Site visit inspection report on performance against HTA quality standards
Calderdale Royal Hospital
HTA licensing number 12108

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**

27-28 September 2011

Executive Summary

A site visit inspection of Calderdale Royal Hospital (the establishment) was carried out by the HTA on 27-28 September 2011.

The establishment was found to meet the majority of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment; and disposal. Three minor shortfalls were found in relation to consent standards. Examples of strengths or good practice are included in the concluding comments section of the report.

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.

All 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 comprises Calderdale Royal Hospital (the hub) and Huddersfield Royal Infirmary (the satellite). Each site has a body store and post mortem suite, and similar numbers of post mortem examinations (about three hundred per year) are carried out at each site. Post mortem tissue is processed into slides in the histopathology laboratory at the hub. Post mortem blocks and slides are archived at Acre Mill, a facility situated near the satellite premises. However, the Acre Mill facility is considered by the HTA to be sufficiently remote from the satellite premises that it is not covered by the satellite licence. Therefore the tissue must be transferred for storage at either the hub or satellite premises, otherwise a satellite licence application for the Acre Mill site should be made (see advice item 11).

The establishment only performs routine adult post mortem examinations, the majority of which are conducted under the authority of HM Coroner for Bradford. Paediatric, forensic and suspected high-risk cases are transferred to other HTA-licensed establishments for post mortem examination. Toxicology specimens and organs for specialist analysis are also transferred to other HTA-licensed establishments.

The establishment has been licensed by the HTA since June 2007, and underwent a routine site visit inspection in November 2007. This report describes the establishment's second routine site visit inspection, during which the HTA inspectors met with staff involved in licensable activities and reviewed documentation. The mortuary premises at each site, the histopathology laboratory, and the storage facility at Acre Mill, were visually inspected.

Two traceability audits were conducted. A horizontal audit of storage locations for five deceased persons (two at the hub, three at the satellite) was carried out by selecting names from the mortuary registers and checking these against fridge numbers and body identification tags. A vertical audit of tissue removed at post mortem examination for histopathological analysis was carried out for four deceased persons. No errors in traceability records were found in these audits; however it was apparent the establishment does not have a robust procedure to ensure relatives' instructions on disposal, repatriation or retention of post-mortem tissue for use for a scheduled purpose are received (see standard C1).

Meeting the HTA's licensing standards

The HTA developed its licensing standards with input from its stakeholders, in order to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA expects licensed establishments to meet these standards.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a licensing standard is not met, the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor' (see Appendix 3: Classification of the level of shortfall).

Unless otherwise advised, the establishment is required to inform the HTA within 14 days of the receipt of the final report of the corrective and preventative actions that will be taken to ensure that the improvements are addressed. A template for this purpose is provided as a separate Word document.

HTA standards not met

Consent

Standard	Inspection findings	Level of shortfall
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.	The establishment uses the Department of Health (DH) form, 'Consent to a post mortem examination on an adult'. This form, which pre-dates the Human Tissue Act 2004 (the HT Act), states that tissue blocks and slides will be retained as part of the deceased person's medical record. The HTA considers that post-mortem tissue blocks and slides stored as part of the medical record are being stored for potential use for a scheduled purpose, and therefore consent is required in accordance with Section 3 of the Human Tissue Act 2004 (the HT Act) and the HTA's Code of practice 1 on Consent. During the inspection, three coronial post mortem examination cases were audited for tissue traceability. In each case, blocks and slides were being retained by the establishment because the relatives' wishes had not been received from the coroner. Without a robust procedure to ensure that relatives' wishes are communicated to the establishment, or a policy on action to take in the event that this information is not forthcoming, there is a risk of the establishment retaining tissue without valid consent when coronial authority has ended.	**Minor** **Minor**
C2 Information about the consent process is provided and in a variety of formats.	The establishment uses outdated DH patient information leaflets to support the seeking of consent for adult and paediatric post mortem examinations. These leaflets state that post mortem tissue blocks and slides will be retained as part of the deceased person's medical record (see C1 above).	**Minor**

Advice

Below are matters which the HTA advises the Designated Individual (DI) to consider.

