Site visit inspection report on compliance with HTA licensing standards

Hemel Hempstead General Hospital

HTA licensing number 12082

Licensed under the Human Tissue Act 2004 for the

- **making of a post mortem examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

29 and 30 November 2017

Summary of inspection findings

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

Although the HTA found that Hemel Hempstead General Hospital had met the majority of the HTA's standards, four minor and two major shortfalls were identified. These were due to issues relating to weaknesses in the following areas: adult hospital consented post-mortem examination processes; baby and perinatal consent for post-mortem examination procedures; incident reporting procedures; risks associated with storage of the deceased and release procedures.

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

The establishment (Hemel Hempstead General Hospital) is licensed by the HTA as a hub and satellite licensing arrangement. Hemel Hempstead General Hospital is the hub premises and Watford General Hospital is the satellite. Mount Vernon Hospital has previously been licensed as a satellite site; however, a request was made by the establishment in 2016 to revoke this licence and all relevant material was transferred to the hub site's premises.

Both the hub and satellite sites are licensed for making of a post-mortem (PM) examination, removal of relevant material from the deceased for scheduled purposes and storage of bodies or relevant material. PM examinations take place only at Hemel Hempstead General Hospital. Storage of bodies takes place in the mortuary and removal of tissue from children following sudden unexpected death in infancy (SUDI), takes place in the A&E department. Mortuary staff work across both hospital sites.

Description of inspection activities undertaken

The establishment has been licensed by the HTA since 2007 and this report describes the establishment's third routine site visit inspection to assess compliance with the HTA's standards. The establishment carries out approximately 500-600 PM examinations each year on behalf of HM Coroner for Hertfordshire. The establishment also undertakes hospital consented PM examinations; only one consented hospital PM examination took place in the 12 months prior to the inspection. Consent for PM examination is sought by mortuary staff, clinicians or the patient affairs team. Consent for perinatal and infant PM examinations is documented on a form adapted from the Stillborn and Neonatal Death Charity's (SANDs) model consent form. Perinatal and baby PM examinations are undertaken by another HTA-licensed establishment.

During the inspection, a visual inspection of the body store, PM room, Histopathology department was carried out. Although the PM room at the satellite site is not used to carry out PM examinations, it was included as part of the visual inspection in addition to the body store area as there may be occasions when it may be used to conduct PM examinations. In the event that the PM room at the satellite site is used to conduct a coronial PM examination, the deceased would be transferred from the hub to the satellite site and would remain at the satellite site until release to the family's appointed funeral director.

The inspection also included interviews with the Mortuary Manager, Histopathology Laboratory Manager, Corporate Licence Holder contact (CLHc), Bereavement Midwife, Head Porter, Consultant Pathologist and Designated Individual (DI). An interview with a Coroner's Officer was held over the telephone prior to the inspection.

The A&E department at the satellite site is an area in which samples may be removed from SUDI cases. The HTA visited the A&E department and met with the Consultant in Paediatric

Emergency Medicine and a member of nursing staff responsible for this activity. They demonstrated an understanding of the requirements of the Human Tissue Act 2004 and explained the establishment's SUDI procedure. The HTA was satisfied with the arrangements in place covering this activity.

The hub site receives bodies from the hospital and the community. Hospital deaths are admitted to the mortuary by porters and community deaths are admitted by funeral directors contracted by the coroner. Perinatal or stillborn babies are transferred directly from the delivery suite to the mortuary at the satellite site. There are no maternity wards or delivery suite at the hub site. Only hospital deaths are admitted to the mortuary at the satellite site.

Porters and funeral directors must complete the relevant paperwork, located in the mortuary's 'admission folder/book', when admitting bodies during the normal working day and out of hours. Mortuary staff are responsible for checking the condition and identification of the deceased that have been admitted. Mortuary staff transcribe the identification details of the deceased into the mortuary register. Deceased with same/similar names are flagged in the mortuary register with a coloured pen.

The body store at the satellite site includes 50 fridge spaces and five freezer spaces. There is also a perinatal fridge which provides 15 spaces and four bariatric spaces. Additional storage outside of the mortuary offers a further 25 fridge spaces. The body store at the hub site includes 50 fridge spaces and five freezer spaces. There is no bariatric storage available at the hub site; however, bariatric bodies may be transferred to another HTA-licensed premises for storage.

