Site visit inspection report on compliance with HTA minimum standards

Liverpool City Mortuary

HTA licensing number 12033

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**

21 October 2015

Summary of inspection findings

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

Although the HTA found that Liverpool City Mortuary (the establishment) had met the majority of the HTA standards, a shortfall was found in relation to standard GQ2. Audits carried out at the establishment are not fully documented. The shortfall was addressed before the publication of this report.

Since the last inspection, there has been a change in the post of operations manager, largely responsible for overall governance procedures at the establishment. As the new post holder had only recently taken up the role, some aspects of governance procedures, in particular the minuting of staff meetings, need refreshing.

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 (DI), 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 undertaking coronial post mortem (PM) examinations on behalf of the Coroner for Liverpool and the Wirral. As no consented PM examinations take place at the establishment, the consent standards do not apply and were therefore not assessed during this inspection.

Around 350 PM examinations are undertaken at the establishment each year. Paediatric and known high risk PM examinations are not performed at the establishment and are transferred to other licensed premises. The establishment has a procedure in place where a high risk infection is discovered during PM examination.

The establishment has 40 fridge spaces, one bank of which is wider and, with the removal of body trays when necessary, may be used to provide greater space for storage of bariatric bodies. Two banks of fridges, the cooling systems of which are separated from the others, are used for bodies which have suffered from decomposition prior to receipt, and access to these is minimised. There is no freezer capacity. All temperatures are monitored daily. The alarm does not sound locally but is a fully remotely monitored system with call out to staff, both in and out of working hours. Preventative maintenance of all mortuary equipment is carried out annually by specialist contractors.

Bodies are delivered to the establishment by funeral directors contracted by the local coroner. In office hours, mortuary staff allow access and take responsibility for placing bodies into the body store, and funeral directors enter patient details in the body store register. Out of hours, funeral directors gain access by use of coded key fobs and take responsibility for placing bodies into the body store, with the accompanying police officer or ambulance technician being responsible for entering details in the body store register. Mortuary staff check identity details on their return to work, as part of the process by which information is transferred from the body store register into the mortuary register.

All bodies received into the body store are given a unique, sequential, mortuary number. In addition, identification details include; name, address, date of birth and, where relevant, police log number. A coroners death register number is subsequently added.

Identification details, including at least three unique identifiers, are contained on a wrist band attached to the body. They are also noted on the body bag in marker pen. When the body has been logged in to the mortuary register a further wristband, bearing the unique mortuary number, is attached. A coloured wristband is attached in cases of same or similar names, and a magnetic marker is placed on the appropriate body store door. Similar markers are used where there is an infection risk, or where tissues are to be repatriated. Bodies which have suffered some decomposition before receipt into the mortuary are stored within a separate bank of the body store.

Authority for PM examination is received by fax or email from the coroner and details of those bodies which have a PM examination are then entered onto an electronic spreadsheet. Prior to PM examination, a mortuary staff member retrieves the body from the body store by reference to the body store register and details on the body bag. The body is transferred into a double-ended through fridge which leads into the PM examination suite and the deceased's name added on each door of that fridge.

When transferring the body to the table for PM examination, both the pathologist and the assisting anatomical pathology technician confirm the identity of the deceased by comparing details on the wristband with those on the coronial authority, the deceased's medical records and any other documentation supplied by the police or general practitioner.

All tissue taken during a PM examination is recorded on histology traceability forms and samples are placed into labelled histology pots before being sent from the establishment to other licensed premises for analysis. This transfer is recorded within a histology log book. Families' wishes with regards to any tissue taken during a PM examination are sent directly from the coroner's office to the licensed premises where the tissue is sent. Disposal of tissue retained at PM examination, or retention for use for scheduled purposes, is the responsibility of the pathologist and takes place at the licensed premises where tissue has been examined.

Only tissues or organs for which repatriation with the body is requested are returned to the establishment. In such cases, the establishment uses a combination of coloured arm covers, magnetic door markers and entries on record paperwork to indicate bodies for which repatriation has been requested.

Bodies which have undergone a PM examination are released to funeral directors following receipt of a faxed authorisation from the coroner, which includes details of the funeral director contracted by the family. Where there has been no PM examination and death has been certified by a general practitioner, the deceased is only released to a funeral director upon presentation of the original registration of death certificate. In both cases, the body store

register is signed by both the funeral director and a member of staff to record release, as is the relevant property form.

This was the third site-visit inspection of the establishment and was a routine inspection to assess whether it is continuing to meet the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's last self assessed compliance information and audit of stored material, as well as pre-inspection discussions with the DI and a review of the previous inspection findings. During the site visit, a visual inspection of the premises, review of documentation and interviews with establishment staff were undertaken. The HTA also observed staff logging in a body received into the mortuary during the previous night and also the release of a body to funeral directors. In both cases, the procedures observed reflected those detailed in the relevant standard operating procedures (SOP) and described by staff.

An audit of traceability was also undertaken:

- Two bodies were selected by reference to details on the body store doors. Identification details recorded on the doors, body bag and wristbands were compared against those recorded in the body store register and mortuary register. In one case a minor typographical error in recording the police log number was noted.

- For two cases where tissue was retained at PM examination, the details of tissue retained recorded in the mortuary register were compared with those recorded on the histology record form and the corresponding electronic spread sheet. No discrepancies were found.

- The records of three coronial authorisations for release of bodies were located in the paper files and checked against the body store register. Details of tissue retained and nominated funeral directors were checked. No discrepancies were found.

