Site visit inspection report on compliance with HTA licensing standards

Birmingham Women's Hospital

HTA licensing number 12565

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**

26 & 27 September 2018

Summary of inspection findings

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

Although the HTA found that Birmingham Women's Hospital had met the majority of the HTA's standards, three major and three minor shortfalls were found against the Consent, Governance and Quality Systems, Traceability and Premises, Facilities and Equipment standards. These related to the referencing of hierarchy of qualifying relationships in the consent policy, SOPs, the use of three identifiers, body storage practices and ventilation in the PM room.

Particular examples of 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

Birmingham Women's Hospital (the establishment) has been licensed by the HTA since May 2007. This report refers to the activities carried out at the mortuary of the establishment. They are licensed for the making of a post-mortem (PM) examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes. The Designated Individual (DI) is a Consultant Microbiologist and Clinical Director and the Corporate Licence Holder contact is the Chief Executive for Birmingham Women's and Children's NHS Foundation Trust. In addition to the DI, the Mortuary Manager has oversight of activities taking place in the mortuary and line management responsibility for the Anatomical Pathology Technologists (APTs).

The establishment provides a PM service for perinatal and paediatric cases, up to the age of two years. This service is utilised by 15 hospitals and 10 Coroner's districts. They receive approximately 770 bodies each year with approximately 600 of these being consented perinatal PM examinations. The establishment conducts high-risk PM examinations (up to category 3); forensic PM examinations occasionally take place at the establishment but most are conducted at another licensed establishment nearby.

Removal of tissue from deceased children in cases of sudden unexpected death in infancy (SUDI) is not performed in the Accident & Emergency department of the hospital.

Trained Bereavement Midwives seek consent for PM examination from parents and provide support and advice throughout the process (see shortfall against standard C1(a)). PM consent forms and information leaflets used by the bereavement team are based on the Stillbirth and Neonatal Death charity (Sands) documentation (see shortfall against standard C1(c)).

The mortuary have walk-in cold room storage, which provides 84 body storage spaces. There are also three contingency fridges located in a store room within the mortuary; these were not in use at the time of inspection. All fridges are connected to a remote monitoring system and have audible alarms, which are connected to the switchboard and notify mortuary staff of temperature deviations from within set ranges, during and outside of working hours. The Head Biomedical Scientist monitors the fridge temperatures for trend analysis on a daily basis and oversees weekly fridge alarm testing carried out by the estates department. The establishment has a written service level agreement (SLA) in place with a local funeral director for contingency storage if the mortuary body store is nearing capacity. There is no adult body store on-site. If there is a maternal death, the body is transferred to a nearby licensed establishment.

The establishment has a maternity unit and a gynaecology ward, where there are fridges for the storage of placentas, fetuses (occasionally) and products of conception (POCs), respectively. Cold cots are routinely used on the delivery suite before transferring babies or fetuses to the mortuary. On a daily basis, porters collect and transfer fetuses and specimens

from both fridges and take them to the mortuary. Both of these fridges are connected to a remote temperature monitoring system and temperatures are monitored daily and are tested by the estates department, with the Head Biomedical Scientist having oversight of these storage areas.

Key code and swipe card access is required for both visitor and undertaker access doors to the mortuary. There is CCTV throughout the mortuary and the undertaker entrance CCTV coverage allows staff in the mortuary office to confirm who is requesting access.

Portering staff are responsible for the transfer of bodies from hospital wards to the mortuary; ward bereavement staff will on occasion accompany families with a baby to the mortuary but only as far as viewing area. On arrival to the mortuary, portering staff place bodies in an available refrigerated storage space, they then update the mortuary whiteboard located outside of the cold room with the full name of the deceased, the mother's name, date received into the mortuary and storage location. The 'Notice of Death' form which details identification information for baby and mother, is then placed into an incoming patient tray and the 'Mortuary Access Sheet' is completed by the porters before leaving.

Coroner's contracted funeral directors and the referring hospitals arrange transfer of perinatal and paediatric cases for PM examination to the mortuary during working hours. All hospital and Coroner's cases are logged onto an electronic mortuary register where a unique mortuary identification number is generated. Referring hospitals have their own unique identification numbers for the cases they refer for PM examination but the establishment generate their own unique PM number for all PM examinations that take place.

Mortuary staff perform body checks of hospital bodies the next working day, verifying the identification band details on the wrist and ankle against the 'Mortuary Registration Form' and making sure all bodies are appropriately shrouded. An orange magnet is placed on the mortuary whiteboard for bodies with same and/or similar names. Internal incidents are raised if bodies are admitted to the mortuary with incorrect wristbands and ward staff are notified.

