long-term storage' which is limited. MO-SOP-BOD RELEASE – This procedure is not always being followed. For example, the SOP states that FDs must bring paperwork which includes the three minimum identifiers. However during inspection it was evident that FDs are arriving with only one or two idenifeiers which poses a risk of release of a wrong body. (see *Advice,* items 3 and 4)	**Minor**

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	Although the establishment has assessed a number of risks associated with licensed activities, the risk of undertaking a PM examination not in line with the consent given, has not been assessed. There is no risk assessment in relation to the transfer of bariatric bodies at the satellite site. As these bodies cannot be transferred to the mortuary via the usual route from the adjacent hospital building, the DI cannot be assured that current practice is appropriate or maintains the dignity of the deceased.	**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	Not all funeral directors bring documentation with them when collecting bodies and those that do, may not state the required three identifiers. During the inspection of the satellite site a release of body was observed. It was noted by the inspection team that the paperwork brought by the FD only stated the full name of the deceased and the spelling of both forename and surname contained discrepancies. The mortuary register signed by the FD and APT as confirmation of release and identification check of the body does not contain sufficient detail to confirm that the correct body is being released and signed for. Although the SOP states that three identifiers are requested from those making appointments and attending to view bodies, it was highlighted that viewings at the satellite site are routinely arranged using name only.	**Major**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained	Whilst the premises were clean, there were several areas which required maintenance work: • The shelf holding the mortuary register at the hub is damaged and tape is being used to cover damaged areas which would make effective decontamination difficult; • Several of the walls in the body store area at the hub had minor damage exposing bare plaster, making the surface porous; • The refrigerated body storage units at the satellite showed areas of minor damage and rust to the bottoms of the doors, making the surface porous.	**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	Bariatric storage arrangements rely solely on the use of the erectable temporary storage units at both sites. These units are also used for additional contingency storage during peak periods. Bodies were identified in refrigerated storage that exceeded the recommended 30-day timeframe, despite there being freezer capacity to store them. (see *Advice,* item 6)	**Minor**
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	Although the fridges have alarms, they are not regularly tested to ensure they will trigger when temperatures deviate from set ranges.	**Minor**
f) Temperatures of fridges and freezers are monitored on a regular basis	There is an electronic temperature monitoring system, but the temperatures are not reviewed by mortuary staff for trends, meaning potential major issues with the equipment may not be identified before they occur.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The establishment do not have records of recent service or maintenance for the PM suite ventilation system at the satellite site, despite the room being used. The DI cannot be assured that the system is providing the necessary ten air changes per hour.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(b)	The DI is advised to produce a robust PM consent SOP which details steps to be followed when seeking consent for PM examination and the responsibilities of the staff groups involved. This is particularly important given that the establishment undertakes adult hospital PM examinations infrequently.
2.	C2(a)	In addressing the shortfall identified against standard C2(a), the DI is advised to explore options to help provide assurance that suitably trained individuals seek consent for adult hospital PM examinations, or are accompanied by someone who is suitably trained and appropriately documented on the PM consent forms.
3.	GQ1(a)	The DI is advised to produce a separate robust documented procedure for the management of long-term bodies, including timescales for escalation and condition checks of bodies.
4.	GQ6(a)	The DI should consider standardising SOP formats for consistency. Some SOPs include a detailed risk assessment (RA) whilst others do not. Standardising the approach to the inclusion of the RA would ensure staff following the processes are also aware of the risks involved, including all risks associated with HTARI categories.
5.	T1(a)	The material of the body labels present a risk that the identification details could be lost if the tag becomes wet, soiled or damaged, whilst bodies are in storage or otherwise. The DI is advised to consider other, more robust identification labels for bodies.
6.	PFE2(c)	The DI is advised to risk assess whether the amount of freezer storage space available at the hub site is sufficient to meet requirements when reviewing the long-term body storage procedure. In addition, the DI is advised to risk assess the bariatric storage arrangements to ensure bariatric storage is maintained during peak periods of activity.

Concluding comments

The DI is well supported in his role by the Quality Manager, the Bereavement Midwife, the bereavement service, the Mortuary Manager and mortuary staff. The mortuary team are experienced and have worked together for a number of years. The team as a whole appear to be conscientious, enthusiastic and understand the importance of good mortuary practices. There are several areas of strength and good practice:

- There is a good communication process between the mortuary and Coroner's office which ensures the timely receipt of both the families wishes form prior to the release of a body and the Coroner's end of inquest authorisation letter, so the fate of tissue/ organs removed at PM examination can be processed promptly;
- The consent training for paediatric/perinatal PM examinations has been well developed between all staff involved and the use of a file on the maternity unit to identify trained individuals quickly is beneficial;
- Whilst there is a number of upcoming improvements to be made to the facilities in the mortuaries at both York and Scarborough, it is evident the staff show due care and diligence in the cleaning of the premises.

There are a number of areas of practice that require improvement, including one major shortfalls and twelve 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 May 2019

Report returned from DI: 30 May 2019

Final report issued: 11 June 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: 11 October 2019

Appendix 1: HTA licensing standards

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

Consent
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice. b) There is a documented standard operating procedure (SOP) detailing the consent process. *Guidance* *This should include who is able to seek consent, what training they should receive, and what information should be provided to those giving consent for post-mortem examination. It should make reference to the use of scanning as an alternative or adjunct to post-mortem examination.* c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice. *Guidance* *Information on consent should be available in different languages and formats, or there is access to interpreters/translators. Family members should be given the opportunity to ask questions.* d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for

burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.

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

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

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

Guidance

This may be based on the HTA's model consent form for adult post-mortem examinations available on the HTA website, or in relation to infants, the resources pack developed by the Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality systems

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

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

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

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

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

Guidance

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

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

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

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

Guidance

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

The family's permission should be obtained for any 'cosmetic' adjustments or other invasive procedures prior to release of bodies, for example, sewing the deceased's mouth to close it or

the removal of a pacemaker. It is also good practice to discuss with the family any condition that may cause them distress, for example when viewing or preparing the body for burial, such as oedema, skin slippage of signs of decomposition.

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

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

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

Contractors, visiting and temporary staff and funeral service staff bringing bodies out of hours

should be required to read relevant standard operating procedures and sign to confirm their understanding.

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

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

Guidance

Records include mortuary registers, PM examination records, tissue retention forms and records of transfer and return of organs/tissue sent elsewhere for examination.

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

Relevant staff should have knowledge of risks and the control measures that have been taken to mitigate them.

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

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

similar names.

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

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

Guidance

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

Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place present a risk to traceability. Full identification checks should be made when theyare placed back into normal storage.

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

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

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

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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

a) The premises are clean and well maintained.

Guidance

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

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

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

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

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

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

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

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

Guidance

Temperature monitoring should enable the establishment to identify trends and may mitigate

the risk of a possible fridge failure.

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

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

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

Guidance

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

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

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

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

Establishments should consider entering in to Mutual Aid Agreements

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

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

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

   i. fridges / freezers
   ii. hydraulic trolleys
   iii. post mortem tables
   iv. hoists
   v. saws (manual and/or oscillating)

Guidance

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

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

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

Guidance

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

d) Staff have access to necessary PPE.

Guidance

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

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

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

Guidance

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

Appendix 2: Classification of the level of shortfall

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

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

1. Critical shortfall:

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

or

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

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

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

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

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

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

2. Major shortfall:

A non-critical shortfall that:

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

or

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

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

3. Minor shortfall:

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

departure from expected standards.

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

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

Follow up actions

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

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

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

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