Site visit inspection report on performance against HTA quality standards
University Hospital of North Durham
HTA licensing number 12461

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**

10 & 11 August 2011

Executive Summary

A site visit inspection of the University Hospital of North Durham (the establishment) was carried out by the HTA on 10 & 11 August 2011.

The establishment was found to have met all HTA standards. Examples of strengths or good practice are included in the concluding comments section of the report.

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.

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 University Hospital of North Durham is the main licensed premises (hub). Darlington Memorial Hospital is also licensed as a satellite to the hub. Mortuaries at both premises undertake consented hospital post-mortem examinations and coronial post-mortem examinations.

Paediatric post-mortem examinations are not performed at the establishment and are transferred to other licensed establishments, as are known high risk cases such as HIV and TB.

This was the second site-visit inspection of the establishment and was a routine inspection to assess how the establishment is meeting the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's recent self assessment compliance information, audit of stored material and pre-inspection discussions with the DI. During the inspection a visual inspection of the premises, review of documentation and interviews with establishment staff were undertaken.

Included in the visual inspection of the premises were the areas in both the hub and satellite sites where tissue may be removed from the bodies of the deceased outside of the mortuary. These areas included the hospital wards at both premises and additionally the A&E department at Darlington. Good practices were taking place, performed by suitable persons in suitable premises; however, the practices being undertaken, although documented locally, were not part of the DI's overall governance system (see advice below).

An audit of three bodies in the hub establishment's body store was undertaken. Identification details were checked between the mortuary register, mortuary white board and the identification tags on the bodies; no anomalies were found. This audit was repeated in the satellite's body store with three further bodies, again no anomalies were found.

Details of five coronial post-mortem examinations from both the hub and satellite premises were also audited. Tissue had been taken in all cases, blocks and slides were located and where applicable, wet tissue. All blocks, slides and wet tissue, as detailed in the establishment's electronic records, were located and no anomalies were found. Fourteen slides representing two of the five cases were stored at the satellite premises with the pathologist but were successfully located. There was however, no electronic record to show that the slides were at the satellite premises in the establishment's laboratory information management System (LIMS) (see advice below).

Signed coroners' forms detailing the family's wishes for the tissue that had been removed during the post-mortem examination were also reviewed for all five cases and in all cases signed family's wishes forms were located.

The establishment does not routinely store tissue following the end of coronial authority or a consented post mortem report being issued and hence blocks, slides and wet tissue that was audited was being held under coronial authority or the authority of the police.

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.

The establishment was found to have met all HTA standards.

Advice

Below are matters which the HTA advises the DI to consider.

No.	Standard	Advice
1.	C1	The establishment is using a consent form taken from the HTA's website following the last inspection. This form has since been updated by the HTA to ensure that it is clear to the person giving consent that consent is needed for retention of tissue for use in a scheduled purpose. In addition, the establishment does not routinely store tissue following the end of coronial authority or a consented post mortem report being issued. Although the coronial 'family's wishes form' does specify that that the establishment will only store tissue until a time deemed suitable by the establishment, the hospital post mortem consent form does not make this practice clear to the person giving consent. The DI is advised to amend the consent forms to clarify that consent is needed for retention of tissue for use in a scheduled purpose. The DI is also advised to reflect the establishment's practice of disposing of tissue after a certain time frame so that the person giving consent is aware of the practice. The consent forms and family information leaflets for the paediatric post mortem examinations do not make it clear that tissue will only be retained for use for a scheduled purpose with appropriate and valid consent. These forms are produced by the other licensed establishment to which such cases are referred. The DI is advised to review the consent forms and family information leaflets in liaison with the other licensed establishment's DI and amend them appropriately to ensure that they are up to date and comply with the requirements of the HT Act 2004.
2.	C2	There is currently a brief patient information leaflet document produced by the trust which is used to support the consent process for the post mortem examination. This document however does not contain sufficient information about the examination itself nor does it detail the choices about any organs or tissue that may be taken during the course of the examination. The DI is in the