No.	Standard	Advice
1.	C1	The DI is advised to work with HM Coroner to revise the 'Short cause of death form' so that: • relatives of deceased persons may consent for retention of relevant material for scheduled purposes under the HT Act; • reference to storage of tissue for the medical record is clarified. The DI is further advised: • to remove the term 'next of kin', and to include the hierarchy of qualifying relationships from the HT Act, in the standard operating procedure (SOP) M20-045 'Procedure for obtaining consent for non-coronial hospital post mortem examinations'; • that a model consent form for adult hospital post mortem examination is available from the HTA website: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/modelconsentforms.cfm
2.	C2	The DI is advised to update the paediatric post mortem information leaflet in order to make it clear that retention of tissue following post mortem examination may only occur with valid consent. The DI may wish to find out whether the establishment where paediatric post mortem examinations are undertaken has a clearer information leaflet which may be used.
3.	C3	Once corrective actions to meet shortfalls against standards C1 and C2 are complete, the DI is advised to update the e-learning module for clinicians who may seek consent for a post mortem examination.
4.	GQ1	The DI is advised to determine whether removal of relevant material from deceased infants occurs in any other areas of the licensed premises, for example Paediatric or Accident and Emergency Departments. If relevant material is removed from deceased infants in such areas, the DI is advised to nominate Persons Designated there, and to either schedule meetings with them or otherwise establish a system of communication, so he has oversight of such removal.
5.	GQ1	The DI is advised that SOPs and risk assessments should accurately reflect current procedures across both sites for body identification. For example, SOP M20-006 'Post mortems' states that a deceased person is identified by their name only, whereas standard practice by mortuary staff and pathologists is to also use the person's date of birth and (where available) the hospital number as additional identifiers.
6.	GQ2, GQ4	The DI is advised to develop a documented procedure for auditing traceability of relevant material, from its removal at post mortem examination through to its repatriation, storage for a scheduled purpose or its disposal. Audit findings should be circulated to relevant staff.
7.	GQ3	Experienced funeral directors will admit deceased persons to the mortuary outside core working hours. To ensure these individuals are fully aware of current mortuary working practices, the DI is advised to provide them with basic training in local policies and protocols. In particular, funeral directors should understand what constitutes a serious untoward incident (SUI), and the requirement to report SUIs to the HTA. A record of training should be kept.

8.	GQ4	The DI is advised to develop a documented approach to correcting errors in written records. For example, errors may be crossed through with a single line, with the signature or initials of the person making the amendment. Use of correction fluid should be avoided.
9.	GQ7	The DI is advised that the SUI reporting SOP (M20-010) should be updated to cite correct HTA contact information and the requirement that SUIs are reported to the HTA within five working days of discovery.
10.	GQ6	Post mortem tissue from the satellite site is taken to the Bacteriology Department prior to transfer to the hub for processing into slides. However, its receipt there is not logged, creating a risk that staff in that department are not aware tissue has been left in their custody. The DI is advised to work with staff in that Department to develop a system to minimise the risk that tissue could be misplaced or fall outside the traceability trail.
11.	PFE1	The DI is advised to transfer post mortem tissue blocks and slides stored at the Acre Mill facility to either the hub or satellite premises. Otherwise, a satellite licence application should be submitted for the Acre Mill site.
12.	PFE2	The DI is advised to clarify in SOPs aspects of mortuary cleaning: • the concentrations of cleaning solutions to be used; • how frequently areas outside the post mortem suite, such as body fridges, will be cleaned.
13.	D2	The DI is advised that the SOPs 'Disposal of slides, tissue blocks and request forms' (SOP 420 060) and 'Post mortem specimens in cellular pathology' (SOP 420 064) should state that: • the number of slides is confirmed in the Apex database prior to disposal; and • the numbers of blocks and slides disposed of is recorded in the appropriate databases.

Concluding comments

Despite the minor shortfalls, numerous examples of strength and good practice were also apparent. There is an e-learning module on consent for a hospital post mortem examination, which clinicians must complete before being permitted to seek consent. There is a strong team-working ethos amongst staff involved with licensable activities at the establishment and good communication across both sites. Quality management is suitable, and a wide range of SOPs and risk assessments covers licensable activities. The mortuary premises at the hub and satellite sites are clean, well maintained and fit for purpose.

As points of good practice, mortuary staff have been trained to carry out audits and have worked with staff on wards to ensure they understand appropriate procedures for maintaining the dignity of deceased persons.

Report sent to DI for factual accuracy: 17 October 2011

Report returned from DI: 18 October 2011

Final report issued: 14 November 2011

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.

Date: 30 December 2011

Appendix 1: HTA inspection process

The Human Tissue Authority regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, transplantation, and education and training. The legal requirements for establishments which carry out such activities are set out in the Human Tissue Act 2004 and The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

We license establishments in England, Wales and Northern Ireland that carry out these activities, and inspect them to make sure legal requirements are met.

Inspections

We use the term 'inspection' to describe when we:

- visit an establishment to meet with staff, view premises and facilities, and review policies and procedures (a site-visit inspection); or
- assess written information we have requested from an establishment (a desk-based assessment / inspection).

We carry out inspections to assess if the Designated Individual (DI) is suitable to supervise the activity covered by the licence, as it is their responsibility to ensure that:

- other staff working under the licence are suitable;
- suitable practices are used when carrying out the activity; and
- the conditions of the licence are met.

We also need to be satisfied that the licence applicant or holder, the establishment's premises, and the practices relating to licensed activities, are suitable.

To help us reach our decisions, we have developed standards under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal.

After every site visit inspection, we write a report documenting our findings. Where we find a particular standard is not fully met, we will describe the level of the shortfall as 'Critical', 'Major' or 'Minor'. In most cases, it will be the responsibility of the DI to seek the HTA's agreement on how they will address the identified shortfalls. More information about the classification of shortfalls can be found in Appendix 3.

The majority of our site-visit inspections are announced. If we have concerns about an establishment, we can also undertake an unannounced site visit inspection.

You can find reports for site visit inspections which took place after 1 November 2010 on our website.

Appendix 2: HTA standards

Standards which are not applicable to this establishment have been highlighted.

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.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.

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 3: 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.

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.

Follow up actions

A template corrective and preventative action plan is available as a separate Word document. 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.