Site visit inspection report on compliance with HTA minimum standards

Brighton and Hove City Mortuary

HTA licensing number 12007

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 May 2012

Summary of inspection findings

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

Although the HTA found that Brighton and Hove City Mortuary the (establishment) had met the majority of the HTA standards, shortfalls were found in relation to GQ1, 2, 3, 6 and 7 and PFE2.

Apart from the need to implement cleaning and temperature records to improve the standards of the premises, shortfalls were predominantly found around the quality management system, record-keeping and document management.

Since the last inspection, organisation of quality management systems has remained at the same level. The previous inspection highlighted concerns with the premises and facilities but given the age of the building, the premises are well-maintained and although there were some problems with maintenance of a downward draught air-flow in the high-risk room, this has been rectified.

The DI was the Person Designate (PD) at the last inspection and became DI shortly after the previous inspection.

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

The establishment carries out approximately 900 post-mortem examinations (PMEs) every year on behalf of the Brighton and Hove District Coroner and the East Sussex Coroner. There are six visiting pathologists on the site, two permanent Anatomical Pathology Technologists (APTs) and one permanent Trainee APT who carry out the PMEs. The DI is the Senior APT. The establishment operates the Coroner's Transfer Service (CTS) and the three APTs respond to calls for collection and transfer of bodies to the mortuary admissions room on a 24 hour on-call basis. The admissions room has space for 12 bodies in three fridges, with another set of fridges reserved for deep freeze or bariatric cases. A viewing gallery, used mostly by medical students, overlooks the main post-mortem room, containing three tables, with the capacity for five tables. There is a self-contained, high-risk room with one table and a hatch allowing access through to the main PM suite. The body storage area has 40 alarmed fridges and a bank of 27 older fridges, which are used when the newer, alarmed fridges are at full capacity. The DI checks this on a daily basis to ensure temperatures remain within the

correct range (see minor shortfall against PFE2). High risk fridges are marked separately and there is a bariatric fridge. As a contingency, the mortuary has the ability to cool an adjoining store room and hold a superbariatric body in that area (see advice PFE2).

The inspection was a routine, one-day inspection of the establishment including: a visual inspection encompassing the admissions room, PM suites, body store and public waiting and viewing rooms; document review; an audit trail and interviews with staff. Three interviews were conducted prior to the inspection date with a Consultant Pathologist, APT and Trainee APT.

The audit trail consisted of tracing three deceased persons at random from the admissions log book to the mortuary register. Two individuals were traced from the registers to the body store, to the fridge records kept in the office. No anomalies were found.

An audit was also completed of documentation for admission and release of two individuals through the mortuary. The first trail showed a release form from the Coroner's office appeared to have been received after the release date of the body, although the DI stated verbal advice from the Coroner's office was always received as a minimum requirement for release of a body (see major shortfall against GQ1).

There was one previous inspection in 2009, highlighting several areas for improvement in the premises and quality improvement systems. Improvements have been made to the premises, such as ensuring maintenance of the downward draught airflow in the high-risk room and demarcation of clean and dirty areas. The previous inspection report advised the establishment to implement improvements in the quality management systems. There were shortfalls found in the quality management systems during this inspection.

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.	Several aspects of the establishment's work are not supported by documented standard operating procedures (SOPs) these include: • managing an unknown high-risk case identified during a routine PM; • out of hours working; • same / similar name SOP; and • pre-evisceration authorisation. While the establishment does maintain a separate register to record the retention, storage and release of paediatric cases returned from PMEs at other establishments, there is no documented SOP to support this procedure.	**Major**

