Site visit inspection report on compliance with HTA licensing standards

Morriston Hospital

HTA licensing number 30015

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**

27 – 28 June 2019

Summary of inspection findings

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

Although the HTA found that Morriston Hospital had met the majority of the HTA's standards, shortfalls were found against the Consent, Governance and Quality Systems, Traceability and Premises, Facilities and Equipment standards.

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

Morriston Hospital (the establishment) has been licensed by the HTA since June 2007. The establishment consists of a hub site at Morriston Hospital and a satellite site at Princess of Wales Hospital. Both sites are licensed for removal of relevant material from the deceased, storage of bodies of the deceased and relevant material for use for scheduled purposes, and the making of a post mortem (PM) examination.

The DI is a Consultant Histopathologist. The Corporate Licence Holder (CLH) is Swansea Bay University Hospital Health Board and the CLH contact is the Executive Director of Therapies and Health Science. A recent change in the arrangement of Health Boards within the region has led to some of the buildings and staff at the satellite site being managed by a different Health Board. In June 2019, the establishment stopped performing coronial PM examinations at Princess of Wales Hospital; at the time of the inspection, this site was still licensed for undertaking PM examinations.

At the time of the inspection, the mortuary at the hub site was staffed by a Mortuary Manager who worked between the hub and satellite site, a Lead Anatomical Pathology Technologist (APT), one trainee APT, two APTs and two Anatomical Support Workers. The mortuary at the satellite site was staffed by two APTs.

The standard operating procedures (SOPs), risks assessments and policies are common to both the hub site and satellite site, where appropriate.

The establishment receives approximately 3,000 bodies per year from the hospital and the community. All bodies are received into the mortuaries by mortuary staff, both in and out of normal working hours. Approximately 950 adult bodies undergo PM examination at the establishment each year, of which around five are Home Office (forensic) PM examinations and between five and ten are adult consented PM examinations. Paediatric and perinatal bodies are transferred to another HTA licenced establishment for PM examination. Since June 2019, bodies at Princess of Wales Hospital are transferred to another HTA-licensed establishment for coronial PM examination (see shortfalls against standards T1(b) and T1(g)).

Tissue retained at PM examination is sent to another establishment for analysis and then all tissue blocks, slides and wet tissue samples are returned to the site at which the PM examination occurred for storage. PM samples are traced using a unique PM reference number. The establishment stores electronic copies of scanned documents detailing the tissue retained at PM examination and the family's wishes for the fate of the samples (see shortfall against standard T1(g)).

The DI or APTs trained in seeking consent take consent for adult PM examinations using the consent form and information booklet provided by the Welsh Government. Staff receive face-

to-face consent training every two years. Most recently, this was provided by the Association of Anatomical Pathology Technologists (AAPT). There are currently only three members of staff at the establishment who are trained to seek consent for adult PM examination. The establishment plans to introduce an in-house PM examination consent training course for staff, which will be held each year.

Consent for paediatric or perinatal hospital PM examinations is sought by obstetricians, midwives and bereavement midwives, using the consent form and information leaflet provided by the Welsh government. Staff receive face-to-face consent training every other year, which is provided by the Health Board. There is a register of staff trained in seeking consent, and only these staff are permitted to seek consent (see shortfall against standard C2(d)).

There is a fridge in the maternity department at Princess of Wales for storage of perinatal or paediatric cases prior to transfer to the mortuary (see shortfall against standard PFE2(e) and *Advice,* item 5).

The establishment adopts the Public Health Wales Procedural Response to Unexpected Deaths in Childhood (PRUDiC) protocol, and therefore, no relevant material is removed from Sudden Unexpected Death in Infants and Children (SUDIC) cases in the Accident and Emergency departments.

Description of inspection activities undertaken

The inspection team conducted a visual inspection of the premises where licensed activities take place. This included the mortuary body store areas, PM suites, viewing suites, maternity department and tissue storage areas. Interviews with key members of staff, a review of governance and quality system documentation and traceability audits were also undertaken. The processes for removal of relevant material in the maternity department in perinatal or neonatal cases were reviewed and discussed with staff (see shortfall against standard GQ1(g)).

Audits of traceability of bodies were conducted at both sites. Body location and identification details on identification bands were crosschecked against the information recorded in the paper mortuary registers and relevant documentation. At Morriston Hospital, audits were conducted for five adult bodies, four in refrigerated storage and one in long-term freezer storage. Audits of five adult bodies were conducted at Princess of Wales Hospital, including one case that had been transferred to another HTA-licensed establishment for PM examination (see shortfall against standards T1(b) and T1(g)).

