Site visit inspection report on compliance with HTA licensing standards

Russells Hall Hospital

HTA licensing number 30009

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**

11 & 12 April 2018

Summary of inspection findings

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

Although the HTA found that Russells Hall Hospital had met the majority of the HTA's standards, eleven minor and three major shortfalls were found against the Consent, Governance and Quality systems, Traceability and Premises, Facilities and Equipment standards. These related to: the documented procedure for seeking consent; the form to record hospital (consented) post-mortem examinations; information for relatives; training in seeking consent for perinatal/paediatric post-mortem (PM) examinations; standard operating procedures (SOPs); audits; staff appraisals; risk assessments; the use of three identifiers; tissue traceability; long term storage; and temperature alarms.

Particular examples of 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

Russells Hall Hospital (the establishment) is part of the Dudley Group NHS Foundation Trust. This report refers to the activities carried out at the mortuary at the establishment. The mortuary operates as a combined service with the Trust's bereavement service; both are managed by Cellular Pathology. The DI is a Consultant Histopathologist who is relatively new to the role of DI. The Coroprate Licence Holder contact is the Chief Executive of the Trust. The establishment is licensed under the Human Tissue Act 2004 (HT Act) for: 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 scheduled purposes.

The establishment receives approximately 2,100 bodies each year from both the hospital and the community and performs around 250 invasive PM examinations annually. This figure includes high-risk (up to category 3) cases and one or two hospital (consented) PM examinations. Routine adult PM examinations are performed under the authority of HM Coroner for the Black Country. Paediatric/perinatal PM examinations are transferred to another HTA-licensed establishment. Consent for paediatric/perinatal PM examinations is sought at the establishment by clinicians who may have received some training in the seeking of consent (see shortfall against C2(a)). Consent for adult hospital PM examinations is sought primarily by trained bereavement staff but mortuary staff are also trained (see *Advice*, item 4). The consent form for adult hospital PM examinations is predominantly based on the HTA's model consent form (see shortfall against C1(f)). The consent form used for paediatric/perinatal PM cases is based on the SANDs form (see *Advice*, item 2). However, the post mortem information documents for parents and relatives for hospital consented PM examinations does not reflect the HT Act or the HTA's codes of practice (see shortfall against C1(c)).

The establishment has 119 refrigerated body spaces including 24 spaces for semi-bariatric bodies and four freezer spaces (see shortfall against PFE2(c)), within the main body store. Fourteen of the refrigerated body spaces are 'double-ended' for direct access in to the PM room. In addition, the establishment has two 'cover-cool' blankets for bariatric bodies that cannot be easily refrigerated. There are an additional 12 refrigerated body spaces within a temporary refrigerated unit owned by the Trust (see shortfall against PFE2(e)) located in a unused PM room and 16 spaces in a secure external body store (see shortfall against GQ6(c)).

Access to the mortuary is controlled by swipe card and there is a camera and intercom system at all external doors so mortuary staff are able to verify who is requesting access. There is internal and external CCTV of the mortuary, including the viewing rooms, that can be monitored when required.

Portering staff transfer and admit all hospital bodies. Most bodies from community deaths are admitted within normal working hours; however, on rare occasions, on-call mortuary staff admit community bodies out-of-hours. Hospital bodies are transferred from the wards using a concealment trolley. Upon admission, the mortuary register and fridge door details are completed by the porters using the information on the 'Notice of Death' (NOD) form transferred with each body. 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 (see *Advice,* item 16). Perinatal cases, pregnancy remains and their associated documentation are transferred to the mortuary by the porters. All bodies are entered on to the mortuary laboratory's electronic information system. Bodies may be released from the mortuary using only one or two identifiers (see shortfall against T1(c)).

The mortuary's PM suite contains four tables, each with an associated dissection unit. Anatomical Pathology Technologists (APTs) carry out initial identification checks of bodies when removing them from the fridges, and again with the pathologist prior to the external examination and evisceration commencing. To help mitigate against any risk of a mix-up of organs and tissue samples between cases, coloured organ bowls are used that correspond with a specific PM table and pathologists complete each PM examination before commencing the next case.

