Site visit inspection report on compliance with HTA minimum standards

Leeds General Infirmary

HTA licensing number 12231

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**

19 – 20 June 2012

Summary of inspection findings

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

Leeds General Infirmary (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 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 consists of premises at the Leeds General Infirmary, the hub, and St James University Hospital, the satellite. Post-mortem (PM) examinations are undertaken at both the hub and satellite premises. The establishment undertakes adult and paediatric post-mortem examinations on behalf of multiple Coroners, in addition to consented, hospital PM examinations. Paediatric and perinatal PM examinations are all undertaken at the satellite premises. Approximately 750 adult coronial, 10 coronial paediatric, 12 adult hospital (consented) and 160 paediatric hospital PM examinations are undertaken per year across both the hub and the satellite site.

PM examination suites at both the hub and satellite premises have isolated examination suites used for performing known, high-risk PM examinations. Forensic PM examinations are not routinely undertaken.

At the satellite site there is an additional body store with six fridge spaces located in the Beckett wing. The body store is operated by the Trust's estates department and is only used as an emergency overflow facility; however, it was visited as part of the visual inspection of the satellite premises and was found to be suitable.

Prior to the inspection, the DI identified areas outside the mortuary where the licensable activity of removing tissue from the body of the deceased takes place. At the hub site these

areas include the accident and emergency department, paediatric intensive care unit (PICU) and the neonatal intensive care unit. At the satellite site activity takes place in the emergency department and the neonatal intensive care unit.

As part of the inspection of the hub premises, the PICU was visited and a brief discussion held with the person designated (PD). The PD demonstrated an understanding of the requirements of the Human Tissue Act 2004 and the establishment's governance systems. There was evidence to show that the DI has undertaken a risk assessment of the PICU to assure himself that the premises are suitable. Similar risk assessments have also been undertaken of the other areas, not visited by the HTA, where licensable activity is taking place.

An audit of bodies stored in the establishment's fridges was undertaken at both the hub and satellite sites. At both sites three bodies were chosen at random and identification details recorded on body tags were checked against details in the mortuary register and on the mortuary fridge doors. At the hub premises the checks also included information recorded on a white board (the satellite site does not use a white board system). No anomalies were found in all six cases; identification details matched and bodies were being stored in the assigned fridge spaces.

Tissue traceability audits were also undertaken at both the hub and satellite sites. At the hub premises four cases were chosen at random where tissue had been taken as part of the PM examination. Records of what tissue had been taken were cross checked with the laboratory's electronic database in addition to the blocks and slides being stored. In three of the four cases blocks and slides were found and the numbers recorded in the database matched the number found. In the fourth case, only the blocks could be located; however the establishment indicated that the slides were still with the pathologist for review. At the satellite site another four cases were chosen where tissue had been taken. In three of the four cases no anomalies were found and in the fourth case one slide out of eleven was not located. Again the establishment indicated that the slide was still with the pathologist. In the cases where the slides were not in the establishment's slide archive, the HTA was satisfied that the whereabouts of the slides was known. In all eight cases the coronial family wishes forms were also sought and reviewed. Families' wishes forms were found for seven cases. As the eighth case was a very recent one, the form had not yet been returned by the coroner. In the cases where the forms were available, they all indicated that the wishes were for retention of the tissue for use for a scheduled purpose. In summary, the HTA was satisfied with the establishment's tissue traceability systems.

The inspection also included a review of a tissue bank, called GIFT, which is storing tissue at the establishment's satellite site for use in research. The GIFT tissue bank is currently applying for full ethical approval as a research tissue bank. Tissue is procured from the deceased, with fully informed consent, at the establishment's satellite premises. The inspection included a review of the GIFT tissue bank's documentation and an audit of stored tissue which included a review of the consent documentation. Some advice has been offered in the report relating to the GIFT tissue bank.

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.	GQ1	The establishment has a procedure that is followed when two bodies with the same or similar names are being stored; however, this procedure is not documented. The DI is advised to document the procedure either in a stand alone SOP or to incorporate it into an existing mortuary SOP.
2.	GQ6	During the audit of tissue at the GIFT tissue bank, an example was found of multiple sections of tissue from the same source being stored in a bag with only a unique tissue identifier on the bag, rather than on each individual tissue cassette. The DI is advised to ensure that each sample of tissue is uniquely identifiable so that full traceability of all tissue can be assured and there is a robust audit trail for all samples.
3.	PFE3	The fridges at the satellite site are linked to an alarm which alerts the switchboard in the event of an equipment failure and temperature increase above a set level. At the hub premises there is no system to alert staff that the fridge temperatures have risen outside of a defined range, meaning that staff may be unaware of an equipment failure. During the inspection the HTA learned that the establishment is in the process of tendering for new cooling plant equipment and that when the new equipment is installed it will include a fridge temperature alarm, similar to that of the satellite site. The DI is advised to develop a system of manual checks in the interim period before the new refrigeration plant is installed, so that staff would be alerted to an equipment failure out of hours, especially over holiday periods and weekends.
4.	PFE3	The establishment has an emergency disaster plan and a contingency plan policy in place. However, the contingency plan for the body store facility becoming full does not include information on when and how staff should alert the mortuary manager that the facility is reaching capacity. The DI is advised to include in the contingency plan policy the occupancy level that should trigger staff to alert the mortuary manager that the facility is reaching capacity, in order that decisions can be made about whether to initiate the contingency plan of moving bodies between the hub and satellite sites.

Concluding comments

Areas of good practice were observed throughout the inspection, some of which are included below.

The establishment benefits from a dedicated member of staff with responsibility for seeking consent for PM examination, supporting clinicians who may be seeking consent for PM examination and for ensuring that the establishment's consent procedures are followed. The specialist nurse for post mortem consent has developed and implemented good systems for assuring that fully informed consent for PM examination and any retention of tissue is sought. The specialist nurse also undertakes audits of all completed consent forms to not only check that they have been correctly completed, but to identify trends in information from the form. The results of these audits are used to inform improvements in the form and consent process and identify the need for more consent training, either generally, or for specific clinicians.

The establishment is meeting the requirement to undertake audits, which is expected by the HTA. The scope of the audits is, however, of particular note. As part of the establishment's audit schedule, vertical audits are performed. These do not only include an audit of records but also records of body receipt and associated paperwork, records of PM examination, records of tissue taken and a count of the blocks and slides, evidence that equipment used was within its service interval, that associated SOPs are within date, that consent for tissue retention, if appropriate, is in place and finally records of body release.

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

Report sent to DI for factual accuracy: 18 July 2012

Report returned from DI: 26 July 2012

Final report issued: 17 August 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.

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 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.