Audits of traceability were conducted for samples from eight PM examinations performed under coronial authority at each site. This audit included cases where the PM examination was undertaken at the establishment and a case where the PM examination was undertaken

at another HTA-licensed establishment and the samples and body were transferred to Morriston Hospital for storage (see shortfall against standard T1(g)). Consent documentation for the retention of samples and disposal records were reviewed. A discrepancy was identified for one case reviewed at Morriston Hospital (see shortfall against standard T1(g)).

Inspection findings

The HTA found the LH the DI to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained	Staff involved in seeking consent for perinatal or paediatric PM examination are not competency assessed following completion of their initial training. This presents a risk that staff seeking consent do not undertake the process in a consistent manner.	**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.	Mortuary SOPs do not contain sufficient details of procedures. For example: • PM-A-SOP (CEL 1664) 'Viewing and identification of deceased persons' does not state that three identifiers of the deceased are obtained from the family and are checked against the wristband on the body immediately before a viewing takes place. • PM-A-POL (CEL 660) 'Recording, storage, release and disposal of samples taken from PM examination' uses the term 'next of kin' in reference to consent for tissue retention. This use of this term does not reflect the requirements of the HT Act or HTA's codes of practice. • PM-B-LI (CEL 2624) 'Release/Return of bodies for post mortem to another HTA establishment with contract undertaker' does not detail what identifiers are used to identify the body prior to release from the mortuary for transfer to another HTA-licensed establishment for PM examination. This SOP does not include details of how the body is recorded into the	**Major**

	mortuary register upon return from another establishment following PM examination. This presents a risk that staff do not undertake mortuary activities in a consistent manner. This is not an exhaustive list of the amendments required to SOPs. The establishment should review all SOPs for licensed activities to ensure that they are accurate and contain sufficient details of the procedures. *Refer to shortfalls against standards T1(b) and T1(g).* *The establishment submitted evidence prior to the publication of this report to demonstrate that standard GQ1(a) is met.*	
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	Licensed activities in the maternity department are not included in the establishment's governance framework for the licence. There is no Persons Designated nominated to help oversee licensed activities in this department. The DI does not have regular contact with staff undertaking licensed activities in this department.	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform	There is no system for ongoing competency assessments of portering staff involved in mortuary activities. A system of cascade training is used, however those performing the training do not undergo competency assessment for the tasks they perform or train others to do.	**Minor**

GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Portering staff are not aware of the establishment's documented incident reporting system, what an HTA reportable incident (HTARI) is or who they should contact in the event of an incident occurring.	**Minor**
d) Information about incidents is shared with all staff to avoid repeat errors	Information is not shared with portering staff about incidents relating to the mortuary activities they undertake. Portering staff are not represented at departmental meetings where mortuary incidents are discussed. This means that portering staff are not provided with opportunities to share learning to avoid repeat errors.	**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	The risk assessments included in mortuary SOPs do not cover all licensed activities or the risks associated with these activities. The risks identified are also not suitably categorised, for example: • Misidentification of the deceased is categorised as a 'chemical risk'; and • Use of incorrect details or number of specimens identified in PM ledger is categorised as 'electrical risk'. While a separate risk assessment document has recently been developed, this document is not referred to in any of the operational SOPs relating to licensed activities. This presents a risk that staff will not be aware of the risks associated with the activities they undertake. *The establishment submitted evidence prior to the publication of this report to demonstrate that standard GQ6(a) is met.*	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
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).	The traceability procedures for bodies transferred to another HTA-licensed establishment for PM examination are weak. i) There is no system to link records of bodies sent to and then returned from another HTA-licensed establishment for PM examination. ii) There are no procedures to ensure that in these cases, tissue retained at PM examination at the other HTA-licensed establishment will be: • returned to the establishment for repatriation; • returned to relatives; or • disposed of lawfully and by whom. iii) There are no details of what identifiers of the deceased should be checked and recorded on return of a body following PM examination at another HTA-licensed establishment.	**Major**