		process of addressing this and has a draft document with more detail included within it. This document however states 'it is strongly recommended that samples will be kept at the hospital' following the post mortem examination. The document does make it clear that consent is needed for this and the uses to which tissue may be put. However, as the establishment does not routinely store tissue following the end of a consented post mortem, this should be made clear in the supporting literature to manage the expectations of the person who is giving consent. The DI is advised to amend the draft document to reflect the practices of the establishment and to launch the document to support the consent process.
3.	GQ1,GQ2, GQ4	The DI is advised to work closely with the people in the areas outside of the mortuary (hospital wards and A&E departments) where tissue may be removed from the deceased and to incorporate the documented procedures that are already in place into the establishment's quality management systems.
4.	GQ6	All tissue blocks and slides are stored at the hub site. The audits undertaken of organs and tissues being stored in the establishment's laboratories demonstrated good systems of traceability. There were, however, some slides that were under review at the satellite site and the establishment's LIMS did not record their location. The DI is advised to implement a system so that the establishment's LIMS tracks any organs or tissues sent to the satellite site for review.
5.	GQ7	The DI is advised to amend the adverse incident standard operating procedure (SOP) to include the reporting of sudden untoward incidents (SUI) to the HTA. The DI is advised to include what constitutes an SUI, who has responsibility for reporting them and how to report them to the HTA. In addition the DI should include who would report the SUI in the absence of the DI to ensure that all SUIs are reported within five days of discovery.
6.	GQ8	The establishment has risk assessments in place of the premises and the practices being undertaken. These risk assessments however are mainly health and safety orientated. The DI is advised to proceed as a matter of priority with the planned work to widen the scope of the risk assessments to include the risks to the bodies of the deceased and any organs or tissues removed during a post mortem examination. An example of such risks may include the risks of loss of traceability of tissue.
7.	PFE3	The DI is advised to develop a procedure to ensure that the body store fridge and freezer temperatures are monitored and recorded on a regular basis at the hub premises (weekday monitoring takes place at the satellite premises). These temperature records will give the establishment a data resource that may be used for trend analysis possibly allowing the early detection of a fault.
8.	PFE5	The DI is advised to periodically test the storage facilities alarm system to ensure that in the case of a unit failure the alarm system does contact the switchboard to alert staff and is operating as expected.
9.	D1	The establishment has a disposal policy in place however this still references the Department of Health's moratorium on tissue disposal, which ended in 2007 The DI is advised to update the policy so that it reflects the HTA's latest version of the code of practice on Disposal.

Concluding comments

Several areas of good practice were observed during the inspection, some examples of which have been included below.

The DI has developed a robust consent procedure for seeking consent to a post mortem examination. When seeking consent, three hospital staff are involved including the treating clinician of the deceased, a consultant pathologist and a mortuary Anatomical Pathology Technician (APT). This ensures that when the clinician seeks consent that there are relevant experts on hand to answer any questions that the person being asked for consent may have.

Evidence of a strong system of personal development linked to the establishment's performance review processes was observed. One of the establishment's APTs has initiated a series of meetings with ward staff to discuss the preparation of bodies prior to them being sent to the mortuary. This will develop closer links with ward staff, help strengthen practices around the dignity of the deceased and provide development opportunities for mortuary staff who may not otherwise interact with ward staff in this way.

Finally the establishment has good procedures around the management and traceability of mega blocks and slides. These larger tissue blocks and slides cannot be stored in the same archive as routine sized samples. The establishment however places a blank tissue cassette and blank slide with the standard sized tissue blocks and slides to indicate that mega blocks exist from a particular case. Mega blocks are also included in the establishment's LIMS. The markers in place with the standard tissue archive help to alert a member of staff looking for tissue from a particular case that mega blocks for that case exist. This serves as an extra system to mitigate the risk of mega blocks and slides being overlooked as they are not stored in the same place as standard blocks and slides.

Report sent to DI for factual accuracy: 2 September 2011

Report returned from DI: 14 September 2011

Final report issued: 12 October 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.