Site visit inspection report on compliance with HTA licensing standards

Northern General Hospital

HTA licensing number 12427

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**

14-15 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.

The HTA found that the Northern General Hospital (the establishment) had one major shortfall in relation to standard operating procedures (SOPs) and four minor shortfalls against Governance and Quality systems (GQS) and Premises, Facilities and Equipment (PFE) standards.

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

The HTA's regulatory requirements

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

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

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

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

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

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

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

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

Background to the establishment

This report refers to the activities carried out at the Northern General Hospital. For HTA licensing purposes, the Northern General Hospital is the 'hub' and the licence arrangements extend to the 'satellite' site at the Royal Hallamshire Hospital. The Jessop Wing, a paediatric body storage facility, is located at the satellite site.

The Designated Individual (DI) is a Consultant Histopathologist for the Trust. The Corporate Licence Holder (CLH) is the Trust with the Medical Director as a named contact. At the time of the inspection, the mortuaries at the hub and satellite sites were staffed by a Mortuary Manager, three Anatomical Pathology Technologists (APTs), two Medical Laboratory Assistants (MLAs) and two Consultant Histopathologists (including the DI) who conduct post-mortem (PM) examinations. A Mortuary Support Officer also assists in the mortuary when needed. Two of the establishment's permanent members of staff were on long-term sick leave at the time of the inspection, however, observations by the inspection team during the inspection showed that staff continued to deliver mortuary services with limited disruption. This was brought to the attention of the inspection team prior to the inspection taking place.

Approximately 15 hospital consented PM examinations are conducted at the establishment each year including high-risk cases. PM examinations requested by the Coroner are carried out infrequently at the establishment with the last one being over a year ago. Consent for adult PM cases is sought by trained staff. Paediatric cases are transferred to another HTA licensed-establishment for PM examination; however, trained staff seek consent for these cases which is recorded using consent forms from the establishment where the PM examinations are conducted. Training in seeking consent for both adult and paediatric PM examination is provided regularly and a list of staff who are trained to seek consent is maintained by the establishment.

Tissue taken during PM examinations is sent to the histology department at the satellite site for processing and is stored or disposed of according to the wishes of the family.

Northern General Hospital (hub site)

The mortuary has 65 refrigerated body storage spaces, an additional 35 spaces in a temperature controlled cold room, and four bariatric spaces. If extra spaces are needed, the establishment may use an additional 22 spaces at the top and bottom of the fridge bays. A fridge bay of five spaces can be converted to frozen storage if needed, but was being used as refrigerated storage at the time of the inspection (see shortfall against standard GQ1(a)). The establishment has additional temporary storage capacity within the PM suite including a refrigerator unit and a temporary storage unit. These additional units hold up to 27 bodies. The temporary storage unit had been deployed and was in use at the time of the inspection (see shortfall against GQ6(a)). In the event that the mortuary reaches capacity, bodies are transferred to the satellite site.

There is CCTV inside and outside the mortuary and swipe card access for authorised staff.

All permanent fridges and the cold room are linked to a temperature monitoring system which is linked to an alarm system. In the event that the storage temperature goes below or above set limits, the system automatically triggers an alarm and alerts security staff who in turn will contact mortuary staff in case of an emergency. Mortuary staff do not conduct regular testing of the temperature monitoring alarm's call out system (see shortfall against standard PFE2(e)).

The mortuary only receives bodies of patients who die in the hospital. Porters admit bodies from the hospital wards to the mortuary, both in and out of normal working hours. All porters undertaking mortuary procedures are trained and are required to shadow an experienced member of staff before they are signed off as competent to admit bodies. Annual refresher training is also provided for the porters.

Due to the design of the hospital, the route that bodies follow when being transferred to the mortuary includes travel outside of the hospital in order to reach the mortuary building (see shortfall against standard GQ6(a)). From discussions with staff, it is understood that the establishment is looking at alternative ways of transferring bodies to the mortuary without the need to transfer bodies outside. When a patient dies on the ward, a porter transfers a concealment trolley from the mortuary to the ward. Two porters will then transport the body in the concealment trolley to the mortuary.

