Site visit inspection report on compliance with HTA licensing standards

Arrowe Park Hospital

HTA licensing number 12027

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**

17-18 October 2018

Summary of inspection findings

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

Although the HTA found that Arrowe Park Hospital had met the majority of the HTA's standards, five major and four minor shortfalls were found against the Governance and Quality Systems, Traceability and Premises, Facilities and Equipment standards. These related to SOPs, the use of three identifiers, procedures for sending bodies off-site for post-mortem (PM) examination, mortuary cleaning records, CCTV and security arrangements regarding access to the mortuary, long-term body storage practices, testing of fridge alarms, and the condition of the PM suite and body store.

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

Arrowe Park Hospital (the establishment) has been licensed by the HTA since April 2008. This report refers to the activities carried out at the establishment. The establishment is licensed for the making of a post-mortem (PM) examination, removal of relevant material from the deceased and storage of bodies of the deceased, and relevant material for use for scheduled purposes. The Designated Individual (DI) is a Consultant Histopathologist and the Corporate Licence Holder contact is the Interim Medical Director for Wirral University Teaching Hospital NHS Foundation Trust. The mortuary is staffed by a senior Anatomical Pathology Technologist (APT) and two APTs who all work full-time.

The establishment receives approximately 2500 bodies each year from the hospital and community and performs around 270 post-mortem examinations annually, all carried out under Coronial authority. The mortuary conducts high-risk PM examinations; forensic cases are transferred to a nearby HTA licensed establishment. Adult hospital (consented) PM examinations are no longer conducted at this establishment which is reflected in the Trust consent policy.

PM examinations for perinatal and paediatric cases are undertaken by another HTA licensed establishment (see shortfall against standard T1(h)), however, trained bereavement midwives seek consent for these cases, which is recorded using consent forms from the referring establishment. The consent form and information leaflet used for paediatric/perinatal PM cases is based on the Stillbirth and Neonatal Death (Sands) charity documentation.

Removal of tissue from deceased children in cases of sudden unexpected death in infancy (SUDI) is not performed in the Accident & Emergency (A&E) department. Staff will notify the police who will invoke the SUDI protocol and refer such cases to another licensed establishment.

The mortuary has 96 refrigerated body storage spaces, which includes four bariatric spaces. There are no freezer body storage spaces within the mortuary or any contingency arrangements for freezer storage (see shortfall against standards PFE2(a) and PFE2(c)). The mortuary has no temporary storage facilities but they do have contingency refrigeration space at a nearby body store. The mortuary has a system for storing perinatal and paediatric cases separately. There is a fridge on the maternity ward, which is rarely used for the temporary storage of fetuses as cold-cots are used predominantly before transfer to the mortuary (see shortfall against PFE2(e)).

Fridge temperatures in the mortuary body store are monitored manually twice daily by mortuary staff and all readings are documented. The alarm sounds locally when the temperatures go outside of range and is also connected externally to the estates office which

is staffed 24/7, who will contact the mortuary team out of hours, if required (see shortfall against standard PFE2(e)).

All doors in to the mortuary have standard key locks; there is no video-intercom system to allow mortuary staff to confirm who is requesting access. In addition, there is no hospital CCTV coverage of the access doors to the mortuary or any coverage within the mortuary itself (see shortfall against standard PFE1(d)).

Portering staff are responsible for the transfer of bodies from hospital wards to the mortuary. On arrival to the mortuary, porters place bodies in an available refrigerated body space and update the 'overnight sheet' with information of bodies brought into the mortuary. It is only the mortuary staff who complete the mortuary register and update the body store location whiteboard with the name of the deceased. The Coroner's contracted funeral directors transfer all community bodies to the mortuary and porters admit these bodies out-of-hours and update the 'overnight sheet'. All community bodies arrive with a wristband, which is attached to the body by the police before arrival at the mortuary (see shortfall against T1(c)). All bodies are logged onto an electronic mortuary register where a unique mortuary identification number is generated.

Mortuary staff perform body checks of all bodies the next working day, verifying the identification band details on the bodies against the overnight sheet and make sure all bodies are appropriately shrouded. Mortuary staff carry out daily visual checks of the fridges, noting details of any bodies with same and/or similar names and placing an asterisk on the whiteboard for these bodies (see *Advice*, item 5).

The mortuary only release bodies during normal working hours and have devised a 'body release form', which undertakers must present to mortuary staff before a body can be released. Certain sections of this form are completed in advance by the bereavement office and will contain the required three identifiers, which can be checked against the wristband on the body. The body release form is required for both hospital and Coroner's bodies; the Coroner will email authorisation for release to the mortuary and copy in the bereavement team, who prepare the body release form for the funeral directors. If for any reason the funeral directors arrive without this form, they will be redirected to the bereavement office and the body will not be released until the form has been completed.

