Site visit inspection report on performance against HTA quality standards
Hull Royal Infirmary
HTA licensing number 12170

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**

6 December 2011

Executive Summary

A site visit inspection of Hull Royal Infirmary (the establishment) was carried out by the HTA on 6 December 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 this 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 carries out between 1200 and 1300 post mortem (PM) examinations a year on behalf of HM Coroner, as well as around 70 hospital (consented) PM examinations, the majority of these being paediatric cases. In addition to the main PM room, which contains five PM tables, there is a separate forensic/high risk post mortem suite and an additional PM room used for training.

Bodies of the deceased are stored in two areas of the mortuary facility, one of which contains freezer units for long-term storage of bodies.

The establishment is staffed by nine qualified Anatomical Pathology Technologists (APTs), including the Mortuary Manager and Deputy Mortuary Manager, and a Mortuary Assistant. Because of the number of PM examinations undertaken, APT duties in the post mortem suite are rotated on a weekly basis so staff are clear about their roles during busy periods. This system of rotation, documented in a standard operating procedure, identifies three roles – A, B and C, with A being the circulating 'clean' technician, B being responsible for preparing bodies for post mortem and C being responsible for assisting the pathologist with the post mortems and undertaking reconstruction of bodies. The circulating technician is responsible for completing tissue retention forms and updating the laboratory database with these details.

Bodies are received into the establishment from the community and from wards within Hull Royal Infirmary. When bodies are received from the community during normal working hours, staff log their details in the mortuary register in the presence of attending funeral directors or police officers for the purposes of confirmation of identity. If a body from the community is brought to the mortuary outside of normal working hours, two mortuary staff are called in to deal with the logging in procedure in the presence of the police. Standardised admission forms are used.

During normal working hours, bodies from within the hospital are brought to the mortuary by porters using hospital transport. Staff confirm the identity of the deceased person with the porter and log the deceased's details in the mortuary register. Out of hours, trained porters deal with this procedure, placing the deceased person into an available fridge space and completing a patient transfer form, which is left for mortuary staff to process the next morning. Mortuary staff then complete the mortuary register entries having checked the identity details of the deceased and carried out initial measurements. If a body from within the hospital does not have the two identity bands (on wrist and ankle), which are required according to the hospital's operational procedures, an incident report is completed and logged on the Trust's incident reporting system.

Each body received into the mortuary is given a sequential mortuary register number, which is prefixed with a code to indicate where in the cycle of mortuary activity it is at any time. The number remains with the body throughout its stay in the mortuary, and is also used to track tissues samples or organs that are retained for examination.

Details from the mortuary register are entered into the "Labcentre" database which is accessible to staff in the mortuary and histopathology laboratory. The database is updated with details of PM examination, tissues retained following PM examination and the number of blocks and slides made.

Where tissues are retained, a Tissue Retention Form (TRF) is completed by the pathologist detailing what tissues or organs have been retained. The TRF form is faxed to the coroner who takes instructions from relatives of the deceased on what they would like to happen to any tissue that has been retained. A copy of the TRF form is then faxed back by the coroner to inform the mortuary of relatives' wishes and, when the wishes of the relatives have been actioned, the date of this is completed on the form and the form signed off by a member of the mortuary team. All disposal of tissue is co-ordinated by the laboratory staff.

Procedures on release of bodies for burial or cremation specify that two staff at the establishment, together with receiving undertakers, must check the identity of the deceased. Property release forms are countersigned by all of them. This procedure is also followed when releasing a body from long term storage.

This inspection was non-routine. The HTA was invited by the Chief Executive to undertake an inspection following a Serious Untoward Incident (SUI) involving the release of a body from long-term freezer storage.

The inspection comprised a visual inspection, document review and interviews with key staff. The focus of the inspection was on current mortuary procedures, including body receipt and release, long-term body storage, systems of traceability and record keeping.