Fridges and freezers at both sites are connected to an electronic temperature alarm monitoring system which has recently been installed; however, the previous alarm monitoring system is still operational (see *Advice*, item 13). In the event of a deviation in the storage temperatures from the expected range, the alarm will notify switchboard via an auto-dialler. The Estates department and Mortuary Manager will be informed in the event that an alarm is triggered. Mortuary staff document storage temperatures on a daily basis between Monday-Friday; however, no temperature trend analysis is undertaken (see *Advice*, item 15).

The deceased are identified, and an external examination undertaken, by the Pathologist the day before the PM examination takes place (see *Advice*, item 6) and a pink band stating 'ID has been checked by Senior staff' is placed on the wrist of the deceased. The identification of the deceased will be checked once again prior to evisceration, on the day of the PM examination.

A 'Transfer of Care' form is completed by the family of the deceased prior to their release. The form must include details of the name of the funeral director, full name of the deceased, date of birth and address. This form must be presented by the funeral director to the mortuary staff prior to release of the deceased. Although this form provides a robust

mechanism to ensure that the correct funeral director collects the deceased, the mortuary uses only two identifiers when releasing the deceased (minor shortfall, T1(c)).

A traceability audit of six bodies, across both the hub and satellite sites was carried out. Bodies were identified from the mortuary register and traced to their actual storage locations, and vice versa. Identity details on each body's wristband were cross checked with the details recorded in the establishment's mortuary register. No discrepancies were identified. A tissue traceability audit of four coronial cases was also carried out. In one case, the date of disposal recorded on the placeholder card in the location where the material was stored prior disposal was incorrect; this was a transcription error and all other records were accurate. No other discrepancies were identified.

An audit of three hospital PM examination consent forms was undertaken. Two of the three consent forms had been completed as expected; consent had been given for the retention of tissue for a scheduled purpose by an appropriate person in the hierarchy of qualifying relationships. The review of the third consent form highlighted issues with the completion of the form. Part two of the consent form, which includes options for the retention and disposal of human tissue for future use, had two differing options selected by the person giving consent, meaning their wishes were not clearly recorded. Furthermore, part three of the consent form, which relates to the detailed examination of organs removed during PM examination, had been struck out (minor shortfall, C2(c)). As a result, it was not clear whether the wishes of the person providing consent had been accurately recorded. The Mortuary Manager confirmed that this consent had been sought by an untrained member of staff, and that no tissue or organs had been removed from the deceased in this case. The consent form had been completed by an appropriate person in the hierarchy of qualifying relationships.

A consent form for a perinatal PM examination was also reviewed. The time period noted on the form for the mother to change her mind was less than 24 hours (see *Advice*, item 1). The consent seeker stated that the PM would not take place until 24 hours had passed, and that this was explained to the person giving consent.

Inspection findings

The HTA found the Licence Holder (LH), the Designated Individual (DI) and the premises to be suitable in accordance with the requirements of the legislation. Since the last site visit inspection, the CLHc has changed to the Chief Executive Officer (CEO) of the Trust. During the inspection, an interview was undertaken with the CEO who was found to be suitable for this role.

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		
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	Although the establishment has a policy in place for seeking consent for PM examinations, it does not reflect that consent can only be sought by a person who is appropriately trained or, if staff are untrained, that they must be supported by a person who is trained. Where an untrained staff member wishes to approach a family to seek consent for PM examination, the policy does not describe the process for identifying a trained member of staff to support the consent seeking process. Furthermore, the policy does not set out the requirement that consent must be sought from the individual themselves in life, their nominated representative or an appropriate person with whom the deceased was in a qualifying relationship with prior to their death and instead refers to consent being sought from a 'relative'.	**Major**
b) There is a documented standard operating procedure (SOP) detailing the consent process	The procedure for seeking consent for adult PM examinations refers to 'next of kin' and not the individual themselves in life, their nominated representative or an appropriate person with whom the deceased was in a qualifying relationship with prior to their death. Furthermore, the procedure does not outline the process of how mortuary staff, who are trained in seeking consent for hospital PM examinations, are alerted by either the Patient Affairs team or the clinician requesting a PM examination that they need to be present when consent is sought. The majority of consent for perinatal PMs is sought by a trained bereavement midwife, however, there is no documented procedure in place that governs the seeking of consent for PM examination for babies or peri-natal cases.	**Minor**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual	During the review of hospital PM consent forms, an example of consent being sought by an untrained member of staff was identified. In this case, the consent form used to record the consent being given had not been completed as expected (see page 5 of the report).	**Major**