Babies over 24 weeks gestation are transferred to the mortuary by a member of the portering staff accompanied by a midwife and are always released from the mortuary. Babies under 24 weeks gestation for hospital cremation are transferred to the histopathology laboratory or, if the family are making their own funeral arrangements, the laboratory liaise with the mortuary and maternity unit regarding release of these bodies.

The mortuary operates an appointment system for viewings, which generally takes place during working hours. Although viewings are discouraged outside of working hours, mortuary

staff will accommodate viewings out-of-hours if there is a particular requirement. Mortuary staff work with the bereavement team with regards to organising and conducting viewings (see shortfall against standard T1(c)).

The PM suite at the establishment has two PM tables and there is dissection benches for the preparation of tissue samples. PM examinations take place one at a time to help minimise the risk of organ and tissue mix-up between cases. The mortuary have devised a 'post-mortem identification checklist' as a record of identification checks throughout the post-mortem examination process. The identification of bodies is always checked by the pathologist and an APT prior to evisceration.

Mortuary staff have access to the necessary PPE within the PM room and body store area and there is demarcation of clean and dirty areas within the mortuary. Material retained at PM examination for histological examination is appropriately labelled in the mortuary and assigned a unique PM number. The mortuary technician completes the 'tissue transport register book' for tissues and organs removed from the deceased and this book acts as a tracking log of all tissue transferred to the histopathology laboratory for on-site analysis.

Tissue samples may be kept, if appropriate consent has been given for retention or for use for scheduled purposes, but the establishment does not routinely store samples for use for research. Blocks and slides are stored in the laboratory and the mortuary uses paper and electronic registers to record sample details, including storage location and family's wishes for the fate of the samples.

Description of inspection activities undertaken

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

Audits were conducted for five bodies in refrigerated storage; three from the community and two from the hospital. Body location and identification details on identification bands were cross-checked against the information recorded in the electronic mortuary register and relevant documentation. No discrepancies were found.

In addition, three Coroner's cases where tissue was retained following the PM examination and one Coroner's case where tissue was disposed of were audited. The audit included details of tissue type, blocks and slides retained, consent forms, and associated paperwork. No discrepancies were found.

Inspection findings

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

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	Some of the SOPs do not accurately reflect current practice and do not contain sufficient detail for staff regarding the procedures that must be followed. Particular examples include but are not limited to: - SOP MSOP03 'Mismatch Body Procedure' states that the police attend the mortuary to correct the 'police book' if there is an error, however, during the visual inspection it was explained that a recent change in police procedure mean they no longer attend the mortuary; - HPSR39 'PM Disposal Procedure' does not detail how tissue blocks and slides are returned to relatives or how mortuary staff are made aware that tissue is to be repatriated with a body before release; To fully address this shortfall, the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail of the procedures.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	Families are not being asked to provide three identifiers when attending the establishment to undertake viewings and often, only the name of the deceased is requested. The mortuary staff may only be able to check two identifiers on community bodies prior to adding an additional red wristband to all PM cases. These wristbands contain three identifiers for establishment staff to check prior to commencing the PM examination. The risk is that establishment staff may place the red wristband on the incorrect body as only two identifiers are being checked during this process. (See *Advice*, items 3 and 4)	**Major**
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	When perinatal/paediatric cases are sent off-site for PM examination, mortuary staff are not currently checking if the bodies are going to be returned to the mortuary for release to funeral directors. There is an assumption that if there has been no communication from the receiving establishment after 2-3 days, that the body will not be returned to the establishment for release. This assumption may lead to loss of traceability of bodies sent off-site for PM examination.	**Minor**

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	A number of issues with the condition of the PM suite and body store were identified: - There is flaking paint in areas throughout the body store; - The base of the fridges where they meet the body store floor show areas of degradation; - The PM suite floor has cracks throughout; - The drain edges on the PM room floor are cracked and there is standing water in the drain gulley; - There is loose grout and cracked tiles on the PM suite walls. Due to the age and condition of the premises, these areas cannot be effectively cleaned or decontaminated and pose a potential health and safety risk to staff.	**Major**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	The mortuary have cleaning records for the PM room but there is no cleaning schedule or records of cleaning for the body store fridges.	**Minor**

