**Site visit inspection report on compliance with HTA minimum standards**

**Fulham Public Mortuary**

**HTA licensing number 12489**

**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 November 2012**

## 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.

Although the HTA found that Fulham Public Mortuary (the establishment) had met the majority of the HTA standards, some shortfalls were found. Three minor shortfalls were identified against governance and quality standards regarding the lack of risk assessment of post-mortem related activities; absence of procedural audits; and insufficient detail within standard operating procedures (SOPs). The fourth minor shortfall, against premises, facilities and equipment standards, relates to the requirement for all deceased persons to be shrouded within the body store.

The establishment continues to maintain a high level of activity with a small number of permanent staff, and the DI has been given advice with respect to the working hours of these staff and how working patterns might impact on the conduct of licensable activities.

Overall, the establishment has continued to comply with the majority of HTA standards; in addition, areas for improvement previously identified have been largely addressed, with the exception of risk assessments, as indicated above. Particular examples of strengths and good practice are included in the concluding comments section of the report.

## The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, 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

Fulham Public Mortuary carries out approximately 750 post-mortem (PM) examinations each year, all of which are coronial cases, including approximately 25 forensic PM examinations. Known high risk cases are undertaken but paediatric cases are transferred to another HTA licensed establishment for PM examination.

This was the second routine inspection of the establishment, the first one having been undertaken in 2009. The majority of advice given following the previous inspection had been duly acted upon.

The inspection comprised interviews with members of staff, a review of relevant documentation and visual inspections of the two post-mortem rooms and body storage area. An audit was carried out in the body store, during which the details on the wrist bands of two of the deceased were compared with corresponding details in the mortuary register, on admission forms and the electronic database. No anomalies were found.

Although tissue is not disposed of by the establishment, records are kept of tissues samples retained at PM examination and where they were sent for analysis. The establishment also receives copies of the form detailing the relatives' wishes with respect to repatriation, disposal or retention of tissue samples and maintains oversight of tissues that should be disposed of by the receiving establishment and when this has been carried out. Two cases in which tissue had been

retained at PM examination were selected and the paper and electronic records of these tissues samples were reviewed. No anomalies were found.

### 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. | The establishment has implemented SOPs, which cover all licensable activity; however, some of the SOPs relating to mortuary activities lack pertinent details. In particular, one SOP (SOP5) describes the process for securing the mortuary before staff leave but does not include locking away the mortuary register, which was described by the mortuary staff. The SOP relating to storage of the deceased (SOP6) does not state what temperature the fridges should be or the action to take if they are found to be out of the normal working range. It also describes that staff should check the deceased for any indication of decomposition but does not include what signs to look for. The SOP for admitting the deceased to the mortuary (SOP7) does not include the procedure for checking whether there is already a deceased with the same or similar name, or what to do to ensure other staff are made aware. The SOP for reporting adverse events (SOP8) does not detail the timescale for reporting serious untoward incidents to the HTA.<br><br>The lack of detail in the SOPs increases the risk of inconsistent practice and may result in errors. | **Minor** |
| GQ2 There is a documented system of quality management and audit. | The establishment has recently implemented a schedule of traceability audits, the first of which was completed in September by a member of staff from another mortuary; however, procedural audits are not conducted.<br><br>Procedural audits assist with continuous improvement by ensuring that processes are carried out in a standardised manner and in some instances can identify training needs. | **Minor** |

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|---|---|---|
| GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately. | The establishment has undertaken a number of risk assessments on the premises and PM processes that relate to health and safety. However, it carries out a high number of forensic PM examinations where a large number of people are present in the post-mortem room and the associated risks are not reflected in the current risk assessments.<br><br>A formal assessment of risks to bodies and tissue samples, such as loss of traceability, has also not been carried out. | **Minor** |

**Premises, Facilities and Equipment**

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records. | Whilst the majority of the deceased stored within the body store were observed during the inspection to be either clothed or placed in a body bag, one deceased was found to be uncovered. This was because an external examination of the body had already been undertaken in preparation for PM examination the following day. The HTA considers that the absence of appropriate shrouding during storage or transportation compromises the dignity of the deceased. | **Minor** |

## Advice

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

| No. | Standard | Advice |
|---|---|---|
| 1. | GQ1 | Evisceration of the deceased is carried out by the two experienced Anatomical Pathology Technologist's (APT) prior to the pathologist's arrival, based on pre-determined documented criteria and a discussion with the pathologist on the case history, where the pathologist gives their authorisation to proceed. The DI is advised to review and risk assess the appropriateness of this practice taking place when casual or locum staff carry out PM examinations in the absence of the APTs. Any subsequent changes in practice should be reflected in appropriate SOPs. |
| 2. | GQ3 | Two permanent members of staff work in the mortuary. One casual member of staff is contracted; otherwise locum staff who are trained in the mortuary procedures provide cover when permanent staff are not available. A large number of forensic PM examinations are undertaken, which occur at short notice and frequently out of hours. As a result, planning appropriate cover is more difficult and the two staff members may attend at non-routine cases over night and then work a full day shift, sometimes totalling 17-20 hours. Whilst contingency arrangements are in place to redirect the routine mortuary service |