	There was no documentation to demonstrate staff have read and understood SOPs. This is especially relevant as the establishment is in the process of recruiting staff for the CTS. During the audit of documentation, there was one incidence where it appeared a body had been released before the fax authorising release had been received from the Coroner's Office. The DI explained staff may sometimes receive a handwritten note after requesting this from the Coroner's Office, rather than the official form. There was however no note seen in this case and no supporting documented procedure. Although informal meetings are held, no minutes or notes are circulated or kept for reference. There are no contingency plans in place to manage circumstances such as maintaining appropriate facilities for a superbariatric body, or ensuring business continuity in the event of a mortuary closure. Although there were a range of SOPs available within the quality manual, the majority of the SOPs were not updated to accurately reflect practices. HTA staff indicated specific areas for improvement during the inspection. While these shortfalls against GQ1 could be seen as several minor shortfalls, due to the number of changes needed, these have been grouped as one major shortfall (see Appendix 2(2)).	
GQ2 There is a documented system of quality management and audit.	The documents in the quality manual are not separated or cross-referenced. This format creates a risk to version control and does not allow staff to ratify individual SOPs. The establishment recently completed an audit trail of documentation for three bodies. Where a faxed release form was not located in one of the trails, the DI noted follow-up actions on the audit form. There was no audit schedule in place to ensure regular audits, record actions and ensure follow-up.	**Minor** **Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	While there is an induction checklist in place, training was not documented and did not include evidence of staff having reviewed SOPs.	**Minor**

GQ6 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	There is no incident register in place. While there is an incident policy referring to serious untoward incidents (SUIs) reportable to the HTA, the SOP does not refer to incidents such as unexpected high-risk cases.	**Minor**
GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	While risk assessments had been completed in the past to consider a variety of OH&S risks, there are no up to date risk assessments in place, especially those assessing the possibility of SUIs occurring (see advice 5).	**Minor**

Premises, facilities and Equipment Standards

Standard	Inspection findings	Level of shortfall
PFE2 Environmental controls are in place to avoid potential contamination	Cleaning records for the entire establishment, such as cleaning records outside of the PM suite, i.e. in the body store area, were not recorded. The relevant SOP did not include a reference to cleaning records. Although the DI undertakes a visual check on a daily basis, fridge temperatures were not recorded. Recording of temperatures would allow for trending analysis and monitoring in the DI's absence.	**Minor** **Minor**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to continue working with the Coroner to ensure the histology notification forms are updated to refer to “for future use” after the reference to keeping the sample with the record and to include the relationship of the next of kin as a field on the form. The DI discussed this with the Coroner on the day of inspection and agreed to implement these changes.
2.	GQ5	Tissue taken from the body could be noted in the mortuary registers to allow for easier identification of instances where tissue was taken, by keeping a full record in one location.
3.	GQ5	The DI could consider implementing a system (e.g. stickers on the fridge card or body tag) to make same / similar name cases stand out more clearly in the body store.
4.	GQ6	The DI could nominate a PD on the licence, to formalise support arrangements in his absence.
5.	GQ7	To write risk assessments, the DI may wish to refer to the list of SUIs on the Guidance for notifying the HTA of serious untoward incidents in the post mortem sector. In addition, body admission and release procedures and performance of simultaneous PMs could also be risk-assessed. [http://www.hta.gov.uk/_db/_documents/Guidance_Document_-_SUI_Notification_201112192847.pdf]
6.	PFE2	If the contingency plans refer to use of the store room adjoining the body store as an additional bariatric storage space, the DI should put in place appropriate signage to denote the change of use.
7.	PFE2	As the mortuary is in an open plan area, with the PM suite leading directly through to the body store and adjoining viewing / office spaces, indicators on the floor to further differentiate between clean and dirty areas could support existing signage.

Concluding comments

Since the last inspection, improvements have been made to the premises, which are secure; access to the mortuary is highly controlled with CCTV surveillance. Several strengths and areas of good practice were identified. Traceability of individuals through the mortuary was good, with complete and legible entries in mortuary registers. The DI has also considered the risk of mix-up of bodies in transit to the mortuary, after collection by CTS and has discussed implementing a new tagging system with the Coroner during pick-up to limit this risk.

The quality management system remains a key area for improvement.

The areas of practice that require improvement, including one major shortfall and seven minor shortfalls. The HTA has given advice to the Designated Individual with respect to C1, GQ5, GQ6, GQ7 and PFE2.

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: 1 June 2012

Report returned from DI: 14 June 2012

Final report issued: 18 June 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: 12 December 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.

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.