Site visit inspection report on performance against HTA quality standards
Dorset County Hospital
HTA licensing number 12449

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**

23 November 2010

Executive Summary

A site-visit inspection of the Dorset County Hospital mortuary and histopathology premises was carried out by the HTA on 23 November 2010.

Overall, the HTA considers the premises and practices to be suitable in accordance with the requirements of the legislation, and the establishment was found to be meeting the majority of HTA standards across the four areas of: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal. However, there were some shortfalls in relation to Consent and Governance and Quality (refer to standards C1, C3, GQ2, GQ6 and GQ8 on pages 4 to 6).

The HTA considers the Corporate Licence Holder (CLH) with a named representative to be a suitable entity to be licensed. The Designated Individual (DI) has previously been assessed as suitable by the HTA however following the current inspection, the DI has been deemed unsuitable.

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

Approximately 500 post mortem (PM) examinations are undertaken per annum, which are generally under the authority of the coroner (including Home Office cases); the last adult hospital PM examination was carried out more than a year ago.

Approximately 40 peri-natal and paediatric hospital PM examinations are undertaken per annum. Known high risk PM examinations are transferred to an HTA-licensed establishment in Bournemouth. Histopathology analyses of relevant material removed during PM examination are carried out in a laboratory within the hospital, except for Home Office cases where tissue is transferred to external laboratories at the request of the pathologist. Additionally, some specialist external pathologists examine slides of tissue sections off site. The licensed premises were extended in 2009 to cover the Maternity Unit and Casualty department at the Dorset County Hospital where the mortuary is located, for the purpose of removing relevant material from deceased children.

There are three full-time equivalent Anatomical Pathology Technologists (APT) including a senior APT with supervisory duties in the mortuary. There are two Trust pathologists (including one paediatric pathologist) and one Trust General Practitioner with pathologist training, who perform PM examinations. Home Office pathologists visit the premises to undertake PM examination of forensic cases.

The inspection was non-routine. The establishment had exceeded the deadline to meet two additional conditions which were placed on the licence following a routine inspection in October 2009. In addition, General Directions issued to the Post Mortem sector in April 2010 had not been complied with. The HTA therefore considered the establishment to be at an increased risk of not meeting the standards and this non-routine inspection was scheduled.

During the previous site visit inspection, the HTA placed additional conditions on the licence which related to the standards for Consent (C1 and C3). These remained outstanding at the time of this inspection. The General Directions issued to the Post Mortem sector in April 2010 have also not been complied with. The establishment submitted its compliance self-assessment, due by 30 June, at the end of September and at the time of this inspection, the audit of retained PM material was still outstanding.

Major changes in the Trust Clinical Governance have been taking place for more than a year and this was identified during the previous inspection as a potential risk to the establishment's ability to meet the licensing requirements. This inspection focused on re-assessment of DI suitability and evaluation of governance arrangements relating to licensable activities.

A visual inspection of the premises included the mortuary and histopathology laboratory. Casualty and the maternity ward were not visited. Interviews with key members of staff

working under the licence were conducted. Relevant policies, operational procedures and records were reviewed in accordance with the checklist provided with the inspection timetable.

Two audit trails were carried out. The first audit trail reviewed mortuary paperwork and body identifiers for two bodies in the body store; no anomalies were found. The second audit trail reviewed traceability of tissue from three deceased persons which had been removed at PM examination. In these cases several issues with traceability were identified (see standard GQ6 on pages 5 and 6).

Meeting the HTA's licensing standards

The failure of the establishment to comply with additional and standard conditions of the licence during the past year and the new organisational structure (effective 29 November 2010) indicate that the DI is no longer in a suitable position to fulfil the statutory duties under the licence. The turnover of Clinical Governance staff has also had a negative impact on the management of the mortuary; issues relating to the licence have also not been identified by the CLH representative. During the current inspection, the HTA considered that, although the DI was a suitable person to undertake the duties of the role, the DI's routine responsibilities (i.e. those which are part of the normal day to day job) led to too little time to devote to fulfilling the DI role and the DI was therefore unsuitable; a member of staff in a role in the new organisational structure more suited to that of DI should be more effective in managing the work carried out under the licence and in liaising with the CLH representative.

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.

