Site visit inspection report on compliance with HTA licensing standards

Glan Clwyd Hospital

HTA licensing number 12153

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**

4-6 April 2017

Summary of inspection findings

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

Although the HTA found that Glan Clwyd Hospital had met the majority of the HTA's standards, three minor shortfalls were found against standards relating to governance and quality systems and premises, facilities and equipment.

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

This report refers to the activities carried out at Glan Clwyd Hospital (the establishment). For HTA licensing purposes, Glan Clwyd Hospital is the 'hub' and the licence arrangements extend to satellite sites at Ysbyty Gwynedd Bangor and Wrexham Maelor Hospital. The Designated Individual (DI) under the licence is a Consultant Histopathologist. The Service Manager for Cellular Pathology is a Person Designated. The Corporate Licence Holder (CLH)

is Betsi Cadwaladr University Local Health Board and the CLH contact is the Directorate General Manager for the Trust. The hub and satellite sites are largely under the same governance arrangements, with some local variation in procedures for body receipt and release.

A combined total of approximately 1,300 post mortem (PM) examinations are carried out at the hub and satellite sites each year, on behalf of HM Coroners for North West, East and Central Wales. A small number of adult hospital consented PM examinations, high risk and forensic PM examinations also take place. The bereavement officer seeks consent for hospital PM examinations and the clinician involved in the patient's care attends. Staff seeking consent receive training and are approved by the Betsi Cadwaladr University Health Board before seeking consent.

Before a PM examination is conducted, the pathologist and APT check the identification and sign the paperwork. The pathologist conducts an external examination before giving the APT permission to eviscerate the body.

Histology samples taken during PM examinations are sent to the histology department at the hub site for analysis. A form is filled out and accompanies every specimen that is sent off site. After the analysis is completed, they are kept or disposed of according to the wishes of the family. The Trust has agreements with the Coroners and follows documented guidance detailing the types of samples (i.e. blood, urine, spleen) to be taken in cases of unexpected deaths in childhood.

Perinatal and paediatric cases are transferred to other licensed establishments. A trained midwife seeks consent for these cases using Wales Health Board- approved forms along with the SANDs leaflet. Staff must be trained in seeking consent and signed off as competent. A central list of trained staff is kept at the referral site. There is no storage on the maternity wards, as these cases are transferred directly to the mortuary by porters.

All fridges and freezers are 24-hour temperature monitored through an audible alarm system, which links to the hospital switchboard. When the temperature goes below or above set limits, the system automatically triggers an alarm and alerts the hospital switchboard. The switchboard contacts the estates department and, if estates staff need to access the mortuary, they call the Service Manager for Cellular Pathology. Regular testing of the fridge/freezer alarms is only carried out at the hub site (see minor shortfall against PFE2e).

Viewings are conducted in and out of hours. If out of hours, the site manager and porters provide access to the mortuary, working to a standard operating procedure (SOP), which requires them to sign a log-book to record their attendance (see advice item 4). Porters are trained by mortuary staff in mortuary and viewing procedures.

Each site has specific receipt and release procedures, but a minimum of three identifiers are checked by staff with funeral directors, against tags on the body and paperwork before release takes place. Detail of site-specific premises and procedures are set out below.

Glan Clwyd Hospital (hub site)

The hub site conducts the largest quantity of PM examinations. There are four consultant histopathogists on site and a Home Office pathologist attends to conduct forensic PM examinations. There are three Anatomical Pathology Technologists (APTs), who report to the Cellular Pathology Manager. There is also a mortuary assistant who assists in the PM room with cleaning and administrative tasks.

The body store has refrigerated space for 50 bodies, including four bariatric spaces. Four of the fridge spaces can be converted to freezer spaces if needed. Contingency arrangements are in place with the satellite sites and funeral directors.

The PM suite has three tables. One of these tables is dedicated to forensic cases. There are also two downdraft dissection benches.

Histology samples removed during PM examination are taken to the histology lab by mortuary staff at the end of each day.

There is a concealed area around the mortuary, accessible via a locked gate, from where bodies are admitted and released. Bodies are admitted 24 hours a day and funeral directors must press a buzzer when they arrive to call an APT during working hours and porters out of hours. There is a video camera outside the gate so that staff can monitor visitors. On receipt, whether in out of hours, the APT checks the condition of the body, the ID details on the body against the paperwork and fridge doors, and then attaches a wrist tag to the body with the unique mortuary identification number.