When bodies are admitted to the mortuary, porters place the deceased in a fridge space and place the identification card relating to the deceased in the allotted space on the fridge door. Anatomical Pathology Technologists (APTs) are responsible for checking all bodies that have been admitted, verifying their identification tags and entering such details in to the mortuary's paper and computerised records. If two or more bodies with a same or similar name are admitted, the card on the fridge door and the name in the mortuary paperwork is highlighted in pink to alert the establishment's staff.

Bodies are released between set hours, Monday to Friday. In the rare event that a body is released outside these hours, the Trust's Matron attends. During normal working hours, funeral directors call the Mortuary Assistant via a video intercom system from outside the mortuary. Upon release, mortuary staff confirm the identity of the deceased with the funeral director by checking identification details on the body against paperwork from the funeral director (see shortfall against GQ1a). The funeral director and APT both sign the paperwork upon release to record that the identification checks have been completed.

Viewings are arranged between the family and the mortuary or bereavement staff. Viewings are carried out during normal working hours and are rarely conducted out of hours. When an out of hours viewing takes place, the Matron attends to conduct the viewing.

The PM suite has four PM examination tables. There are also downdraft dissection benches where pathologists can inspect the organs. Maintenance records for the mortuary and PM room reviewed during the inspection demonstrated the appropriate number of air changes per hour is achieved. To mitigate the risk of returning organs to the wrong body, only one PM examination is carried out at any one time. At the time of inspection, temporary refrigerated storage units had been deployed and were in use at the far end of the PM suite (see *Advice*, item 5)

Tissue taken during the PM examination is taken to the hub's histology department for transfer to the histology department at the satellite site where it is processed, analysed, disposed of or retained in accordance with the wishes of the family.

The inspection team were also made aware that the establishment will be holding a two-day surgical skills training course which will take place in the PM room during June 2018 using fresh frozen body parts sourced from another HTA licenced establishment. Advice was given during the inspection in relation to this (see *Advice*, item 5).

Royal Hallamshire Hospital (satellite site)

The satellite site has 42 refrigerated body storage spaces, 6 bariatric spaces, and a dedicated storage facility for paediatric cases. There are no freezer spaces at the satellite site. There is CCTV and the mortuary is alarmed with restricted access.

Staff at both the hub and satellite sites follow the same procedures for the viewing, receipt and release of bodies, with the only exception being the route that the bodies take into the mortuary. The satellite site has a lift, controlled by key access, to bring bodies to the mortuary.

The PM suite has three workstations, where PM examinations are conducted, and a dedicated dissection bench.

The Jessop Wing is located at the satellite site in another part of the hospital, and is where all paediatric bodies are stored. There are eight refrigerated spaces for the storage of paediatric cases. Fridge temperatures are monitored and an automatic alarm with a call out system to alert staff when temperatures exceed pre-defined limits. There are also small fridges on the gynaecology wards used for storage of products of conception pending transfer to the Jessop Wing. In the event that the Jessop Wing mortuary reaches capacity, bodies will be stored in the dedicated paediatric fridge in the mortuary.

There is secure key access to the Jessop Wing and trained porters admit bodies both in and out of normal working hours. During release, bereavement staff are present and check identification details on the body against paperwork from funeral directors. In the rare event

of an out of hours release, the Duty Matron attends. There are dedicated rooms for viewings and cold cots are available for families.

Description of inspection activities undertaken

This was the fourth site visit inspection of the establishment; the previous inspection took place in 2014. The inspection team carried out a visual inspection of the body stores, PM suites and viewing areas at the hub and satellite sites, the histology department and the Jessop Wing at the satellite site.

Interviews with key members of staff, a review of governance and quality system documentation and traceability audits were also undertaken. Audits were conducted on five bodies being stored in the establishment's fridges including a long stay body and a body with the same/similar name. Body location and identification details on ID tags were cross-referenced against the information recorded in paper and computer records. One minor anomaly at the satellite site was identified where the date of birth was recorded incorrectly in the mortuary day notebook. At the Jessop Wing, one paediatric body was audited. Identification tags on the body were checked against relevant paperwork. No discrepancies were found.

