Site visit inspection report on compliance with HTA licensing standards

Royal United Bath Hospital

HTA licensing number 12250

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**

29 & 30 May 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 Royal United Bath Hospital had met the majority of the HTA's standards, three minor shortfalls were found against the Governance and Quality system standards 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

This report refers to the activities carried out at Royal United Bath Hospital (the establishment) which has been licensed by the HTA since August 2007. It 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 Designated Individual (DI) is a Consultant Gynaecologist and Obstetrician and the Corporate Licence Holder contact is the Interim Divisional Manager for Surgery at Royal United Hospitals Bath NHS Foundation Trust. The mortuary is staffed by two full-time Anatomical Pathology Technologists (APTs) and one HTA Co-ordinator. 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*, items 1 and 4).

The body store receives approximately 2500 bodies annually, from both the hospital and community. They conduct on average 250 adult PM examinations, the majority of which are undertaken under Coronial authority; four adult hospital (consented) PM examinations were conducted in the year prior to the inspection. Consent for adult PM examination is sought by consultants who are trained in seeking consent for PM examination.

The mortuary has the facility to conduct high-risk PM examinations but such cases are often transferred to another nearby HTA-licensed establishment; this is also the case for forensic PM examinations. PM examinations for prenatal, perinatal and paediatric cases are transferred to another HTA licensed establishment; however, trained staff seek consent for these cases, which is recorded using consent forms from Royal United Bath Hospital. Training in seeking consent for both adult and paediatric PM examinations is provided regularly and a list of staff who are trained to seek consent is maintained by the establishment. All paediatric cases are traced through the mortuary using the same traceability systems as for adult cases.

Removal of tissue from deceased children in cases of sudden unexpected death in infancy (SUDI) is performed in the A&E department and the establishment has a designated senior matron in place as a Person Designated under the licence for SUDI. A bereavement midwife, also a Person Designated under the licence, liaises with families in the maternity ward with regards to providing information for perinatal and paediatric hospital PM examinations (see *Advice*, item 2). Consent is sought by trained consultants and information leaflets used are provided by the Stillbirth and Neonatal Death (Sands) charity.

The mortuary has 84 refrigerated body storage spaces in the body store which includes four freezer spaces and sixteen bariatric spaces (see *Advice*, item 8). There are dedicated

spaces within the fridges for paediatric cases. The establishment has a chiller unit which provides contingency storage for 6 additional bodies or 1 bariatric body. There is an additional refrigerated temporary storage unit providing a further 12 spaces. The establishment has the temporary storage unit on contract lease for the next three years; both temporary stores were not in use at the time of inspection and are serviced annually.

There is CCTV outside and at access points to the mortuary. There is controlled swipe card access for staff. The entrance to the mortuary has an intercom system (with video) to verify the identity of the person requesting entry to the mortuary.

Bodies are placed into the body store by trained hospital portering staff, the hospital site team or by the coroner's contracted funeral directors, working to procedures shown to them by the mortuary staff (see shortfall against standard GQ1(a)).

The procedure followed outside office hours involves the site team meeting the contracted undertakers and granting access to the secure areas of the mortuary. Bodies are placed in an available body store fridge space, and a death notice is placed on the door of the body store space which alerts mortuary staff to presence of the recently received body.

Mortuary staff check the newly deceased every morning, verifying their identification tags and log these onto the electronic mortuary register (see *Advice*, item 3). This forms part of the software system used to trace the body, and any tissues retained. Each body is allocated a unique identification number when booked in; bodies that undergo PM examination are allocated a further 'PM' number. The bereavement office work closely with the mortuary and make daily contact to check for any overnight deaths to help assure themselves that their records are up-to-date.

Mortuary staff carry out daily visual checks of the fridges, noting details of any patients with same or similar names. Establishment staff use yellow stickers on the fridge spaces where there are bodies with same or similar names located inside.

All fridges are linked to a temperature monitoring system which is linked to an alarm system (see *Advice*, item 7). In the event that the storage temperature goes below or above set limits, the system automatically triggers an alarm and alerts the switchboard in the hospital (see shortfall against standard PFE2 (e)). In the case of an emergency or equipment failure, switchboard operators will contact the site managers who in turn will contact mortuary staff (see *Advice*, item 5)

Bodies are released between set hours, Monday to Friday. In the event that a body is released outside these hours, the hospital site team attends. The mortuary staff remind the funeral directors attending that they bring the correct release paperwork with them when collecting bodies. Funeral directors call mortuary staff via a video intercom system from outside the mortuary. Upon release, mortuary staff confirm the identity of the deceased with

the funeral director, checking identification details on the body against paperwork from the funeral director. The funeral director and mortuary staff sign the paperwork upon release to record that the identification checks have been completed. Mortuary staff will not release bodies if the funeral directors do not bring the correct paperwork (see *Advice*, item 6).

