Site visit inspection report on compliance with HTA minimum standards

Brent, Harrow and Barnet Public Mortuary

HTA licensing number 12017

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**

25 November 2015

Summary of inspection findings

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

The HTA found that Brent,Harrow and Barnet had met all of the HTA standards.

The HTA's consent standards do not apply, as the establishment is not involved in activities requiring consent under the Human Tissue Act.

Particular examples of strengths and good practice are included in the concluding comments section of the report.The establishment was provided with advice and guidance about areas that could be improved 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 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

This report describes the third site visit inspection of Brent, Harrow and Barnet Public Mortuary (the establishment), which is licensed to carry out post-mortem (PM) examinations and the removal and storage of PM tissue for use for scheduled purposes under the Human Tissue Act 2004. The establishment is located on the Northwick Park (NWP) Hospital site. The establishment undertakes around 550 PM examinations a year under the jurisdiction of HM Coroner for North London. These include forensic and high risk PM examinations. It does not carry out paediatric PM examinations but may store paediatric bodies before release. The establishment is a designated 'emergency mortuary'.

Funeral directors bring in bodies out of hours and place them in a dedicated 'overnight' bank of fridges, which accommodates up to 20 bodies. Funeral directors must report and sign in to NWP Hospital's scurity staff, who provide them with a key to access the mortuary. They are are then required to complete a 'reception details form'. Mortuary staff check the overnight bank of fridges for new admissions daily and move bodies from their overnight locations to the main body store fridges. A unique reference number (URN) number is generated by the mortuary's electronic database for each body that is admitted to the mortuary. The URN is added to the deceased's wrist band and also body bag.

The body store has 101 fridge spaces, including 11 for the storage of bariatric bodies. The bariatric fridge spaces can also be converted into freezer spaces. The mortuary had recently undergone refurbishment which included the installation of additional fridges and a new ventilation system in the PM suites. To increase capacity in the body store, bodies may also

be stored on trays at the bottom of the banks of fridges, however, these would only be used to store bodies in an emergency.

The mortuary fridges are connected to an audible alarm, which sounds if the fridge or freezer temperatures go outside of normal parameters and is subject to twice yearly testing carried out by the maintenance company. An auto dial-out system notifies mortuary staff of any issues that occur out of hours. Mortuary staff monitor fridge and freezer temperatures daily using an electronic system.

The main post-mortem suite has four dissection tables. There is also a forensic PM suite which is used to carry out more extensive PM examinations. PM examinations are conducted by visiting pathologists. Where tissue is retained, the wet tissue is placed in formalin pots and labelled in the PM room. The Coroner's officers arrange for the Coroner's contracted courier to collect the specimens and transport them to a local hospital for histological examination. Organs are also fixed on site and transferred by courier to other centres for specialist examination. The courier is required to sign a form which details the type of tissue removed, name of the recipient establishment, removal date and time.

The HTA inspection included a visual inspection of the viewing room, body store and post-mortem suite and interviews with a Pathologist, Coroner's officer, Mortuary Manager, Trainee Anatomical Pathology Technologist (APT), the Regulatory Services Manager for Brent Borough Council and the Designated Individual, Head of Regulatory Services Brent Borough Council. A document review was also undertaken.

Traceability audits of two bodies were carried out. Bodies were identified by checking the full name and URN on the white board against the the electronic database and the physical location of the deceased. The identification on the wrist band was also checked for the two bodies. No discrepancies were found. A tissue traceability audit using paper and electronic records was undertaken of samples removed during three PM examinations. In one of the cases, tissue had been repatriated with the deceased prior to release, in line with the wishes of the family. No discrepancies were found.

Inspection findings

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

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	GQ1	The DI is advised to review the current 'Identification and Viewing' procedure (MOP 025) so that staff enquire with the family whom they are coming to see as opposed to the family confirming the name of the deceased provided by mortuary staff on arrival. This will help mitigate the risk of an incident involving viewing of a wrong body.

2.	GQ2	The Regulatory Services Manager is responsible for undertaking mortuary audits and has a sound understanding of the audit process. However, the audit reports do not provide sufficient evidence about which areas of mortuary practice have been reviewed to assess compliance. For example, where body audits had been carried out, they captured basic information that bodies had been 'checked' and that no problems were identified, however, the report did not capture any other information to support these findings. To improve the approach, the DI is advised to develop an audit proforma tool to enable information to be recorded in a concise and consistent manner. Furthermore the DI should consider devising an audit schedule.
3.	GQ7	The 'Guidance to establishments for reporting HTARIs in the Post Mortem Sector' was updated in June 2015 to include a revised description for the 'accidental damage' incident category as well as for near misses. The DI should reflect these changes in written procedures when next reviewing the HTARI SOP. Additionally, the DI may wish to consider asking Pathologists attending the mortuary to familiarize themselves with MOP 002 (HTA RI) so that they have a better understanding of the HTARI categories.
4.	GQ8	The establishment's risk assessments take into account the health and safety of mortuary staff as well as risks to the deceased or tissue in storage. However, the DI is advised that when the risk assessments are next reviewed, he should pay particular attention to whether all risk assessments capture the control measures accurately. For example, the establishment has a robust procedure in place to help minimize the risk of fridge or freezer break down, however, this has not been captured as a control measure in the risk assessment.
5.	PFE3	To increase storage capacity, the floor of the fridges and freezers can accommodate bodies on additional trays. However, the additional space will only be used when all other storage spaces are occupied. On a daily basis, this area of the fridges or freezers is not used. The DI is advised to include this arrangement in the establishment's written procedures so that there is clarity for staff about the circumstances in which these areas can be used.

Concluding comments

The establishment's staff demonstrated an excellent working relationship and are keen to ensure that they are continuously improving. Mortuary staff work cohesively to ensure a high level of compliance and are dedicated to their work. There were a number of areas of good practice that were noted during the inspection:

- The identification of the deceased is checked at three points prior to the evisceration of a body to minimize the risk of a PM on a wrong body occuring;
- A body check is carried out at the end of each working day; in addition to being a thorough audit of the body store, this enables mortuary staff to account for each body in storage;.
- There is visual guidance available for funderal directors to follow when admitting or releasing a body out of hours;
- Mortuary staff are involved in undertaking audits that focus on the condition of the deceased;
- SOPs and risk assessments are signed off by all mortuary staff to demonstrate they have read and understood them;

- The establishment has drafted a ‘Body Identification Discrepancy’ SOP to deal with ID discrepancies when bodies are transferred by funderal directors or from the hospital mortuary;
- A continuous electronic temperature monitoring system has been implemented;
- There is a robust alarm-dial out system; in the event that the dial out fails, a further audible alarm in the corridor near the hospital sounds to alert members of staff of a problem.

The HTA has given advice to the Designated Individual on a range of issues to make further improvements.

Report sent to DI for factual accuracy: 21 December 2015

Report returned from DI: 20 January 2016 (with comments)

Final report issued: 28 January 2016

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 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.