Site visit inspection report on compliance with HTA minimum standards

Alder Hey Children's NHS Foundation Trust

HTA licensing number 12213

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**

15 January 2013

Summary of inspection findings

Alder Hey Children's NHS Foundation Trust (the establishment) was subject to a themed inspection focusing on consent, quality management and prevention of major equipment failures. The HTA inspector was accompanied by the HTA Director of Regulation, who observed the inspection process.

The establishment was found to have met all HTA standards relating to each theme.

The existing Designated Individual (DI) and the Licence Holder were assessed and found to be suitable in accordance with the requirements of the legislation at the establishment's previous inspection in November 2009.

An application for change of DI had been processed by the HTA and approved in advance of the inspection. The replacement DI took part in discussions between the inspector and the existing DI, and was also assessed as being suitable in accordance with the legislation.

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.

A themed inspection may be carried out at establishments which have been found previously to represent a lower risk of regulatory non-compliance. Themed inspections focus on standards against which the HTA has identified common shortfalls across the post mortem sector and areas of risk identified from analysis of serious untoward incidents reported to the HTA. The themes selected for 2012/13 business year are outlined in the table below.

Themes	**HTA Standards**
Appropriate consent is in place for post-mortem examinations not under the Coroner's jurisdiction and in the event that tissue is to be retained for future use. Where there is no consent for retention, tissue is disposed of.	
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.	C1
Information about the consent process is provided and in a variety of formats.	C2
Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	C3

Governance and quality systems promote robust traceability systems, reducing the risk of serious untoward incidents.	
All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process.	GQ1
There is a documented system of quality management and audit.	GQ2
A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	GQ6
There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	GQ7
Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	GQ8
Fridges and freezers safeguard the integrity of the deceased.	
There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	PFE3

In addition to the standards listed above, the HTA will follow-up on any other issues that have arisen since the establishment's last inspection.

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

Alder Hey Children's NHS Foundation Trust is a tertiary referral centre providing specialist hospital services for children. A purpose-built histopathology facility was opened in 2001 and houses services such as paediatric histopathology, mortuary and bereavement support. The Trust performs 250-300 paediatric post mortem (PM) examinations on average, per annum. This total consists of referrals from several surrounding coronial districts, consented paediatric PM examinations from within Alder Hey hospital and also referrals from eight other hospitals within a wider geographical area.

There are facilities to allow high risk and forensic PM examinations to be carried out at the establishment, but high risk cases are currently referred to another specialist hospital within the area.

Mortuary staff deal with receipt of all bodies or specimens into the mortuary. The procedures used are the same for cases arising from referring hospitals, coroners or from Alder Hey hospital itself. Identity is checked and appropriate details entered into a mortuary register and proprietary electronic software system, which allocates a unique, sequential, body number. For cases referred from within Alder Hey hospital itself, details are also recorded in a separate “Hospital Register”.

The establishment has space for storage of 12 bodies. Fridges are monitored and alarmed. The alarm sounds locally, at the hospital switchboard, and also dials out to the on-call engineer’s mobile telephone. This is tested monthly. In addition, staff record fridge temperatures on each working day, to analyse trends so that pre-emptive maintenance may be scheduled. There is no planned maintenance schedule, but the establishment has a contingency arrangement in place in case of equipment failure or when full capacity is approached. There is no freezer facility; bodies requiring longer term storage are transferred elsewhere for that storage.

When a PM examination is authorised by the coroner, or consented to by the bereaved parent, the pathology department software system allocates a unique number (the “N” number). The N number is used to label documentation, sample pots and labels, tissue blocks and slides, and any subsequent reports relative to that PM examination.

During the PM examination, the pathologist, or mortuary technician assisting, completes a form detailing the tissue blocks sent to the laboratory for processing. Tissues are cassetted within the PM room into pre-labelled cassettes and sent to the laboratory, accompanied by the appropriate form detailing the tissues retained and any specialist stains required. This information is entered onto the electronic record within the mortuary and updated within the laboratory following production of slides.

Subsequently, the electronic case record is updated with details of slides being transferred for examination, either within the department or to external specialists, and their subsequent return.

Details of storage location of those tissues for which consent to store has been received are also recorded within the electronic record as is the date and reason for disposal.

Tissue storage locations are subject to periodic audit or inventory and there is a system of vertical and horizontal audits within the mortuary and laboratory covering documentation and processes.

