Site visit inspection report on compliance with HTA licensing standards

Manor Hospital

HTA licensing number 12102

Licensed under the Human Tissue Act 2004 for the

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

27 & 28 March 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 Manor Hospital had met the majority of the HTA's standards, four major shortfalls and 11 minor shortfalls were found in relation to the standards for Consent, Governance and quality systems, and Premises, facilities and equipment.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Background to the establishment

Manor Hospital's (the establishment) mortuary is located on the main hospital complex and is linked to the wards via underground corridors; it is secured by pin code door locks and access is limited to mortuary and histology staff and hospital porters. The Designated Individual, for the purposes of HTA licensing, is a Consultant Histopathologist, and the Chief Executive of the Hospital acts as the Corporate Licence Holder Contact.

The level of activity has increased significantly in the 12 to 18 month period prior to the inspection; there were 360 post-mortem (PM) examinations undertaken during 2017, an increase of almost one third over the previous year; however, there has been no increase in the number of establishment staff over this period. The majority of PM examinations are undertaken on behalf of the Black Country Coroner.

Occasional hospital (consented) PM examinations are also carried out. Consent for adult hospital PM examinations is sought by clinicians; however, the clinician interviewed during the inspection had not received training in the requirements of the Human Tissue Act 2004. Perinatal and paediatric cases are sent to another HTA-licensed establishment for PM examination. Consent for these cases is sought by clinicians, who again have not received any specific training in relation to seeking consent for PM examination or the requirements of the Human Tissue Act 2004 (see shortfall under standard C2(a)).

The main body store area has capacity for up to 80 bodies. This is made up of six freezer spaces, four isolation spaces, 56 standard sized spaces, six bariatric spaces and a walk-in fridge space that has racking for eight bodies that could be removed to accommodate a bed for a super bariatric case. Pre-term babies and products of conception are stored in a dedicated area within one of the adult fridges. Additionally, there are two external storage blocks, both of which can accommodate 36 bodies; one was not in use at the time of inspection. The internal fridges are old, show significant signs of rust and have broken down on a number of occasions. The Trust has now approved new fridges to be installed during the Summer of 2018; this will include freezer spaces that can accommodate bariatric bodies (see shortfalls under PFE 2 (c) and (d)).

All the fridges and freezers are linked to a remote monitoring system that incorporates an alarm which automatically contacts a pre-agreed list of people should the storage temperatures deviate from their expected ranges.

Hospital porters transfer the deceased from within the hospital to the mortuary. Bodies of those who die in the community are brought in by funeral directors appointed by the Coroner. If the funeral directors bring a body in outside of core working hours, the porters meet them at the mortuary and complete the transfer into the mortuary. Mortuary staff train all porters individually and provide refresher training when needed.

The PM suite has three fixed, height-adjustable, PM tables and one portable PM table. Pathologists complete the examination of each body and the organs prior to commencing the next case. This helps to minimise the risk of a mix-up of organs and tissue samples removed during PM examinations. Protective equipment for conducting both routine and high-risk PM examinations is available to staff, including face fitted masks; however, staff had not received formal training in the use of the masks. Tissue samples taken at PM examination, to help determine the cause of death, are cassetted and labelled in the PM suite.

Viewings of the deceased are arranged with bereavement officers or mortuary staff themselves. For hospital cases, bereavement staff meet visitors in the main hospital reception and escort them to the viewing suite. Out-of-hours viewings are rare and mortuary staff attend to provide access. The door from the viewing reception area is not lockable and could allow access to the body store area (see shortfall under standard PFE1(e)). There is a room dedicated as a washing room for families who wish to wash the body of their relative.

Description of inspection activities undertaken

The establishment has been licensed since 2007 and this was the third routine site-visit inspection. The HTA conducted a visual inspection of the premises, reviewed documentation and carried out interviews with the Designated Individual and establishment staff.
As part of the inspection, an audit of bodies within the body store was undertaken, where four bodies were selected at random, including one from the freezer and one from the external storage area. Details from the body identification tags and the physical location of the bodies were cross checked against the establishment's paper and electronic mortuary register. No anomalies were found during this audit.