There are currently two Consultant Histopathologists who conduct routine PM examinations at the establishment. Tissue removed during PM examinations is sent to the establishment's histopathology laboratory but can also be sent to other laboratories for specialist analysis if required. Records of traceability are kept by the mortuary for PM tissue sent to histopathology and when tissue is sent to other organisations for specialist examination (see shortfall against T1(g)). The storage and disposal of PM tissue that has undergone histological analysis is managed by the mortuary staff. The mortuary is staffed by three APTs, including a Mortuary Supervisor.

At the request of the Coroner, the establishment releases bodies to an external site for post-mortem computerised tomography (PMCT) scanning. Transfer of bodies for this purpose and their subsequent return, are recorded by the mortuary and facilitated by the Coroner's contracted funeral director.

Description of inspection activities undertaken

The establishment has been licensed by the HTA since June 2007. Previous routine site visit inspections took place in July 2010 and June 2014. This report describes the third routine site visit inspection visit in April 2018. Formal interviews were conducted with the DI, mortuary lead, mortuary staff, Consultant Pathologists, staff involved in the seeking of consent (adult and perinatal), portering staff and a Coroner's Officer. The inspectors also carried out a visual inspection of the mortuary, including the body storage areas, post mortem room and viewing suite. An audit of body identifiers, storage locations, mortuary

register details and associated documentation was carried out for four adult bodies (two hospital and two community deaths) and one perinatal body. No anomalies were found.

In addition, audits of four cases where tissue had been removed for histological analysis during the PM examinations were conducted. The inspection team reviewed the stored tissue in the mortuary, visited the histopathology laboratory and reviewed the associated traceability records. In addition, records of the relative's wishes regarding the fate of the tissue following its analysis were reviewed to verify that they had been acted upon appropriately. Two anomalies were found:

- Records of the amount and types of tissue blocks taken at post mortem are not kept by the mortuary. This information is recorded only on the histology request form sent with the samples to the histopathology laboratory (see shortfall against T1(g));

- Although the amount of tissue blocks entered on the laboratory computer system was correct in one case, the tissue type had not been entered.

Inspection findings

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

Compliance with HTA standards **Standard**	**Inspection findings**	**Level of shortfall**
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
b) There is a documented standard operating procedure (SOP) detailing the consent process	The SOP 'Consent for Post Mortem and Retention and Use of Organs' (SOP/CP/MB/13), version 5, does not fully reflect the requirements of the HT Act 2004 or the HTA's codes of practice. For example: i) The procedure refers to the 'Next of Kin' (NOK) which could imply that a person not ranked highest in the hierarchy of qualifying relationships could give consent to a PM examination or retention and future use of tissues; ii) Section 5 states that the Chief Executive of the Trust may give consent for PM examination in the absence of any 'next of kin'. This is incorrect; iii) The policy states that those with parental responsibility for a child are the only ones who can consent to a PM examination and scheduled purposes following death. A child who is deemed 'Gillick competent' before their death can also give consent for scheduled purposes to be carried out after their death; iv) The person who is named as NOK by the Coroner's office may not be the correct person to give consent regarding any tissues retained after post-mortem examination once the Coroner's authority ceases. The person ranked highest in the hierarchy of qualifying relationships should give this instruction; v) Section 7 states the reference to the HTA's model consent form is from 2009. It is actually 2011; vi) Section 12 states that training for seeking PM consent is carried out by the DI. This training is actually carried out by the Mortuary Lead and Supervisor; vii) Section 15 refers to the HTA's previous code of practice on consent; viii) Some of the appendices of the SOP do not reflect the documents actually in use; ix) All the document page numbers are '1 of 37'.	**Minor**

