Site visit inspection report on compliance with HTA minimum standards

Haringey Public Mortuary

HTA licensing number 12263

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**

1 and 2 May 2012

Summary of inspection findings

The HTA found significant shortfalls against governance and quality standards, which need to be addressed as a matter of urgency. These shortfalls indicate a lack of oversight by the former Designated Individual (DI) to secure suitable practices are taking place at the establishment and a lack of awareness on the part of the Corporate Licence Holder, which has failed to ensure a sound system of governance. This lack of good governance, together with the current staffing issues, presents a significant risk to the establishment's ability to provide a satisfactory standard of service.

The Designated Individual (DI) has been in this role since October 2010. However, due to an extended period of leave, which commenced in March 2012, the HTA was not able to assure itself of his suitability for this role during the inspection. In his absence, the Corporate Licence Holder Contact has applied to vary the licence to substitute another individual for the DI and has himself taken on the statutory duties (set down in Paragraph 18 of the Human Tissue Act 2004) to ensure 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 has approved this application.

On inspection, the HTA found that Haringey Public Mortuary (the establishment) did not meet any of the HTA standards relating to governance and quality systems and identified four major shortfalls and four minor shortfalls in this area. A further minor shortfall was found in relation to procedures for disposal of tissue.

A combination of factors has led to the shortfalls identified:

- written procedures are not sufficiently detailed
- when procedures are detailed, they are not always adhered to by staff
- traceability systems are not robust
- there is a lack of audit and risk assessment of practices and processes.

The establishment was last inspected in 2009 when conditions were placed on the licence. Evidence submitted by the establishment thereafter demonstrated improvements had been made and the conditions were subsequently closed by the HTA. However, the findings of the latest inspection demonstrate that continuous improvement has stalled, resulting in similar shortfalls to those identified during the previous HTA inspection. In particular, SOPs did not always reflect practice, no audits are taking place and there is poor record keeping of tissue that has been taken during post mortem examination, posing a risk to traceability.

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 Paragraph 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

Haringey Public Mortuary is managed by the local authority; Haringey Council. The mortuary was built in 2009 replacing the old Hornsey Mortuary. The establishment began licensed activity in this facility in February 2009, carrying out post-mortem (PM) examinations on behalf of the coroner, including forensic PM examinations. It has refrigeration space for 42 bodies and freezer space for 12 bodies. Included is space for three bariatric cases. No consented PM examinations take place and tissue is not retained by the establishment for use for scheduled purposes; therefore, the consent standards do not apply in this case.

The establishment was architecturally designed and built in 2009. The high quality of the build is noticeable in the security arrangements, ventilation, design and layout.

A routine inspection by the HTA had been scheduled for June 2012. However, the CLHC informed the HTA that the DI had not been present to oversee licensed activity since the beginning of March 2012 and will not return until at least the end of May 2012. Furthermore, he informed the HTA that the only remaining permanent member of staff had left the establishment in mid-April 2012, leaving the mortuary staffed by two locum Anatomical Pathology Technologists (APTs). The HTA deemed it appropriate to bring the inspection forward and to focus on the governance and quality systems in place.

The inspection also provided an opportunity to assess the suitability of the CLHC to take on the role of the DI.

Inspection findings - Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	1. The establishment had undertaken a review of operational procedures in March 2011. However, the HTA found that, in general, procedures were not sufficiently detailed and on some occasions referenced the wrong forms. This may inhibit locum or new staff from following expected procedures. Example - 'Preparation of Deceased for a Post Mortem Examination': • 5.1 states that 'identity is checked against coroner's history HMKT 08' but it does not specify who has responsibility for carrying out the check, what information should be checked, and where it should be recorded. In practice, one APT carries out identification checks, rather than two which is accepted as good practice. Lack of information in written procedures increases the risk of a PM examination being carried out on the wrong body. • 5.4 (histology samples) references the wrong forms to be completed 2. Written procedures did not specify: • when a body should be transferred from the fridge to the freezer and how the body should be labelled with identification tags • managing high risk post-mortem examinations • managing same/similar name or unknown cases. 3. The HTA observed that on some occasions, written procedures were not followed, increasing the risk of the occurrence of a serious untoward incident or non-compliance with statutory requirements. Examples observed during the inspection include: • The release of a body without receipt of the Coroner's Authorisation release form. This control is designed to ensure that staff have received authority from the Coroner to release the body and is detailed within the SOP on release of the deceased. It further prevents the release of a body without tissue that the family has requested be repatriated with the body of the deceased before cremation or burial. • There was no evidence that staff had contacted the Coroner's officers to inform them that tissue had been returned to the mortuary post-analysis and obtained information from them in order to act on the family's wishes. In addition, procedures do not specify the need to record this communication.	**Major**

