Site visit inspection report on compliance with HTA minimum standards

University Hospital of Wales

HTA licensing number 12163

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 September 2012

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.

Although the HTA found that the University Hospital of Wales (the establishment) had met the majority of the HTA standards, two minor shortfalls were found in relation to the consent and premises, facilities and equipment standards. The establishment has designed a consent training programme for professionals who take consent for adult post-mortem examinations, but this has not been put into practice. There are no procedures in place during weekends and public holidays to monitor the temperature of the fridges and the walk-in cold room used to store bodies in the mortuary.

Overall, since the previous HTA inspection in September 2009, a great deal of work has been done to meet HTA standards, and the HTA recognises the commitment to continuous improvement shown by staff at University Hospital of Wales.

The establishment uses a barcoding system to track bodies, tissues removed during post-mortem (PM) examinations and tissues and organs received by the establishment for

specialist examination. A designated member of staff (Organ Retention Officer) is responsible for ensuring that tissue samples are retained only in accordance with the consent given and that all other tissue samples are disposed of. The use of checklists before and after PM examinations helps to ensure that the identity of bodies, consent given, the extent of the PM, and any infection risks, are checked before any PM examination is undertaken. Similarly, it ensures that all tissue removed during a PM examination is correctly labelled with the unique barcode and other identifiers as appropriate. Other 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 the establishment and description of inspection activities undertaken

University Hospital of Wales (HTA licensing number 12163) is licensed to carry out PM examinations and the removal and storage of PM tissue for use for scheduled purposes under the HT Act. The corporate licence holder is Cardiff and Vale University Local Health Board, which also holds the licence for the mortuary at University Hospital Llandough (HTA licensing number 12210).

The establishment undertakes around 500 PM examinations each year, which include over 200 examinations on behalf of fourteen Coroners, including HM Coroner, Gloucester District,

and HM Coroners in Wales. Of these, there are around 100 forensic PM examinations, 100 paediatric PM examinations and around twenty PM examinations to confirm cases of neurodegenerative disease or Creutzfeldt-Jakob Disease. High risk PM examinations are usually undertaken in the forensic suite. However, both autopsy rooms in the mortuary meet standards required for high risk PM examinations. Staff are trained to handle such cases and are provided with appropriate protective equipment such as full face visors and steel mesh gloves. The establishment is a referral centre for neuropathology, and brain tissue is occasionally removed with consent.

The mortuary is staffed by four Anatomical Pathology Technologists (APTs). The mortuary manager line manages staff at this site and at University Hospital, Llandough. PM examinations are undertaken by pathologists based at University Hospital of Wales and visiting 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 following a PM examination. Each Coroner uses their own form to record the wishes of the next of kin together with the name of the person who stated the wishes and their relationship to the deceased. The forms vary in the amount of detail provided to the next of kin regarding disposal of tissues.

All bodies in the mortuary are labelled using a unique barcode label which is fixed to a wrist band. APTs receive and register bodies which are brought to the mortuary by Funeral Directors during the working week and after hours. Hospital porters bring bodies from the hospital and record details in the mortuary register if the bodies are 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 University Hospital of Wales was undertaken on 6th September 2012. This was the third inspection of the establishment and included interviews with the Head of Service for Histopathology (DI), Senior Lecturer in Neuropathology, Mortuary Manager, the Senior Nurse, Bereavement Services and an APT.

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

An audit trail was undertaken of two bodies stored in the mortuary. Details in the mortuary register, name, unique barcode, storage location and identity tags were checked; in the case of one of the bodies, the barcode label on the wrist tag was not present (see item 3 in the Advice section). No other discrepancies were noted. Records relating to three PM examinations - one adult consented PM examination, a consented paediatric PM examination and a PM examination authorised by the Coroner - were traced from the mortuary register to stored blocks and slides or disposal records as appropriate. Scanned records, including the Coroner's authorisation form or consent form as appropriate, disposal/retention of tissue forms and disposal records in the mortuary database system were reviewed. One of the cases included records of the return of tissues to the body. The number of blocks and slides relating to each case was checked against the computer records. Two discrepancies were noted – one related to the date of the PM examination and the other was a missing page on the scanned copy of the consent form (see item 2 in the Advice section). There were no other discrepancies.

