Site visit inspection report on compliance with HTA minimum standards

Derriford Hospital

HTA licensing number 12034

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**

11-12 October 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.

Derriford hospital (the establishment) was found to have met all HTA standards.

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 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 inspection covered the licensable activities taking place at Derriford Hospital, which is a specialist tertiary referral centre and acts as a major trauma centre for Devon. The mortuary is incorporated within the Cellular and Anatomical Pathology department and serves as a public mortuary, providing a comprehensive adult autopsy service for HM Coroner for the county of Devon (Plymouth and South-West Devon) and HM Coroner for Cornwall.

The mortuary undertakes approximately 800 post-mortem (PM) examinations per year, most of which are on behalf of the coroner. Paediatric cases are transferred to another HTA-licensed establishment for PM examination. Home Office contracted pathologists carry out forensic PM examinations at the establishment and forensic material, in the form of blocks and slides, are stored there. Under s39 of the Human Tissue Act 2004, 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, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored at the hub site were reviewed by the HTA during the inspection. Any findings in relation to 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.

The body storage area of the mortuary consists of a main body store, an annex within the main complex and an additional securely-locked area for temporary storage, which is located outside but adjacent to the mortuary. CCTV cameras are located outside as well as within the mortuary. Entry is by proximity swipe card access.

The mortuary has refrigerated storage capacity for 145 adults. This consists of 78 spaces within the main body store, of which ten are for narrow bodies and eight for large bodies. There is also a separate refrigerated storage space for three bariatric bodies. Within the annex, there are 40 additional storages spaces and in the external secure area, twenty-four overflow spaces provided by Nutwell units. There are separate refrigerated spaces for up to five paediatric cases and a second unit for up to 20 still births. There is also a deep freeze for up to nine bodies. The temperatures for all these storage units are monitored

daily by an automatic temperature monitoring system and temperature excursions trigger an alarm which sounded locally, as well as with the switchboard. All staff in the mortuary can access the temperature monitoring system remotely to review any notifications of temperature excursions out of hours.

There is no allocated high-risk body storage space as all bodies are treated as high risk. Where they are known to be high risk, a label, 'danger infection', is placed at the front of the tray and bodies are enclosed in body bags.

The porters admit bodies brought from within the hospital following the mortuary's standard operating procedures (SOP). Bodies from the community are brought to the mortuary by the Plymouth Coroner's Ambulance service or by funeral directors sub-contracted by the Coroner.

The PM suite has three down-draft PM tables and bodies eviscerated, after they have been examined by the pathologist, are prepared for PM examination up to three at a time. To prevent any mix up, the organs are kept with the deceased until the pathologist has completed their examination of the first body, the organs returned to the deceased and the examination area washed down. If a high-risk PM examination has to be carried out, it is scheduled to be the last one of the day. If the pathologist retains tissue for histology, it is placed in cassettes in the PM room so there is no excess tissue sent to the Pathology laboratory. Tissue is then stored or disposed of according to the wishes of the family.

Details of all tissue retained during a PM examination are recorded in an electronic database; details of slides made are recorded in a second database. Paper records containing this information are also kept. To assist with traceability, different coloured forms are used to detail different organs and tissue types; for example, if the brain is removed, this is recorded on a blue form; removal of the heart is recorded on a pink form, other whole organs on a yellow form and tissue on a green form.

The Histopathology laboratory, also covered by the HTA licence, is currently storing surplus tissue from patients with brain tumours, who have consented for their tissue to be used in tumour research at the medical school. This research has recognised research ethics approval. However, the HTA licence enables the laboratory to store tissue samples for the purpose of research should relevant ethics committee approval lapse or should the laboratory wish to hold the material for the benefit of future research.

This was the third, routine, HTA site visit inspection. It comprised a visual inspection of the mortuary, including the body store and post mortem suite. A visit to the Maternity unit was also made as consent for PM examination is sought from women who have suffered a miscarriage or still birth. The midwife responsible for seeking consent was interviewed to ascertain the nature of the activity taking place. The HTA also met with a Consultant Histopathologist, an Anatomical Pathology Technologist (APT), the mortuary manager, the laboratory manager, a representative from HM Coroner for the county of Devon, the Serco representative responsible for porter training and the Person Designated (PD) in the Accident and Emergency (A&E) department, where removal of tissue samples in cases of sudden and unexpected death in infancy cases (SUDI) takes place.

A number of traceability checks were conducted. The identification tags of three adult bodies and one baby were checked and all associated paper reviewed. The body of one baby had been sent to another licensed establishment for PM examination and the empty box, left in the body store, labelled with identification detail of the deceased was in addition, marked as 'away'. For deceased with the same or similar names, the establishment places an asterisk on the fridge door next to the name of the deceased. An asterisk is also placed next to name of the deceased in the mortuary register.

The establishment has adopted the convention of writing the surname followed by the forename of the deceased on the door of the refrigerator or freezer. During the inspection, it was noted that this procedure had not been followed for one of the bodies and in addition, the forename had been incorrectly spelt. However, the name in the mortuary register corresponded to the name on the body tags.

In the Histopathology laboratory, tissue blocks from two cases were reviewed, including the consent forms to confirm the wishes of the family regarding retention for research or disposal. All tissues were fully traceable with no anomalies.

A traceability audit of three research samples and associated consent forms were also undertaken and no discrepancies were noted.

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

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.	GQ6	The DI is advised to ensure that the naming convention used in the body store reflects the SOP.
2.	GQ6	High risk bodies are identified by hooking a sign onto the tray. The DI is advised to consider placing a second alert notice alongside the deceased's name on the door of the refrigerator, so that a visual cue remains in case the label accidental falls off.
3.	GQ6	A system to highlight bodies of deceased with the same or similar sounding name is in place. The DI is advised to capture this in the relevant SOP.
4.	PFE5	Alarm systems are in place for the fridge and freezers and staff test the alarms regularly to make sure they are in full working order. However, the details of tests are not documented to demonstrate that the tests have been carried out and any issues identified and addressed.

Concluding comments

During the inspection, a number of good practices were observed. The mortuary is a clean, well-kept facility. The tissue traceability systems are robust and very thorough and regular audits, which follow the process from acceptance to release of a body, are conducted. There is a culture of continuous improvement as evidenced by the daily meetings held by staff in the mortuary to review the day's proceedings, and any decision made is recorded in an "informal" meetings book and, where feasible, actioned. The staff in the mortuary are also developing an electronic record system to assist with record checking and data reporting. The records for the storage of tissue to be used for research

are captured electronically, including the consent form, which greatly facilitated the conduct of the audit trail by the HTA.

The establishment was found to have met all the HTA standards. The DI has been given advice and guidance on a range of issues covering governance and quality standards as well as mortuary facilities, to further improve practice.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 9 November 2016

Report returned from DI: 18 November 2016

Final report issued: 21 November 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:
    - 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 and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- 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.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

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.