Bodies are usually released between set times from Monday to Friday. Outside these hours, release must be arranged with mortuary staff beforehand. At least three identifiers are checked against the paperwork before release takes place.

Ysbyty Gwynedd Bangor (satellite site)

Approximately 450 PM examinations are conducted at this site each year. High risk and forensic cases are sent to the hub site for PM examination. The PM examinations are conducted on Tuesdays and Thursdays by a visiting pathologist. At the time of the inspection, the mortuary was staffed by a full-time permanent APT and a locum APT.

The body store has refrigerated space for 31 bodies, three of which are suitable for bariatric bodies. There are three freezer spaces. There is a separate fridge for Products of Conception (POCs) and fetuses and one for pregnancy terminations. A Bereavement Officer based in the mortuary oversees the management of POCs and fetuses (see advice item 1).

The PM suite has two downdraft tables and one dissection bench. Histology taken at PM examination is collected from the mortuary by porters, taken to the lab in the hospital and then picked up and transferred to the histology department at the hub site.

The mortuary is in a secluded area of the hospital. There is CCTV outside the mortuary and the funeral director rings a bell to let mortuary staff know they have arrived.

The mortuary only accepts bodies from the community between set times, Monday to Friday. If a death occurs in the community out of hours, the body is held by the funeral director until they can gain access. APTs take receipt of the body and check the identification details on paperwork against the identification tags on the body before placing the body in the fridge. They then input the information into the computer system, which assigns the body a unique mortuary ID. At the end of each day, they print out the details of each body, which also serves as a fridge location check. The computer system flags up same/similar names.

Hospital cases are admitted both in and out of hours. During hours, the same process is followed by APTs as for bodies from the community. Out of hours, porters place the body into the fridge and leave the identification card on a desk in the body store. On the next working day, APTs checks the information on the identification card against the body and enter the information into the computer system.

Bodies are released between specified hours, Monday to Friday. Upon release, at least three identification details are checked by the APT and the funeral director. Two identical release forms are printed from the computer system and one form is given to the funeral director. The identification card is signed by both the funeral director and the APT.

Wrexham Maelor Hospital (satellite site)

Approximately 400 PM examinations are conducted at this site, by two Consultant Pathologists who travel from the hub site on Tuesdays and Thursdays. Forensic cases are sent to the hub site. At the time of the inspection there was a full-time permanent APT and a locum APT working on site (see shortfall against standard GQ6a).

The body store has refrigerated space for 45 bodies, four of which are suitable for bariatric bodies; however, one of the bariatric spaces was not in use due to a damaged fridge tray. There is also a cold room that can hold six bodies or two hospital beds if necessary. The PM suite has two downdraft tables and one dissection bench.

During normal working hours, the mortuary accepts bodies from the community between set times. Outside these hours, funeral directors have their own key to access the fridge area. When funeral directors arrive in hours, they ring a bell to let mortuary staff know they have arrived. They are then required to complete a form with the deceased's identification details, place the body in the fridge and write the name of the deceased on the fridge door. The APT then checks the body and identification details. This procedure is the same for bodies admitted out of hours.

For hospital deaths in and out of hours, porters admit bodies into the mortuary by filling out a record of deceased form, placing the body in the fridge and recording the name of the deceased on the fridge door. The APT then checks the paperwork, the body in the fridge, and name on the fridge door. They write the name on the whiteboard that corresponds with the fridge, and enter the deceased's information into the computer and a paper register. Each body is assigned a unique ID number that is recorded on both the computer and paper register.

When bodies are released, at least three identification details are checked and signed off by the APT and the Funeral Director.

Viewings are arranged directly between the family and mortuary staff. Occasionally, out of hours viewings are conducted, and this is arranged with the Site Manager and portering staff. On the inspection, it was noted that site managers did not have a viewing logbook (see advice item 4).

Description of inspection activities undertaken

This was the third site visit inspection of Glan Clwyd Hospital (the previous inspection took place in 2013). This inspection included: a visual inspection of the body stores, PM suites, and viewing areas at the hub and satellite sites, and histology at the hub site; a document review, including review of the Procedural Response to Unexpected Deaths in Childhood (PRUDIC) protocol; iinterviews with members of staff; and traceability audits.