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	Although the incident reporting procedure covers all the HTA reportable incident (HTARI) categories and timeframes for reporting them to the HTA, it does not include the requirement to report near misses. This is particularly important, as during the inspection a review of incidents from the past 12 months was carried out and identified an incident that should have been reported to the HTA as a near miss. *Following the inspection, satisfactory information has been received from the establishment and the HTA considers the shortfall to have been met.*	**Minor**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	Occasionally, the bottom of the fridges are used to store bodies in body bags during periods of peak activity in the mortuary. There is no documented procedure in place that relates to this activity. In addition,a risk assessment, identifying any risks arising from this practice and the measures to mitigate them, has not been undertaken. *Following the inspection, satisfactory information has been received from the establishment and the HTA considers the shortfall to have been met.*	**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	The mortuary relies upon confirmation of two identifiers during the release of hospital and community death bodies. For hospital deaths, the full name and date of birth are used and for community deaths, the full name and age are used. The reliance on only two identifiers presents a risk that a body may be wrongfully identified during its release to a funeral director. (see *Advice*, item 11).	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(f)	The establishment provides a 24-hour cooling-off period for parents who have consented to a PM examination of their baby. During the review of a consent form, it was noted that a shorter timeframe had been documented on the consent form. Although the HTA-licensed establishment responsible for conducting the PM examination will not commence the activity until the full 24 hour period has elapsed, the establishment is not documenting the correct timeframe in which the parents must contact the establishment should they change their minds. The DI is advised to review this practice to assure themselves that the correct timeframe is documented and that families are fully informed about when thay are able to change their minds regarding consent for PM examination.
2.	C1(g)	The hospital PM examination consent form includes a section where mortuary staff confirm that they have checked the completion of the consent form. The HTA audit identified forms where this section had not been completed. The DI is advised to ensure that this section is always completed and, where issues in the completion of the consent form are identified, that these are documented and reviewed with the person who completed the form.

		In the future, if mortuary staff become solely responsible for seeking consent for hospital PM examinations, the DI may wish to include another member of the mortuary team to check the consent forms for completeness and accuracy. This will provide provide a second check of the form and also help the DI to assure themself that any errors in the form's completion are identified.
3.	C2(a)	Mortuary staff are trained in the seeking of consent for adult PM examinations. At the time of the inspection, there was an on-going discussion about whether the responsibility for seeking consent should become the sole responsibility of mortuary staff who have the understanding of the PM process and the requirements of the Human Tissue Act 2004. Until this is agreed, the DI may wish to consider providing consent training for Trust clinicians in the seeking consent for PM examination.
4.	GQ1(a)	Although the mortuary standard operating procedures (SOPs) contain sufficient detail, there were some details in a small number of SOPs that have since become obsolete. The DI is advised to review the establishment's SOPs to assure themselves that they accurately reflect all current practices.
5.	GQ1(a)	The on-call Trust Managers at the hub site may be involved in out of hour's viewings for the identification and verification of the deceased. Even though there have been no requests for such vieiwings, the DI may wish to consider organising formal training for on-call Trust Managers, who may be called upon to assist with these types of viewings.
6.	GQ1(a)	The DI is advised to review key SOPs that involve the identification of the deceased - for example, receipt, viewing, PM examination and release - to assure themselves that these documents mandate that a minimum of three identifiers, including one that is unique, are verified whenever identification of the deceased takes place.
7.	GQ1(e)	The DI may wish to consider adding Consultant Pathologists onto the distribution list for SOPs that are relevant to them; for example, procedures relating to preparing for a PM examination. This will enable any changes in procedures to be communicated to this group via the document control system.
8.	GQ2(a)	The establishment carries out a range of observational audits of the mortuary's procedures. To strengthen the approach to audits, the DI is advised to include vertical audits of cases. Furthermore the DI is advised to ensure that greater detail about the audit findings is formally documented so it is clear what was found. This could include, for example, how many records were reviewed or what time period was covered, as well as more detail about actions taken in response to findings.
9.	GQ3(c)	All porters are trained by mortuary staff. The DI is advised to also consider the developing written work instructions for porters to follow for key areas of mortuary activity that they are involved in.
10.	GQ6(b)	The establishment has a range of risk assessments which reflect the HTA Reportable Incident (HTARI) categories. The DI is advised to review these to assure themselves that the control measures that have been identified to mitigate each risk identified are described with the appropriate level of detail; for example, including reference to a relevant SOP.
11.	T1(c)	The establishment uses a 'transfer of care' form, which is provided to families so that they may complete the details of the deceased and is given to the nominated funeral director to present to the establishment during the release of the deceased. For hospital deaths, the DI may wish to consider whether it is

