Site visit inspection report on compliance with HTA minimum standards

Glan Clwyd Hospital

HTA licensing number 12153

Licensed under the Human Tissue Act 2004 for the

- **making of a post mortem examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose.**

6 February 2013

Summary of inspection findings

The HTA found the Designated Individual, the Licence Holder and the premises to be suitable in accordance with the requirements of the legislation.

Glan Clwyd Hospital was found to have met all the HTA standards.

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 licenses 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 and description of inspection activities undertaken

Glan Clwyd Hospital (the establishment) is licensed to carry out PM examinations and the removal and storage of PM tissue for use for scheduled purposes under the HT Act. For HTA licensing purposes, Glan Clwyd Hopsital is a 'hub' and the licence arrangements extend to satellite sites at Wrexham Maelor Hospital and Ysbyty Gwynedd, Bangor. The corporate licence holder is the Betsi Cadwaladr University Local Health Board and the corporate licence holder contact is the Associate Chief of Staff.

Glan Clwyd Hospital undertakes around 700 PM examinations each year, and each of the satellite sites undertake around 500 PM examinations annually. PM examinations are undertaken on behalf of the Coroner for North West Wales and the Coroner for North Central and North East Wales.

The mortuary has storage capacity for 50 bodies, including a bariatric storage area and a freezer. Contingency arrangements for additional storage are in place with the satellite sites and funeral directors in the event that it is required. The autopsy room has three tables.

The mortuary is staffed by three Anatomical Pathology Technologists (APTs) who report to the Cellular Pathology Service Manager. APTs based in the satellite sites also work at the hub site when required. PM examinations are undertaken by pathologists based at Glan Clwyd Hospital and visiting Home Office pathologists. The Coroner's officer faxes authorisation for a PM examination to the mortuary and obtains the wishes of the next of kin regarding disposal of any tissues retained at a PM examination. The Coroner's officers undertake regular audits of cases to ensure that the wishes of the next of kin in relation to any tissues retained have been obtained. Bereavement staff seek consent for hospital PM examinations and provide support for consultants and midwives who seek consent for baby

and child PM examinations, athough these are undertaken at another HTA licensed establishment. Consent training is provided to staff by an experienced APT and trained staff are listed on the All Wales Consent database.

All bodies that enter the mortuary receive a wrist tag marked with a unique number alongside a separate wrist tag marked with other details such as name, date of birth and address or NHS number as appropriate. APTs receive and register bodies which are brought to the mortuary by funeral directors during the working week. Hospital porters bring bodies from the hospital and receive bodies brought into the morturary by funeral directors out of hours. The following day, APTs check bodies and record details in the mortuary register of the bodies brought in out of hours. Disposal of PM tissue takes place in the histopathology laboratory in accordance with written procedures for disposal of organs, wet tissues and blocks and slides.

A site visit inspection of Glan Clwyd Hospital was undertaken on 6th February 2013. This was the second inspection of the establishment and was undertaken as PM activites had recently moved to a new mortuary built within the hospital site. The inspection included interviews with the Consultant Histopathologist (DI), Service Manager Cellular Pathology (PD), Head Mortuary technician, Bereavement Officer, an Anatomical Pathology Technologist and a Coroner's Officer. The inspection did not include visits to the satellite sites.

A document review was carried out. The documents reviewed included: standard operating procedures (SOPs) relating to PM examinations; policies; paper and computer records, as appropriate, of bodies booked into the mortuary, tissues removed during PM examinations and disposal records; paper records of incident reports, investigations of incidents and follow up actions; audit records; cleaning records; and training records. The inspection did not review records relating to receipt and transportation of tissues for specialist examination.

An audit trail was undertaken of two bodies stored in the mortuary. Details in the mortuary register, storage location and identity tags were checked. There were no discrepancies. Records relating to tissues removed during two PM examinations were traced from the mortuary register to the paper and computer records in the histopathology laboratory. Paper and computer records including the Coroner's authorisation form, disposal/retention of tissue forms and disposal records in the computer database used to track tissue samples and organs removed during PM examinations were reviewed. There were no discrepancies and tissues were identified for disposal in accordance with the wishes of the next of kin. A completed consent form for a hospital PM examination was also reviewed.

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

All applicable HTA standards have been assessed as fully met.

Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	GQ1	The DI is advised to consider amending the following SOPs when they are next reviewed: • Mort 0007 - Bodies received into the mortuary; to include current practice such as the same name check of bodies when they are received into the mortuary and yellow card system used to label bodies. • Mort 0039 - Release of bodies; to include current practice such as the use of the yellow card system to label bodies 'not to be released'. • Mort 0043 – Removal of tissue for donation; to replace the phrase 'lack of objection' with 'consent'.
2.	GQ8	The DI is advised to review the risk assessments relating to staffing levels in the mortuary on a regular basis during this period of organisational change to ensure that staffing levels are adequate and the establishment is able to maintain the level of PM activity required.
3.	PFE1	The new purpose built mortuary is away from the main hospital building and surrounded by a building site which will in the future be developed into new hospital buildings as part of the hospital upgrade. The DI is advised to ensure that the intruder alarm system is tested regularly as the building site is easily accessible.
4.	PFE2	The mortuary has new fridges and freezers which have continuous digital temperature recording and monitoring, and an alarm system that alerts the hospital switchboard. The DI is advised to check that the fridge and freezer temperature local audible alarms are in working order as it was not clear if they had been checked following installation.

Concluding comments

The HTA found the new mortuary premises to be suitable. The DI, pathologists, pathology service manager, Coroner's officers and staff in the mortuary and histopathology laboratory work well together as a team. Staff at the establishment hold regular meetings with the Coroners and there was evidence of good communication with Coroner's officers.

There were several examples of good practice. The establishment has an HTA working group which meets regularly to discuss issues relating to post mortem activities and links in with the All Wales DI group. The establishment has implemented a documented name check to confirm the identity of the body before commencing a PM examination. There is an appointment system to release bodies to Funeral Directors. All porters are trained by mortuary staff before they are allowed to transfer bodies to the mortuary and training is recorded. The traceability system at the mortuary is underpinned by labelling each body and all tissues from the body with the same unique number.

The mortuary uses a 'yellow card' system to alert staff when a body is not to be released, for example, when the wishes of the next of kin in relation to tissues removed during PM examinations have not yet been received. There is a comprehensive programme of audits including audits of bodies stored for more than seven days, cleaning, tissues in storage as well as audits focussing on practices such as reconstruction of bodies. There was evidence of continuous improvement such as plans to issue feedback questionnaires on the service provided by the mortuary to funeral directors in order to improve the standard of services provided.

The HTA has given advice to the DI with respect to extending the range of risk assessments and additional checks on new equipment which has been installed in the mortuary.

Report sent to DI for factual accuracy: 5th March 2013

Report returned from DI: 12 March 2013

Final report issued: 20 March 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.

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 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.