Audit trails were conducted at the hub and satellite sites on a total of eight bodies in the body stores. These included hospital and community deaths. Body location and identification details on body tags were cross-referenced against the information on whiteboards, computer and paper records. A minor discrepancy was found in one case at the satellite site in Wrexham where the incorrect fridge number was entered on paper records.

Audit trails were also conducted at the hub and satellite sites on a total of nine cases where histology samples had been retained during the PM examination and transferred to the hub site for analysis. Relevant paper records including consent forms and computer records were

checked. Procedures for transferring samples to histology and recording disposal of samples were also checked. No anomalies were found, however the inspection team identified a gap between sites in relation to staff receiving confirmation of disposal of samples (see advice item 11).

Materials held for the police

Under s39 of the Human Tissue Act 2004, 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, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored at the hub site were reviewed by the HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act

Inspection findings

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

Compliance with HTA standards

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.	At the time of the inspection, there was one permanent and one locum APT working in the mortuary at Wrexham. Locum staff are not always available, can change frequently and are often unfamiliar with mortuary procedures specific to the establishment. The establishment has not sufficiently assessed the risk posed by having a single APT undertake mortuary activities when there is no other staff available. Efforts are being made to recruit more permanent mortuary staff. In the meantime, the risks associated with lone working should be assessed and appropriate mitigating actions taken. **See advice item 7**	Minor

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased.	PM examinations at the Bangor satellite site are conducted on the same day that the bodies are brought into the mortuary. After a PM examination, the body is placed back onto the funeral director's stretcher, covered and placed in the body store awaiting collection later that day. The body is only refrigerated if it is not collected. Bodies brought in for PM examination should always be refrigerated, regardless of when the body is collected, to mitigate the risk of decomposition and maintain the dignity of the deceased.	Minor

e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	The fridge and freezer alarms at Wrexham and Bangor are not subject to regular testing. **See advice item 9**	Minor

Advice

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

No.	Standard	Advice
1.	GQ1(a)	**Bangor** A bereavement officer oversees the management of fetuses and POCs at the satellite site at Ysbyty Gwynedd Bangor. She receives an email from the establishment where the PM was conducted when the specimens are ready to be returned. The POCs/fetuses are kept in a separate fridge in the mortuary and there is a record on the outside of the fridge door that lists what is in the fridge. There is also a fetal register along with the information in the computer system. Each case is assigned a unique mortuary ID number, which is logged on the computer. During the review of this procedure, the inspection team noted that the paper record on the outside of the fridge door was from September 2016 and did not correspond to what was currently in the fridge. In order to improve the management of POCs/fetuses,the DI is advised to : • ensure that the most current record is kept on the outside of the fridge door; • record the unique mortuary ID number on the fetal register to help strengthen traceability; and • include mortuary staff in the email notification of specimens to be returned, in case the bereavement officer is absent.
2.	GQ1(a)	**Wrexham** The establishment keeps all paperwork relating to post mortem cases in the mortuary for 30 years, in line with Trust Policy. The Trust has a storage location off site. At the satellite site, the filing cabinets where records are stored are almost full and the DI is advised to move the records to the off-site storage to free up space for the storage of records.
3.	GQ1(a)	**All sites** To ensure there is awareness of, and compliance with, statutory and regulatory requirements, the DI is advised to appoint a Person Designated (PD) in the following areas: • A&E, where removal of tissue samples may occur in sudden unexpected death in infancy cases; and

		• Mortuary/Histology, where management of POCs/fetuses occurs. The DI should notify the HTA of the names of these Persons Designated so that its licensing records can be updated.
4.	GQ3(a)	**Wrexham** Staff who conduct viewings out of hours must sign a logbook. At the satellite site in Wrexham, staff record viewings on a piece of paper, rather than a logbook. The DI is advised to provide a logbook and communicate with staff responsible for conducting viewings the importance of filling out the log, in case there are any issues relating to the deceased that they need to discuss with the site manager.
5.	GQ3(a)	**All sites** The DI is advised to review the out of hours viewing procedure and the training that porters and onsite managers receive, to see if adequate training is given in relation to dealing with difficult bodies and reporting incidents to mortuary staff.
6.	GQ5(a)	**Wrexham** Mortuary staff are advised to add a comment section to the 'record of deceased form' in case the funeral directors need to communicate any issues regarding bodies they bring in out of hours.
7.	GQ6(a)	**All sites** The establishment is planning to appoint a Mortuary Manger to help co-ordinate the overall running of the mortuary service, which will help mitigate risk. In the meantime, the following risks should be assessed: • injury to staff using equipment (manual handling injuries) • employees overworked resulting in damage to bodies/mistakes in paperwork • stress to employees having to take on more work • delay in services because not enough staff for the amount of work.
8.	PFE2(c)	**All sites** There is no documented procedure in place outlining when bodies should be moved into long-term freezer storage. The HTA recommends that bodies should be moved into freezer storage at 30 days or sooner, depending on the condition of the body. The DI is advised to align procedures with the HTA's guidance set out on page 7 (paragraph 24) of its report on storage capacity and contingency arrangements in mortuaries: https://www.hta.gov.uk/sites/default/files/Capacity%20and%20Contingency%20Report%20Nov%2015.pdf In the event that a body cannot be moved into long-term freezer storage within the 30 days, the DI is advised to log the reason, make a note of the condition of the body and keep the situation under review in case alternative