Viewings are arranged between the family and bereavement team and are carried out during working hours and occasionally out of hours if ward staff feel this is necessary. In the event of a request for an out of hours viewing, the site team are contacted to organise it.

The PM room has three PM examination tables (see shortfall against standard PFE3 (c)). There is a dedicated downdraft dissection bench where pathologists can examine the organs. The pathologists conduct an external examination and ID check before evisceration and complete each case before starting the following PM examination to help avoid a mix-up of organs. Tissue removed during the PM examination is placed in formalin pots and taken directly to the on-site histology laboratory where it is processed and analysed.

The HTA Co-ordinator oversees the administration of tissue taken at PM. Details of tissue retained and the wishes of the family with regards to any tissues retained following PM examination are entered onto a specific 'Tissue Retention' database. Letters are sent to the Coroner for updates where family wishes are unclear. If tissues or organs are sent to other centres outside of the Trust for specialist examination, this is recorded on another database. A fax-back system is used to maintain traceability and confirm receipt of organs and tissues sent to external facilities. Weekly and monthly reports are run of cases where family's instructions with regards to return, storage or disposal of tissue are outstanding, or where the establishment is awaiting confirmation of the closure of inquests from the Coroner.

Description of inspection activities undertaken

This was the third site visit inspection of the establishment; the previous inspection took place in 2014. The inspection team carried out a visual inspection of the body store, PM room, viewing area and the histology laboratory.

Interviews with key members of staff, a review of governance and quality system documentation and traceability audits were also undertaken. Audits were conducted on three bodies being stored in the establishment's fridges and one body in frozen storage. Body location and identification details on ID tags were crosschecked against the information recorded in the electronic mortuary register. No discrepancies were found.

In addition, one hospital consented PM examination and two Coroner's cases where tissue was retained following the PM examination were audited. The audit included details of tissue, blocks and slides retained, consent forms, and associated paperwork. No discrepancies were found.

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

Governance and Quality

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.	SOPs do not reflect the establishment's current procedures. Relevant SOPs do not include details regarding the current practice of checking a minimum of three identifiers or include details of which identifiers are used (e.g. full name, address, hospital number/unique mortuary number). With reference in particular to: QMS/SOP/MO/16/8 – 'Viewing arrangement procedures for the mortuary'. Out of hours arrangements and practices are also not covered in sufficient detail. There are a number of SOPs that reference the HTA's previous Codes of Practice and Standards for example: QMS/SOP/MO/22/8 - 'Mortuary/histopathology departmental procedures regarding material retained at post mortem'. There are also some SOPs that use the term 'next of kin' rather than the appropriate person who may give consent as defined by the Human Tissue Act 2004 for example: QMS/SOP/MO/22/8 –'Mortuary/histopathology departmental procedures regarding material retained at post mortem'. **See *Advice*, item 1**	**Minor**

Premises, facilities and equipment

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	The body store 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**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	Whilst the establishment has records of maintenance of PM suite ventilation system, these service records show that the system does not provide the necessary ten air changes per hour.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1 (a)	The DI is advised to introduce a bespoke set of SOPs for site managers to follow as they are involved in many of the mortuary processes. In addition, the SOPs should be clear what porters and site managers need to do in the event of an incident and highlight which incidents require reporting to the HTA. The DI is also advised to update relevant SOPs so they explicitly refer 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.
2.	GQ1 (g)	The DI is advised to invite Persons Designated in A&E and maternity to attend some of the establishment's governance meetings. This may help the DI in maintaining oversight of all areas under the licence and also involve staff conducting licensable activities in HTA-related issues and mortuary activities.
3.	GQ2 (b)	The DI is advised to strengthen the audits of mortuary activities to include checks that the required standards are being met and keep up to date with the audit schedule. This will help to assure the DI that any issues can be identified and followed up in a timely manner.
4.	GQ3 (a)	The DI is advised to train Site Managers alongside porters in mortuary activities for a streamlined training approach and to help assure the DI that staff conducting licensable activities are appropriately trained and competent in the tasks they perform.

