Site visit inspection report on compliance with HTA minimum standards

Public Mortuary

HTA licensing number 12057

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**

30 July 2015

Summary of inspection findings

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

Public Mortuary (the establishment) was found to have met all applicable HTA standards. HTA consent standards do not apply to this establishment, as all post mortem (PM) examinations are performed under the authority of HM Coroner and no PM tissues are stored for use for scheduled purposes when coronial authority has ended. The HTA has given advice to the Designated Individual with respect to consent, risk assessments, storage of the deceased and disposal arrangements.

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

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

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.

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. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, 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 given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

The establishment is a public mortuary serving the community of Stoke on Trent. It has been licensed by the HTA since June 2007 for the making of a PM examination, removal of relevant material from the deceased and storage of the deceased and relevant material for use for scheduled purposes.

Consultant Histopathologists working for the Coroner carry out approximately 700 adult PM examinations each year. There are no Home Office, consented or perinatal/paediatric PM examinations conducted at the establishment.

The mortuary is staffed by 1 APT and the Mortuary Services Manager. The body storage area has 42 refrigerated spaces, and six freezer spaces. There is no dedicated storage for bariatric cases, which are transferred to a neighbouring hospital (HTA licensing number 12224) under the terms of a formal agreement. The mortuary provides storage facilities for community deaths.

Bodies admitted to the mortuary during office hours are dealt with by mortuary staff, who check identification details and log details of the deceased in the mortuary's paper-based records. Out of hours, bodies may be delivered to the mortuary by the Coroner's removal team or the local ambulance service, both of which have keys to access the mortuary. People

admitting bodies out of hours use specific forms to record details of the deceased placed into storage for the information of mortuary staff when they attend the next working day.

All bodies brought to the mortuary have an ankle and wrist band containing details of the deceased's name, age and place and date of death. A further wrist band is applied by mortuary staff after admission to the mortuary, which includes the unique mortuary number and storage location.

New members of staff from the funeral directors providing contracted removal services for HM Coroner are trained by mortuary staff on the procedures to be followed when admitting bodies. The ambulance service has also been provided with written instructions detailing those procedures.

When a PM examination is necessary, authorisation is received from the Coroner by email. The APT and Mortuary Services Manager remove the body from storage, checking identification details and these are re-checked by the visiting pathologist and assisting APT prior to commencement of the PM examination. Tissues removed during PM examination are transported by courier service to a local HTA-licensed establishment for further examination.

Temporary storage of blood, urine and small tissue samples for toxicological analysis takes place at the establishment, pending the Coroner's decision on whether this is required. If not needed, samples are disposed of at the establishment (refer to advice item 2). If the family wishes material no longer required by the Coroner to be retained for use for scheduled purposes, the material is transferred to the neighbouring hospital for storage under licence 12224. If the family opts to dispose of this material, it is sent to that hospital for disposal.

Bodies are released only after receipt of confirmation from the Coroner. Where a body has been subject to a PM examination, release may only take place after written authorisation is received; in other cases, authorisation may be by email.

The last HTA site visit inspection of the establishment was in September 2011. That inspection resulted in three minor shortfalls, which were addressed by the establishment completing a Corrective and Preventative Action (CAPA) plan to the HTA's satisfaction. This report describes the third routine site visit inspection of the establishment. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted a visual inspection of the mortuary.

Audits of traceability were conducted for tissue samples from two coronial PM cases, including audits of the consent documentation for the retention of these samples. No anomalies were found. A traceability audit was conducted for two adult bodies in storage. One discrepancy was identified as one body was missing an ankle band, which had not been applied by the funeral director (refer to advice item 3).

Inspection findings

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

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C2	The form currently used by the Coroner's office staff to record the family's wishes with regard to the fate of material no longer required by the Coroner (form H2) meets the requirements of The Coroners (Investigations) Regulations 2013 but it could be extended to include separate sections for tissues or organs and to cover individual scheduled purposes separately. The DI is advised to consult with the Coroner about the possibility of making these improvements.
2.	GQ1	The DI is advised to review the document covering audit of retained samples, to clarify and cover in detail the methods of disposal used at the establishment.
3.	GQ6	The DI is advised to introduce a local record of minor non-conformances arising from a failure to follow documented procedures, including information on how these have been addressed. For example, when a body is brought in by the local ambulance service or the Coroner's removal team and a tag is missing, as identified during the inspection.
4.	GQ8	The DI is advised to ensure documented risk assessments detail all existing control measures. For example, the risk assessment relevant to tissue traceability should include that a dissection board is used above each body during a PM examination to ensure that tissues and organs are returned to the correct body, and that a card indicating that tissue needs to be repatriated is placed on the shrouding of the body following a PM examination to ensure that no bodies are released before tissues or organs have been returned to them.
5.	PFE3	Although bodies kept in refrigerated storage are shrouded, in some cases, the head of the deceased is not covered. The DI is advised to ensure that all bodies are fully covered during storage, to maintain the dignity of the deceased at all times.
6.	D2	Small amounts of relevant material are temporarily stored at the establishment for potential DNA or toxicology analysis. Where the Coroner decides that they are not required, the DI is advised to treat this material as clinical waste and dispose of it appropriately, following the HTA Code of Practice on Disposal.

Concluding comments

This report describes the third HTA site visit inspection of the Public Mortuary at Stoke on Trent. During the inspection, several areas of strength were observed.

The mortuary staff have worked at the establishment for a number of years and are motivated and experienced in their roles. They are well trained and have worked towards developing robust mortuary procedures. The team is dedicated to ensuring that the dignity of the deceased is maintained and that relatives visiting the mortuary are treated sensitively. The mortuary staff have developed good working relationships with staff in other establishments and the Coroner's office, visiting pathologists and local funeral directors.

The DI has a good understanding of the HT Act and works to ensure improvements are implemented as required. She works closely with staff in the mortuary and the Coroner's

Office. The DI is well supported by the staff and Services Manager. Staff working under the HTA licence at the establishment demonstrated a commitment to continual quality improvement.

The HTA has given advice to the Designated Individual with respect to consent, risk assessments, storage of the deceased and disposal arrangements.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 19 August 2015

Report returned from DI: No comments received

Final report issued: 17 September 2015

Appendix 1: HTA standards

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

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.
- There is a documented training programme for new mortuary staff (e.g. competency checklist).

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

- 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.
- There are documented SOPs for record management.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- 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.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's

family.

- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

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.