GQ2 There is a documented system of quality management and audit.	The quality management system does not include a system of audit. This makes it difficult to ascertain compliance with written procedures, records (for completeness) and traceability. Failure to follow procedures could lead to a serious untoward incident, for example, an error in identifying a body and wrongful release for burial/cremation. Furthermore, there is no system to check or audit bodies in storage against information held on the electronic register or on admission forms.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	Although the two locum APTs are experienced in their field, they have been employed by the establishment for only a few weeks. They therefore rely on the training provided by the previous APT before her departure and on written operational procedures that the HTA considers to be inadequate. There were no records of induction into the mortuary's work or operational procedures. In addition, the locum APTs received limited training in the operation of the mortuary's electronic register during the handover period with the previous permanent APT. They have not received ongoing support in its use and there may be added functionality that the APTs may not have received training in, for example, searching the database for specific cases or a list of bodies in storage.	**Major**
GQ4 There is a systematic and planned approach to the management of records.	Management of paper records is poor and there is no filing system for mortuary paperwork. Completed forms (e.g. record of histology taken, admission and release forms) are placed in boxes and it is unclear what happens to them thereafter. As a result, some records for the traceability audit could not be found. This may have been due to a number of reasons: • tissue may not have been taken for histology; • if tissue was taken, the pathologist conducting the post-mortem examination may not have completed the form (it is understood that some pathologists complete the establishment's paperwork but some do not); • if tissue was taken, the form was completed but had been misplaced due to poor record keeping practice.	**Major**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	The traceability audit confirmed that practice deviated from written procedures and showed that there is poor record keeping and insufficient robust systems to ensure the traceability of bodies and tissue.	**Major**

	The HTA carried out a number of audits during the inspection. Six bodies were selected at random to ensure that identification labels, the register and admission forms were accurate and complete. When a new body is delivered to the establishment a case admission form should be completed. This form has two carbon copies. The top copy is placed with the body on the storage tray after it has been used to transfer details of the deceased to the establishment's electronic register; one copy stays in the book, and one copy is provided to the funeral director to confirm receipt of by the body by the mortuary. This is a significant document, which has a number of purposes. It is used to complete the electronic register and to make certain that the body is placed in the correct fridge tray after PM examination. During the audit there was a case where a body had no copy of the case admission form located with it, although the copy in the book confirmed that it had been completed. In another case where there was no copy with the body, no carbon copy was evident in the book, suggesting that the form had not been completed at all. In a further case, an identification band had not been placed on a body in freezer storage. However, there was a band attached to the body bag which matched the admission form and the electronic register. The audit of stored tissue revealed that on two occasions there was no evidence to explain why tissue samples were being retained at the establishment. There was no evidence of communication with the Coroner's officer to inform them that tissue had returned following analysis and the outcome of that communication, that is, the family's wishes indicating what should be done with the tissue. These findings suggest there may be a risk that tissue is retained without consent. Furthermore, it may present reputational risks for the licence holder if the establishment has not acted in accordance with the family's wishes.	
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	The written procedure outlines steps to be taken by staff should they discover an incident has occurred. However, it does not specify the requirement to report incidents to the HTA.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Although written procedures were reviewed in March 2011, the establishment's practices and processes have not been risk assessed since 2009. Risk assessment may have provided insight into practices which were not sufficiently robust, preventing the likelihood of serious untoward incidents.	**Minor**

Disposal

Standard	Inspection findings	Level of shortfall
D2 The reasons for disposal and the methods used are carefully documented.	The form used to record when tissue is disposed does not include the reason for its disposal.	**Minor**

Concluding comments

Whilst the establishment demonstrated improvements following its previous HTA inspection in 2009, the findings of the latest inspection demonstrate that continuous improvement has stalled, resulting in similar shortfalls to those identified previously.

There are a number of areas of practice that require improvement, specifically four major and four minor shortfalls. Seven of the eight shortfalls relate to governance and quality systems, the remaining shortfall relating to disposal.

Due to the significance of the concerns found in relation to governance and quality systems, the HTA has issued Directions to the DI and the Licence Holder to ensure all major shortfalls are met within an appropriate timeframe.

The HTA requires that the Designated Individual addresses the minor shortfalls 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.

Report sent to DI for factual accuracy: 11 May 2012

Report returned from DI: 23 May 2012

Final report issued: 25 May 2012

Completion of Directions issued 14 May 2012

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

Date: 25 June 2012

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 or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- 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.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal records include the date, method and reason for disposal.
- Tissue is disposed of in a timely fashion.

  (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)

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.