Coroner's bodies are released from the mortuary using a release form sent from the Coroner's Office. Hospital bodies and hospital transfers are released using the Certificate for Burial and Cremation (Green disposal form) and a fully completed 'Body Release Form' (see shortfall against standard T1(c)). During working hours two members of the mortuary staff are present to go through the process of release. When only one APT is available, support will be sought from the bereavement team to ensure appropriate identification checks take place before release. Mortuary staff will facilitate out-of-hours body releases by prior arrangement only. The on-call senior histologist facilitates releases outside of working hours and ensures that the funeral director brings the appropriate paperwork with them. The on-call histologist arranges for a member of the ward staff to assist with release so the two-person check still occurs.

Bereavement services facilitate viewings of the deceased and have an appointment system in place. Mortuary staff work with the bereavement team during working hours to prepare the bodies for viewings. Viewings generally take place during working hours but the bereavement team do have an out-of-hours viewing policy for ward and portering staff to follow and will accommodate these viewings where possible.

The PM suite has three downdraught PM tables and one spare height-adjustable table. There are dissection benches for the preparation of tissue samples. High-risk PM examinations can be undertaken in the PM room at the end of each session. PM examinations take place one at a time to minimise the risk of mix-up of organs and tissue samples between cases. The identification of the body is always checked by the pathologist and an APT prior to evisceration. There is one APT per pathologist at all times in the PM room to ensure samples taken at PM are appropriately checked and recorded. Mortuary staff have access to the necessary PPE within the PM room and body store area and there is demarcation of clean and dirty areas within the mortuary. There is a temperature monitored freezer in the PM room which alarmed and tested. This freezer is used to store liver samples with consent for genetic testing and samples under police authority. The PM room is access controlled and locked when not in use at the end of each PM session.

Material retained at PM examination for histological examination is appropriately labelled in the mortuary and assigned a unique PM number and transferred to the on-site histopathology laboratory for analysis. Blocks and slides are stored on site if there is consent for retention; tissue samples may be kept, with consent, for use for scheduled purposes but the establishment does not routinely store samples for use for research. Blocks and slides are stored in an on-site store room, which has keypad controlled access. The mortuary and histopathology laboratory use the same electronic database to record PM tissue sample details, including storage location and family wishes for the fate of the samples.

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 carried out a visual inspection of the body store, PM room, viewing area and audits of bodies and tissue blocks and slides in storage.

Interviews with key members of staff, a review of governance and quality system documentation and traceability audits were also undertaken. A traceability audit was carried out of four perinatal cases; three of these cases were hospital consented PM examinations, including one referral case from another hospital and a Coroner’s case. One of these cases was a long-term body from June 2018; the storage arrangements were not appropriate to maintain the condition of that body (see shortfall against standards PFE2 (a) and (c)). Body location and identification details on bodies were cross-checked against the information recorded in the mortuary register and relevant documentation. No discrepancies were found.

In addition, two hospital consented cases where tissue was retained for scheduled purposes and two Coroner's cases where tissue was repatriated following the PM examination were audited. The audit included details of tissue type, blocks and slides retained, consent forms, review of the electronic mortuary and laboratory databases and associated paperwork. No discrepancies were found.

Home Office PM examinations are conducted at the establishment. Under section 39 of HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority contained a recommendation that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process. Therefore, procedures for Home Office PM examinations and management of tissues and organs taken for criminal justice purposes were reviewed by the HTA at this site visit inspection.

Inspection findings

The HTA found the Licence Holder, 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		
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	The 'Post Mortem Consent and Retention of Tissues and Organs Policy' uses the term 'Next of Kin' throughout, which could imply that a person not ranked highest in the hierarchy of qualifying relationships could give consent to a PM examination or retention and future use of tissues. The policy also states that those with parental responsibility for a child are the only ones who can consent to a PM examination and use of tissues for scheduled purposes following death. If there is no person with parental responsibility (for example, if the parents died at the same time as the child), then consent should be sought from someone ranked highest in the list of qualifying relationships as outlined in Code A - Guiding Principles and the Fundamental Principles of Consent.	**Minor**
c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	The information given to parents for consented PM examinations, 'Information for Parent(s) Considering Giving Consent for a Post Mortem', contains a phone number, in the 'changing your mind' section, which does not match the phone numbers provided on the 'Consent for PM examination of a Baby or Child' consent form. In addition, the consent form is not version controlled and references the HTA's previous Code of Practice 3.	**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 do not accurately reflect current practice and do not contain sufficient detail for staff regarding the procedures that must be followed. Particular examples include but are not limited to: - SOP for the release of bodies do not include details of the minimum three identifiers that must be checked and what they must be checked against; - SOP for viewing of bodies do not include details of the minimum three identifiers that must be checked and what they must be checked against; This is not an exhaustive list of the amendments required to SOPs, and to fully address this shortfall, the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail of the procedures.	**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 staff do not consistently obtain three identifiers for bodies from funeral directors on release. The mortuary request they bring a 'Body Release Form', which asks for the name of the child, the name of the mother, address and date of death. Clarity around the date of birth/date of death is required to ensure that three points of identification are consistently obtained. In addition, the various release forms sent from the different Coroner's Offices do not always contain three identifiers, which are required to sufficiently check the identification of a body prior to release. (see *Advice*, item 5) The use of less than three separate identifiers (one being unique) when identifying bodies, presents a risk of releasing the wrong body.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The establishment does not have dedicated or contingency freezer storage. As a result, bodies that require long-term storage are not being frozen after the 30-day recommended timescale. This does not ensure that the condition and integrity of these bodies is maintained.	**Major**
c) Storage for long-term storage and bariatric bodies is sufficient to meet needs		