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.	i) The information given to relatives for adult consented PM examinations, 'The PM Examination Procedure – A Guide for Relatives', contains out-of-date contact details for the Bereavement Officer and the pathologist. In addition, the contact details for the mortuary should also be included. ii) The information given to parents for paediatric or perinatal PM examination, 'Notes For Parents Considering Giving Consent For A Post Mortem' (November 2012, version 1), states that: • tissues taken for microscopic examination are kept indefinitely; • tissues or organs taken for teaching, will be preserved and held indefinitely. This does not reflect the information provided in the consent form currently used by the establishment, the HTA's codes of practice or the HT Act 2004 (see *Advice*, item 1).	**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 that relatives can withdraw their consent, the timescale for this (the date and time) is not recorded for the relatives to refer to. In addition, the contact details for the Bereavement Officer need updating and the contact details for the mortuary should also be included to ensure that relatives can contact the relevant people as soon as possible, if they change their mind.	**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	Clinicians with responsibility for seeking consent for paediatric/perinatal PM examination may have had PM consent training as part of their medical training, but there is no evidence they have received any refresher training. As a result, the consent standards C2(b), (c) and (d) cannot be met for paediatric/perinatal consent seeking. (See *Advice*, item 3)	**Major**

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

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	Not all of the establishment's documented procedures reflect current practices being undertaken. Examples of this include but are not limited to: i) The SOP 'Receipt of Bodies into Mortuary' (SOP/CP/MT17), section 7.2 doesn't state that a NOD is completed by mortuary staff for a body admitted out-of-hours. In addition the additional ankle identification band is completed using information from the mortuary IT system and placed on the body at the time of admission, not following PM examination as described in the procedure; ii) The SOP 'Release of Bodies from the Mortuary' (SOP/CP/MT09), states that three identifiers are checked with the paperwork brought by the funeral director. However, the predominant documentation currently used to release bodies (the green disposal order), does not include three identifiers that can be checked. In addition, the SOP does not detail the additional information and checks that mortuary staff undertake for bodies with same and/or similar names (see shortfall against T1(c)); iii) The SOP 'Viewing Bodies with Infectious Diseases' (SOP/CP/MT13), does not include the requirement to check the identification of the body and what those identifiers could be. In addition, mortuary staff have procedures that they have developed which are helpful to them that are not formally documented in SOPs. For example, when pacemakers are removed this is marked on the fridge door of the body it relates to.	**Minor**
e) There is a system for recording that staff have read and understood the latest versions of these documents	The majority of SOPs have been distributed and acknowledged by the mortuary staff. However, the SOP 'Transport of Deceased Persons, Fetal Remains or Tissue/Body fluid', (SOP/CP/MT/15), has been acknowledged by only two members of staff. In addition, the 'Pathology Lone Working Policy' (PATH/POL/007), has not been distributed to mortuary staff to read and acknowledge.	**Minor**

GQ2 There is a documented system of audit		
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	The mortuary audits relating to the retained tissue are not incorporated into the formal schedule of audits on Q-Pulse. It was identified that findings from these audits are not always followed up and documented.	**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	Risk assessments are contained within a single document and cover the majority of activities and risks within the mortuary. However, the risk of accidental damage to bodies has not been considered. In addition, there is no risk assessment in place for lone working. (See *Advice*, item 15)	**Minor**
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	The risk assessment for 'Mortuary Emergency Overflow' carried out in January 2018, relating to refrigerated storage capacity, has a high risk-rating score and requires incorporating into the Trust's organisational risk register. This will help to raise the requirement for the permanent fridge capacity to be kept under review at senior level.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	i) Community bodies admitted to the mortuary for PM examination are routinely identified using only two identifiers (full name and address). There should be a minimum of three, including one that is unique (see *Advice*, item 18). ii) Bodies are released from the mortuary using the 'green disposal order', which does not contain sufficient identifiers to check the identification of a body to the required standard. Therefore staff are releasing bodies from the mortuary using the full name only. Additional identifiers are checked only if the deceased has a same or similar name to that of another (see *Advice*, item 17). iii) The establishment complete a diary to record the identification details given for a deceased when viewings or formal identifications are arranged. However, only one or two identifiers are checked with relatives when they attend for a viewing (see *Advice*, item 19).	**Major**