The establishment provides training for staff who take consent for adult PM examinations. Following the inspection, the establishment provided evidence that Pathologists and the lead

Bereavement Nurse have received training in taking consent. A 'lean' consent training package for clinicians was recently developed and is available on the establishment's intranet. Clinicians can access the training module and complete it before they take consent. Staff who seek consent for paediatric PM examinations also receive training in taking consent. There is an all-Wales list of persons who have received training in taking consent for paediatric PM examinations and this list is checked before the establishment accepts consent forms for paediatric PM examinations.

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

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	Staff in the mortuary monitor and record fridge and freezer temperatures during the working week. A local alarm system is in place which has been tested. The alarm is not detected remotely and there is no procedure in place to monitor the temperature of fridges, freezers and the walk-in body storage room, or respond to any alarms during weekends and public holidays. The mortuary has storage space for at least 100 bodies with the potential to store more bodies in the walk-in cold room, and acts as the contingency store for University Hospital Llandough. The absence of effective temperature monitoring during weekends and public holidays increases the risk to the dignity of the deceased and the outcome of PM examinations, should a fridge failure cause bodies to decompose. *Following the inspection, the establishment conducted a risk assessment of the risk to bodies and tissues stored in fridges and freezers in the mortuary and is taking corrective action.*	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ4	The DI is advised to implement regular audits of computer records relating to PM examinations and tissue samples in the histopathology laboratory. During the inspection two discrepancies were noted between the paper records and the computer records. Regular audits of records take place within the mortuary.
2.	GQ6	The DI is advised to review the barcode labels which are attached to wrist bands on bodies in order to ensure that the adhesive on the labels is resistant to moisture and the labels do not easily come off the wrist band.
3.	GQ8	The DI is advised to increase the range of risk assessments relating to the safety and security of bodies and tissues stored in the mortuary, and undertake risk assessments against each of the categories of serious untoward incident listed in the HTA's Guidance for notifying the HTA of serious untoward incidents in the PM sector – see http://www.hta.gov.uk/_db/_documents/Guidance_Document_-_SUI_Notification_201112192847.pdf
4.	D2	The establishment uses a database (Mortuary Database System) linked to the unique barcode number in order to track the status of tissues. The DI is advised to put a schedule in place in order to ensure that the status of tissue samples is checked regularly and tissue samples are disposed of in a timely fashion once they are no longer needed, for example when the coroner's or police authority ends or consented post-mortem examination is complete.

Concluding comments

The DI, pathologists, pathology service manager and staff in the mortuary and histopathology laboratory work well together as a team. There were several examples of good practice. The traceability system at the mortuary is underpinned by labelling bodies and all tissues from a body with the same unique barcode label, the use of a checklist before and after PM examinations to ensure accuracy of labelling and the use of the 'tissue from the deceased worksheet 3', which consolidates records relating to tissues and organs removed, disposal wishes, date of completion of case as well as date of disposal of tissues. The establishment uses a computer database (Mortuary Database System) to track tissue samples and organs removed during PM examinations.

The mortuary uses a colour coding system where the instruments and bowls associated with each of the five work stations is labelled with a specific colour. This reduces the risk of any mix-up of tissues when more than one PM examination is undertaken at the same time in the mortuary.

There are some areas of practice that require improvement. The HTA has given advice to the DI with respect to extending the range of risk assessments undertaken by the establishment, to extend the audit of records undertaken and to implement a schedule to check the status of tissues in order to ensure that timely disposal of tissues takes place.

The HTA requires that the Designated Individual addresses the shortfall 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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 25 September 2012

Report returned from DI: 15 October 2012

Final report issued: 2nd 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: 18 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.

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.