Site visit inspection report on compliance with HTA licensing standards

Colchester General Hospital

HTA licensing number 11104

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**

23 and 24 January 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 Colchester General Hospital had met the majority of the HTA's standards, one major and eight minor shortfalls were found against standards within Governance and Quality systems, Traceability, and Premises, facilities and equipment. The majority of the minor shortfalls relate to documentation relating to the establishment's current procedures, while the major shortfall relates to the reported practice of evisceration occurring prior to the pathologist undertaking an external examination of the body.

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

Colchester General Hospital (the establishment) is part of Colchester University Hospital NHS Foundation Trust. The establishment has been licensed by the HTA since October 2008 and this was the fourth routine site inspection of the establishment, the last occurring in February 2014. The Mortuary and Bereavement Services Manager oversees activities within the mortuary. The Corporate Licence Holder is Colchester University Hospital NHS Foundation Trust with the Chief Executive officer acting as a contact, and the DI is a Consultant Histopathologist.

The establishment receives over 2500 bodies each year from the hospital and community, performing around 670 post-mortem (PM) examinations, the majority of which are routine coronial cases undertaken on behalf of HM Coroner for Essex. Paediatric and perinatal cases are transferred to another HTA-licensed establishment for PM examination, consent is sought on site by qualified staff in the maternity unit (See *Advice*, item 3). Hospital consented PM examinations are occassionally carried out at the establishment. Consent for adult hospital consented PM examinations is sought by mortuary staff with the support of clinicians. Consent forms for adult hospital PM examinations are based on the HTA's model consent form, while the consent form for paediatric and perinatal cases is provided by the establishment undertaking the PM examinations and is based on the Sitlbirth and neonatal death charity's (SANDs) guidelines. Both forms are compliant with statutory and regulatory requirements.

The remains of stillborn infants or miscarriages may be stored on the Maternity Ward prior to being transferred to the mortuary so that, where appropriate, families have the opportunity to view the infants while on the ward. Remains are stored in a fridge that is kept in a small locked room, away from the main ward. While not connected to a monitoring system, the fridge temperature is checked and recorded, twice daily, and had an audible alarm that can be heard on the ward.

The mortuary consists of a body store and a PM suite within the main hospital site. The body store comprises 60 standard-sized fridge spaces, four bariatric fridge spaces that may be changed to freezer units, four dedicated freezer spaces, six bariatric fridge spaces and four dedicated fridge spaces for paediatric cases. At the time of inspection, all standard-sized freezer spaces were occupied by forensic cases. For bariatric bodies requiring long term storage, or when the freezer units are fully occupied, the mortuary staff seek permission to have the body embalmed. One of the mortuary staff members is a qualified and practising embalmer and is competent to perform the embalming process. There is an additional storage area containing two temporary refrigerated storage units, each with 12 spaces which are in routine use. The mortuary is in good condition and the staff have procedures in place to ensure rapid follow up and transfer of bodies to a funeral director in a short time frame, enabling the body store to work within its limited capacity. The establishment has a contract with a local funeral director for an additional 40 spaces should they need further storage during busy periods.

The temperatures of the fridges and freezers are monitored using a remote system that, in the event of deviations in temperatures from the expected ranges, automatically contacts the switchboard, from where operator staff contact the hospital Estates services and on call contracted engineer. On call mortuary staff will attend if the engineer is unable to resolve the issue. The temperature alarms are recorded electronically and records are retained by Estates (see shortfalls against PFE2(e), PFE2(f) and PFE3(f)).

Porters that transfer deceased patients to the mortuary are trained by mortuary staff, to make them aware of mortuary practices (See *Advice*, item 7). The mortuary has created paperwork that is completed on the ward, prior to porters transporting bodies to the mortuary. This includes a body diagram for ward staff to complete, noting any damage to the body, which is checked on receipt at the mortuary. Community deaths are brought to the mortuary by one of three Funeral Directors appointed by the Coroner. To facilitate the recording of all pertinent information, the mortuary has developed an information record sheet which is completed by the Funeral Directors prior to the community bodies being received into the mortuary. Ambulances will occasionally deliver bodies directly to the mortuary where individuals have died en-route to the hospital. The entrance used by funeral directors is covered and is not overlooked by other departments in the hospital.

In addition to the storage activities described above, the removal of tissue from the body of deceased children occasionally takes place in the Emergency Department (ED) in cases of a sudden unexpected death of an infant (SUDI). Removal of tissue takes place under the authority of the Coroner and there are guidelines for clinical staff to follow on the type and quantity of samples to take. Any tissue removed is sent immediately for clinical analysis. Written information about tissue sampling in SUDI cases is available and can be shared with the parents as necessary.

