Site visit inspection report on compliance with HTA licensing standards

Royal Preston Hospital

HTA licensing number 12037

Licensed under the Human Tissue Act 2004 for the

- **making of 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**

13 and 14 December 2017.

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 Royal Preston Hospital had met the majority of the HTA's standards, four minor shortfalls and four major shortfalls were found against the Consent, Governance and quality systems, Traceability and Premises, facilities and equipment standards. 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

Royal Preston Hospital (the establishment) is part of Lancashire Teaching Hospitals NHS Foundation Trust. The establishment has been licensed by the HTA since June 2007. The establishment is licensed for the making of a post-mortem (PM) examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes. The DI is a consultant pathologist, the Corporate Licence Holder (CLH) is Lancashire Teaching Hospitals NHS Foundation Trust and the CLH contact is the Medical Director for the Trust.

The mortuary admits approximately 2300 bodies per year from the hospital and community. The establishment has undertaken approximately 600 adult PM examinations in the past 12 months, with the vast majority performed under coronial authority. Perinatal and paediatric cases are transferred to another HTA-licensed establishment. The establishment undertakes high-risk PM examinations (cases known or suspected to involve up to hazard group 3 biological agents). Home Office PM examinations are also conducted, with 36 carried out in 2017. Adult hospital (consented) PM examinations take place very occasionally with five having been carried out since 2011. In adult cases, consent is sought by clinical staff who are accompanied by trained facilitators from the bereavement services using a Lancaster Teaching Hospitals NHS Foundation Trust consent form. Training on HTA standards and consent is provided by the DI for bereavement services, persons designated and Coroner's staff as part of their induction (see *Advice*, item 3). Consent for perinatal and paediatric hospital PM examinations is sought by clinical staff who use a consent form (provided by the establishment to which the cases are referred) which is supported by information leaflets provided by the Trust or Stillbirth and Neonatal Death (Sands) charity. The bereavement midwife is the lead consent seeker for perinatal cases in the Trust and has attended specific consent training conducted by Sands. This training is cascaded to clinicians and includes relevant information on the HTA Codes of Practice.

The mortuary has four full-time Anatomical Pathology Technologists (APTs). There are also two apprentices that rotate between the mortuary and the histology laboratories. A lead biomedical scientist is the Mortuary Manager. Porters are responsible for the transfer of bodies from hospital wards to the mortuary. During working hours, mortuary staff, ward staff and members of the bereavement services team are involved in organising and conducting viewings of the deceased. Out of hours, viewings are organised and conducted by the site manager with assistance from ward staff and porters (see *Advice*, item 20).

The mortuary is located within the main hospital building. The entrances to the mortuary from the hospital, and at the rear, are secured by swipe card access and there is an intercom system (with video) to verify the identity of the person requesting entry to the mortuary. There is closed-circuit television (CCTV) monitoring of some external mortuary areas and out-of-hours, the mortuary is locked and alarmed. The 'BORIS' refrigerated body

storage facility is located outside, close to the rear entrance of the mortuary and is secured by a key lock (see *Advice*, item 18).

The mortuary has 52 refrigerated spaces for the storage of bodies. This includes four spaces for bariatric cases, eight isolation spaces that are used for infectious and/or forensic cases and four dedicated spaces for perinatal/paediatric bodies (see *Advice*, item 14). There are 30 additional refrigerated spaces in the 'BORIS' facility. There are four freezer spaces in the mortuary (see *Advice*, item 16) and although at the time of the inspection the freezer had spaces available, staff informed the HTA that more freezer space is required throughout the year (see *Advice*, item 19). The establishment has contingency arrangements for the refrigerated storage of bodies at an unlicensed body store at the Trusts other main hospital site at Chorley.

The temperature of the mortuary fridges and 'BORIS' facility are monitored and alarmed locally. There is also an external alarm system linked to two mortuary mobile phones. In the event of a deviation from the expected storage temperatures, mortuary staff hear the alarm system in the office and out of hours, the on call APT will be alerted by an automated call to the mortuary mobile phone. The temperature is recorded by a monitoring system and trends are reviewed weekly. Although the system often alarms when staff access the fridges, mortuary staff do not conduct regular testing of the fridge alarm system to verify that it triggers and is responded to as expected (see shortfall against standard PFE2(e)). All mortuary fridges and freezers are served by the hospital's emergency power supply system and are maintained under service contracts.

Bodies are transferred from hospital wards to the mortuary by portering staff. The mortuary supervisors are trained by mortuary staff who cascade the training to the wider portering team (see *Advice,* item 10). Perinatal and paediatric cases are transferred from the Maternity department to the mortuary by ward staff or porters. There is no refrigerated storage in the Maternity department. Porters complete the mortuary register for each body admitted to the mortuary. In addition to paper records, the mortuary uses a bespoke electronic register to record the deceased's details, including identification information, admission, release and any samples taken during PM examinations. The electronic register includes a system to automatically identify bodies with same or similar names. Bodies are released from the mortuary by mortuary staff only.