In addition, three hospital consented PM examinations where tissue was retained following the examination were audited. The audit included details of tissue, blocks and slides taken, consent forms, and associated paperwork. The location of the actual tissue stored in the freezer at the hub site and blocks and slides in the histology department at the satellite site, were also checked. 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

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	There are a wide range of SOPs, however some of the SOPs do not reflect current practice: For example: • The SOP for taking consent for PM examination does not state that the mortuary manager seeks consent for PM examination. It also refers to the previous DI. (section 3.3, page 10) • The SOPs for viewings and release of bodies to funeral directors do not include the current practice of checking the minimum of three identifiers or state which identifiers are used (e.g. full name, DOB, address). • The SOP for the release of perinatal and paediatric cases to funeral directors does not state which identifiers are used on release. • The SOP for managing long stay bodies does not include a procedure for moving bodies from refrigerator to freezer storage. The establishment does not utilise their freezer storage and this was evidenced by eight long stay cases in the fridges at the time of inspection.	Major

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	Risk assessments include most of the procedures relating to licenced activities, but the following activities have not been risk assessed: • The movement of bodies from the ward to the mortuary at the hub site • The use of the temporary storage unit in the PM suite	Minor
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.	Risk assessments lack detail on the measures identified to mitigate the identified risks. Risk assessments should detail all of the control measures that have been taken to mitigate them.	Minor

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.	The inspection team noted that the sink drain in the PM suite at the satellite site was contaminated with organic material, and the floor was sticky even though the room had been cleaned and disinfected. The issues identified above, pose a potential health and safety risk to mortuary staff and others who work in the mortuary.	Minor

PFE2 There are appropriate facilities for the storage of bodies and human tissue		
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range.	The temporary fridge storage unit, which is located in the PM room, has an audible alarm only. Mortuary staff rely on the porters hearing the alarm out of hours when bringing bodies to the mortuary. However, this alarm has never been tested for audibility outside of the PM room or if the porters will respond. In addition, there is no testing of the call out systems for the permanent fridge alarms. See *Advice*, item 3	Minor

Advice

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

No.	Standard	Advice
1.	GQ1 (a)	In relation to the major shortfall above relating to the procedures around long stay bodies, the DI is advised to implement a system to undertake and record checks of the long stay bodies in the mortuary which include ID checks, reason for continued storage, and condition of the body. This will help to assure the DI that there is a written record of the checks and that staff have undertaken the appropriate steps to maintain the dignity of the deceased. The frequency of these long stay body checks should be decided by the DI and be of a frequency sufficient to assure themselves that long stay cases are being appropriately monitored. In addition, if a long stay body cannot be moved into freezer storage after 30 days, the reason for continued fridge storage should be logged.
2.	GQ5 (a)	The DI is advised to include a list of all the HTARI categories in the incident SOP so staff are aware of which incidents should be reported to the HTA. *This advice was acted upon by the establishment during the inspection.*
3.	PFE2 (e)	In addressing the shortfall identified against PFE2(e), the DI is advised to provide instructions in the mortuary for portering staff to follow if they hear the alarm sounding out of hours. The call out procedures should be communicated to portering staff and documented so they know the steps to take if they hear the alarm sounding out of hours.
5.	N/A	The DI informed the inspection team that the temporary body storage unit will be removed prior to the commencement of the surgical skills training course and that they are developing a code of conduct for delegates to read and sign prior to participating in the course. The DI should notify the HTA once these actions are completed.

Concluding comments

Areas of good practice were observed during the audit. Some of these are included below:

- It appears that staff at the establishment show commitment to overcome the temporary pressures arising from the lower than usual staff numbers;

- Audits are carried out against HTA standards to help the DI in identifying any areas for improvement;

- Bereavement staff on the Jessop wing are continually researching ways to improve the service. This was evident as the team were piloting a new pathway for paediatric/perinatal cases;

- The Trust encourages a culture of transparency which is clear in the high numbers of incidents reported; and

- All incidents are discussed at senior level.

Several areas of practice require improvement including one major shortfall regarding SOPs and four minor shortfalls in relation to GQS and PFE standards. Advice was given in relation to information in SOPs, procedures for long stay bodies, risk assessments, and testing of fridge temperatures and alarms.

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: 16 April 2018

Report returned from DI: 20 April 2018

Final report issued: 23 April 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

b) 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.

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

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

e) 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.

f) 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.

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.