The PM suite has four height adjustable tables. Pathologists complete the examination of the organs from each body before commencing their examination of the next case to help mitigate the risk of a mix up of organs between bodies. Establishment pathologists generally use trays at each PM table when examining organs, visiting pathologists may use the dissection area (See *Advice*, item 4). When bodies are identified as requiring a PM examination, the pathologist is notified of this on the day before the examination is planned. On the day of the PM examination, mortuary staff prepare the body and perform the evisceration prior to the arrival of the pathologist. The pathologist does not always identify the body and perform an external examination prior to the PM examination commencing (see shortfall against GQ1(b)).

Tissue taken during PM examinations is either placed into cassettes in the PM room or placed into pots and transferred to the Histopathology Laboratory for processing. A ‘Tissue Organ Retention and Disposal (TORD)’ form, which records details of the tissue removed during the PM examination, is sent to the laboratory with the tissue. Staff at the Histopathology Laboratory sign the TORD form on receipt of the tissue, and e-mail a copy back to the mortuary to confirm receipt. After processing and assessment of the tissue, the total number of slides generated from each block is recorded on the TORD form. When the analysis of the tissue has been completed, blocks and slides are returned to the mortuary with the updated TORD form and are stored in a storage area adjacent to the PM room. On return to the mortuary, blocks and slides are retained, disposed or reunited with the body, in accordance with the consent given, or wishes of the deceased’s family, which were received via the Coroner.

Description of inspection activities undertaken

The timetable for the site visit inspection was developed in consideration of the establishment’s last self-assessed compliance information, as well as pre-inspection discussions with the DI and review of the previous inspection findings. During the site visit, a visual inspection of the premises, review of documentation and interviews with establishment staff were undertaken.

As part of the inspection process, an audit of bodies in the body store was undertaken. Four bodies were selected, including one, which was in frozen storage, and one being stored in

the temporary refrigerated storage unit. Two bodies were from hospital deaths and two were from the deaths occurring in the community. Details from the body identification tags and the physical location of the bodies were crosschecked against the establishment's paper and electronic mortuary register. While all bodies were traceable, one of the bodies received from the community retained the original ID bracelet with only two points of ID (see shortfall against T1(c)) although the paperwork provided by the Funeral Director with the body contained additional information. Additionally, the establishment rely on a visual review of the fridges to locate bodies within the facility, although they do log the initial fridge space where bodies are placed on admittance to the mortuary. The body in frozen storage was recorded in its original fridge location in the mortuary record book which had not been updated to reflect the moving of the body to the freezer. However, there were paper records demonstrating that permission had been sought to move the body to the freezer and while there was no facility in the electronic system to currently log storage location, the acronym 'DF' had been appended to the patients name to indicate movement to frozen storage (see *Advice*, item 9).

In addition to the body store audit, details of tissue retained during four PM examinations were crosschecked against the establishment's records. The review of retained tissue included documents indicating the wishes of the deceased's family with regards to the fate of the tissue at the end of Coronial authority. In each case reviewed, the physical tissue blocks and slides were sought and their details included in the audit. One anomaly was found where the electronic system recorded tissue as being retained for research and waiting for notification of end of Coronial authority, while the consent form recorded that it should be retained as part of the medical record (see *Advice*, items 2 and 9). The tissue was located in the mortuary store.

Inspection findings

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

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed	In some cases, evisceration takes place before the pathologist has undertaken an external examination of the body. This is contrary to professional guidance issued by the Royal College of Pathologists on the conduct of PM examinations ('Standards for Coroners' pathologists in post-mortem examinations of death that appear not to be suspicious'), and an external examination prior to evisceration is required by the HTA's codes of practice and standards.	**Major**
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	A number of SOPs have been reviewed and/or authorised by the same person that wrote the procedure. These included, but were not limited to: MOR003 Admission of Deceased Edition No. 2.1 MOR0047 Tracking and Disposal of Organs and Tissue See *Advice*, item 5.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The establishment routinely performs audits of retained tissue and bodies within the mortuary. However, at the time of inspection there were no procedural audits being performed to ensure that SOPs and policies were being followed by all hospital staff working within the mortuary.	**Minor**
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Although there is a schedule of audits, there was no evidence of audit reports, or actions resulting from audit findings. Any audits conducted are therefore not documented and are not shared for future learning. Audit findings need to record details of any audit that is undertaken and document any corrective and preventative actions arising from the audit findings. Any actions arising from an audit should be assigned to a member of staff, who is responsible for ensuring that they are implemented.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	One of the bodies in the mortuary that had been received from the community had only two identifiers on its identification bracelet. The lack of three identifiers leads to an increased risk of misidentification of the deceased. Families of the deceased schedule viewing appointments with the mortuary. It was noted during the inspection that there is no procedure in place requiring families to provide a minimum of three points of identification which can be used when preparing the deceased for the viewing. See *Advice*, item 10.	**Minor**