Inspection findings

The HTA found the DI and the Licence Holder to be suitable in accordance with the requirements of the legislation. The DI and the HTA discussed the possibility of the DI role being assumed by someone with a more direct operational function at some point in the future.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.	Both vertical and horizontal audits are carried out at the establishment. The vertical audits are documented and follow-up actions are detailed. A senior staff member carries out a variety of horizontal audits of body and tissue traceability records each month. However these audits are not formally documented and are not, therefore, available to staff; follow up and any corrective actions that result from the audits are also not recorded. **This shortfall was identified during the inspection but evidence that it had been addressed by the establishment was exhibited to the HTA prior to publication of this report.**	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	The DI is advised to formalise and document the schedule used for review of SOP documentation, risk assessments and audits. The HTA notes that monthly audits are carried out, and that other elements of review of governance documentation are carried out at the same time as health and safety assessments scheduled by a department external to the establishment. Staff review SOPs regularly but not to a defined schedule. By formalising the schedule of review of governance documentation, the DI will assist staff in ensuring that it remains relevant, reflects current practice and takes into account any change in risk or practices carried out.
2.	GQ1	The DI is advised to formalise the plan to continue the practice of the previous operations manger, whereby mortuary meetings were minuted. The HTA notes that regular meetings of staff take place and that these have previously been minuted. By ensuring that this practice continues, and by allowing staff to have access to minutes, the DI will enable staff who were not present at meetings to remain updated with regard to matters discussed.
3.	GQ2	The DI is advised to incorporate observational audits of staff carrying out procedures in accordance with documented SOPs into the overall audit programme and to refer to these in staff appraisal meetings. By carrying out observational audits, any deviations of procedures followed by staff may be noted, which will aid the DI to ensure that procedural

		documentation reflects the practice carried out and help to identify any issues which need to be addressed by staff training.
4.	GQ4	The DI is advised to draft an SOP detailing how governance documentation and records are created, altered and maintained. The HTA notes that there is an overarching Liverpool City Council records management policy document. However, it is not specific to the mortuary and appears to be out of date. The HTA also notes that various SOPs provide guidance to staff on which records must be created during specific procedures. However, there is no easily accessible resource which provides staff with clear guidance on how to create governance documentation or to manage document revision or correction of records. By having such a resource in document form, staff will have clearer guidance which may assist in maintaining the consistency of documentation used within the establishment and the accuracy of records created.
5.	GQ7	The DI is advised to combine the two SOPs (OP4 and OP4a) which detail how HTA Reportable Incidents (HTARI) are reported internally and then reported to the HTA. By combining these two SOPs staff will be provided with all required information within one document, minimising the risk of confusion, particularly with regard to the responsibilities of staff in reporting and following up HTARIs.
6.	GQ8	The DI is advised to include all of the HTARI categories within the establishment's suite of risk assessments. The HTA notes that, in addition to Health and Safety risk assessments, various regulatory risks have been covered in the risk assessment entitled "Prevention of release of the wrong body/maintaining identity of the deceased". By ensuring that all HTARI categories are risk assessed, and by using the results of the assessments to inform review of SOPs, the DI will help to ensure best practice to militate against occurrence of a HTARI.
7.	PFE3	The DI is advised to document the contingency arrangements agreed with a local body store. This will help to ensure staff are aware of the procedures to be followed, and the details of appropriate contacts, in the event of need to invoke contingency storage arrangements.
8.	PFE5	The DI is advised to require contractors appointed to maintain mortuary equipment and facilities to confirm that calibration of equipment such as temperature probes and air handling units meets the relevant industry requirements for equipment of that type. The HTA notes that specialist contractors have been used for routine maintenance of equipment in the mortuary and that this contract has now been re-tendered. However, the records available to staff do not detail the calibration of temperature probes, nor specify how many air changes the air handling unit achieves. By having this information, the DI will be able to analyse any equipment performance issues.
9.	N/A	The DI is advised to consider whether his workload and other responsibilities may impinge on his ability to fulfil the role of DI effectively in the future. The HTA notes that he attends the mortuary often, has good communication with staff and is in a position within the council to influence change. However, he feels that someone with more day-to-day oversight of operational matters may, subject to appropriate training and approval by the HTA, be better placed to fulfil the DI

		role, provided that there is maintenance of the link to senior management within the council.

Concluding comments

The HTA saw various examples of good practice during the inspection.

- In an attempt to minimise the potential distress caused to relatives, staff have provided colour changing lighting within the viewing room to help correct the skin colour appearance of bodies affected by noticeable post mortem change.

- Senior members of the establishment staff carry out training for police officers on mortuary procedures, with particular emphasis on accurate information entry and the requirements of good record keeping for the purposes of traceability.

- Where relatives wish organs or tissues to be repatriated with the deceased, the establishment uses magnetic markers on the relevant body store door, together with coloured sleeves placed on the deceased, to minimise the risk of inadvertent release prior to the return of the organs.

- The establishment has assessed the risk to staff and other stored bodies where a body received in a state of decomposition needs the wristband to be accessed for identification. This has led to a change in the way bodies are placed within multiple body bags, in order to ensure minimal time of exposure of the body during identification procedures.

There is an area of practice, in relation to documenting audits, that requires improvement, resulting in one minor shortfall. The HTA has given advice to the DI with respect to some areas of governance documentation and risk assessment.

The HTA requires that the DI addresses the shortfall by submitting a completed corrective and preventative action (CAPA) plan 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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 28 October 2015

Report returned from DI: 9 November 2015

Final report issued: 12 November 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 outline 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.