Site visit inspection report on compliance with HTA licensing standards

UCL Hospitals

HTA licensing number 12054

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**

20 – 22 February 2018

Summary of inspection findings

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

Although the HTA found that UCL Hospitals had met the majority of the HTA's standards, shortfalls were found in relation to information provided when seeking consent, the scope of audits being undertaken, staff training, incident reporting and tissue disposal.

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 activities carried out at four licensed locations: University College Hospital (the hub, for the purposes of HTA licensing); and three satellites: the Rockefeller Building; the National Hospital for Neurology and Neurosurgery (NHNN); and the Department of Clinical Parasitology at the Hospital for Tropical Diseases.

The hub is licensed 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. The Rockefeller Building, and the Department of Clinical Parasitology are licensed for the storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose; and NHNN is licensed for the 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.

The Designated Individual (DI) is the Divisional Director for Pathology. The Corporate Licence Holder (CLH) is UCL Hospitals NHS Foundation Trust, with the Medical Director as a named contact. There are seven Persons Designated (PDs) working under the licence.

The Hub

The hub is staffed by three Anatomical Pathology Technicians (APT), including a mortuary manager, deputy mortuary manager and a trainee APT.

The body store consists of 38 fridge spaces and eight freezer spaces; there are an additional 12 spaces available in a refrigerated temporary storage unit, which can be deployed during busy periods. Babies and fetuses are stored on dedicated trays; however, a separate fridge is available but not yet in use, as it has not yet been linked to the building management system used to monitor storage temperatures. Through the use of coloured magnets, a white board used to record the details of bodies in storage is also used to highlight bodies with same or similar names, high risk bodies and bodies that are due for community burial or that have been stored for a prolonged period of time. In addition to the magnets, a separate sheet is used to record the bodies with same/similar names and this is kept in the body storage area for review by establishment staff as needed.

Fridge and freezer temperatures are monitored manually by establishment staff twice daily. In addition, the temperatures are monitored by an electronic system which is linked to a

building management system to alert establishment staff to deviations in storage temperatures from their expected ranges. In normal working hours, mortuary staff will respond to the alarm. Out of hours, the building maintenance team will be alerted to attend the mortuary; they also contact the on-call APT, who will attend if necessary. Staff conduct monthly tests of the alarm system to help assure themselves that the alarm triggers and is responded to as expected.

Bodies are received into the mortuary from the hospital, and occasionally from NHNN or external hospitals, for post-mortem (PM) examination. Bodies from deaths in the community are sent to nearby HTA-licensed public mortuaries. Hospital porters bring the deceased to the mortuary from the wards. The Head Porter has been trained by mortuary staff in mortuary procedures, and cascades this training to others. Upon receipt at the mortuary, the identification of the body is checked by at least one member of mortuary staff, and the body is assigned a unique mortuary reference number, which is noted in the mortuary register and on the mortuary door.

When a body is released, three identifiers on the wristband are checked against the paperwork held in the mortuary and the paperwork provided by the funeral directors. Bodies are released during mortuary working hours, and there is an on-call service for out of hours releases if necessary. Viewings of bodies are conducted in and out of hours. During normal working hours, mortuary staff conduct viewings; out of hours, viewings are undertaken by nurses and porters. Although training is made available to nurses by mortuary staff on an ad hoc basis, however, as this is done on a voluntary basis, there is no assurance that all nurses involved in mortuary activities are trained. At the time of inspection, there was no method for recording who had accessed the mortuary to undertake an out of hours viewing. Staff are reliant on reviewing the CCTV to determine whether a viewing took place.

Approximately 50 PM examinations take place per year and they are a combination of PM examinations being performed under the authority of various Coroners across the United Kingdom and hospital (consented) PM examinations. A small proportion of Coronial PM examinations are undertaken at the establishment to determine whether the individual had Creutzfeldt-Jakob disease (CJD).

The PM suite has two downdraft tables and a dedicated area for the dissection of organs. A separate high risk suite is used for high risk cases e.g. CJD.

Consent for a hospital (consented) PM examination is sought by the clinician who was treating the deceased in life. Before seeking consent, the clinician must speak with the DI, who will discuss the case and convey any potential questions the family may have. In addition, they must complete an e-learning module related to the seeking of consent for PM examination. The family are also provided with an opportunity to discuss the case with a pathologist if they wish. Prior to the PM examination, mortuary staff will reconfirm that the

clinician has completed the online training. If training has not been completed, the PM examination will not go ahead until appropriate consent has been sought.