The mortuary's main PM suite contains three PM tables and one dissection bench. APTs carry out identification checks and external examinations prior to the evisceration of a body (see shortfall against standard GQ1(b)). A 'one-at-a-time' system is used to avoid mix-ups of organs and tissue samples removed during PM examinations. The main PM suite is showing signs of wear and requires some work to address these (see shortfall against PFE1(a)). There is a separate high risk PM suite with one downdraft PM table and one dissection bench.

Material taken during PM examinations is transferred to the establishment's pathology department for histological analysis or to other establishments for toxicology or other tests. Tissue transfer forms, histology forms and a tissue transfer book is completed to maintain traceability of the tissues. Organs, tissues and slides are stored in the pathology department which is secured by swipe card access. The establishment uses paper records and electronic databases to record sample details (see shortfall against standard T1(g)).

Sampling of tissues from deceased children in cases of sudden unexpected death in infancy (SUDI) is performed in the mortuary and not in any other area of the hospital premises.

The establishment performs post mortem computerised tomography (PMCT) scanning and is preparing to provide a council contracted full CT scan PM service on all suitable Coroner's cases in Spring 2018. Porters are involved in transferring bodies to the PMCT and mortuary staff are currently being trained in PMCT techniques (see *Advice,* item 6). Building work is currently underway to provide access to the CT scanner via the mortuary's main PM suite. This will prevent the PM suite being used for PM examinations during times when access to the PMCT scanner is required (see *Advice,* item 13).

Description of inspection activities undertaken

This report describes the HTA's third, routine site visit inspection of Royal Preston Hospital. The inspection team interviewed staff undertaking licensed activities, reviewed the establishment's documentation and conducted visual inspections of the mortuary including the body storage areas, PM suites, viewing room and the pathology department's storage areas.

A traceability audit was conducted for six adult bodies, including one body from the freezer, and one perinatal case. Storage locations and body identifiers were cross checked between the paper and electronic mortuary records to those on the bodies. No discrepancies were found. However, in relation to one adult case, the body was not fully shrouded to a standard that ensures the dignity of the deceased is maintained (see shortfall against standard PFE2(g)).The identification details of the perinatal case was not written on the fridge door in accordance with the establishment's documented procedures (see *Advice*, item 14).

Audits of traceability were conducted for whole organs, tissue blocks and slides from four PM cases, and included a review of the relevant consent documentation relating to the retention of the tissue. The following discrepancies were found (see shortfall against standard T1(g)):

- Two consent forms had been completed for one case, with contradicting consent statements.

- In one case, specimen documentation recording the number of blocks generated from tissue taken during PM examination did not match with electronic records and the number of blocks.
- In two cases, specimen documentation recording the number of slides generated from the respective tissue blocks did not match with the electronic records and the number of slides.

Consent forms from five adult hospital PM examinations were reviewed. The timeframe for withdrawing consent for the PM examination was not filled out on two out of the five forms (see *Advice*, item 2).

Home Office PM examinations are undertaken at the establishment. There are also specimens stored in the pathology department that have been sent to the establishment for specialist examination by Home Office pathologists. 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. 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		
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 Consent to examination and treatment policy (TP – 23) refers to the hierarchy of qualifying relationships as defined by the Human Tissue Act 2004 (HT Act) and the next of kin. This poses a risk that when seeking consent, the most appropriate person may not be approached. The consent to examination and treatment policy (TP – 23) does not refer to the adult hospital PM consent form; however, it does refer to, and provides a link to the paediatric forms.	**Minor**

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
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.	Evisceration of bodies for PM examination routinely takes place prior to examination by the pathologist. This is also contrary to the Royal College of Pathologist's guidelines on the conduct of a PM examination.	**Major**