5.	GQ5 (a)	The DI is advised to improve awareness of the HTARI reporting requirements. This could include signage in the mortuary to remind staff of the requirements and procedures for reporting incidents.
6.	GQ6 (c)	The DI is advised to reflect all of the risk mitigating measures in the risk assessments of HTA licensable activities outlined in GQ1(a). Although the current risk assessments are suitable and identify risk and measures in place to mitigate against them, the risk assessments could have more detail in the 'mitigating actions' sections, detailing all of the steps that have already been taken by the establishment to mitigate risk but which have not been documented. This will help to reflect and record the existing good practices in place. 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.
7.	PFE2 (e)	The DI is advised to develop a system through which the temporary body stores are linked to the main remote alarm monitoring system in addition to their local alarms.
8.	PFE3 (f)	The DI is advised to continue with plans to formalise a regular maintenance schedule for mortuary fridges. Although the fridges are on the Trust's refrigeration maintenance contract and are serviced regularly, formalising this arrangement will help assure the DI that they are serviced annually without having to request a service. This may help to mitigate the risk that a service is not requested as expected.

Concluding comments

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

All staff involved in the inspection demonstrated a sensitive approach to their work and dedication to providing dignity to the deceased and high levels of patient care. The establishment were proud to share a video of a relative explaining the care and understanding they had received. This video was shared with Trust staff as a way to highlight the importance of patient focussed care.

The 'tissue retention at post mortem' database is maintained by a dedicated member of staff. This is an effective method of helping to assure the DI that there is sufficient oversight of traceability of retained tissue. Reports can be generated easily, detailing cases where the establishment is awaiting wishes of the family regarding fate of tissue and keeping track of where tissue has been sent off site for analysis or sent for disposal. The inspection team were informed that staff witness the packing of tissue due to be sent off site for external analysis helping to assure the DI that all tissues being sent for analysis has been included in the package which represents another form of good practice.

The communication between the mortuary and bereavement office has created a smooth process which is reflected in the quick turnaround times and there is also a good working relationship with the Coroner.

The establishment has a quality manager who has oversight of the electronic management system and looks for areas that could be improved. The quality manager has also been involved in training two members of staff on conducting audits and has attended the AAPT consent training day delivered by the HTA in order to feedback to the consultants involved in seeking consent for post mortem examinations.

There are a number of areas of practice that require improvement, including three minor shortfalls in relation to SOPs, ventilation and testing of fridge and freezer alarms.

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: 25 June 2018

Report returned from DI: 9 July 2018

Final report issued: 10 July 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: 17 May 2019

Appendix 1: HTA licensing standards

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

Consent

C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice

a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.

b) There is a documented standard operating procedure (SOP) detailing the consent process.

Guidance

This should include who is able to seek consent, what training they should receive, and what information should be provided to those giving consent for post-mortem examination. It should make reference to the use of scanning as an alternative or adjunct to post-mortem examination.

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.

Guidance

Information on consent should be available in different languages and formats, or there is access to interpreters/translators. Family members should be given the opportunity to ask questions.

d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.

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

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

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

Guidance

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

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality systems

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

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

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

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

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

Guidance

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

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

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

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

Guidance

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

The family's permission should be obtained for any 'cosmetic' adjustments or other invasive procedures prior to release of bodies, for example, sewing the deceased's mouth to close it or the removal of a pacemaker. It is also good practice to discuss with the family any condition that may cause them distress, for example when viewing or preparing the body for burial, such as oedema, skin slippage of signs of decomposition.

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

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

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

Contractors, visiting and temporary staff and funeral service staff bringing bodies out of hours should be required to read relevant standard operating procedures and sign to confirm their understanding.

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

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

Guidance

Records include mortuary registers, PM examination records, tissue retention forms and

records of transfer and return of organs/tissue sent elsewhere for examination.

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

Relevant staff should have knowledge of risks and the control measures that have been taken

to mitigate them.

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place

present a risk to traceability. Full identification checks should be made when they are placed back into normal storage.

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

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

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

   ii. receipt upon return to the laboratory or mortuary

   iii. the number of blocks and slides made

   iv. repatriation with the body

   v. return for burial or cremation

   vi. disposal or retention for future use.

   Guidance

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

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

   Guidance

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

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

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

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

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

   Guidance

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

this purpose.

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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

a) The premises are clean and well maintained.

Guidance

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

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

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

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

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

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

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

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

Guidance

Temperature monitoring should enable the establishment to identify trends and may mitigate the risk of a possible fridge failure.

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

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

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

Guidance

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

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

assessments and same/similar name systems.

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

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

Establishments should consider entering in to Mutual Aid Agreements

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

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

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

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

Guidance

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

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

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

Guidance

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

d) Staff have access to necessary PPE.

Guidance

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

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

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

Guidance

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

Appendix 2: Classification of the level of shortfall

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

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

1. Critical shortfall:

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

or

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

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

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

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

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

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

2. Major shortfall:

A non-critical shortfall that:

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

or

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

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

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

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

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

Follow up actions

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

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

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

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