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**

31 January 2012

Executive Summary

A site visit inspection of Dorset County Hospital (the establishment) was carried out by the HTA on 31 January 2012.

The establishment was found to have met the majority of HTA standards. However, there were some minor shortfalls in relation to Governance and Quality Systems, and Premises Facilities and Equipment.

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 approximately 500 post mortem (PM) examinations per annum, under the authority of the coroner (including Home Office cases). One adult hospital PM examination has been carried out in the last year. Approximately 30 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 tissues removed during PM examination are carried out in a laboratory within the hospital, except for Home Office cases where tissue may be transferred to external laboratories at the request of the pathologist. Additionally, some specialist external pathologists examine slides of tissue sections off site. The laboratory also carries out preparation of slides for PM examinations carried out at other sites, which are then sent to out of the hospital to the pathologist concerned. The licensed premises also cover the Maternity Unit and Casualty department at the hospital, for the purpose of removing relevant material from deceased children.

At the time of inspection there were two full-time equivalent Anatomical Pathology Technologists (APT), one being a senior APT with supervisory duties and the other a trainee. The establishment was carrying out a recruitment programme for a further qualified APT. The APTs are supported in the day to day administration of the mortuary by the Bereavement Officer. There are two Trust pathologists (including one paediatric pathologist) and one Trust General Practitioner with pathology training, who perform PM examinations. Home Office pathologists visit the premises to undertake forensic PM examinations for the district of West Dorset. Other forensic examination cases are dealt with at an HTA Licensed establishment in Bournemouth.

There are defined procedures governing receipt of bodies into the mortuary depending on whether the body originated from within the hospital or from the community.

Porters and nursing staff bring bodies from within the hospital and place them into refrigerator spaces in the body storage area. They complete a form to hand over to mortuary staff detailing identity of the deceased, property and which location has been used to store the body. Mortuary staff then check identity details and carry out measurements, check property and then transfer all relevant details to the mortuary register and onto a database spreadsheet.

Where bodies are received from the community, receipt always involves mortuary staff, either during office hours or as on call staff out of hours. Again a specific form is completed to detail the identity of the deceased, the location they have been brought from, details of police officer involved and property. Information is transferred to the mortuary register and database as described above.

Each body received into the mortuary is given a unique sequential number. Where a PM examination is carried out, that too is allocated a separate sequential PM number.
Bodies are only released on the receipt of an authorisation from the coroner, or a release form signed by relatives. In both cases, this details the identity of the undertaker who has authority to take the body. At handover to the undertaker, a mortuary staff member checks

identity and property details with the undertaker and the register is completed and signed by both to confirm release.

Tissues taken at PM examination are cassetted into blocks within the PM examination room, details of what tissues have been sampled are recorded on documents during the examination itself and then those details are entered onto a separate histopathology database. The tissues are then taken by a member of the establishment staff to the laboratory.

Tissues arriving at the laboratory are given a further unique number and details entered into a CoPath database. This subsequently also records the numbers of slides produced and when slides have been sent to and received from pathologists for examination.

The inspection was routine, and follows on from a change of DI subsequent to the last inspection in November 2010.

The inspection comprised a visual inspection, document review and interviews with key staff, with emphasis placed on reviewing the mortuary procedures for receipt of bodies into store, transfer for PM examination and release for burial or cremation, and the corresponding traceability records relating to bodies, and to tissues retained following PM examination.

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

- The location and identity details of two bodies within the main body store were correlated to entries in the mortuary register and the whiteboard used as a visual record of location.
- In two cases where tissue was retained at PM examination, this was traced from PM records, on paper and electronic database through the laboratory to storage.
- Two electronic records were compared against their paper counterparts.

Only one minor discrepancy was noted. The inspection team found the traceability systems to be complicated, particularly the use of three different unique numbering systems and advice has been provided regarding this; see page 6 of this report.

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. The HTA expects licensed establishments to meet these standards. See Appendix 2 for the standards applicable to this establishment.

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

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process	Standard Operating Procedures (SOP) MORT SOP 03 and 04, detailing the processes to be followed when receiving bodies from the ward or from the community do not accurately reflect the procedures carried out, in that they do not detail the need to complete the forms used in each case to record receipt. The forms used are not subject to document control as they are not referred to or annexed to the relevant SOP, these forms being the Deceased Admitted from Ward form and Deceased Dead on Arrival form. These procedures are critical to the effective traceability of bodies, and the two forms are used to accurately detail some of the information subsequently transferred to the mortuary register. The fact that the process is not accurately documented and forms not controlled presents an increased risk of loss of traceability.	**Minor**