		possible for the Patient Affairs team to add the Hospital/NHS number of the deceased to this form, before it is provided to the family. Staff use all the information available for identification but in most cases bodies from the community do not have a date of birth written on the ID tag and in many cases the paperwork used to release does not have a date of birth on it. In addition, bodies from deaths in the community are only labelled with two points of identification when brought to the mortuary. The DI is advised to liaise with the Coroner to request that a third point of identication is added to the deceased's wrist band. This additional information could be included on the transfer of care form which is brought by the funeral director at the time of release.
12.	T2(b)	The coroner's family wishes form contains a statement that tissue removed at PM examination will be disposed of if families do not express their wishes within three months. The mortuary will store this tissue for a period of 12 months before carrying out disposal in case the family get in touch with the Coroner's Office or the Mortuary. The DI is advised to agree, with the Coroner's Office, a suitable timeframe for the storage of tissue where the wishes of the family are unknown.
13.	PFE2(e)	At both the hub and satellite sites, the establishment's previous temperature monitoring alarm system is still connected and in operation despite a new electronic system being installed. The DI is advised to consider whether having two alarm systems active simulatneously poses any risks that an alarm may not be triggered or responded to appropriately.
14.	PFE2(e)	The trigger points, which activate the fridge alarms, are as follows: i) -3^0 C is the lower limit set point; ii) 10^0 C is the upper limit set points. The DI is advised to review these alarm trigger settings to assure themselves that the establishment's fridges are maintained at approximately 4^0C and that the alarm is triggered when the temperature deviates from this sufficiently to pose a risk to the integrity of the stored bodies.
15.	PFE2(f)	The DI is advised to develop a procedure to review the establishment's temperature monitoring data to identify unexpected temperature deviations. Trend analysis will help the mortuary to plan for maintenance of fridges and freezers and may help to identify a potential failure prior to it occurring.
16.	N/A	Although the option for repatriation is offered to families who request it, the coroner's family wishes form only provides three options to the family, which are: retention for a scheduled purpose, disposal, or return to the family.The option for repatriation of an organ is not included on this form. The DI should consider liaising with the Coroner with the aim of developing additional wording to include the option of repatriation.

Concluding comments

The establishment has undertaken significant work to achieve compliance with the HTA's new standards. There are a number of areas of good practice that were noted on the inspection which are as follows:

- Comprehensive competency logs are kept for mortuary staff including the use of observational audits of mortuary staff carrying out mortuary tasks;

- The training of new funeral directors in mortuary admission procedures;
- The use of different coloured pens, as a visual reminder to mortuary staff, to highlight the deceased that are newly admitted and those that have been under the care of the mortuary for a duration of a week, two weeks or a month; and,
- The use of disposal cards, with the date of disposal, which are placed in the space where the blocks were initially stored.

There are a number of areas of practice that require improvement, including four minor and two major shortfalls. These were due to issues relating to weaknesses in the following areas: adult hospital consented post-mortem examination processes; baby and perinatal consent for post-mortem examination procedures; incident reporting procedures; risks associated with storage of the deceased and release procedures. Advice has been given across a broad range of standards.

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: 18 January 2018

Report returned from DI: 9 February 2018 (with comments)

Final report issued: 21 February 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: 29 November 2018

Appendix 1: HTA licensing standards

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

Consent

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

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

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

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

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

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality systems

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

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

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

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

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

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

to mitigate them.

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

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

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

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

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

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

this purpose.

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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

a) The premises are clean and well maintained.

Guidance

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

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

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

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

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

assessments and same/similar name systems.

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

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

Establishments should consider entering in to Mutual Aid Agreements

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

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

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

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

Guidance

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

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

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

Guidance

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

d) Staff have access to necessary PPE.

Guidance

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

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

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

Guidance

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

Appendix 2: Classification of the level of shortfall

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

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

1. Critical shortfall:

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

or

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

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

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

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

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

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

2. Major shortfall:

A non-critical shortfall that:

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

or

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

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

3. Minor shortfall:

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

departure from expected standards.

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

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

Follow up actions

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

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

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

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