HTA standards not met

Consent

Standard	Inspection findings	Level of shortfall
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.	The Trust consent literature *"Information for giving consent to a post mortem examination":* • advises that the Histopathology department should be contacted for information about the PM examination process, however this is a key factor in obtaining informed consent and this is expected to be provided during the consent process (bottom of first paragraph on page 3). • refers to tissue which is "routinely" taken during post mortem. This is inaccurate as no tissue can be removed during PM without consent or coroner's authorisation. This section also states that the Trust "strongly recommend" tissue removed during PM be kept in the medical record. Again, there is no statement relating to the consent requirement for this retention in both hospital and coronial cases (second paragraph on page 3). • implies that a pathologist may remove a whole organ during PM and discuss it with the family afterwards. However, consent for removal of any tissue must be in place before removal is carried out (second paragraph, page 4). • identifies the Histopathology Department as the contact for any follow up questions. It is more appropriate for the contact to be the individual who sought consent (e.g. clinician or pathologist); however, a Bereavement Officer has now been appointed and she may also be an appropriate contact. • became effective in April 2009 and was due for review in April 2010, however there is no evidence that this review has been carried out.	**Major**

	During the inspection the HTA was not provided with a consent policy or standard operating procedure (SOP). There are "action plan guidelines" for seeking consent for PM examination of a baby which were updated in November 2010 but it is not clear whether it is intended for these to inform a policy or SOP. The second guideline discusses that consent should be sought by someone trained, but does not explicitly state that this training should relate to the requirements of the HT Act. The consent form for PM examination of a baby does not refer to the requirement for consent for retention of tissue blocks and slides (Section 3).	
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	Individuals involved in seeking consent for PM have been trained by a visitor from another HTA licensed establishment, however the content of the training programme and documentation of the training were not provided to the HTA. At present there is no system in place to ensure that in the event of an adult hospital PM being requested, only trained individuals seek consent.	**Minor**

Governance and Quality

Standard	**Inspection findings**	**Level of shortfall**
GQ2 There is a documented system of quality management and audit.	SOPs are controlled documents, however some documents were observed to be past the review date (for example, the information provided to those from whom consent is sought). Audits are carried out in the Histopathology Department but not the mortuary. Processes (i.e. fitness of and adherence to SOPs), records and traceability of bodies and tissue are not regularly audited. Audits are not documented, and corrective and preventative actions are not identified along with the responsible parties and deadlines.	**Minor**

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	The mortuary does not record (or keep a record in Home Office cases) where tissue is removed during PM, which is of particular concern when tissue is sent or taken off site for analyses and examination. Additionally, APTs do not assist in peri-natal and paediatric PM cases and they are not provided with any documentation from the pathologist about tissue removed during PM. The establishment is not keeping accurate and adequately detailed records of tissue types and quantities removed during PM in order that they can assure themselves that tissue is fully traceable at all times and is handled in accordance with the wishes of the family and coroner's instructions. The audit of traceability of tissue removed during PM which was carried out during the inspection revealed: • the absence of a copy of the coroner's Cause of Death form for one case; these forms are normally held in the mortuary as a record of tissue taken during PM. Information about the tissue was found in the computer database which indicates it had likely been given verbally. • one coroner's Cause of Death form did not identify that any tissue was taken at PM; however, there was an entry about tissue in this case on the computer database, which means the information was likely given verbally. • a transcription error among the three numbers assigned to tissue removed during PM (a PM number assigned in the mortuary, an autopsy number assigned by the Histopathology office and a, CoPath number assigned by the Histopathology laboratory). Verbal information sharing (which was evident during the inspection) is not a robust means of ensuring accurate record keeping or traceability. It also creates a significant risk that tissue will not be identified by the coroner as having been retained and therefore no instructions will be provided for how to handle it when the coroner's authority ends.	**Minor**

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Risk assessments have been carried out in relation to health and safety hazards. However, there are no written and monitored (i.e. audited) assessments of risk in relation to the integrity of bodies and tissue or the dignity of the deceased. Key activities for which risk assessments have not been conducted include, but are not limited to, conducting PM examinations (including more than one PM examination at a time), movement of relevant material removed during PM (i.e. to the on-site laboratory and to off-site premises), and admission and release of bodies in the mortuary.	**Minor**

Advice

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

No.	Standard	Advice
1	GQ4	The DI is advised to reconsider the use of pencil and correction fluid in paper records, which compromise the integrity of the information recorded. When an error is made, a single line can be drawn through the text and the correct entry made. It is good practice for error corrections to be initialled by the individual making the change.
2	PFE5	The DI is advised that three of the temperatures of three of the fridges in the body store are not being monitored. Additionally, the DI is advised that the upper and lower limits should be documented for staff reference, along with the procedure to follow in the event of an alarm.
3	D2	The DI is advised that the current disposal SOP (MORT-22) does not reflect thecurrent practice of maintaining computer records for traceability of tissue taken at post mortem; the SOP refers to the record-keeping requirements for paper records only.

Concluding comments

The premises are clean and well maintained and the majority of the HTA standards are being met by the establishment. This means that the difficulties in the management of the mortuary have not had significant adverse effects on the quality of the service provided by the establishment.

Report sent to DI for factual accuracy: 22 December 2010

Report returned from DI: No comments received.

Final report issued: 11 January 2011

Once the establishment has been able to comment on the factual accuracy of the report, it will be published on the HTA website.

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.