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 establishment records when the temperature monitoring system alarm is triggered, providing some assurance that it is functioning as required. However, there is no system of testing that the alarm triggers, and is responded to appropriately, in the event of a deviation of the storage temperatures from the expected range.	**Minor**
f) Temperatures of fridges and freezers are monitored on a regular basis	The temperature monitoring of the mortuary fridges is undertaken by hospital Estates services. At the time of inspection, mortuary staff were unable to provide any documentation showing that the temperatures were actively monitored or recorded.	**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	At the time of inspection, mortuary staff were unable to provide service records or other documentation confirming that the ventilation system provides the necessary ten air changes per hour.	**Minor**
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	At the time of inspection, mortuary staff were unable to provide servicing documents relating to the mortuary fridges and freezers. See *Advice*, item 14.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(a)	The DI is advised to review the SOP on Seeking Consent for Post Mortem Examination to clarify the order of the hierarchy of individuals that may provide consent, and to ensure that the SOP refers to the HTA Codes of Practice that came into force in April 2017.
2.	C1(e)	The establishment has developed a procedure where PM tissue that has been 'retained for Research' is sensitively disposed of, with approval from the Coroner, if no appropriate research is identified. The DI should liaise with the Coroner to assure themselves that individuals providing consent for tissue to be retained for research are aware that it will not be retained indefinitely, and will be sensitively disposed of if not used for relevant research.

3.	C2(c)	Consent for perinatal and paediatric PM examination is taken by trained Consultant, or Registrar, clinicians with a midwife in attendance. The DI is advised to consider providing consent training for the midwives involved in seeking consent for PM examination so they can support the process.
4.	GQ1(a)	The PM suite contains four PM tables. While the establishment's pathologists dissect organs at each PM table, there is no procedure in place to prevent mix-up of organs should visiting pathologists choose to dissect organs in the bench area. Although the pathologist only performs a PM examination on one body at a time, the DI is advised to risk assess this activity and develop a process to assure themselves that organs are examined from one case at a time, and are returned to the body, before the next PM examination is commenced.
5.	GQ1(d)	During a review of SOPs and policies, it was noted that several documents had been reviewed and/or authorised by the document's author. The DI is advised to update the 'Mortuary & Bereavement Suite Quality Manual' to state that 'Policies and SOPs are reviewed regularly by someone other than the author'. Existing SOPs and policies should be reviewed to ensure they have been written and reviewed by at least two individuals.
6.	GQ1(e)	The DI is advised to consider implementing an electronic system to record when establishment staff have read and understood new or revised SOPs and policies.
7.	GQ3(a)	While mortuary staff train porters, it was noted that the training did not include incidents reportable to the HTA. The DI is advised to update porter training in mortuary practices to include details of HTA reportable incidents. This may help to assure the DI that porters are aware of the requirements for what types of adverse incident need to be reported to the HTA, the requirement for them to be reported within five days of discovery, and to whom any incidents should be reported or escalated.
8.	GQ6(a)	The mortuary risk assessments 'Use of Temporary Mortuary Facility' and 'Manual Handling' detail a potential 'risk of harm to the deceased' and potential 'risk to all deceased patients', respectively, with actions to mitigate the potential risk. The DI is advised to review these risk assessments and specifically state the potential risks (e.g. risk of accidental damage to the deceased) and to assure themselves that the establishment's risk assessments cover all of the areas of risk identified in the HTA Reportable Incident categories (examples of risks to be assessed can be found in the 'Regulation of the Post Mortem Sector: What we have learned' document on the HTA website).
9.	T1(b)	The electronic mortuary register does not currently record the location of bodies in storage, although there is a note added to the name to indicate bodies in temporary or freezer storage. The DI is advised to develop the electronic system to record the location of bodies and any movement within the mortuary, to supplement the current practice of relying on a visual review of the refrigerated spaces to locate bodies in refrigerated storage. The electronic system also records details of tissue that has been retained or disposed of following PM examination and the ending of coronial authority. During the tissue audit, it was noted that a set of tissue samples that were 'to be retained for the medical record' had been mislabelled as 'retain for research'. This appeared to be a result of the electronic pull down menu not listing an option of 'to be retained for the medical record'.

