Site visit inspection report on compliance with HTA licensing standards

Craigavon Area Hospital

HTA licensing number 12042

Licensed under the Human Tissue Act 2004 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**

11 - 12 April 2019

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 Craigavon Area Hospital had met the majority of the HTA's standards, one major and eight minor shortfalls were found against standards for Consent, Governance and Quality, Traceability and Premises, Facilities and Equipment.

The shortfalls relate to the post-mortem (PM) examination consent refresher training procedures; standard operating procedures (SOPs); incidents; traceability and security of premises.

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

Craigavon Area Hospital (CAH), (the establishment) has been licensed by the HTA since August 2007. The establishment is licensed for removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes. Daisy Hill Hospital (DHH) is licensed as a satellite of CAH and is licensed for removal only. The Designated Individual (DI) is a Consultant Cellular Pathologist and the Corporate Licence Holder contact is the Director of Acute Services for Southern Health and Social Care Trust. Mortuary staff work cross-site, there is a full-time Lead Mortuary Technician, one part-time Mortuary Technician and two part-time Mortuary Assistants. Due to the mortuary staff working patterns, Mortuary Technicians work alone at both hospitals, most of the time.

The establishment receives around 2,700 bodies annually; no PM examinations take place at either hospital. All bodies requiring a hospital (consented) or Coronial PM examination are transferred to other HTA licensed establishments.

Consent for adult hospital and paediatric/perinatal PM examinations are taken by trained consultants or senior registrars. The training is delivered by the Trust Bereavement Coordinator and a Trust Grade Doctor, in accordance with a policy issued by the Health and Social Care (HSC) Bereavement Network. This policy was developed to standardise practice regarding consent for hospital PM examinations across all HSC Trusts. The policy has also been updated to reflect the revised HTA Codes of Practice (April 2017).

The establishment uses a two-stage consent training programme consisting of an e-learning package and face-to-face training. Consent for PM examination is recorded using regionally approved consent forms and family information booklets. The consent forms are in the process of being reviewed and the establishment are in discussions to base their consent forms on the Stillbirth and Neonatal Death (Sands) charity documentation for paediatric/perinatal cases. Only staff who complete the consent training are permitted to seek consent for adult and paediatric/perinatal PM examination (see shortfall against C2(b)).

Removal of tissue from deceased children in cases of sudden unexpected death in infancy (SUDI) is performed in the Accident & Emergency (A&E) department of both CAH and DHH. Staff involved in taking samples in SUDI cases follow a regional protocol (see *Advice*, item 1). Staff inform the Coroner on a case-by-case basis in advance of removing samples for investigation.

The mortuary at CAH has 12 refrigerated body storage spaces, including four bariatric and two freezer units for the storage of products of conception awaiting appropriate, sensitive disposal. Paediatric/perinatal cases are stored in a dedicated fridge space. All fridges and freezers are subject to annual maintenance servicing. There is 24-hour temperature monitoring and an audible alarm system, which sends a call-out message to all staff on the call-out system when the temperature goes below or above set limits. Fridge temperature

records are reviewed for trends and alarm testing is carried out. There are no fridges on the maternity wards for the temporary storage of foetuses at CAH and DHH as cold-cots are used before transfer to the mortuary.

Although limited storage is available, bodies are stored in most cases for only a few hours or a day before being transferred for PM examination, burial or cremation, as the local practice is for burial within three days of death.

The entrances to the CAH mortuary are secured by key locks and access is limited to mortuary and trained portering staff and there is a video intercom system in place as well as CCTV.

Portering staff are responsible for the transfer of bodies from hospital wards to the mortuary; the porters have access to a mortuary vehicle for the transfer of bodies, as the mortuary is a separate building situated some distance away from the main hospital site. On arrival at the mortuary, porters place bodies in to an available refrigerated body space and update the 'Porters Admission Sheet' with information of bodies brought into the mortuary. In addition, they bring the 'Body Transfer Form' for each body from the ward and leave this in a designated tray in the mortuary. Community bodies are admitted to the mortuary in cases were the Coroner or Police are involved. Only mortuary staff can admit bodies from the community to the mortuary and are on-call to assist with these.

Mortuary staff perform checks of all bodies the next working day, verifying the identification (ID) band details on the bodies against the 'Body Transfer Form' and 'Admission Sheet' for hospital bodies and make sure all bodies are appropriately shrouded. Mortuary staff create a record for all bodies admitted to the mortuary on LabCentre. This electronic mortuary register enables staff to record receipt and release of bodies and is also used to retain scanned images of any documentation associated with receipt and release.

