Site visit inspection report on compliance with HTA minimum standards

Glangwili General 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**

10&11 February 2016

Summary of inspection findings

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

Glangwili General Hospital (the establishment) was found to have met all applicable HTA standards. The HTA has given advice to the DI with respect to consent, document management and control, staff training, tissue traceability and mortuary contingency arrangements.

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 Section 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

The establishment has been licensed by the HTA since July 2007 for the making of a post mortem (PM) examination, removal of relevant material from the deceased and storage of the deceased and relevant material for use for scheduled purposes.

Glangwili General Hospital (the hub) is based in Carmarthen. The mortuary at Withybush General Hospital (the satellite), part of the same Health Board, is licensed for the same activities. The mortuary at the hub undertakes approximately 600 adult post mortem examinations per year, most of which are carried out under the jurisdiction of the Pembrokeshire and Carmarthenshire Coroner. The establishment does not undertake paediatric PM examinations or any where there is a known high risk of infection. As part of the planned contingency, autopsies can be carried out at the maintained satellite site at Withybush General Hospital. This autopsy suite has been used once since the last HTA visit when there was flooding at the hub autopsy suite.

The establishment is staffed by nine full time staff working across the mortuary/body store area and the licensed mortuary sites are staffed by seven permanent members of staff, one of whom is the mortuary manager. There is storage space for 35 bodies at the hub site including 28 (x 750mm) standard spaces, 3 bariatric spaces and 4 potential (x 750mm) isolation units. There is storage space for 25 bodies at the satellite site including five spaces which can act as freezer and isolation units. The Health Board has four General Hospitals, where two of the Hospitals have unlicensed body stores. At one of these Hospitals, there are 18 (x 600mm) body stores including 3 optional isolation units. The other Hospital site has body storage for 20 bodies. Therefore, in summary, the Health Board across the four General Hospitals has body storage for 98 bodies and includes storage spaces for 3 bariatric bodies, 9 potential freezer units and 12 potential isolation units. A portable refrigeration system is

currently on temporary short-term lease within the mortuary suite at the hub site providing additional storage space for 12 bodies. The need for further permanent body storage spaces is being actively pursued with the Health Board Capital Programme (see advice item 11).

Within the post-mortem suite at the hub site there are two post-mortem tables with dedicated tissue preparation areas. There is a separate isolation room with a single post-mortem table where any high-risk autopsy examinations are performed. Following PM examination, retained tissue may, with appropriate consent, be stored for use for a scheduled purpose in the histology laboratory or in a dedicated storage facility on the hospital premises. Currently all specimens for toxicological examination, usually at the request of the Coroner, are sent to another establishment. Routinely organs are not retained for further examination. Very infrequently organs may be retained for referral to specialist centres at the request of the family of the deceased or the Coroner (see advice item 8).

Bodies admitted to the mortuary during office hours are dealt with by mortuary staff, who check identification details and log details of the deceased in the mortuary's records. Outside routine mortuary hours all bodies are received to the body stores by the portering staff. Portering staff evaluate each case and in certain community cases the anatomical pathology technician providing the 'out of hours' service may be called in to receive the body. Only portering staff and mortuary staff have access to the otherwise secure facilities at all mortuary/body stores. Those admitting bodies to the mortuary/body stores in 'out of hours' periods complete a 'body receipt form' providing relevant information of the deceased for the mortuary staff/anatomical pathology technicians when they attend the next working day. The anatomical pathology technicians clarify details with the Coroner service on bodies brought in dead in the 'out of hours' period. All bodies brought to the mortuary/body stores have either an ankle or wrist band with the deceased's name and age together with place and date of death.

This was the third routine inspection of the establishment, the previous inspection having been carried out in 2011. The inspection comprised a visual inspection of the premises, including the mortuary and maternity department at the hub and the satellite sites, histopathology laboratory, a document review and interviews with key staff, including mortuary staff, maternity ward staff and Cellular Pathology Laboratory staff.

A traceability audit was conducted for three bodies in storage at the hub site and their identity and location compared with entries in the mortuary register. No discrepancies were found. A traceability audit was also conducted for two bodies in storage at the satellite site. No discrepancies were found.

Blocks from two coronial PM cases were located in the laboratory information management system (LIMS) and tracked back to storage to ensure consistency of recording and appropriate consent. Blocks from a further two cases were traced from storage to the management system. A discrepancy was identified for one of the cases, where five slides could not be located in storage following completion of the pathologist's report (see advice item 10).