Tissue samples removed during PM examination are cassetted in the PM suite, collected by porters and transferred to the satellite site at the Rockefeller Building. Staff in the Department of Pathology confirm receipt of samples. Following analysis, samples are returned, retained, or disposed of according to the family's wishes.

Brains relating to suspected or confirmed CJD cases are stored in the high risk PM suite before being transferred by courier to the NHNN satellite site once the tissue has been fixed. Following their examination, brains are returned to the deceased, retained, or disposed of according to the family's wishes.

In addition to Coronial and hospital PM examinations, tissue is occasionally removed from the deceased for use in an ethically approved research study: the posthumous tissue donation in cancer (PEACE) study. Participants are recruited in life, or where they have shown an interest but not make a decision to provide consent in life, their family is approached after their death. With appropriate consent, tissue is removed under the PM licence, and stored under the establishment's research licence.

Where perinatal and paediatric deaths require a PM examination, bodies are transferred to other HTA-licensed premises. Consent is sought by establishment staff using the SANDS guidelines, and the family have an opportunity to ask any questions. Consent is sought by a trained consultant or senior registrar who are often accompanied by a midwife. Consent seekers must complete an e-learning package and observe a PM examination as part of their training before they are permitted to seek consent.

NHNN

The satellite at NHNN contains a body store with six fridge spaces. Bodies are received only from the hospital and are transported from the wards to the body store by porters. As with the hub site, the trained Head Porter cascades training to other relevant staff. Where a body requires a PM examination, mortuary staff arrange for transfer of the body to the hub premises using a contracted funeral director.

In addition to the body store, relevant material such as whole organs or tissue blocks and slides are stored at the satellite site at NHNN. Where relevant material is being stored for future use (for example, for use for 'research in connection with disorders, or the functioning, of the human body'), this is transferred to the governance of the Trust's research sector licence.

Hospital for Tropical Diseases

The Department of Parasitology at the Hospital for Tropical Diseases provides investigative services related to human parasitic diseases. A number of research projects with approval from a recognised research ethics committee (REC) are being undertaken at this site. At the time of inspection, the ethical approval for these projects was still valid; however, these approvals are approaching expiry. Appropriate consent is in place for their future storage and use of the research tissue samples, however when the recognised ethical approval expires, the samples will fall under the governance of the establishment's PM sector licence. One stored research sample from the deceased was reviewed as part of an audit undertaken by the inspection team at the site. No anomalies were found.

Description of inspection activities undertaken

This was the third routine site visit inspection of the establishment. The first and second inspections took place in 2010 and 2014, respectively. The inspection included a visual inspection of both body stores, the PM suites, the viewing areas, the histology laboratory, the maternity department, and the satellite sites. The DI confirmed that no removal of relevant material for use for scheduled purposes is undertaken in any area outside of the mortuary, for example in the Emergency Department. Interviews with members of staff working under the licence and a review of documentation were undertaken. Audits of four bodies stored at the hub and one body at the satellite were conducted. The location of the body, and identification details from the body's identification bracelet, were cross-referenced against the information in the mortuary ledger and paper records. In one case at the hub, the spelling of the surname on the ankle tag did not match the wrist tags or associated documentation and this had not been recorded. In a second case, a body that had been in storage for a prolonged period, the unique identifier recorded on the fridge door did not match the record in the mortuary ledger (see *Advice*, item 6).

Audits of tissue removed during the PM examination for four cases were undertaken. Relevant paper and electronic records, consent records and location of samples in the Pathology Department were reviewed. In one case, the number of blocks recorded at PM examination did not correlate with the number recorded on the electronic system. All blocks were accounted for, however, there was no evidence of this discrepancy being investigated. In a second case, tissue blocks and slides had not been disposed of within the expected timeframe (see shortfalls under C1(c) and T2(a)). Following the inspection, the establishment provided evidence that the blocks had been disposed of.

A review of adverse incidents which had occurred at the establishment over the preceding 24 months identified that two incidents that should have been reported to the HTA as HTA Reportable Incidents (HTARIs) had not been reported (see shortfall under GQ5(a)). Both incidents occurred out of hours and involved untrained nursing staff.

The Labour Ward was visited and a fridge used for the storage of early pregnancy remains, miscarriages and stillbirths was reviewed. The fridge is in a keypad locked room and the code is known only to the midwives to prevent any unauthorised access. The fridge is temperature monitored and has an audible alarm when the temperature deviates from its expected range. The fridge is manually checked daily, including weekends, and the alarm is tested monthly.

