Site visit inspection report on compliance with HTA minimum standards

Royal Derby Hospital

HTA licensing number 12537

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**

30 October 2012

Summary of inspection findings

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.

Although the HTA found that Royal Derby Hospital (the establishment) had met the majority of the HTA standards, shortfalls were found in relation to the consent standards.

The information booklet presented to those consenting for adult hospital post mortem (PM) examinations is out of date and does not reference the Human Tissue Act 2004 or the HTA Code of practice on consent. In particular, there is no reference to the need for consent to be given for retention of tissues, nor of the requirement for retention to be for use for a scheduled purpose.

The Bereavement Officer, who has received training in taking consent, accompanies clinical staff who take consent. The practice followed does not accord with the Trust's consent policy, which provides that consent may only be taken by trained clinical staff who have observed a PM. While some, not all, staff involved in the consent procedure have received training, this has not been refreshed.

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

Royal Derby Hospital carries out approximately 1,200 post mortem (PM) examinations each year. These are adult only PMs and consist mainly of examinations under the authority of the Coroner, together with around five consented hospital post mortems.

The main post mortem room has facilities for up to six PM examinations to be carried out simultaneously. Forensic and high risk PM examinations are carried out in a separate room, which has a single dissection table. Both the main room and the high risk post mortem room have viewing areas with floor-to-ceiling glass screens, and the latter has intercom and video links between the viewing area and the room. This is used for teaching and for accommodating police observers where appropriate.

Bodies are received into the establishment from the community and from hospital wards. The receipt procedures used for each differ slightly, as receipt of bodies from the community is always carried out by mortuary staff, including on call staff if required, while out of hours receipt of bodies from the wards is handled by trained pottering staff. In both cases, mortuary staff check wristband identifiers, transfer identity details into the mortuary register, wallboards

in the body store and in the office, and also onto an electronic software package used in both the mortuary and histopathology laboratory. The shrouds of bodies received into the body store are marked with a label when identity checks have been verified by mortuary staff, property accounted for and body measurements completed. This provides a visual confirmation that details of all bodies have been entered into the mortuary systems when the daily body check of all store spaces is carried out. Each body received is assigned a unique, sequential, number.

The establishment has space for 158 bodies, included in that number being 13 high risk or isolation spaces, five deep freeze spaces and nine spaces for bariatric cases. The establishment has separate storage facilities for products of conception and fetal tissues.

The Coroner provides authority for PM examination by sending this via a secure email service, using the same method for sending scanned copies of relatives' wishes regarding ultimate disposal of tissues or organs retained at PM.

Consent for hospital PM examinations is taken by the consultant or registrar involved in the deceased's care, supported by trained bereavement officers.

The establishment does not carry out paediatric PM examinations; these cases are referred to a nearby specialist centre, which is licensed by the HTA. Consent for is taken by Derby Royal Hospital clinicians, who have attended a training session run by the specialist centre, using consent forms and information leaflets supplied, and supported by bereavement office staff. Training records for the paediatric clinicians were not reviewed during the inspection, so it was not possible to verify whether training had been recorded.

Tissue samples retained during PM examinations are cassetted in the dissection room into blocks marked with the deceased's unique number. They are transferred to the histopathology laboratory by mortuary staff, with each set of blocks being accompanied by a form detailing the tissues retained and the type of slide stains required. Details are entered onto the software system and this tracks the number of blocks and slides, with details of any special stains required. The system also tracks release of slides to the histopathologist for examination.

After examination, blocks and slides are placed into store pending receipt of authority from the hospital bereavement office or the coroner for ultimate disposal in line with relatives' wishes. At that time, the blocks and slides are collected, numbers reconciled, and transferred to the mortuary, where staff deal with them in accordance with instructions. Records of disposal are maintained.

Where any tissues or organs are sent outside the establishment for specialist examination, or where paediatric cases are referred elsewhere, traceability records are maintained by the use of record forms, tracked courier services and secure email of receipt

The establishment has been inspected before, in September 2009, and this was a routine, scheduled, inspection.

The inspection comprised a visual inspection, review of a selection of governance documentation and interviews with key staff from the mortuary, laboratory, bereavement office and maternity services. The inspection team also observed the release of a body to undertakers and, as this body had a similar surname to another, the same or similar name procedure was also observed in the context of body release.

An audit of traceability was carried out:

- Two bodies were selected from the main body store and one body from the longer term storage freezer and wristband details checked against the corresponding entries in the mortuary register, wall board and electronic record.

- The hospital record for a patient who had undergone a hospital, consented PM examination was reviewed to determine the presence of all relevant consent and traceability forms, including consent for the brain, spinal cord and medial nerve to be retained for use for research

- Similar records were reviewed for a coroner's case where there was an industrial disease; traceability records were checked, including communications with the solicitors acting for the family detailing the transfer of the tissue to the custody of the solicitor and continued storage pending legal action.