Additionally, details of tissue retained following three PM examinations, including a hospital consented examination were audited. Details of the tissue were compared with records documenting the wishes of the family with regards to the fate of the tissue following its analysis and the physical tissue stored in the mortuary. A review of the consent form for the hospital (consented) PM examinations highlighted conflicting requests in relation to the fate of tissue samples taken as part of the PM examination, indicating that the consent giver may not have understood the options. Mortuary staff confirmed that they did double-check this with the consent giver but this wasn't indicated on the form or noted elsewhere (see shortfall under C1(a)). For Coronial cases, the Coroner retains details of the consent given by the family and manages the body release process accordingly. In cases where the family requested that blocks and slides or an organ sent for specialist analysis are returned to the body before the funeral, the Coroner will only issue the release form when informed that the organ has been returned to the establishment for repatriation. No anomalies were found in the audit of the Coronial cases.

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
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.	The Consent policy shared with the inspectors does not reflect the requirements of the HT Act and the HTA's Codes of Practice: - It stated that if no living relatives can be traced, and there is no evidence of an objection on the part of the deceased, then the Chief Executive could approve for a PM examination to go ahead. This is an offence under the Human Tissue Act as appropriate and valid consent is required. There was no evidence however, that this has ever happened; - There is a lack of information about the role of the nominated representative, and their standing in relation to the hierarchy of qualifying relationships; - The policy states that if the family have requested the tissue to be used for education and research, the blocks and slides are kept in a departmental archive and after 10 years are disposed of in a sensitive manner; however, the Coroner's form states that they are kept for a minimum of 30 years; - There is no procedure in the policy describing what steps to take if there is an issue with the consent, or if the form has been completed incorrectly.	**Major**
c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.	The leaflet provided to families is supposed to only be for cases where a hospital (consented) PM examination has been requested; however, the document also refers to coronial PM examinations, which could lead to confusion for those reading the document. If the document is also shared with those where a coronial PM examination is required, there is conflicting information on the forms as the hospital document is focussed on families storing tissue for their own use or for research, but this is not an option on the Coroner's forms viewed on inspection.	**Minor**

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	The guide for families in relation to PM examination stated that, unless they requested otherwise, samples taken for toxicology would be kept for six months. There was no mechanism in place, on any of the three versions of the consent form seen by the inspection team, for the family to object.	**Minor**
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	Information given in the information leaflet is not compatible with the options given on the recently used consent forms. The leaflet highlights the benefit of the family keeping samples for their own future analysis if required but this option also includes use for research or education and training. If the tissue is used for research then it may not be available for the family in the future (see *Advice*, item 2).	**Minor**
g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	The consent form annexed in the Trust's consent policy is the model consent form from the HTA website, without any of the HTA's recommended adaptations. If shown to a family, this would lead to confusion about what the family are consenting to. The inspection team found a second version of the consent form on the establishment's document management system, which was different. This form stated that blocks and slides would be kept indefinitely without giving the option for disposal or return to the family. Neither of these versions of the consent form were the form used to record consent for the previous five hospital (consented) PM examinations reviewed by the inspection team during the traceability audit.	**Major**

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	There is a training presentation on seeking consent for PM examinations that considers the requirements of the HT Act and the HTA's Codes of Practice. However, not all consent seekers have seen this training or had any other training about the HT Act. One consent seeker thought that the individual who accompanies the patient into the hospital or named as the primary contact, would always be the appropriate person to give consent. However, the person listed as next of kin by the hospital may not be the highest ranking person in the hierarchy of qualifying relationships. In the Maternity department, consent is sought by consultants who may have seen an adult PM examination as part of their training but have not undergone any specific training in relation to the HT Act or seeking consent for a perinatal/paediatric PM examination (See *Advice*, item 3).	**Major**
b) Records demonstrate up-to-date staff training	There were records of people who had reviewed the consent presentation; however there was no mechanism in place to verify that anyone wishing to seek consent has seen the presentation.	**Minor**
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual	The DI does not have oversight of those seeking consent and through the audits undertaken during the inspection it was identified that untrained staff have sought consent without being accompanied by a trained member of staff.	**Minor**
d) Competency is assessed and maintained	Two of the consent forms reviewed by the inspection team contained errors or inconsistencies. There was no evidence that these issues had been raised with the staff who sought the consent in these two cases or if further training and/or guidance had been provided.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	The SOPs for viewings and washing do not detail how the deceased are to be identified or highlight that three identifiers are required. The establishment accept age rather than date of birth as an identifier.	**Minor**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The doors leading from the mortuary viewing suite to the mortuary reception and body storage areas does not have a lock. The lack of access control on these doors raises a potential risk that visitors for viewings may enter the body storage area, posing a further risk to the dignity of the deceased, and the safety of staff.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	There is no provision for frozen storage of bariatric bodies. In addition, the current freezer spaces are old and relatively narrow. The refurbishment of the body store scheduled for Summer 2018 should address this shortfall.	**Minor**
d) Fridge and freezer units are in good working condition and well maintained	The fridges and freezers are old and show significant signs of rust. They have also broken down on a number of occasions. The planned refurbishment of the body store scheduled for Summer 2018 should address this shortfall.	**Major**
g) Bodies are shrouded or in body bags whilst in storage	The inspection team noted that the deceased in storage were not fully covered. The mortuary staff demonstrated that the shrouds provided by the Trust easily tore and were not fit for purpose.	**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	There are gaps where the flooring of the PM room meets the wall which makes effective cleaning of the area difficult. *This shortfall was addressed prior to publications of the report.*	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(a)	The Coroner has recently updated their 'cause of death' form. The DI is advised to ensure this is added to the Consent Policy as it includes 'Digital Autopsy' and the new Coroner details.

