Site visit inspection report on compliance with HTA minimum standards

Waltham Forest Public Mortuary

HTA licensing number 12420

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**

12 August 2015

Summary of inspection findings

A site visit inspection of the Waltham Forest Public Mortuary (the establishment), was carried out by the HTA on 12 August 2015.

Although the HTA found that the establishment had met the majority of HTA standards, three minor shortfalls were identified in relation to governance and quality systems and premises facilities and equipment.

As no consented post-mortem (PM) examinations take place at this establishment and the mortuary does not retain any tissue samples outside the authority of the coroner, the consent and disposal standards do not apply.

Particular examples of strengths and good practice are included in the concluding comments section of the report, along with advice and guidance on how to improve systems further.

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 (DI) are set down in Section 18 of the Human Tissue Act 2004 (HT Act). 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 licenses 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

Waltham Forest Public Mortuary has been licensed by the HTA since 2007. The establishment conducts 400-450 coronial post-mortem (PM) examinations each year. High risk and perinatal/paediatric cases are transferred to another HTA-licensed establishment for PM examination.

The mortuary is located in the same grounds as the Walthamstow Coroner's Court, which has enabled staff to build strong relationships with the Coroner and their officers. This is evident from how smoothly the communication process works and the speed with which bodies are released.

The mortuary facility has a separate entrance, secured by a large double gate which can be locked; there is CCTV and floodlighting, which provide additional security to the forecourt area. Access to the mortuary building itself is by coded keypad, which opens an industrial roller shutter. The establishment uses only one funeral directing company to bring the bodies of the deceased to the mortuary. Staff from this company know the entry codes and so can

bring bodies at any time. Each door within the mortuary has a different keypad code so the office areas can be secured separately.

When the contract was granted to the funeral director, mortuary staff carried out an induction for their staff; in addition, there is a contact number clearly visible at the entrance should they have any queries in the absence of mortuary staff. However, there is very little other signage or guidance visible within the mortuary, to assist new or untrained staff should they attend from the funeral director (see advice item 5).

The mortuary receives bodies from local hospitals and from the community so the identifiers can vary upon arrival; however, due to their good relationship with the coroner's office, staff can get the information required relatively quickly. The funeral directors complete an admittance form when they bring a body in; out of hours, this form is placed in a locked letter box. Information from the admittance form is then entered onto the mortuary database by mortuary staff.

The mortuary has 35 fridge spaces, ten of which can accommodate bariatric bodies and five that can be converted to freezers. Additionally, one of the fridge store rooms has a chiller unit so the entire room can be used to provide additional space if required; this area can also accommodate the larger bariatric bodies. The fridges are temperature alarmed to an external system, which calls out an engineer to investigate if triggered. The mortuary staff were unaware of what the upper and lower trigger temperatures were and do not check the alarm regularly themselves or monitor fridge temperatures in order that they can anticipate a possible future failure (see shortfall against standards PFE3).

The PM suite has two fixed, height adjustable tables and can accommodate two further bodies on trolleys. A 'one at a time' system avoids any possibility of mix up of organs. The pathologists who work at the establishment are independent and participate in a weekly rota.

This was the third routine site inspection, the last having taken place in September 2011. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted a visual inspection of the mortuary and PM suite. In addition, an audit was carried out against two bodies in the body store comparing the information on the identity tags on the deceased, the name of the fridge door and the details on the mortuary database. Some anomalies were found (see advice item 2).

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

Standard	Inspection findings	Level of shortfall
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail	The body store audit highlighted anomalies between the information on identity tags, the spelling of names on the fridge doors, and the details recorded in the mortuary database. The database is the most accurate version, as it contains information supplied by the Coroner. When the register is updated, amendments to the name on the fridge door or details on the identity tag are not changed, which could lead to identification errors if there is another body in the mortuary of a deceased person with the same or similar name. The DI is advised to ensure that all identity details are updated.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Risk assessments address issues that relate to health and safety but do not consider risks to the deceased, such as fridge failure or release of the wrong body. *The establishment provided documentary evidence to address this shortfall prior to the issue of the final report. The HTA has assessed this evidence as satisfactory to address the shortfall.*	**Minor**
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	Mortuary staff confirmed that the fridges are alarmed but are unaware of what the upper and lower triggers are for the alarm. Apart from regular maintenance checks, the alarms are not tested by mortuary staff and the temperature of the fridges is not monitored on a regular basis (see advice item 7). *The establishment provided documentary evidence to address this shortfall prior to the issue of the final report. The HTA has assessed this evidence as satisfactory to address the shortfall.*	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	The standard operating procedures (SOPs) for receipt, release and PM examination all refer to identification of the deceased but do not state which identifiers to use or confirm how many to use. The DI is advised to update the SOPs to clarify which identifiers should be used; the HTA recommends a minimum of three, one of which must be unique.

2.	GQ2	The establishment performs a number of audits but does not currently audit the information relating to tissue samples on the mortuary database to check it tallies with that on the forms completed by the pathologist. The DI is advised to include this in the audit schedule to ensure that all tissue is accounted for.
3.	GQ3	The mortuary has a small team that works very well together. They also offer occasional APT support to another HTA-licensed establishment when necessary. There is an informal agreement from management that locum support could be used if necessary but there is no detail as to what this would entail or where they would come from. The DI is advised to ensure there is a formal agreement for locum support and a SOP in place to ensure that adequate cover can be obtained when needed.
4.	GQ3	Whilst the mortuary team have worked closely with the funeral directors to ensure they are aware of local practices and procedures, there may be occasions when staff that have not received a formal induction access the mortuary. The DI is advised to consider areas where additional signage would assist, particularly in relation to identifying which fridges are for bariatric bodies, how to identify what is the best size fridge space to use and what to do if the available bariatric fridge is too small.
5.	GQ7	The DI is advised to update the HTARI SOP to include who should report a HTARI if he is away.
6.	GQ8	The DI should consider using the HTARI categories as a base to identify potential incidents that could go wrong as part of their risk assessment.
7.	PFE3	The DI is advised to ensure staff are aware of the minimum and maximum temperature ranges for the fridges and freezers, to monitor the temperature daily for any fluctuations and the test the alarm on a regular basis internally. The SOP that addresses what to do if the fridge alarms go off should be checked to ensure it includes information on what to do if the engineer is called and there is a fridge failure that can't be fixed.

Concluding comments

This report outlines the third HTA site visit inspection of Waltham Forest Public Mortuary, the last inspection being in September 2011. In addition to the areas requiring improvement set out above, a number of examples of good practice were observed.

It was clear that the mortuary team works well together, has a positive attitude and places emphasis on providing a quality service to the community. There is also evidence to suggest a proactive approach to quality improvement; for example, when there were issues with a local hospital which was not supplying sufficient information on body identity tags, mortuary staff initiated a meeting with staff there to agree a process that was mutually satisfactory.

The establishment has a good working relationship with the Coroner, which means that bodies are usually released within one or two days, to the benefit of the family. Additionally, they send a monthly email to the local council's bereavement service, listing the names of the deceased who have been in the mortuary longer than expected; this reminds them to speak with the families and helps reduce the amount of long-term storage.

The mortuary database was developed in-house and has excellent functionality that can manage, filter and run statistical reports on all the information held on the system which makes it easy to search for any specific individual or PM examination. In addition, the database is backed-up every evening and an extra hard copy is generated.

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.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report. The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Report sent to DI for factual accuracy: 28 August 2015

Report returned from DI: 07 September 2015

Final report issued: 12 October 2015

Completion of corrective and preventative actions (CAPA) plan

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

Date: 16 December 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.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

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.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.

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.