Site visit inspection report on performance against HTA quality standards
Glangwili Hospital
HTA licensing number 12136

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**

8 and 9 November 2011

Executive Summary

A site visit inspection of Glangwili Hospital (the establishment) was carried out by the HTA on 8 and 9 November 2011.

The establishment was found to meet the majority of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment and disposal, but some shortfalls were found in relation to the governance and quality standards. Examples of strengths or good practice are included in the concluding comments section of the report.

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

Glangwili Hospital (the hub) has a mortuary where both coronial and hospital (consented) post mortem (PM) examinations are carried out. Cases with a known high risk such as HIV, TB and CJD are not routinely examined at the establishment; however, the mortuary includes a dedicated high risk PM examination suite. Paediatric PM examinations are not performed at the establishment.

The establishment holds a satellite licence for premises at Prince Phillip Hospital, Llanelli. Occasionally and currently, due to staffing constraints, PM examinations are not being undertaken at the satellite site, although licensable activities take place in the body store and histopathology laboratories. Bodies requiring PM examination are transferred from there to the hub site.

Processing of post mortem tissue into blocks and slides is carried out at the satellite site, tissue samples being transferred there using the hospital courier. Once processed into blocks, slides are cut and returned to the respective pathologists, based both in the hub and satellite sites for review; blocks remain in storage at the satellite site. Once reviewed by the pathologist, slides are stored at the pathologist's site with slides currently being stored at both the hub and satellite premises.

This was the second site-visit inspection of the establishment and was a routine inspection to assess whether it is continuing to meet the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's recent self assessment compliance information and audit of stored material, as well as pre-inspection discussions with the Designated Individual (DI) and review of the previous inspections findings. During the site visit, a visual inspection of the premises, review of documentation and interviews with establishment staff were undertaken.

At the hub premises, an audit of two bodies in the body store was undertaken. Identification details contained on body tags were checked against details in the mortuary register and on the mortuary fridge doors; no anomalies were found. All bodies admitted into the establishment are assigned a unique mortuary 'M number'. Bodies that undergo PM examination are also given a unique PM number and in addition, if histology is taken, a histology 'A number'. These numbers are recorded in the establishment's electronic database.

Details of two PM examinations (one coronial and one consented) were also taken and records of tissue that had been retained were reviewed. Slides were stored at the hub site and all were correctly recorded in the establishment's Laboratory Information Management System (LIMS). The number of physical slides also matched the electronic records. Signed consent forms and coronial forms were reviewed and no anomalies were found. A reverse audit of slides in the slide archive was also undertaken. A sample of slides which were stored and slides that had been disposed of was reviewed. The slides that had been disposed of were identified via a record slip which is placed in the slide archive whenever slides are removed for disposal. Again, records of slide storage and disposal were correct in the LIMS and no anomalies were found.

A similar audit exercise was undertaken at the satellite premises. Two bodies were audited in the establishment's body store and two coronial PM examinations where tissue has been taken were reviewed. In addition, blocks were sought from the PM cases where tissue had been retained during PM examination at the hub premises, since they are stored in the satellite's block archive. No anomalies were found.

The DI confirmed that removal of tissue from bodies of the deceased does not take place in other areas of the hospital. However, staff in the maternity department may seek consent for

hospital PM examinations of deceased infants that are transferred to other establishments (see advice below).

The establishment has commenced operations in a brand new mortuary facility at the hub premises since the last inspection. Although there is some advice given below regarding temperature monitoring of the storage facilities, the new premises are of a high standard. The satellite premises are older, but they remain in good general order and of a standard that is suitable for the undertaking of licensable activity.

During the inspection, the HTA learned that the establishment has routinely been storing tissue blocks and slides for a period of 15 years under the authority of the previous coroner. The new coroner, who at the time of the inspection had only been in post for one week, has indicated that the 15 year retention period should no longer be applied to post mortem tissue. The HTA advised the Designated Individual to liaise with the coroner to clarify action to take in relation to the current tissue store and to seek further advice from the HTA as necessary.

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 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

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit	At the time of the inspection, the establishment had not been undertaking any audits of processes or traceability. These help ensure that the establishment's systems are performing as intended and that procedures are being followed. A new member of staff has recently joined the department who will be responsible for quality management and a comprehensive schedule of audits is planned; however, no audits have yet been undertaken.	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	Not all staff at the establishment receive regular appraisals, which are important for monitoring performance, identifying training needs and ensuring continuous development.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately	The establishment is currently rotating staff between the hub, satellite and another licensed establishment within the same Health Board. Following an internal investigation into a previous Serious Untoward Incident (SUI), staff shortage was identified as being a contributing factor. The establishment has additionally identified staff shortage in its risk assessments as leading to an increased risk of errors occurring or procedures not being followed. Although the temporary cessation of performing PM examinations at the satellite site, the rotation of staff between sites and the future, temporary appointment of a locum APT will mitigate some of the risks, a formal staffing needs analysis has not been undertaken. The establishment therefore has no formal measure of how staff absences either through leave or sickness can be covered and what impact these may have on service provision. The HTA is concerned that although risk assessments have been undertaken, which have identified staffing levels as having a potential to increase the risk to the establishment's operations not being undertaken appropriately, identified risks have not been escalated or added to the Hospital's overall risk register.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The coronial 'family's-wishes' form option for retention of tissue taken during PM examination for future uses states that tissue will be retained as part of the deceased's 'medical record'. The DI is advised to liaise with the coroner in order to clarify the term 'medical record' and that if tissue is being retained, then it is being retained for use for a scheduled purpose.
2.	C1	Staff in the maternity department seek consent for PM examination. The staff have received training from the licensed establishment where the paediatric PM examinations are performed. The DI has not identified a member of staff within the maternity department who can act as a lead person. By identifying a lead person, the DI will be able to update staff of changes in practice and alerts from the HTA in addition to being updated himself about any changes in practice. The