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The establishment does not have any records of service or maintenance for the PM suite ventilation system and the mortuary staff are not aware if the ventilation system has ever been tested. Therefore, it could not be established that the system is providing the necessary ten air changes per hour.	**Major**

Advice

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

No.	Standard	Advice
1.	T1 (c)	The DI is advised to consider strengthening the procedure for viewings by introducing a form to be completed by relatives when they attend the mortuary for viewings. This can include relevant identification information so that three identifiers on the body can be checked before the viewing takes place.
2.	T1 (c)	The DI is advised to enhance the system for flagging same and/or similar names by adding an additional wristband to the bodies as another way of alerting staff to check.
3.	T1 (c)	In addressing the shortfall against T1(c) the DI may wish to consider introducing a standardised release form for funeral directors that is completed by them prior to arrival at the mortuary and brought in addition to other documentation by the funeral director. This form could contain the required three identifiers to release a body. In addition, the DI is advised to liaise with the Coroners' office to request that the relevant three identifiers are included on the release forms sent by them to the mortuary.
4.	T2 (a)	The Coroner's Office does not always confirm the dates of inquest or the decisions of the family regarding fate of tissue samples taken at PM examination. The DI is advised to consider developing a standardised letter that can be issued to the Coroner, which states that if the establishment do not receive relatives wishes for tissue within a certain timeframe (three months, for example), it will be disposed of, as consent is not in place for the establishment to retain the tissue.
5.	PFE1 (b)	The DI is advised to review demarcation of the clean, dirty and transitional areas of the PM room. Currently there is yellow hazard tape on the ceiling and side of the walls, but nothing on the floor to indicate the change from a clean to a dirty area.

Concluding comments

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

All staff involved in the inspection were dedicated and committed to providing high-levels of care and demonstrated a sensitive approach to their work. The mortuary staff have received positive feedback cards from families and received Trust service awards for their exceptional performance.

The mortuary has a good working relationship with key members of staff such as porters, ward and bereavement staff, as well as with referring hospital Trusts. They display a very caring attitude and provide blankets and hats, where required and all clothes are washed.

The mortuary pride themselves on the training of APTs and ensure training is up-to-date and new APTs are supported in their work.

The Bereavement Midwives are experienced and demonstrated passion and expertise regarding seeking consent for perinatal PM examination. They hold regional consent training

days and have implemented training for doctors for seeking consent for PM examination.. They have regular meetings with mortuary staff and work closely with them and pride themselves in ensuring families are treated with dignity, respect and are fully informed.

All incidents are discussed as a team and there is excellent awareness of HTA reportable incidents at this establishment. All of the HTARI categories are displayed in the mortuary and on the gynaecology and maternity ward fridges for porter and ward staff reference.

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

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

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

Report sent to DI for factual accuracy: 24 October 2018

Report returned from DI: 6 November 2018

Final report issued: 9 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 injures and let them know that reconstruction may be required.

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

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

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

to mitigate them.

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

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

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

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

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

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

this purpose.

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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

a) The premises are clean and well maintained.

Guidance

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

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

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

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

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

assessments and same/similar name systems.

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

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

Establishments should consider entering in to Mutual Aid Agreements

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

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

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

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

   Guidance

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

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

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

   Guidance

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

d) Staff have access to necessary PPE.

   Guidance

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

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

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

Guidance

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

Appendix 2: Classification of the level of shortfall

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

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

1. Critical shortfall:

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

or

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

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

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

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

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

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

2. Major shortfall:

A non-critical shortfall that:

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

or

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

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

3. Minor shortfall:

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

departure from expected standards.

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

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

Follow up actions

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

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

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

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