- Two other cases were selected; the corresponding blocks and slides, as appropriate, were located in store, the corresponding records located within the electronic database and these traced back to hard copy paperwork held by the mortuary. In one case where tissues had been disposed of, the relevant disposal records were reviewed.

Only a minor discrepancy was found in that a library card had not been placed in the slide store detailing the disposal of the slides it replaced, contrary to the documented procedure.

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

Consent

Standard	Inspection findings	Level of shortfall
C2 Information about the consent process is provided and in a variety of formats.	While the establishment provides written information to those giving consent for a hospital PM examination, the information booklet predates the Human Tissue Act and therefore does not detail the requirement for retention of tissues or organs to be with consent for use for scheduled purposes. It also contradicts the consent form used, which does provide this detail.	**Minor**
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	The Trust policy states that consent should be taken by consultant clinicians involved in the patient's care, who have received training in consent, have attended a PM examination, and are supported by bereavement office staff. In practice, consent is taken by consultant clinicians who may not have received specific consent training or indeed attended a PM. Bereavement officers sit in on each consent process and they have all attended HTA courses on taking consent for PM. However, this consent training was completed some time ago and has not been refreshed.	**Minor**

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 review the consent form used for adult hospital PM examinations against printed information provided to those giving consent, to ensure that similar terminology is used; this will help minimise the risk of misunderstanding on the part of those giving consent.
2.	GQ1	The DI is advised to produce an SOP detailing a procedure for periodic testing of the body store fridge and freezer alarms, and to record the results of that testing.
3.	GQ2	The DI is advised to extend the current spread of audits to include a vertical audit of all documentation relating to the passage of bodies through the facility, subsequent PM and tissue traceability, to supplement the various elements of

		the whole procedure which are currently audited.
4.	GQ1	The DI is advised to produce an SOP detailing the need to record the reason for any long term freezer storage of bodies, and to require periodic audit of bodies in longer term storage and follow up with those requesting that storage.
5.	GQ6	The DI is advised to consider instituting a system to record when slides have been sent to a histopathologist for examination, and their eventual return into slide store. This will minimise the use of staff time when clearance for ultimate disposal of blocks and slides is received, as the current location within the department will be more easily determined.
6.	GQ7	The DI is advised to ensure that, when the Trust incident policy is next reviewed, it makes reference to the need to advise the HTA of Serious Untoward Incidents as well as Serious Adverse Events or Reactions.
7.	GQ8	The DI is advised to extend the current suite of risk assessments to include risks related to the various categories of Serious Untoward Incidents reportable to the HTA.
8.	N/A	The DI is reminded to advise the HTA when a decision is made on the change of Corporate Licence Holder Contact.

Concluding comments

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

There is good interaction between mortuary staff and pathologists.

Control of documentation is robust as the establishment uses a proprietary electronic document control system. Records are kept in a very clear format, and the use of a single, unique number for each body and associated tissue samples, facilitates easy traceability. In particular, the procedures and documentation used to record authority for retention, and to trace the passage of tissues to their ultimate disposal, appear robust.

The system used to record bodies with similar or same names is elegant in its simplicity. A white board containing a grid with letters of the alphabet down the left side shows patient details horizontally in the row corresponding to each initial letter, also detailing location in the store.

The procedure used for same or similar names requires staff to highlight any names with the same or similar spelling, or those phonetically similar, in red marker. This enables staff, when releasing a body or preparing for a viewing, to check a row of all surnames starting with each letter, rather than having to review the whole board and highlights those cases where there are potential similarities, helping to minimise the risk of errors in body release...

The establishment has good communication with the local coroner, using secure email for transmission of authority for PM and relatives wishes. Details of PM results and clearance for release of bodies and tissues are also sent by this method.

Despite having an alarm system for the body store fridges and freezers, establishment staff

still record temperatures on a daily basis to enable trending. Preventative maintenance is then scheduled on the basis of trends identified.

Portering staff have been trained by mortuary staff on the various mortuary procedures they must follow and the mortuary retains a record of that training.

The establishment forms part of a recently built general hospital and the DI and mortuary manager were heavily involved in the design of the mortuary facility. This is reflected in the very practical layout of the facility and the way the requirements of those working within the facility have been addressed.

There are areas of practice that require improvement, including two minor shortfalls. The HTA has given advice to the Designated Individual with respect to some elements of documentation, risk assessment and audit.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 6 November 2012

Report returned from DI: 15 November 2012

Final report issued: 15 November 2012

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 27 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.