		DI is advised to nominate a person designate to provide a link to the consent seeking activities.
3.	GQ1	During the inspection the HTA observed that some procedures had been written for reference purposes and attached to the mortuary wall. These do not form part of an SOP and are not subject to document control. The DI is advised to include these 'work instructions' within the relevant SOPs so that they may be reviewed in line with the establishment's review processes and updated as necessary. This will help to ensure that no uncontrolled documents are in circulation and that work instructions are updated as processes change.
4.	GQ1	The HTA observed that some SOPs do not reflect current practice. For example, the cleaning SOP does not stipulate that disinfectant is always made freshly prior to cleaning. The DI is advised to review the establishment's SOPs to ensure that they reflect working practices. The HTA understands that the establishment will be moving document management into Q-pulse. This transition will provide a good opportunity to review the SOPs.
5.	GQ1	Although staff were able to describe procedures for moving bodies to funeral directors and other mortuary premises, the establishment has no documented contingency procedure to cover the eventuality of the body store reaching full capacity. The DI is advised to document the arrangements that are in place. In addition, the DI is advised to complete the business continuity plan covering service continuity arrangements in the event of a major incident, which has not been completed with all the relevant details, for example contact numbers.
6.	GQ3	From speaking with newer members of the establishment's staff, it was evident that there is a good system of induction consisting of shadowing more experienced colleagues and working under close supervision until the trainee is competent to undertake work alone. Although good training is being delivered, it is not recorded in the trainee's training and development folder. The DI is advised to document when training is undertaken and in addition to develop a system to record when trainees become competent in a particular aspect of their work.
7.	GQ4	During the inspection, the use of correction fluid in the mortuary register was observed. The DI is advised to ensure that correction fluid is not used to correct transcription errors. Any errors should be struck through with a single line so that the original record is still readable. In addition, examples of records were seen where practices had changed but the forms used to capture information had not been updated. An example of this is the establishment's 'Mortuary Admission' forms used at the satellite site. The forms contained blank fields for information that was collected in the past but now is no longer recorded on these forms as it is recorded in other systems. The DI is advised to review the forms in use to ensure that they still meet the establishment's requirements and where applicable, amend them.
8.	GQ6	The establishment uses record slips in the slide archive to identify where slides have been removed and disposed of. However, these slips do not record the number of slides that were removed from the archive, although a record is kept in the establishment's LIMS. The DI is advised to record the number of slides that are removed for disposal when using the record slips in the slide archive.
9.	GQ7	The establishment has a newly developed SUI SOP in place however this SOP does not capture all of the SUI categories or who may notify the HTA of SUIs in the DIs absence. The DI is advised to update this SOP so that all SUI categories

		are included and details of who will notify the HTA of SUIs in the absence of the DI are included.
10.	PFE2	Regular cleaning takes place within the mortuary at both the hub and satellite sites. However, cleaning is not recorded at the satellite site. The DI is advised to ensure that when cleaning of the mortuary is undertaken it is recorded.
11.	PFE3	The establishment has a fridge which is used for the storage of products of conception (POCs) and stillbirths, which is separate from the main bank of body storage. This separate fridge is currently not included in the establishment's electronic temperature monitoring and alarm system. During the inspection, staff indicated that POCs and stillbirths could be stored within a dedicated area of the main bank of body storage until the separate fridge is alarmed. The DI is advised to include the separate storage fridge in the electronic temperature monitoring and alarm system.
12.	D1	The establishment's disposal policy only references disposal of blocks and organs. The DI is advised to amend the policy to include the disposal of slides since these are classified as relevant material under the Human Tissue Act 2004.
13.	D2	The establishment records the method and date of disposal in addition to the numbers of blocks and slides that are disposed of. The reason for disposal however is not recorded. The Di is advised to record the reasons for disposal when it takes place.

Concluding comments

Areas of good practice were observed during the inspection, some examples of which have been included below.

The APTs at the establishment spend a lot of time guiding the relatives of the bereaved through the various processes following a bereavement such as viewing bodies, dealing with the coroner and registering the death and advising on organising funeral directors. In performing this 'Relative Services' role they provide a single point of contact to the relatives which they believe is of great help and comfort to the recently bereaved.

In addition the APTs are part of the consent process and use their knowledge of post mortem work to aid in providing relevant information to the consent giver.

Report sent to DI for factual accuracy: 6 December 2011

Report returned from DI: 16 December 2011

Final report issued: 10 January 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: 01 June 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.