		The DI is advised to review the available options within the electronic system to ensure they reflect the requirements. The form that is used to record the family of the deceased's wishes with regards to tissue taken during coronial post-mortem examinations refers to tissue being stored as part of the deceased's 'medical record'. Where tissue is being retained for use in scheduled purposes as defined by the Human Tissue Act 2004, this should be made clear to the person giving their consent to the retention so that they are fully informed about possible future uses of the tissue. The DI is advised to liaise with the Coroner to discuss amending the Coronial Family wishes form so that those giving consent to retention of tissue have additional information regarding the purposes for which the tissue may be stored.
10.	T1(c)	During the inspection, it was observed that bodies from the community may be received with only two points of identification on their wrist and ankle bracelets. As additional points of identification are included with the paperwork that the Funeral Director completes, the DI is advised to consider methods to assure themselves that either the Funeral Director completes three points of identification on the wrist and ankle bracelets, or that mortuary staff will amend/add the additional point(s) of identification when confirming the identification of newly admitted bodies from the community. This would mean that a minimum of three points of identification was available. SOPs should be updated to state a minimum of three points of identification are required whenever a body is being identified (for example, prior to a viewing, prior to a post mortem examination or during release to a funeral director) and to note that first name and last name is one point of ID.
11.	T1(g)	Traceability information relating to tissue samples sent to Histology is maintained in a number of separate records, including the mortuary TORD form. The DI may wish to consider developing a spreadsheet or database, to record traceability information in a single place. This may facilitate any review or access to tissue traceability information.
12.	PFE2(b)	The mortuary has limited fridge and freezer capacity, and it is because of the the procedures that the establishment has put in place that their capacity has not been exceeded. The DI is advised to risk assess the fridge and freezer storage capacity, and contingency planning, to ensure that capacity remains appropriate for now and in the future.
13.	PFE2(f)	Fridges and freezers within the mortuary were on an alarm system. A record of temperature excursions that had caused the alarm to activate was available and indicated the type of excursion, but not the temperature reached. The DI is advised to develop a procedure through which fridge and freezer temperature records are regularly reviewed by establishment staff to help identify trends in the equipment's performance. This may help to identify a potential equipment failure prior to it occurring.
14.	PFE3(f)	Servicing and maintenance of the establishment's fridges and freezers is overseen by the hospital's Estates services and mortuary staff were unable to provide any documentation to indicate that equipment had been serviced. In addressing the shortfall against PFE3(f), the DI is advised to implement a procedure through which they can access records of maintenance and servicing of the establishment's equipment and storage facility. This may help the DI in assuring themselves that servicing and

		maintenance is taking place as expected and that any settings, such as the temperature monitoring alarm system, have been returned to the appropriate settings following a maintenance visit.

Concluding comments

This report outlines the fourth routine site visit inspection of Colchester General Hospital. Although one major and eight minor shortfalls were identified, a number of strengths and areas of good practice were observed during the inspection, including:

- The establishment places the name and date that a body has been admitted to the mortuary onto the doors of the refrigerated storage. This allows the mortuary staff to rapidly and easily determine how long bodies have been stored at the mortuary.
- The establishment has generated paper documentation to ensure completion of several processes within the mortuary. These include i) a body map to detail any damage to the body, which is completed on the ward and countersigned on receipt in the mortuary and ii) a movement tracking form which is kept with each body and is used to record movement of the body within the mortuary, including viewings that may occur out of hours.
- The mortuary has established procedures, which, together with communication between the mortuary and external partners such as funeral directors and the Coroner, help to assure the DI that bodies are held in the mortuary for the shortest time possible.

There are a number of areas of practice that require improvement, including one major and eight 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: 21 February 2018

Report returned from DI: 09 March 2018

Final report issued: 15 March 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: 03 March 2019

Appendix 1: HTA licensing standards

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

Consent

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

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

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

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

This may be based on the HTA's model consent form for adult post-mortem examinations available on the HTA website, or in relation to infants, the resources pack developed by the

Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality systems

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

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

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

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

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

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

to mitigate them.

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

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

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

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

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

   ii. receipt upon return to the laboratory or mortuary

   iii. the number of blocks and slides made

   iv. repatriation with the body

   v. return for burial or cremation

   vi. disposal or retention for future use.

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

this purpose.

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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

a) The premises are clean and well maintained.

Guidance

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

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

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

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

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

assessments and same/similar name systems.

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

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

Establishments should consider entering in to Mutual Aid Agreements

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

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

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

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

Guidance

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

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

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

Guidance

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

d) Staff have access to necessary PPE.

Guidance

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

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

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

Guidance

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

Appendix 2: Classification of the level of shortfall

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

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

1. Critical shortfall:

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

or

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

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

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

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

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

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

2. Major shortfall:

A non-critical shortfall that:

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

or

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

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

3. Minor shortfall:

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

departure from expected standards.

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

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

Follow up actions

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

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

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

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