The mortuary staff release bodies during normal working hours and use the details on the 'Body Transfer Form' to check against the wristband of the deceased. Funeral directors do not bring any paperwork with them for release of hospital or Coroner's bodies (see shortfall against T1(c)).

Babies over 24 weeks gestation are transferred to the mortuary by a member of the portering and maternity staff and are always released from the mortuary. Babies under 24 weeks gestation for hospital cremation are transferred to the histopathology laboratory or, if the family are making their own funeral arrangements, the laboratory liaise with the mortuary and maternity unit regarding release of these bodies. Families also have the option to take their baby home with them. Due to bodies being released quickly from the mortuary, viewings by the family in the mortuary are rare. The mortuary operates an appointment system for viewings, which generally takes place during working hours (see shortfall against T1(c)).

As PM examinations do not take place at either hospital, only archived PM tissue blocks and slides are stored at CAH mortuary, if appropriate consent has been given for retention or for use for scheduled purposes; the establishment does not routinely store samples for use for research. Relatives' wishes with regards to the fate of any tissue retained following PM examination is managed by the laboratory staff who update the electronic patient records with this information.

Daisy Hill Hospital (DHH)

The mortuary at DHH is located at the rear of the main hospital building. Portering staff are responsible for the transfer of bodies from hospital wards to the mortuary. Currently the pathway to the mortuary is through a staff car park (see *Advice,* item 8). The mortuary is accessed via key locks at both the hospital and funeral director entrance; there is currently no hospital CCTV, although there are plans for this to be installed (see *Advice,* item 4), and there is an audio-visual intercom system at the funeral director entrance to confirm who is requesting access to the mortuary. The body store has six refrigerated spaces and one freezer for the storage of products of conception awaiting appropriate, sensitive disposal. The fridges are connected to a remote monitoring alarm system, which contacts on-call staff if the temperature deviates outside the normal temperature ranges (see shortfall against PFE2(e)). Bodies from A&E are admitted to the mortuary by mortuary staff only who work on-call to facilitate this. Viewings are not undertaken at this site, only formal identifications for the police.

Description of inspection activities undertaken

This was the third site visit inspection of the establishment; the previous inspection took place in 2015. The inspection team reviewed governance and quality system documentation, carried out interviews with key members of staff, a visual inspection of the mortuary body store areas, viewing suites and conducted traceability audits of bodies and tissue blocks and slides in storage.

An audit trail was undertaken at each of the sites:

• CAH – only two hospital bodies were in the refrigerated storage at the time of inspection. Both bodies were audited; ID details on the body were cross-checked against the relevant documentation. No discrepancies were identified.

• DHH – No bodies were in storage on the day of the inspection.

In addition, tissue traceability audits were conducted for seven cases between 2008 and 2012 at the CAH archive. The audits included details of tissue type, number of tissue blocks and slides retained, consent forms, other associated paperwork and electronic database records. A discrepancy was identified on the PM report cover sheet in three of the seven

cases audited. In the ‘tissue arrangements’ section it was documented that the tissue blocks and slides were for ‘hospital disposal’, whereas the consent wishes of the family were for retention for a scheduled purpose(s). The tissue samples were audited and were being stored in-line with the correct consent (see shortfall against standard T1(g)).

Inspection findings

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

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
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	The consent forms audited during the HTA inspection did not contain details of whom to contact if the family wished to withdraw consent, and the timeframe that was available for them to do so. As PM examinations take place very quickly after death in Northern Ireland, often within 24 hours, it is important that families are clear on the timeframe they have to change their mind.	**Minor**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training	Staff involved in seeking consent for adult and perinatal/paediatric PM examinations have received training in PM consent and demonstrate a good knowledge of the consent process and the HTA Codes of Practice. However, not all staff who have been consent trained have subsequently received refresher training. As hospital (consented) PM examinations are rare, it is important refresher training is regularly undertaken. As a result, the consent standard C2(d) cannot be met in relation to all staff trained in seeking consent for PM examination.	**Minor**