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	A record of the quantity of tissue blocks retained after the PM examination is recorded only on the histology request form that is sent with the tissue to the laboratory. The details of the specimens taken are recorded only after they are booked in at the laboratory. The mortuary records demonstrate only that tissue was taken (this includes specimens for toxicology). Recording the quantities and types of tissue taken will help to provide more accurate traceability records which can then be audited.	**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	The establishment currently has four freezer spaces for the storage of long-term bodies. This is not sufficient to meet the needs of the service, to ensure that all bodies can be satisfactorily stored to prevent unnecessary deterioration in their condition. Staff stated they have to priortise which cases are placed into long-term storage when space is limited. This means that bodies are kept in refrigerated storage for longer than 30 days. (see *Advice*, item 21)	**Major**
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	At the time of the inspection, the temporary refrigerated body storage unit was not linked to the remote fridge alarm system. This poses a risk that any equipment failure may go undetected, which could compromise the integrity of the stored bodies.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
d) Staff have access to necessary PPE	Although mortuary staff may have been face-fitted for the masks available in the PM room, it was unclear if this was to reduce the risks from formalin (chemical) exposure or airborne biological hazards. All staff, including the pathologists, are required to be face-fitted for FFP3 masks to safeguard against the latter.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(c)	In addressing the shortfall identified against standard C1(c), in relation to consent for pediatric/perinatal consent, the DI is advised to liaise with the establishment that undertakes these PM examinations to ensure they are using the most recent version of the information leaflet given to parents regarding the PM procedure (see *Advice*, item 2).
2.	C1(g)	The paediatric/perinatal consent form in use refers to the HTA's previous 'Code of Practice 3: Post Mortem Examination' (2009). The DI is advised to liaise with the establishment that undertakes these PM examinations to ensure they are using the most recent version of the consent form.
3.	C2(a)	The DI may wish to consider contacting the establishment that undertakes the paediatric/perinatal consented PM cases to enquire if they provide training regarding the seeking of consent for PM examination.
4.	C2(a)	The DI is advised to consider sourcing external training for the senior APTs who are responsible for seeking consent for adult consented PM examinations. This will provide assurance that their knowledge is kept up-to-date and they have sufficient understanding of the consent requirements under the HT Act. This training would need to be refreshed periodically.
5.	GQ1(d)	The DI is advised to ensure that the format of the document control of all SOPs is consistent. For example, some SOPs state the 'edition' number, while other state 'version' number.
6.	GQ1(g)	The DI is advised to appoint Persons Designated (PDs) in the maternity unit and A&E department, to be a point of contact and help provide assurance that suitable activities are taking place.
7.	GQ1(h)	The DI is advised to implement regular meetings with the PDs. This will help the DI to maintain oversight of the activities in the areas in which they have been appointed.
8.	GQ1(h)	As the DI does not attend the mortuary to perform routine Coroner's PM examinations, he is advised to attend the formal quarterly mortuary staff meetings and have regular contact with the mortuary staff to help maintain oversight of the activities taking place under the licence.
9.	GQ1(h)	The Mortuary Lead and Mortuary Supervisor are not always able to attend the scheduled meetings in the mortuary or the histopathology laboratory, respectively. The DI is advised to liaise with the appropriate people to try and rota these meetings so that relevant staff can regularly attend them.
10.	GQ2(a)	The DI is advised to include more process audits within the audit schedule and increase the frequency of these to help give assurance that mortuary practices reflect documented procedures.
11.	GQ2(b)	The vertical audit (AUD/2018/11) was carried out using the HTA's previous licensing standards. The DI is advised to review the audit process so that future audits are carried out using the HTA's updated standards (implemented April 2017).