GQ6 Risk assessments of the establishment's practises and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities are risk assessed on a regular basis.	The establishment's risk assessments do not identify all potential risks posed to the deceased and retained relevant material. *Refer to Advice, item 12*	**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	The establishment's procedures for identification of bodies do not always use three identifiers. • Bodies may be released from the mortuary using one, two or three identifiers. Some funeral directors do not bring any paperwork, stating only a name on collection of a body. • Identification of the deceased for viewings may be based on only one identifier (the deceased's name) provided by the family. • Labels on specimen containers for retained organs do not always contain three identifiers. This presents a significant risk of misidentification of the deceased or specimens from the deceased. The SOPs describing procedures for identification of bodies do not include details of the minimum number of identifiers that should be used, how the identification checks should be performed and the procedures to follow in the event of discrepancies being identified. *Refer to Advice, item 15*	**Major**
g) Organs or tissue taken during post mortem examination are fully traceable, including blocks and slides (including police holdings).	During the audit of retained tissue it was found that not all blocks and slides were fully traceable. There were discrepancies between the number of blocks and slides recorded in the electronic database and paper records to those actually stored. The contents of specimen containers in storage are not always recorded on the container itself or on the specimen checklist. Where these details have been recorded, examples were found where the information was inaccurate.	**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.	Although the mortuary premises are subject to regular cleaning, deterioration of some areas means that they cannot be cleaned and decontaminated effectively. Examples include: • Cracking of the floor tiles in the main PM suite and failure of the grouting. • The drains on the mortuary floor are becoming rusty and are cracking at the edges leading to porous surfaces. • In the main PM suite, there is a porous wooden bench and a unit which is cracked and splitting due to prolonged exposure to liquids. • The sealant around the floor and base of the PM tables in the main PM suite is failing.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
e) Fridge and freezer units are alarmed and tested regularly to ensure that they trigger when temperatures go out of upper and lower set range.	The fridge temperature monitoring alarm system is not tested regularly to assure the DI that it activates and is responded to appropriately in the event of deviations in temperature from the expected ranges.	**Minor**
g) Bodies are shrouded or in body bags whilst in storage.	Some bodies stored in the fridges were not shrouded to an acceptable standard. Some shrouds were not wrapped sufficiently and some shrouds were not big enough to cover the deceased. This compromises the dignity of the deceased.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(c)	The wording of the 'retention of tissue samples' paragraph on the consent form for adult hospital PM examinations does not clearly state that consent is required for blocks and slides to be retained for scheduled purposes. The DI is advised to rephrase this section of the form to help assure the DI that those giving consent are fully informed. The HTA have a model consent form available on the website, which the DI may wish to reference.
2.	C1(g)	The DI is advised to remind staff seeking consent for adult hospital PM examinations of the importance of completing consent forms in a consistent manner. This will help to ensure that the establishment can evidence that appropriate consent for hospital PM examinations and storage of PM samples has been given in accordance with the requirements of the HT Act. Consent forms should be audited to ensure that they are completed in a consistent manner and identify any additional training requirements for staff seeking consent.
3.	C2(b)	The DI is advised to update the presentation: HTA talk 2010 V2 as it refers to the old Codes of Practice. Although HTA training is provided to new staff, the HTA recommends that refresher training is provided on a regular basis, for example, annually.
4.	C2(d)	The DI is advised to undertake observations of those seeking consent in order to assess their competency. This may help to provide the DI with assurance that staff seeking consent are doing so appropriately.
5.	GQ1(a)	The DI is advised to ensure that references to the HTA's Codes of Practice in the establishment's documents are up-to-date. For example the 'Hospital PM request procedure (adult)' does not reference the current Codes of Practice.
6.	GQ1(a)	The DI is advised to ensure that SOPs relating to the new PMCT scanning service are developed. For example, the SOP for porters should include details of how they are notified of which bodies require PMCT examination, how body

		identification checks are performed and how bodies should be transferred to the scanner.
7.	GQ1(a)	The 'S PH PMPROCED_17.1' SOP refers to the 'next of kin'. The DI is advised to update this SOP so that it refers to the most appropriate person to give consent: the deceased themselves in life; their nominated representative; or, in the absence of these, a person who was in a qualifying relationship with the deceased prior to their death, and who is ranked the highest in the hierarchy.
8.	GQ1(d)	The following forms used by the Bereavement Services at Royal Preston Hospital are not subject to document control; • Hospital PM (adult) request procedure • SOP for Taking Consent for a Hospital Post Mortem The DI is advised to ensure all documents are subject to the same document control procedures to prevent unauthorised and 'out of date' copies being used inadvertently.
9.	GQ2(a)	The DI is advised to strengthen the audits of mortuary activities which are undertaken to include checks that the required standards are being met. For example, process audits of identification procedures should include verifying that three identifiers are used for identification of the deceased. Consent documentation relating to retained PM material should be audited to assure the DI that the wishes of the consent giver are being met. Audits can help to assure the DI that procedures are performed in accordance with the establishment's SOPs and identify areas where additional training may be required or where a documented process may require amending.
10.	GQ3(a)	Although the portering supervisors are trained by the mortuary staff and this training is cascaded to the wider portering team, refresher training is not scheduled. The DI is advised to deliver refresher training on a regular basis; for example, annually. The DI should also ensure that attendance at training is documented as this provides evidence that staff have received up-to-date training.
11.	GQ5(a)	The DI should improve awareness of the HTARI reporting requirements and the establishment's procedures for reporting incidents. The DI is advised include signs in the mortuary to remind staff of the requirements and procedures for reporting incidents, including near-miss incidents.
12.	GQ6(a)	In order to strengthen the establishment's risk assessments, the DI is advised to risk assess the activities outlined in GQ1 using the HTA reportable incident categories as a template to help identify potential risks. In particular, risks to the dignity and integrity of bodies and stored tissue should be included. Risk assessments should be reviewed regularly and after any changes to procedures. The DI is advised to ensure that staff have access to risk assessments and that familiarity with them is incorporated into the staff training programme. The DI may wish to review the 'Regulation of the Post Mortem Sector 2014-16' document on the HTA website, In particular, 'What we have learned' (page 20) provides helpful information in relation to risk assessments.
13.	GQ6(a)	The DI is advised to risk assess the current plans to access the CT scanner through the PM suite to assure himself that the transit of bodies through the