Body release is dealt with only by mortuary technicians. When bodies or specimens are released to referring hospitals, the establishment tracks receipt by use of a faxback form.

This inspection was the second inspection of the establishment, the previous one being in November 2009, and comprised a visual inspection of the body store, PM examination room

and histopathology laboratory as well as a review of relevant documentation and discussions with key staff.

In addition, an audit of traceability was carried out:

- Two bodies were located within the body store and identity details checked against those recorded in the mortuary register and electronic record.

- Two cases were selected from the mortuary register and the details compared with those retained in the electronic record. The appropriate coronial authority for one case, and the signed consent for the other, were also located and reviewed.

- One further case was selected and the mortuary register details checked against the electronic record. This was then checked for details of blocks and slides produced, and the blocks were located in store; the system showed that slides were with the pathologist for examination. The relevant documentation, including authority for PM examination and the tissue block form, were located and reviewed.

- A library card, used to indicate the former location of slides which had been disposed of, was located within store and details checked on the electronic record to confirm reason for, and date of, disposal. The form detailing the next of kin's request for disposal was reviewed, as was the paper disposal record and destruction certificate.

- The consent form and next of kin instructions relating to two organs held in storage awaiting ultimate disposal were located and details checked. Again, the electronic record was reviewed to confirm that the storage location was recorded.

In all cases, no discrepancies were found.

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.	C1, C2	The DI is advised to consider the wording of the information provided to those consenting to hospital PM examination, to resolve any contradiction between this and the terms of the consent form itself, particularly with regard to the need for consent for on-going storage of tissue samples.

		By ensuring that language used is consistent in both the information provided and the consent form itself, the potential for confusion of those giving consent will be minimised.
2.	GQ6	When reviewing the relevant risk assessment, the DI is advised to consider the risks related to cases with same or similar names and any reasonable steps which may be taken to further mitigate those risks.
3.	GQ6	The DI is advised to institute a procedure whereby return of bodies or specimens to referring hospitals follows on receipt of a written request, rather than a verbal request received by telephone. Having a written request maintains a paper trail of traceability, will evidence that staff have acted appropriately on receipt of request for release and should help minimise the risk of error.
4.	GQ8	The DI is advised to consider adding the schedule of review of risk assessments to the electronic document control system, in order to ensure that the periodic review of risk assessments is timetabled in a similar fashion to the audits currently managed electronically. This will help to ensure that risk assessments are reviewed within defined timescales, ensuring compliance with the relevant HTA standard, and the results of such review may be used to inform development of policies and procedures, helping to further improve quality of service.
5.	N/A	The DI is advised to ensure that only equipment required for use within the day to day running of the mortuary is stored within the mortuary or body store areas. This will help maintain standards of cleanliness and minimise any health and safety risk to staff.

Concluding comments

The HTA saw various examples of good practice during the inspection.

Consent procedures and related training have been carefully considered. Training is offered to various members of staff within the hospital and is regularly refreshed. The consent policy is prescriptive as to who may take consent.

In support of this, a register of those trained and approved to take consent for hospital PM examinations is maintained in order that clinicians who wish a PM examination can contact a named individual to provide appropriate information, answer any queries and take consent from the family. Consent takers and the family members involved are supported during the consent process by trained bereavement staff and the patient's clinician is also available to answer questions raised by families.

The establishment carries out a comprehensive suite of audits within both the laboratory and the mortuary. These are both vertical and horizontal and include audit of documents and records, tissue storage and also procedures carried out against Standard Operating Procedures, by way of observed competency assessment.

Regulatory risks have also been considered and appropriate risk assessments carried out.

Non compliances in audit and findings in risk assessments are subject to on-going review and

are used to inform the development of policies and procedures.

The HTA has given advice to the DI on a range of issues, including the review of wording contained within information provided to families, consideration of the same name process, documentation used in the return of samples or bodies to referring hospitals, scheduling of risk assessments and storage of non-mortuary equipment within the mortuary.

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

Report sent to DI for factual accuracy: 30 January 2013

Report returned from DI: 12 February 2013

Final report issued: 18 February 2013

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

GQ4 There is a systematic and planned approach to the management of records

- There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- There are documented SOPs for record management.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as

health and safety risks.

- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal records include the date, method and reason for disposal.
- Tissue is disposed of in a timely fashion.

  (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.