		arrangements have to be made.
9.	PFE2(e)	**Bangor and Wrexham** Mortuary staff are advised to incorporate regular documented tests of the fridge/freezer alarms to ensure the call out systems are working. Staff should be aware of the trigger points (upper and lower) for the fridge/freezer alarms. Fridges and freezers should be checked for trends in order to highlight any issues which may occur before a fridge/freezer breakdown occurs.
10.	PFE3(a)	**Wrexham** PM needles are kept in wooden holders in the mortuary. The use of porous material, such as wood can easily become contaminated and difficult to disinfect. Mortuary staff are advised to dispose of the wooden holders and find a more suitable place to store the needles.
11.	T2(d)	**Bangor and Wrexham:** Mortuary staff are advised to confirm with the histology department at the hub site when tissue taken from PM examination has been disposed of so that they can be assured that the wishes of the family are met. Disposal should be recorded and local records updated. All staff should be aware of the procedure for accessing disposal records.
12.	N/A	The establishment has an upcoming external audit of the mortuary services. They would like to reorganise and centralise the services at the hub site and conduct all PM examinations there. Apart from general improvements in the management of the mortuary, this may help improve many aspects of the mortuary service, providing for: • shorter turnaround time for PM examinations; • increased efficiency of work by reducing staff travel time between sites; and • improved traceability of records relating to PM examinations.

Concluding comments

Staff at the establishment have many years of experience and it is apparent they take pride in their work. There are thorough audits of licensable activities, including all aspects of mortuary work and management of POCs and fetuses. The establishment encourages and uses external auditors to evaluate the mortuary service and uses their feedback to make improvements.

There are a some areas of practice that require improvement, including three minor shortfalls. Advice was given in relation to governance and quality systems, traceability and premises, facilities and equipment.

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 / subject to compliance with the additional conditions applied to the licence.

Report sent to DI for factual accuracy: 26 April 2017

Report returned from DI: 17 May 2017

Final report issued: 22 May 2017

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 31 August 2017

Appendix 1: HTA licensing standards

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

Consent

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

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

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

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

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

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality systems

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

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

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

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

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

Guidance

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

applicable.

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

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

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

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

Guidance

Records include mortuary registers, PM examination records, tissue retention forms and records of transfer and return of organs/tissue sent elsewhere for examination.

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

Risks to the dignity and integrity of bodies and stored tissue should be covered. The HTA's

reportable incident categories provide a good basis for risk assessments. Risk assessments should be reviewed at regular intervals, for example every 1-3 years or when circumstances change. Staff should be involved in the risk assessment process.

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

Guidance

Relevant staff should have knowledge of risks and the control measures that have been taken to mitigate them.

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

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

similar names.

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

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

Guidance

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

Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place present a risk to traceability. Full identification checks should be made when theyare placed back into normal storage.

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

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

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

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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

a) The premises are clean and well maintained.

Guidance

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

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

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

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

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

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

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

Establishments should consider entering in to Mutual Aid Agreements

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

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

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

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

Guidance

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

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

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

Guidance

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

d) Staff have access to necessary PPE.

Guidance

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

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

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

Guidance

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

Appendix 2: Classification of the level of shortfall

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

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

1. **Critical shortfall:**

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

   or

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

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

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

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

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

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

2. **Major shortfall:**

   A non-critical shortfall that:

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

   or

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

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

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

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

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

Follow up actions

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

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

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

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