12.	GQ3(d)	The DI is advised to ensure the annual appraisals for the mortuary staff (due March 2018) are undertaken as soon as possible. The inspection team were advised by the Mortuary Lead that this lapse was due to the Trust introducing a new format for staff appraisals.
13.	GQ5(b)	The DI is advised to include the HTA in the documented list for 'external assessment visits' in the SOP 'Quality Actions' (PATH/SOP/003), Section 4.3.1.
14.	GQ5(b)	The Trust policy 'Incident Reporting Policy' does not include the HTA in the 'External Reporting Arrangements', Appendix 3, in relation to reporting HTARIs. The DI is advised to include the HTA in this policy when it is next reviewed in March 2019.
15.	GQ6(a)	The DI is advised to consider reviewing the mortuary risk assessments to ensure they cover all the licensed activities outlined in GQ1 and the HTARI categories. This will help to ensure that the risks to the dignity and integrity of bodies and stored tissue are covered. The HTA's publication 'Regulation of the Post Mortem Sector: What we have learned' (October 2016) provides guidance and information in relation to risk assessments. This is available on the HTA's website.
16.	T1(b)	To further strengthen traceability of bodies and tissue while in the care of the mortuary, the DI may wish to consider implementing the following: • Using the mortuary register number of the deceased on the fridge door in addition to the full name. The mortuary register number is unique to that body, acting as an additional identifier while in the care of the mortuary. This can also be helpful when distinguishing between bodies with same and or similar names and bodies of unknown identity; • Using a darker line to differentiate between the mortuary register entries; • Using ruled lines within the 'PM Book' to differentiate between the cases and tissues entered in there.
17.	T1(b)	The DI is advised to consider introducing a standardised release form for funeral directors that is completed by them prior to arrival at the mortuary and brought in addition to other documentation brought by the funeral director. This form could contain the required three identifiers to release a body; for example, full name, DOB and address. The DI may also wish to consider having this form signed by the deceased's relatives.
18.	T1(c)	The DI is advised to liaise with the relevant parties to develop a procedure through which all bodies brought in from the community are identified with a minimum of three points of identification, one being unique.
19.	T1(c)	The DI may wish to consider strengthening the procedure for viewings by introducing a form to be completed by relatives when they attend for viewings. This can include relevant identification information so that three identifiers on the deceased may be checked before the viewing takes place.
20.	PFE1(d)	The DI is advised to ensure that the door leading from the PM room into the body store area is not used during during PM sessions. This will help ensure appropriate demarcation of the PM room (a 'dirty area' when in use) is maintained. In addition, the DI is advised to use a sign on the body store side of this door advising access is not permitted to help mitigate the risk of unauthorised and unintentional access into the PM room.

21.	PFE2(c)	The DI may wish to consider utilising an existing bank of separate fridges, that can be converted to a freezer, for the long-term storage of bodies when required.
22.	N/A	The DI is advised to consider the use of coloured signs or magnets on body store doors to highlight potential infectious disease risks from bodies. This is currently recorded only in the mortuary register.
23.	N/A	The DI is advised to review procedures and documentation relating to handling bodies that pose a possible infection risk. Appendix 1; Guidelines for Handling Cadavers with Infections' of the SOP 'Receipt of Bodies into Mortuary' states that bodies with HIV/AIDS are advised to be placed in to a body bag. However, the appendix states that bodies infected with other hazard group three pathogens, for example, Hepatitis C, require a body bag. Any deceased known or suspected to have a hazard group three infection should be routinely placed in a body bag to help reduce the risk of infection spreading to those handling the body.

Concluding comments

The mortuary staff are a well established team and appear to work well together, demonstrating interest and care in the work they undertake. Mortuary staff received praise from different people interviewed throughout the inspection and have good relationships with service users. There are some areas of strength and good practice, which include:

- The use of colour-coded bowls allocated to a specific PM table to help mitigate the risk or mixing up organs;
- Audits that are undertaken by staff external to the mortuary

There are a number of areas of practice that require improvement, including three major shortfalls and eleven 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: 10/05/18

Report returned from DI: 22/5/18

Final report issued: 11/6/18

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 01/11/18

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.