Since the SUI, a number of steps have been taken to mitigate the risk of a similar incident happening again. When a body is placed in one of the freezers for long-term storage, a new procedure dictates that this only takes place on receipt of written authorisation from the coroner or the police and the reason for the storage is documented. Two staff members check the identity of the body and add a pink wrist band confirming the completion of an identification check. The body is then placed in a body bag which is sealed with a tamperproof seal bearing a unique number. This seal forms part of a cable securing the body bag to the freezer tray on which it is placed. Details of the tamperproof seal and confirmation of identity checks before placement in the freezer are added to the form documenting the reason for storage. Weekly audits of bodies in long-term storage are undertaken to check their safe condition and review the reason and authorisation for their continued storage.

As part of the inspection an audit of traceability was carried out:

- The location and identification details of two bodies within the main body store and one body in a freezer within the forensic/high risk body store were correlated to entries in the mortuary register and the Labcentre database.
- In two cases where tissue was retained at PM examination, the tissue was traced from post mortem records through the laboratory to, in one case, its storage location within the laboratory, and in the other case to the record of disposal on the TRF.
- Three TRF forms were compared with the electronic database records.

No discrepancies were found.

During the inspection, the HTA observed the release of a body to undertakers and noted that the procedure used followed the relevant SOP at all stages.

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.

The HTA considered that the establishment met all standards. Some advice and guidance was provided and is detailed on the following page.

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to consider revising policy CP 268 and SOP MO040 so that staff are clear that when seeking consent from the appropriate person in a qualifying relationship, the hierarchy of relationships must be adhered to, except when an individual does not wish to deal with the matter of consent or is not traceable and therefore cannot be consulted (see HTA code of practice on consent, code 1, paragraphs 83 to 88; http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm).
2.	C3	The DI is advised to arrange for the two members of mortuary staff involved in taking consent for hospital post mortems to have periodic refresher training on the principles of consent and the statutory requirements of the Human Tissue Act 2004.
3.	GQ1	The DI is advised to review governance documentation in order to consolidate documents where there is duplication so that staff do not need to refer to several procedures covering the same issue and to reduce the risk of them referring inadvertently to the incorrect procedure. For example, documents MO/HR/004, MO/CH/002 and MO/HR/009 all cover portering duties in relation to admission of bodies.
4.	GQ3	The DI is advised to increase the external, non mandatory training opportunities that are made available to staff and to ensure that sufficient PCs are available to them so that they can access on-line information sources, including the HTA website.
5.	GQ6	The DI is advised to update policy number MO/009, which in part deals with identification processes, to make reference to the need for two identification bands to be attached to bodies, to reflect Trust policy and current practice within the mortuary.
6.	GQ7	The DI is advised to request that Trust policy number CP129 is revised to reflect the need to inform the HTA of any incident which could be reportable as an SUI.
7.	GQ8	The DI is advised to continue with the planned programme of process and regulatory risk assessments, to ensure that all processes carried out at the establishment have been risk assessed, in order to inform future revision of SOPs.
8.	D2	The DI is advised take steps to ensure that post mortem reports are completed in good time, to avoid any unnecessary delays in the disposal of tissue samples in line with the wishes of families.

Concluding comments

The HTA observed many examples of good practice. For example:

- The DI has set up a human tissue committee involving staff from across the organisation who are subject to HTA regulation, as well as colleagues from linked organisations, such as the local Unversity Anatomy School.
- Governance documentation is comprehensive and up to date, with document review scheduled by a proprietary document management system, also used to schedule risk assessments and audits.
- Consent for hospital PM examinations is taken by a small number of APTs trained in consent, following an initial approach to the family by the clinician.
- A daily audit of bodies within the body store is carried out, using a report generated from the Labcentre database. Regular audit of bodies in long-term storage is scheduled to begin in the New Year.
- Staff interviewed demonstrated commitment to providing a good service. They work effectively together and there is good communication about mortuary-related matters.
- The system of rotation of APT duties in the PM room ensures that post mortem examinations are undertaken efficiently and that the risk of errors is minimised.
- The establishment responded quickly and effectively to the SUI referred to above by changing its processes in relation to identification of bodies at key stages in their passage through the mortuary, updating relevant SOPs and considering and creating new policies and procedures for dealing with long term storage of bodies in freezers.

Report sent to DI for factual accuracy: 6 January 2012

Report returned from DI: 18 January 2012

Final report issued: 23 January 2012

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.