GQ2 There is a documented system of quality management and audit.	Some limited audits have been carried out, of records and of processes followed against SOPs. However, there is no defined audit schedule governing what audits should be carried out. No vertical audits of traceability, from PM examination to storage or disposal of tissues, have been carried out. Similarly, there has been no audit of records within the CoPath system to reconcile records of slides or tissues being sent for examination, either to pathologists within the establishment or to external specialists, with the return of same. Staff assume that, where slides are marked out to pathologists and are not shown as having been returned, they are still held by the pathologist. By scheduling regular audit of records, traceability and procedures, the DI will be able to identify any areas where processes are not being followed or where errors are arising, allowing her to adapt processes or address training needs. This is particularly important as traceability within the establishment is dependent on a complicated system of three different numbers; for bodies, PM examinations and tissues, meaning there is an increased risk of loss of traceability. Audit will inform continued improvement of procedures at the establishment and with particular reference to the CoPath records relating to sending and receipt of tissues or slides. It will also minimise the reputational risk of tissues being retained after ending of the coroner's authority in cases where relatives' wishes are for disposal.	**Minor**
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly	The SOP detailing the procedure to be followed in the event of an adverse event or serious untoward incident does not make clear to staff subject to that procedure what categories of serious untoward incident are reportable to the HTA. Staff appeared unclear of the need to report some types of incident to the HTA. By reviewing and amending the SOP and training staff on its content, awareness of staff to the possibility of such incidences occurring will be increased, making staff more aware of the risk and will also help ensure that the DI is able to meet the five day reporting timescales required.	**Minor**

Premises Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	Three of the fridges at the establishment, comprising nine fridge spaces, are not covered by the temperature monitoring and alarm system. Although staff advised that the temperature of these fridges was noted daily, by reference to the thermometer dials applicable to each, this was not recorded, meaning that there is no analysis of trends. By having a daily procedure to note and record temperatures of the fridges not covered by the alarm system, staff will be able to analyse any trend to increasing temperature enabling them to identify failing refrigeration plant and take action to minimise the risk of decomposition damage to bodies.	**Minor**
N/A	The DI has been in post for just over one year but has not yet completed the HTA DI e-learning training, which, as a standard condition of the licence, is to be completed within 12 months of taking the role. By completing the training, the DI will be provided with additional background to the Human Tissue Act as well as the standards of compliance she is working to, which will help inform her role as a DI.	**Minor**

Advice

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

No.	Standard	Advice
1.	C3	The DI is advised to adapt the current training materials used to train midwives on obtaining consent to hospital post mortem examinations for use in refresher training of pathologists who may be asked to assist or advise clinical colleagues obtaining consent for a hospital post mortem examination of an adult. This will help to ensure that pathologists are fully familiar with the requirements of the HTAs Code of Practice on consent, particularly with reference to qualifying relationships and the scheduled purposes for which tissue may be retained. The DI is further advised to ensure that attendance at any refresher training is recorded.
2.	GQ1	The DI is advised to review updated policies and procedures to ensure that the written procedure accurately reflects the actual procedures being carried out, for example as detailed in SOPs MORT 03, 04 and 30 and that the review date has been updated in the document footers to accord with the written review date recorded in the sign off sheets attached to each document.

3.	GQ1	The DI is advised to ensure that any work instructions, flowcharts, non SOP guidance documents or procedural reminders used within the department are subject to document control, either as standalone documents or as annexes to other controlled documents. As an example the document “Transfer of bodies within the mortuary” should be a controlled document referred to within or be part of SOP MORT 30.
4.	GQ3	The DI is advised to formalise the meetings she has with the senior APT to ensure that they run to a formal agenda and are minuted, with minutes being circulated to other staff members involved in the carrying out of the licensed activity. The DI is further advised to have regular formal meetings to which all staff members are invited for the purpose of sharing of knowledge and updating on procedures. At such meetings matters relevant to the licence can be addressed and issues dealt with across departments involved in the licensed activity.
5.	GQ6	The DI is advised to ensure that where blocks or tissues are received into the laboratory, the accompanying documentation details the number of blocks or pieces of tissue sent. The DI is further advised to draft a procedure for laboratory staff detailing the need to check the number of blocks or pieces of tissue sent against the accompanying paperwork, and for how to address the issue if there is a discrepancy.
6.	GQ6	The DI is advised to consider how the numbering system used for bodies, post mortem examinations and tissues arising from same could be simplified in order to assist staff in carrying out audits.
7.	GQ8	The DI is advised to ensure, when risk assessments have been carried out and potential risks identified, such as the absence of temperature recording for fridges not covered by an alarm system, appropriate mitigating actions are carried out, in order to minimise or address the risk.

Concluding comments

The premises were seen to be clean and well maintained. It was evident that much work had been carried out to address shortfalls found during the last inspection and staff were aware and acknowledged that there were still areas for improvement. The HTA noted that the establishment was seeking to replace a qualified staff member who had left and that, in the interim, there was increased pressure on remaining staff, but that staff were working in a flexible manner to ensure the mortuary service was being maintained.
The HTA also noted that staff acknowledged the areas where improvements could be made and that, notwithstanding the staffing pressures, expressed a willingness to address any shortfalls or matters of advice raised.

Report sent to DI for factual accuracy: 15 February 2012

Report returned from DI: 27 February 2012

Final report issued: 2 March 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: 30 May 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.