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.	Some of the SOPs in the Mortuary Manual require updating: - The section on 'who may give consent' does not have 'grandparents/grandchild' listed in the hierarchy of qualifying relationships; - The section on 'release of a body' states that three points of ID should be checked before release, however funeral directors are bringing no release paperwork with them, so release is currently on a verbal request only; - The section on 'viewing of the deceased' does not state that three identifiers are required from the family which can be checked against the wristband of the deceased before viewing takes place. In addition, process for the transfer of products of conception from the maternity unit to the histopathology laboratory is not documented in an SOP. The details of the paperwork that needs to be completed and the use of appropriate transport containers should also be included.	**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&E, maternity and portering staff undertaking licensable activities, lacked awareness of incidents that require reporting to the HTA (HTARIs) and the reporting requirements.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	i) Funeral directors do not bring paperwork with them to release a body, meaning the mortuary staff are releasing bodies on a verbal request of name only. ii) Families are not being asked to provide three identifiers when attending the establishment to undertake viewings and often, only the name of the deceased is requested. The use of less than three separate identifiers when identifying bodies, presents a risk of releasing and viewing the wrong body.	**Major**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The establishment use the consent forms stating the relatives wishes for tissue in their tissue audits to ensure that relatives wishes are acted upon and tissue is only retained with consent. However, the relatives' wishes documented on the PM report cover sheets for almost half (three) of the cases audited was incorrect. This presents a risk of tissue being disposed of or retained against the wishes of the family, if the cover sheet is used to determine the fate of tissue.	**Minor**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	On the day of the inspection of DHH, the inspection team were granted access to the mortuary by a member of the hospital maintenance staff undertaking work in the mortuary, without requesting any identification from the inspection team. In addition, the back door to the mortuary was left open to allow the maintenance staff to access the mortuary.	**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	Alarm trigger points for the mortuary fridges and freezers were set at temperatures that could pose a risk to the integrity of the bodies in storage if the units were to fail. The alarm system is challenged by the Estates Department annually. The frequency of this test should be increased to provide the DI with sufficient assurance that this is being done and that the alarm will trigger when required. The dates of the alarm system challenges should also be documented.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
b) Equipment is appropriate for the management of bariatric bodies	The establishment do not have suitable equipment for the transfer of bariatric bodies to the mortuary. Current practices do not ensure the dignity of the deceased and could cause distress to other users of the hospital.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ3(c)	The DI is advised to liaise with A&E staff at DHH to introduce training simulations for the purposes of SUDI, in line with the current process followed at CAH.
2.	GQ5(a)	The DI is advised to raise awareness of the importance of reporting incidents including awareness of the HTA Reportable Incident (HTARI) categories. This should be shared with all staff conducting licensable activities.
3.	T1(c)	In addressing the shortfall identified under this standard the DI is advised to consider ways to strengthen the procedure for undertaking viewings. The DI may wish to consider the introduction of a form to be completed by relatives when they attend for viewings. This form could include relevant identification information so that three identifiers can be checked on the body before the viewing takes place. Similarly, the DI is advised to consider creating a form for funeral directors to complete and bring with them to the mortuary so three identifiers can be checked and used to identify the deceased before release.
4.	PFE1(d)	The DI is advised to continue with the installation of the CCTV at DHH mortuary at both the front and rear entrances.

5.	PFE2(e)	The DI is advised to ensure fridge temperatures in both mortuaries are maintained between 4-6°C, with lower and upper triggers points of around 2°C and 8°C, respectively, with an appropriate time period before the alarm triggers. This will prevent the on-call staff being unnecessarily alerted each time the fridge doors are left open when staff are working in the body store. In addition, the DI is also advised to reduce the freezer trigger points within +/-4°C of the set running temperature, which should also be in–line with the HTA's guideline of -20°C.
6.	PFE3(b)	The DI is advised to consider the options available for equipment for the transfer of bariatric bodies to the mortuary, such as a bariatric concealment cover for hospital beds for use at both hospital sites.
7.	N/A	The DI is advised to review the establishment's policy for lone working in the mortuary to ensure that lone working arrangements are sufficient, appropriate and protect the safety of staff. As staff are routinely working alone across both hospital sites, the introduction of a man-down alarm may help to provide assurance of staff welfare.
8.	N/A	The DI may wish to consider making the current porter/staff access door to the mortuary at DHH the same access door for funeral directors when admitting and releasing bodies. The current access point at the front of the mortuary for funeral directors is blocked by the laboratory staff car park, which means that the mortuary staff have to contact all of the laboratory staff in advance to move their cars before the funeral directors arrive.

Concluding comments

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

All staff involved in the inspection demonstrated a sensitive and dedicated approach to their work. The establishment staff are a cohesive, long-standing, experienced team, who communicate well with each other and are open to accepting advice and guidance.

Staff are engaged and have good knowledge of licensable activities across all areas of the licence including A&E and maternity.

The establishment uses identical mortuary procedures at both hospitals, helping to minimise the risk of staff error as staff work across sites.

The electronic quality management system is used to control documentation, schedule audits and risk assessments, record training, manage incident reporting and investigations, share learning, and is available to staff at all locations.

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. The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 7th May 2019

Report returned from DI: 3rd June 2019

Final report issued: 5th June 2019

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: 20th November 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.