Inspection findings

The HTA found the Licence Holder, the Designated Individual and the premises 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		
c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.	The written information provided to those giving consent is not fit for purpose. The consent form clearly states that tissue blocks and slides will be retained as part of the medical record which does not make it clear for which purposes the retained tissue is being may be used. The document 'A simple guide to the post mortem examination procedure' is a Department of Health document published in 2003, which is prior to the implementation of the HT Act. The document contains out of date references, and does not reflect the requirements of the HT Act and the HTA's Codes of Practice such as tissue can only be retained if appropriate and valid consent for the retention is given.	**Major**

GQ2 There is a documented system of audit		
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	While there is a schedule of regular audits in place, the audits are not sufficiently detailed. Audits that were undertaken did not identify the types of discrepancies identified during the inspection (see also *Advice*, item 4).	**Minor**

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	Two incidents have occurred in the past 24 months where nursing and portering staff left family members unattended in the mortuary, or allowed them access to restricted areas within the mortuary. Nurses and porters involved in these incidents had not received training in mortuary-related practices.	**Minor**

GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	A review of adverse incidents which had occurred at the establishment over the preceding 24 months identified that two incidents that should have been reported to the HTA as HTA Reportable Incidents (HTARIs) had not been reported by the establishment.	**Minor**

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	During the tissue traceability audit, a case where the tissue should have been disposed of was identified. Authorisation for disposal had been provided a number of months previous, and this had not been acted upon. *The establishment provided documentary evidence to address this shortfall prior to the issue of the final report. The HTA has assessed this evidence as satisfactory to address this shortfall.*	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(a)	The consent policy currently refers to the previous HTA codes of practice, and does not have all parts of the consent seeking process included. The DI is advised to review this policy to ensure it contains the most up to date references to HTA documents and includes details of the full consent seeking procedure.
2.	GQ1(d)	During the inspection, is was found that policies and SOPs were not consistently authored and reviewed by a different person. The DI is advised that all documents should be authored and reviewed by different people, and that they should develop and implement procedures to assure themselves that this is the case.
3.	GQ2(a)	The current schedule of audits does not currently include procedural audits. Procedural audits help to ensure that the documents being used are fit for purpose. The DI is advised to add regular audits of key procedures related to mortuary activities. These audits should be performed using the relevant document and walking through the procedure, noting any differences. In addition to ensuring that documents reflect current practices, particular attention should be paid to the labelling of documents to ensure they are consistently referred to by the same title.
4.	GQ2(c)	While there has been a notable amount of work done on the audit schedule recently, there are some areas that require improvement. The audit schedule in place is not sufficiently robust to capture the discrepancies noted during the HTA site visit. The establishment does not undertake any procedural audits to verify if procedures are being followed or that they remain accurate reflections of practices The DI is advised to review the manner in which audits are conducted. This should include a review of the audits conducted on retained material, including the number of blocks removed at PM examination, and the retention periods.
5.	GQ6(a)	While the risk assessments consider the majority of risks to the deceased, not all HTARI categories have been considered. The DI is advised to expand the risk assessments to ensure all HTARI categories are included.
6.	T1(b)	The DI is advised to review the procedures relating to the storage and auditing of bodies held in long term storage to assure themselves that discrepancies in records are appropriately identified. In addition, the DI is advised that regular reviews of the documentation and records relating to bodies in long term storage should be performed to ensure records match.
7.	PFE1(a)	The floor in the PM suite has a number of areas which are discoloured due to the bleach being used. Although the floor is fit for purpose, the reaction between the floor and the bleach may lead to future degradation. The DI is advised to keep the condition of the floor under review.

8.	PFE3(b)	The DI is advised to risk assess the suitability of the trolley used to transfer bodies from the ward to the mortuary at the NHNN satellite. In particular, the DI should assure themselves that the trolley is suitable for the transfer of bariatric bodies.
9.	PFE3(d)	The DI is advised to ensure staff working in the PM suite, particularly in the high risk suite, utilise the available PPE; for example, face-fitted masks or where these are not appropriate, respiratory hoods.

Concluding comments

A couple of strengths were noted during the inspection:

- Mortuary staff work well together, and appear dedicated to providing a good service.
- The recent appointment of a quality officer has allowed for a comprehensive review of procedures and audits which has helped identify areas of weakness in the mortuary, and to identify areas in which the establishment can improve its procedures.

There are a number of areas of practice that require improvement, including one major and four minor shortfalls.

The HTA requires the Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 20 March 2018

Report returned from DI: 04 April 2018

Final report issued: 27 April 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: 04 September 2018

Appendix 1: HTA licensing standards

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

Consent

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

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

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

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality systems

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

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

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

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

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

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

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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