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**

10 and 11 July 2012

Summary of inspection findings

The purpose of this non-routine inspection at Haringey Public Mortuary (the establishment) was to follow-up its progress in addressing the major shortfalls against governance and quality standards that the HTA found during an inspection on 1 and 2 May 2012.

The Designated Individual (DI) (previously the Corporate Licence Holder Contact (CLHC)), has been in post for two months and has demonstrated to the HTA that he is a suitable person to continue in this role in accordance with the requirements of the legislation.

Since the previous inspection, the HTA has observed that the Corporate Licence Holder has provided the resources necessary to substantially improve governance arrangements at the establishment. Consequently, staffing levels have remained stable and shortfalls relating to practices have now mostly been improved upon.

Although the HTA found the establishment had met the majority of the HTA standards, or had a Corrective and Preventative Action (CAPA) plan in place to address shortfalls identified at the earlier inspection, two minor shortfalls remain in relation to its governance and quality systems and disposal arrangements.

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, and the high quality of the build is noticeable in the security arrangements, ventilation, design and layout. The establishment began to undertake licensed activity in February 2009, carrying out post-mortem (PM) examinations on behalf of HM 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 for use for scheduled purposes is not retained by the establishment; therefore, the consent standards do not apply.

A routine inspection by the HTA was originally 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 was unlikely to return until 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. The inspection took place on 1 and 2 May 2012.

Following the inspection, the HTA issued Directions to the DI to address four major and one minor shortfall. The DI immediately took the necessary action to address these shortfalls to the satisfaction of the HTA. A Corrective and Preventative Action (CAPA) plan to address the outstanding minor shortfalls was agreed by the HTA at the follow-up inspection on 10 and 11 July 2012.

As the purpose of the inspection was for the HTA to assure itself that the establishment had improved its compliance with HTA governance and quality standards, those relating to the premises, facilities and equipment were not assessed.

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

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.	Written procedures do not specify management of high risk post-mortem examinations.	**Minor**
D2 The reasons for disposal and the methods used are carefully documented.	Mortuary forms and written procedures do not include details of: • tissue returned from a laboratory post-analysis and actions thereafter, that is, disposal or repatriation with the deceased. • disposal methods.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	Operational practice has been reviewed and modified but written procedures have not always been amended to reflect these improvements. Therefore, the HTA advises the following: <u>Procedure 1.1 Admitting Deceased into the Mortuary</u> a. 5.1.5 – consider how identity checks are made if the Coroner's Office has not yet provided information about the deceased b. 5.1.7 - state in more detail the infectious disease cases, categories 3 and 4, that are transferred to another licensed establishment and those that will be undertaken on the premises c. 5.1.12 – reflect current practice by including the whiteboard as an additional measure for alerting staff to similar / same name cases d. 5.1.14 – reflect current practice by stating that the white admission form is destroyed after data is recorded onto the electronic register e. 5.3 – reflect current practice by including the process of obtaining an electronic report of bodies in store before alerting the Coroner's Office of cases which may require transfer to the freezer for longer term storage <u>Procedure 1.2 Releasing the Deceased from the Mortuary</u>

		f. 4.0 – update to include all related documents, including the Histology / Toxicology Data Sheet g. 5.1.2-3 – specify the documents to be checked before releasing the deceased to an undertaker h. 5.2 – specify the records to be completed before releasing the deceased to the next of kin <u>Procedure 1.3 Preparation of the Deceased for a Post-Mortem Examination</u> i. 5.1.2 - reflect current practice in relation to fridge labelling prior to a post-mortem examination j. 5.1.3 – when plans take effect to record on the Histology / Toxicology Data Sheet the identification checks on the deceased before the PM examination, ensure that written procedures are updated k. 5.1.5 – APTs carry out external examination of bodies prior to evisceration and findings are discussed with the pathologist, usually by telephone, before proceeding with the evisceration. It is recommended that APTs document the detail of these conversations and that written procedures are updated to reflect this practice. Furthermore, the HTA advises that, for the avoidance of doubt, staff are provided with written guidance on the circumstances in which they should not proceed with evisceration and instead wait for the arrival of the pathologist. l. 5.4 – be clear about the information that is recorded on labels of pots when tissue is removed during the PM examination. Also be clear about procedures for storing tissue in the new fridge as well as those relating to storage of tissue that requires fixing. m. 5.5 – provide clarity on the procedure for removing whole organs, including reference to written procedures for repatriation <u>Procedure 1.6 Reuniting Tissue or Disposal of Tissue</u> n. 5.1.6 – reference the forms to be used when recording that tissue has been disposed.

Concluding comments

The DI has worked hard with the APTs to address the shortfalls indentified at the inspection on 1 and 2 May 2012. This was confirmed on 10 and 11 July 2012 when the HTA further reviewed the procedural and practical improvements. It is satisfied that HTA standards are now largely met.

There are two areas requiring some improvement. The HTA provided additional advice to the DI with respect to written procedures so that they reflect current practice and set out what is expected of staff.

The HTA requires that the DI addresses the 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.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 8 August 2012

Report returned from DI: 21 August 2012

Final report issued: 3 September 2012

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: 14 October 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.

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 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 licen sable 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.