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.	C1	The DI is advised to update the current flowchart used for consent for hospital PM examination, to reflect differences in process and documentation for seeking consent for adult and paediatric cases; they should also consider incorporating this flowchart into the document control system.
2.	GQ1	Although staff at the establishment carry out identification checks using at least one unique identifier prior to PM examination, viewings or release of a body, this is not accurately described in the relevant SOPs. The DI is advised to update all relevant SOPs to include specific details of unique identifiers used by mortuary staff to identify the deceased and mitigate the risk of error.
3.	GQ1	Although bodies are rarely moved into the freezer storage available, there is currently no formalised process detailing under what circumstances this will occur. The DI is advised to develop appropriate documentation, detailing when a body should move from fridge to freezer storage, what records should be made to maintain traceability and any other arrangements that would be required. The HTA recommends that bodies are moved into freezer storage after 30 days if there is no likelihood of their imminent release.
4.	GQ1	Although appropriate identification checks are in place prior to evisceration, and involve both the APT and the pathologist, these are not currently recorded. The DI is advised to implement a system to ensure that body identification prior to evisceration is adequately recorded.
5.	GQ2	When changes are made in the mortuary register, these are occasionally not initialled or dated, which could compromise record accuracy. The DI is advised to ensure that members of staff who may make changes to the register include their initials and the date; audits of the register should be carried out periodically to check practice.
6.	GQ3	The DI is advised to ensure that as part of their induction, porters at both sites are reminded that they are required to familiarise themselves with all relevant SOPs and policies, and that when these are updated, they need to acknowledge that they have read the updated document version by signing the associated acknowledgement sheet.
7.	GQ3	The DI is advised to enhance training opportunities for mortuary staff, particularly for external training. For instance, mortuary staff could attend the AAPT annual conference or bereavement training courses, to increase awareness and experience.
8.	GQ6	Toxicology samples are sent from the autopsy suite at request of the Coroner to an off-site establishment for toxicological investigation, and there is currently no notification system in place to confirm sample receipt by the other establishment. In addition, the establishment responsible for sample analysis is not notified when samples are sent, increasing the risk of traceability loss. The DI is advised to implement a tracking system to ensure that receipt of toxicology samples is confirmed and recorded, to ensure that sample traceability is maintained.

9.	GQ6	Staff in the maternity department of the satellite site are committed to maintaining traceability of samples taken at the department, which will be further reinforced by the implementation of the Trust-wide policy currently in development. The DI is advised to appoint named Persons Designated in the maternity department at the hub and the satellite sites. This will help with governance of licensed activities and maintenance of traceability of samples collected within those departments and arrangements for storage prior to movement to the mortuary. In addition, the Persons Designated could ensure that appropriate systems are in place for temperature monitoring of the fridge used for storage of samples taken within the department, and that an appropriate risk assessment has been carried out for these activities.
10.	GQ6	During one tissue traceability audit, five slides could not be located. The DI is advised to monitor the return of material used by pathologists back to storage.
11.	PFE3	Current mortuary contingency arrangements involve the use of a portable refrigeration system, which is currently on temporary lease within the mortuary suite at the hub. The system is not connected to an alarm and the temperature is not monitored at the weekend, which increases the risk of an adverse event taking place, particularly as the system is constantly in use and a potential failure may not be detected promptly. The DI is advised to consider what options are available to permanently increase fridge space both at the hub and the satellite premises, to ensure that bodies are kept at appropriately monitored conditions at all times.
12.	-	The DI is advised to encourage current Persons Designated to request HTA portal access, in order that they can report any HTA reportable incidents when required.

Concluding comments

This report describes the third HTA site visit inspection of the Glangwili General Hospital. During the inspection, several areas of strength were observed.

The team is committed to ensuring that the dignity of the deceased is maintained and staff members work together to ensure that body release for burial or cremation is expedited as quickly as possible. The bereavement service is comprehensive and caring, aiming to provide extensive support to families throughout the process.

There is a rigorous audit schedule, which includes frequent horizontal and vertical audits.

The HTA has given advice to the DI with respect to consent, document management and control, staff training, tissue traceability and mortuary contingency arrangements.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 7 March 2016

Report returned from DI: 31 March 2016

Final report issued: 31 March 2016

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.

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 and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- 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 outlines 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.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

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.