Site visit inspection report on compliance with HTA minimum standards

Bradford Public Mortuary and Forensic Science Centre

HTA licensing number 12046

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**

21 January 2016

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 Bradford Public Mortuary and Forensic Science Centre had met the majority of the HTA standards, a minor shortfall was found in relation to GQ1. The establishment's standard operating procedures (SOPs) are comprehensive, but the HTA found that staff are unaware of some procedures and are therefore not observing them when carrying out their duties (minor shortfall against, standard GQ1).

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 Bradford Public Mortuary and Public Science Centre (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 undertakes approximately 1,400 PM examinations a year under the jurisdiction of HM Coroner for West Yorkshire. These include high-risk PM examinations. Home Office PM (forensic) examinations are conducted at this establishment. Paediatric cases get transferred directly to other licensed establishments and the bodies of deceased infants or children are not stored in the mortuary. The establishment also has a CT scanning facility located on its HTA-licensed premises, which is used to conduct digital PM examinations with authorisation from the Coroner and consent from the family.

The mortuary has 250 storage spaces, including 20 freezer spaces, 19 bariatric spaces and 12 'forensic' spaces leading into the forensic PM suite. The fridges are located in two separate rooms; however, only one room is used to store bodies on a daily basis. The other room is used only for contingency purposes. Bodies are admitted by the mortuary staff, who are responsible for completing the paperwork and checking the identification of the deceased. An additional wrist band is placed on the deceased with their full name, height and weight. Bodies are assigned a unique mortuary number, which is recorded in the Mortuary Ledger.

Out of hours, staff from the Coroner's contracted funeral directors bring bodies and place them in the fridge. The funeral directors are required to log any admissions that occur out of

hours on the establishment's 'patient admission form', which mortuary staff check against the wrist/ankle band containing the identification of the deceased that is placed on the body by funeral directors for admission. The condition of the body is also checked by mortuary staff. The funeral directors are able to access the mortuary body store using swipe card access only and the system allows establishment staff to monitor this activity.

The mortuary fridges are connected to an audible alarm, which sounds in the office if the fridge or freezer temperatures goes outside of normal parameters. An auto dial-out system notifies mortuary staff of any issues that occur out of hours and a member of staff will attend. The establishment does not currently test the fridge alarms, which is contrary to its documented procedure (Minor shortfall, GQ1). Mortuary staff manually record fridge and freezer temperatures daily (advice & guidance, item 5).

There are three post mortem suites in total, two of which contain four dissection tables each and are used for routine PM examinations. The third suite is used for forensic PM examinations and has three dissection tables. High risk PM examinations take place after all other cases have been completed and personal and protective equipment is available to mortuary staff. Visiting pathologists undertake all PM examinations and a unique PM number is assigned to each body. When tissue is retained, it is casetted before it is transported by establishment staff to local hospital, licensed by the HTA, using a mortuary-owned vehicle. The 'Mortuary Ledger' is used to document when tissue is removed from the deceased (advice and guidance, item 1).

The HTA inspection included a visual inspection of the viewing room, body store and post-mortem suites. Interviews took place with a Pathologist, Coroner, Mortuary Manager, Trainee Anatomical Pathology Technologist (APT) and Lead APT (Person Designated). A document review was also undertaken.

Traceability audits of three bodies were carried out. Bodies were identified by checking the name, date of birth, date of death, address, body dimensions and weight, and mortuary ID on the wrist and ankle tags of each body. These were compared to the paper records, including the mortuary ledger. There was one minor discrepancy where the incorrect year for the date of death had been entered in the mortuary ledger. Each body location was also compared to the paper records and mortuary ledger and no discrepancies were found. A tissue traceability audit was carried out using the paper and electronic records relating to two separate bodies where tissue had been retained for examination. Four lung and four heart tissue samples had been retained in one case, and four lung and two heart tissue samples in the other case. Samples had been sent to an HTA-licensed PM establishment for examination. There were no discrepancies.