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|---|---|---|
| | | elsewhere in these instances, these are not regularly employed. The DI is advised to risk assess whether the level of staffing is sufficient for the requirements of the service and to consider the effects of possible fatigue on staff's ability to carry out PM examinations safely and without errors in identity checks and records. On completion of the risk assessment the DI is advised to set out in a policy the maximum number of hours staff may routinely work and specify when the contingency arrangement must be brought into effect. |
| 3. | GQ4 | Medication belonging to the deceased and/or paperwork generated by the London Ambulance service relating to the deceased is left on a table in an area accessible to funeral directors bringing in bodies out of hours. The DI is advised to ensure this paper work is regularly stored away securely so that only those authorised have access and nothing inadvertently goes missing. The appropriate SOP should also be updated to reflect these changes in practice. |
| 4. | GQ6 | The DI is advised to review the practice of sticking identification labels only to the lids of jars containing tissues collected at PM examination. If lids were to be removed from multiple jars at the same time, there is potential for losing the traceability of what label applies to which specimen. |
| 5. | GQ7 | The establishment has a system for reporting serious incidents; however no incidents have needed to be reported for over a year. A new incident logbook has been introduced and the DI is encouraged to ensure that minor incidents are recorded so that trends can be analysed and underlying issues addressed. |
| 6. | GQ8 | The DI is advised to use the HTA serious untoward incident notification list as a basis for risk assessing processes where serious incidents could occur. |
| 7. | PFE2 | Although the main PM examination room and the isolation room have a designated entry/exit passage where staff change into appropriate personal protective equipment (PPE) and signs indicate that you are about to enter a potentially contaminated area, there are doors that allow direct transition of trolleys and personnel between clean and dirty areas which do not have signs on them. The DI is advised to ensure that the direct access doors have appropriate signs and demarcation to ensure that personnel are aware of the clean and dirty zones and that access via this route is not permitted during a PM examination.<br><br>Currently mortuary staff have to leave the PM examination room mid-session to attend to phone calls. A proposal has been put forward to have a phone connected in the mortuary itself, but this has not yet been approved. The HTA sees merits in this proposal since it will help minimise movement between dirty and clean areas and reduce the risk of contaminating clean areas. |
| 8. | PFE3 | The body store does not currently contain any designated bariatric fridge spaces. The DI is advised to monitor the number of bariatric cases brought to the mortuary and either ensure appropriate equipment and processes are in place for handling these cases, or implement a policy whereby a maximum size and weight is determined, above which cases will not be accepted. |

## Concluding comments

During the inspection a number of areas of good practice were noted, examples of which are given below.

Lone working is not permitted in the mortuary. Only locum staff that have previously worked there and who have completed the mortuary induction programme provide cover when

permanent or casual staff are not available. If these staff are not available, the mortuary service is redirected to another mortuary in line with the establishment's contingency plan.

The local council is in the process of further improving security in the mortuary. In addition to the electric gates that restrict access to the premises, CCTV covering multiple areas (which is continuously recorded), and strict protocols for locking up the building when staff go home, the key lock access of the doors is being replaced with swipe card access. This means that if a card is lost it can be deactivated and no unauthorised copies can be made, unlike a conventional key.

A unique mortuary identification number is allocated to each deceased on admission to the mortuary. This number is prefixed with a letter which increases each year. This is recorded in the mortuary register, on admission paperwork, as well as being included on the mortuary identification tag on the deceased and the label for any histology tissues collected at PM examination. This helps ensure traceability and reduce the risk of errors in identification.

The establishment maintains oversight of the histology tissues once they have been sent to other establishments for analysis and ensures that the relatives' wishes with respect to repatriation, disposal or retention of tissue samples are carried out. Since the establishment themselves is not responsible for the disposal of tissue samples this is an example of very good practice and plays an important role in reducing the possibility of samples being retained against the wishes of the relatives.

Advice was provided to the DI during the previous inspection and, with the exception of risk assessments, all the advice has been acted upon. However, there are a number of areas of practice identified during this inspection that require improvement, including four minor shortfalls. The HTA has given advice to the Designated Individual with respect to risk assessment of staffing levels and licensable activities, the reporting and trending of incidents and the use of signs and labels.

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 (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:** 28/11/12

**Report returned from DI:** 12/12/12

**Final report issued:** 09/01/13

**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: 04 July 2013**

## 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.)*

## 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.