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)	The current access arrangements to the mortuary present a potential risk to the security of the establishment, the staff and the bodies in storage: - As there is no camera or mortuary CCTV, staff cannot visually verify who is requesting access at the entrance for funeral directors. There is also no Trust CCTV covering this area; - There is also no hospital CCTV coverage or video- intercom system, to allow mortuary staff to visually verify who is requesting access from the hospital entrance to the mortuary; - The access door for the pathologists to enter the mortuary directly from the main hospital corridor, does not lock automatically. Currently, pathologists have to remember to manually lock the door behind them. If for any reason this does not happen, then this area, which leads directly into the PM room, can be easily accessed by unauthorised persons; - The inspection team noted that when mortuary staff were releasing bodies, the rear door of the mortuary was wedged open. There is a risk of unauthorised access and this door has a line of sight directly into the body store area.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased.	The establishment have a bank of fridges, which they reduce the temperature as low as possible, for bodies that require long-term storage.This does not ensure that the condition and integrity of these bodies is maintained.	**Major**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The establishment does not have a freezer or contingency freezer storage, therefore are not able to freeze bodies that require long-term storage after the recommended 30-day timescale.	
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 establishment are not testing the fridge alarms. This provides no assurance that if the fridges were to fail, the mortuary staff would be made aware in time, which poses a risk to the bodies in storage. The fridge on maternity which may be used for the temporary storage of fetuses, is not currently temperature monitored or connected to an external alarm, to alert staff if the fridge is failing.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	The mortuary fridges were installed a number of years ago; one bank is the original installation from when the mortuary was first built. The internal structures of the fridges are in poor condition. The fridge tray racking and trays have rust patches internally, there is exposed wood on the fridge doors and the seals have come away, making the doors difficult to close and will compromise the fridges ability to maintain their temperature. In addition, this means these areas cannot be effectively cleaned or decontaminated. Posing a potential health and safety risk to staff	**Major**

Advice

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

No.	Standard	Advice
1.	C2(b)	The DI is advised to maintain a record of staff who have been trained to seek consent for perinatal/paediatric consent. This record will also allow the DI to identify staff who require refresher training.
2.	GQ1(e)	The DI is advised to proceed with plans to add the mortuary SOPs to the Q-pulse system so staff can acknowledge electronically, when they have read an SOP and move away from paper records and 'ticking' when something has been read.
3.	GQ1(h)	The DI is advised to have regular meetings with Persons Designated under the licence in order to help maintain oversight of licensable activities, which are taking place in other areas of the hospital under the post-mortem licence, such as the maternity ward.
4.	T1(c)	The DI is advised to consider liaising with the Coroner's contracted funeral directors to request that all bodies are consistently identified using three identifiers, as currently the full name and DOB are the main identifiers captured. This will allow three identifiers to be checked when adding the mortuary red wristband to the bodies for PM examination.
5.	T1(c)	In addressing the shortfall identified under this standard the DI is advised to consider ways to strengthen the procedure for undertaking viewings. The DI may wish to consider the introduction of a form to be completed by relatives when they attend for viewings. This form could include relevant identification information so that three identifiers can be checked on the body before the viewing takes place.
6.	T1(d)	The DI is advised to strengthen procedures for same and/or similar named bodies. Currently the mortuary staff are only checking if the surnames are same and/or similar. This may cause issues if the first name of the deceased is the same surname of another.

Concluding comments

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

All staff involved in the inspection demonstrated a sensitive and dedicated approach to their work. The mortuary staff are a cohesive, long-standing and experienced team, communicate well with each other and are open to accepting advice and guidance.
The establishment are very open to sharing learning particularly with regards to HTA reportable incidents and work together to improve practices to prevent further incidents.

The establishment has a comprehensive audit schedule and all of their mortuary risk assessments have good consideration of the risks to the deceased.

The establishment have developed their own 'body release form' and forms for checking identification of the deceased, which has spaces for members of staff to sign at each stage of the identification process. They have also developed their own competency assessment forms for mortuary procedures.

The establishment have already submitted a business case for replacing the PM room floor in the mortuary. They have taken a proactive approach to try and address some of the issues identified during the inspection

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

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

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

Report sent to DI for factual accuracy: 12 November 2018

Report returned from DI: 26 November 2018

Final report issued: 19 December 2018

Completion of corrective and preventative actions (CAPA) plan

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

Date: 23 June 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

ng for those responsible for seeking consent for post-mortem examination and tissue retention, which requirements of the HT Act and the HTA's codes of practice.

Guidance

Refresher training should be available (for example annually).

nstrate up-to-date staff training.

ff are involved in seeking consent, they are always accompanied by a trained individual.

s 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.