Tissue samples and organs retained for police purposes are sent to other establishments for analysis. Under s39 of the Human Tissue Act 2004 (the HT Act), relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority contained a recommendation that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process. Therefore, procedures for Home Office PM examinations and the management of tissues and organs taken for criminal justice purposes were reviewed by HTA at this site visit inspection. Any findings in relation to Home Office PM examinations and/or police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Inspection findings

The HTA found 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 establishments work are supported by ratified documented policies and procedures as part of the overall governance process	Although the establishment has in place a range of well developed and comprehensive SOPs, not all staff involved in body release were aware of the establishment's red wrist band system contained in SOP Mort 002 (Deceased Release) & SOP Mort 006 (Tissue Retention), which is used to flag organs/tissue requiring repatriation with a body prior to release. Furthermore, written procedures contained in the mortuary's procedure, 'AM Mort 001', which state that the fridge/freezer alarms are to be tested weekly, are not being followed.	Minor

Advice

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

No.	Standard	Advice
1.	GQ1	There are seven items of advice in this section: 1. The Mortuary's procedure, 'AM MORT 001' provides information on all types of audits/checks that should be carried out on a daily, weekly, monthly and annual basis. The procedure states that the fridge alarm system should be tested once a week. In addressing the minor shortfall against GQ1, the DI should also consider amending the procedure because, in its current format, it states that the security team monitoring the CCTV should be notified before the alarm is tested. The DI should consider revising this procedure, to ensure that it includes checking of the response of the security team. Ocassional alarm tests should be undertaken without prior warning to the security team. 2. The DI is advised to ensure that all staff sign and initial SOPs to

		demonstrate that they have read and understood them. This should also be carried forward for amendments made to documents. 3. The DI should consider updating the format of SOPs to include a version number. 4. The DI should ensure that any amendments to forms are made with a single strike through using pen so that the text is still visible. The DI is advised that amendments to the mortuary ledger should include the initials of the person making the ledger to improve the audit trail. 5. The DI is advised to review and update SOP MORT 012 (Patient I.D. and Viewings) to include the establishment's current practice of asking the relatives attending a viewing to confirm whom they are here to see. 6. The DI is advised to review and update SOP MORT 021 (Deep Freezer Storage) to include the current time duration that a body may be placed in refridgeration before it is transferred to the deep freezer. The HTA recommends 30 days. 7. The DI should consider formally minuting meetings held with mortuary staff so there is a record of dicussions and any actions that are agreed.
2.	GQ3	There is a well thought out approach taken to staff training, including induction training, with a formal assessment being made of staff competence to undertake a particular task. The DI is advised to keep detailed records of such training for each member of staff. Evidence on inspection showed that a particular member of staff's records did not clearly demonstrate how her competence had been assessed.
3.	GQ6	The establishment has a robust traceability system using both a paper based and electronic system. Mortuary staff ensure that deceased patients with a same or similar name, who are high risk or who have had organs or tissue removed during a PM examination are highlighted in the mortuary ledger and paper records. The DI may wish to consider using fridge magnets to act as a visual reminder to mortuary staff.
4.	GQ8	The establishment has carried out a range of risk assessments taking into account health and safety risks as well as risks to the bodies and tissue in storage. The DI is advised to extend the scope of risk assessments to include other HTARI categories that may be relevant.
5.	PFE3	Mortuary staff are involved in daily temperature monitoring of the fridges and freezers. The DI is advised to carry out trend analysis of the temperatures observed. This will enable the establishment to plan maintenance or servicing when the need arises.

Concluding comments

The establishment's staff demonstrated a good working relationship and are keen to ensure that they are continuously improving. Several areas of good practice were noted, including:

- a robust audit trail from the point a patient is received into the care of the mortuary to release;
- a robust 'chain of custody' for all tissue samples retained following a PM examination, including the transfer of tissue to other premises for examination;
- a daily check of all patients in storage using a fridge plan;
- three-monthly checks of the condition of bodies in deep freeze;
- regular audits of cleanliness, stock check and condition of stored bodies;

There are some areas of practice that require improvement, including a minor shortfall in relation to standard GQ1. The HTA has given advice to the Designated Individual on a range of issues to make further improvements.

The HTA requires that the Designated Individual addresses the shortfall 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: 16 February 2016

Report returned from DI: 21 March 2016

Final report issued: 22 March 2016

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 April 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.

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: o post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases o record keeping o receipt and release of bodies, which reflect out of hours arrangements o lone working in the mortuary o transfer of bodies and tissue (including blocks and slides) to other establishments or off site o ensuring that tissue is handled in line with documented wishes of the relatives o 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.