		main PM suite does not pose any additional risks, either to the deceased being transferred or those undergoing PM examinations.
14.	T1(a)	The DI is advised to ensure that the identification details of all bodies are clearly written on the relevant fridge doors, including all paediatric and perinatal cases in accordance with the establishment's procedures. The DI may wish to consider adding this procedure to the audit schedule.
15.	T1(c)	In addressing the shortfall against standard T1(c), the DI is advised to amend SOPs to help give assurance that a minimum of three identifiers, including at least one unique identifier, are used to identify bodies. SOPs describing the procedures for checking the identification of bodies should describe, as a minimum: • The minimum number of identifiers that must be used and what these identifiers are expected to be; • What records or documented information are required for the identification check and who this is provided by; • How the identification check should be performed; • The actions to take in the event of any discrepancies in the identifiers. The DI should ensure that the procedure for viewings includes details of what information the family are required to provide to mortuary staff so that the identification check of the deceased is conducted in line with the required standards. The DI may wish to consider introducing a form to gather this information from the family in a way that is sensitive and ensures that the required standard is met for the identification check of the deceased. The DI should ensure that there are three identifiers on all specimens removed from bodies at PM examination, including the organs (and tissue) retained for scheduled purposes. Furthermore, the specific contents of the containers must be identified.
16.	T1(e)	The DI is advised to ensure that when a body is transferred to frozen storage the identification tag on the body is positioned so that it can be easily read. This will help to ensure that the identification of bodies in frozen storage can be checked periodically and during release from the mortuary.
17.	T2(a)	The establishment informed the HTA that an agreement has recently been put in place with a Home Office pathologist (based at the establishment) to perform a six monthly audit of all materials held under PACE. The DI is advised to ensure that this takes place and that all retained material under PACE is included. This may help to mitigate any risk of retaining tissue for longer than necessary.
18.	PFE1(d)	The BORIS facility door is secured by a key lock to prevent unauthorised access. The DI is advised to increase security for the BORIS facility. For example, the facility could be covered by hospital's CCTV and linked to the existing mortuary alarm system. A risk assessment is advised.
19.	PFE2(c)	The HTA were informed that additional contingency freezer capacity is currently being organised using a facility at a local hospital. The DI is advised to finalise this arrangement to assure himself that the establishment has sufficient freezer storage if required. Further advice on contingency storage arrangements can be found in the HTA's guidance document 'Storage capacity and contingency arrangements in

		mortuaries: Guidance for DIs in HTA-licensed establishments', which is available on the HTA's website.
20.	PFE1(e)	The DI is advised to consider introducing a visitor log so any staff entering the mortuary out of hours would be recorded.
21.	PFE2(f)	Staff informed the HTA that repairs are often carried out on the PM tables. The DI is advised to put these essential items of equipment on maintenance contracts to mitigate against the risk of potential failures in the future.
22.	N/A	All staff working under the licence are advised to subscribe to the HTA monthly newsletter, via the HTA website, to keep abreast of relevant information for the areas they work in.

Concluding comments

The HTA observed some areas of strength and good practice during the inspection.

- Staff involved in the inspection, including those working in the mortuary and in bereavement services demonstrated a sensitive approach to their work and dedication to providing a good service;
- Staff demonstrated a willingness for continuous improvement and compliance with the regulatory requirements, and were open to the advice given by the HTA;
- The establishment seeks to ensure that mortuary staff are well trained, competent and provides opportunities for career development;
- The electronic records system has been custom-developed and provides a valuable means of facilitating traceability of bodies and tissue. This helps to assure the DI that there is audit trail for all bodies and relevant material.

There are a number of areas of practice that require improvement, including four major shortfalls and four 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: 15 January 2018

Report returned from DI: 22 January 2018

Final report issued: 29 January 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: 05 October 2018

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.