2.	C1(e)	The DI should consider separating the options given in relation to the fate of tissue after analysis to clearly distinguish between the options of use for research and training, and storage for future use for the family.
3.	C2(a)	There is a new Person Designated in the maternity department who has arranged for themselves and a number of midwives to attend consent training and view a perinatal PM examination at another HTA licensed establishment. The DI is advised to put systems in place to ensure that only those who have attended the training are involved in seeking consent for PM examination.
4.	GQ1(a)	Mortuary staff check the duration of stay of bodies on a monthly basis and escalate any cases that have been with them for longer than 30 days to bereavement services. The DI is advised to increase the frequency of these checks and to change the timeframe for escalation, for example, when a body has been in storage for 20 days. This will allow more time for the mortuary to decide whether transfer to the freezer units is appropriate.
5.	GQ1(g)	The DI is advised to add a member of the mortuary staff as a Person Designated on the licence to ensure that the HTA have improved contact details for the mortuary and that communications can be shared more widely with staff.
6.	GQ1(h)	The DI is advised to consider inviting Persons Designated (PDs) from other departments to the quarterly mortuary meetings, particularly while the new PD in the maternity department settles in.
7.	GQ6(a)	The majority of the risks to the deceased are addressed by the establishment; however, the DI is advised that there should be greater focus on the risk of accidental damage when the deceased are being transferred into and out of the fridges. Additionally, the risk of viewing the wrong body should be included in the risk assessment for viewings.
8.	T1(c)	The DI is advised to ensure that release identity details include date of birth rather than age.
9.	T1(c)	Mortuary staff assist with viewings of the deceased. Relatives contact the mortuary to provide details of the deceased they wish to visit and arrange a time for the viewing. The DI is advised to develop a procedure to assure themselves that the family provide a minimum of three identifiers for the deceased.
10.	T2(c)	The establishment processes tissue from PM examinations at another HTA licensed establishment. For these samples, the relevant Coroner has asked that they are all be disposed of when their authority ends. This does not take into consideration of any families which may wish to retain tissue for future review or other scheduled purposes in the future. The DI is advised to liaise with the relevant Coroner to ensure that copies of the family wishes forms are received for each case so they can assure themselves that they are acting in accordance with the wishes of the family.
11.	PFE3(a)	There is a mallet in the PM suite with a laminated wooden handle. The chemicals used for decontamination can damage the laminate covering, the DI is advised to regularly check the condition of the handle to ensure it remains non porous.
12.	PFE3(d)	The DI is advised to undertake appropriate training for mortuary staff with regards to the use of face fitted masks.

Concluding comments

The mortuary appears to be well run, particularly considering the amount of pressure on staff from the large increase in activity over the 15 months prior to the inspection. Feedback from relevant stakeholders complimented the staff on their dedication over this period. The system to identify which spaces are free for porters and any other details for staff, such as same or similar name or high risk, is clear and provides a visual aid to those working in the mortuary. Release of the deceased is on an appointment-only basis; with the increased level of activity, this helps to mitigate the risk of release of the wrong body due to multiple funeral directors attending at the same time. Despite the issues with blocks and slides mentioned in *Advice*, item 10, management of tissue and ensuring the wishes of the family are met, is well managed.

There are a number of areas of practice that require improvement, including four major shortfalls and 11 minor shortfalls.

The HTA requires the Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.
The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 24 April 2018

Report returned from DI: 4 May 2018

Final report issued: 10 May 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: 26 October 2018

Appendix 1: HTA licensing standards

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

Consent

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

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

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

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

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

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality systems

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

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

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

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

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

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

to mitigate them.

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

present a risk to traceability. Full identification checks should be made when 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.