	The inspection audit identified minor discrepancies in the traceability records for a body returned for storage at the establishment following PM examination: • the date the body was returned from the other establishment was not recorded in the mortuary register; • the body was received into the mortuary using only two identifiers of the deceased; and there was no system to link the two mortuary register records for this body. *The establishment submitted evidence prior to the publication of this report to demonstrate that standard T1(b) is met.*	
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	*Princess of Wales Hospital* The establishment's procedures for identification of bodies do not use a minimum of three identifiers of the deceased. For viewings of bodies, only the name of the deceased is requested from families when they arrive at the mortuary to be crosschecked against the identification bands on the body. This presents a risk of misidentification. *The establishment submitted evidence prior to the publication of this report to demonstrate that standard T1(c) is met.* *See Advice, items 1, 2 and 3.*	**Major**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	*Morriston Hospital* The inspection identified a discrepancy in traceability of PM samples where thirteen tissue blocks recorded on the database could not be located in storage. As the establishment have only recently begun conducting audits of tissue retained at PM examination, they are not able to determine if absent tissue has been disposed of but not recorded, or has been lost. A container of wet tissue stored with a body in long-term storage was labelled with only two identifiers of the deceased. The bags of wet tissue inside the container were labelled with only one identifier; a number used by the establishment at which the PM examination was conducted. No identifiers used by the establishment storing the material were present. This presents a risk of loss of traceability of material. *The establishment submitted evidence prior to the publication of this report to demonstrate that standard T1(g) is met.*	**Major**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
e) Security arrangements protect against unauthorised access and ensure oversight of visitors and contractors who have a legitimate right of access	Staff use a route through the body store area to access the mortuary office. This presents the risk of non-mortuary staff overseeing mortuary activities. Cellular pathology staff have access to the PM suite to use equipment stored there. While there is a verbal agreement that mortuary staff should be consulted on appropriate times to access the PM suite, this access is not restricted. This presents a risk that non-mortuary staff could access the PM suite at inappropriate times.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	Staff do not manually challenge the alarms on a regular basis and they do not record each time the alarm is tested. This means that the establishment cannot provide assurance that the alarms will trigger when temperatures deviate from the expected ranges. The fridge in the maternity department at Princess of Wales for storage of perinatal or paediatric cases is fitted with a temperature alarm but the alarm only sounds locally and may not be heard by staff. Staff do not manually challenge this temperature alarm.	**Major**

Advice

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

No.	Standard	Advice
1.	T1(c)	The DI may wish to consider including date of birth of the deceased on the 'mortuary card' system and in the mortuary register. This will help to facilitate use of a minimum of three identifiers for identification of bodies. The DI may also wish to consider adding the unique mortuary identifier to the identity bands of all bodies when they are received into the mortuary. This would provide a unique identifier directly attached to the body, helping to further strengthen identification procedures.
2.	T1(c)	When revising the identification procedures for viewings of bodies to address the shortfall against standard T1(c), the DI may wish to consider recording the three identifiers of the deceased provided by the family upon arrival at the mortuary for a viewing. This record could be used to crosscheck the information on the identity band on the body prior to viewing.

3.	T1(c)	The DI is advised to ensure that all clinicians are reminded that written identifiers should be used to perform identification of a body for completion of cremation paperwork. The written identifiers of the deceased should be used to crosscheck the information on the identity band on the body. This will help to mitigate the risk of misidentification of the body.
4.	T1(d)	The DI may wish to consider strengthening the system to highlight where bodies have the same or similar name by using an additional visual aid, such as a coloured wristband, attached to the body to make staff aware of the same or similar surname of the body.
5.	T1(h)	The DI may wish to consider the introduction of a record system to be held by the maternity department to help to ensure full traceability of all relevant material that has been collected and is transferred to the mortuary.
6.	PFE1(a)	The design of the height-adjustable dissection benches means that there are gaps between the sides and back of the benches. This could make it difficult to clean and decontaminate this area effectively. The DI is advised to consider options to seal these gaps between the benches.
7.	PFE1(d)	The DI may wish to consider advising funeral directors attending the mortuary to fully reverse their vehicles into the concealed area at the rear entrance to the mortuary. This will help to ensure that the rear entrance to the mortuary cannot be overseen.
8.	PFE2c	The DI is advised to keep under review the availability of freezer storage, including for bariatric bodies, to ensure that storage capacity and contingency storage arrangements remain sufficient to meet needs.

Concluding comments

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

The HTA requires the DI 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: 19 July 2019

Report returned from DI: 30 July 2019

Final report issued: 02 August 2019

Appendix 1: HTA licensing standards

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

Consent

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

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

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

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

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

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality systems

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

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

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

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

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

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

to mitigate them.

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

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

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

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

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

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

Guidance

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

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

Guidance

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