Site visit inspection report on compliance with HTA minimum standards

The Princess of Wales Hospital
HTA licensing number 12173

Following this HTA inspection, Princess of Wales Hospital (HTA licence 12173) has become of satellite under Morriston Hospital (HTA licence 30015). Details for both hospitals are therefore now under HTA licence 30015.

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**

17 February 2016

Summary of inspection findings

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.

Although the HTA found that the Princess of Wales hospital had met the majority of the HTA standards, two minor shortfalls were identified in relation to the lack of audits within the mortuary and the condition of the floor in the post mortem (PM) suite.

Particular examples of strengths and good practice are included in the concluding comments section of the report, along with advice and guidance on how to improve systems further.

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 (DI) are set down in Section 18 of the Human Tissue Act 2004 (HT Act). 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 Princess of Wales Hospital in Bridgend (the establishment) is one of four hospitals that form the Abertawe Bro Morgannwg University Health Board. The establishment has been licensed by the HTA since 2007 and this was its third routine inspection, the last being in 2013.

The establishment conducts approximately 350 adult PM examinations each year. High risk, Home Office and perinatal/paediatric cases are transferred to other HTA-licensed establishments for PM examination. The majority of PM examinations undertaken at the establishment are performed under coronial authority.

Consent for occasional adult hospital PM examinations is sought by trained mortuary staff, using a PM examination specific consent form with an information leaflet about the process so next of kin have enough information to make an informed decision and are given the opportunity to ask questions. The establishment only conducted one hospital PM examination in the year prior to inspection.

The mortuary is located in a separate building on the hospital site, secured by locked doors with keyfob access and an intercom system which identifies visitors prior to entry. There is

closed-circuit television (CCTV) monitoring of the building entrances and the body store area. The mortuary also has an alarm which is activated at 17.30 each evening and over the weekend; the porters' keyfobs can de-activate the alarm to allow them to enter out of hours. Internal doors from the main reception area and the viewing suite all have pincode locks.

The mortuary receives bodies from the hospital and the community. Bodies from the hospital have printed hospital identification wrist tags, including the patient's unique hospital number. Additionally porters bring one of the ward patient labels with the body, which helps prevent difficulties relating to handwritten documentation. Bodies admitted from the community have identity tags attached by the police. Establishment staff come to the mortuary for out of hours community admissions and will not accept a body without the identification tag.

The establishment uses a series of forms and an electronic database to record the details of body admission, PM examination and release to a funeral director.

The mortuary has 68 fridge spaces, including eight spaces for bariatric bodies. A designated bank of fridges can operate in freezer mode should bodies require longer-term storage. Perinatal/paediatric cases are stored on dedicated trays within the adult fridges. The establishment has contingency arrangements for the storage of bodies at a nearby hospital, including storage of bariatric cases. The contingency plan has never been used. Storage temperatures are continually monitored and there is an automated alarm call-out procedure in the event of temperature deviation.

The PM suite has three tables, none of which are height-adjustable. A secure platform provides staff the means by which they can gain a better height to perform PM examinations. Only one dissection bench is used, with a one at a time system in place to avoid any mix up of organs. Tissue samples taken for histopathological analysis are put in cassettes in a dedicated room and transferred to another HTA-licensed establishment for processing. Blocks and slides are returned to the establishment for storage or disposal depending on the family's wishes. The establishment maintains records of PM samples on an electronic database.

Bereavement services are situated in the same building as the mortuary and have a close working relationship with mortuary staff. They arrange viewings with families and escort them to the viewing suite. The viewing room has a pull cord alarm for family to alert mortuary or bereavement staff if they require assistance. Viewings are generally done during office hours; however, there are occasional out of hours viewings. Currently there is no system in place to address potential risks to staff safety on these occasions (see advice item 4).

This report describes the third, routine site visit inspection of the establishment. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted a visual inspection of the mortuary. In the mortuary, storage locations for three adult bodies were checked against paper and electronic records. The traceability records and stored tissue blocks for one hospital and two coronial examinations were also audited. No anomalies were identified.

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

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.	As part of its SOP review, the establishment conducts process audits and staff audit tissues stored against the wishes of the family. However, there is no documented audit schedule and many areas of mortuary practice remain unaudited (see advice and guidance 2 below).	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are fit for purpose.	There are cracks around the plinth at the base of one of the PM tables and at the base of a dissection table. The cracks are wide enough for material to get lodged and difficult to clean thoroughly.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	Staff within the mortuary have regular minuted meetings, the DI is advised to attend these meetings where possible to ensure that matters relating to regulation and the conduct of licensed activities are included.
2.	GQ2	In establishing a schedule of regular audits, the DI should ensure that follow-up actions and timeframes for completion of actions are included in audit documentation.
3.	GQ6	There is a system in place to highlight bodies with the same name. The DI is advised to consider extending the system to also highlight similar or similar sounding names to mitigate the risk of release of the wrong body.
4.	GQ8	Risk assessments are included in the establishment's procedural documentation and address health and safety risks and some risks to the deceased such as PM examination on the wrong body. However there are a number of risks that are not considered and the DI is advised to consider the HTARI categories when reviewing risk assessments to ensure all possible risks, such as accidental damage, are considered.

5.		Out of hours viewings are rare but currently there is no system in place to ensure the safety of staff when they do occur. The DI is advised to implement a suitable process to protect them when alone for viewings.

Concluding comments

Despite the shortfalls identified, many areas of strength and good practice were observed.

The establishment uses an electronic database, developed in-house, to track bodies and tissue samples retained during PM examination. Images can be attached to individual records in the database and a copy of the signed form with the family wishes, in relation to tissue removed during PM examination, is attached to the relevant record. This assists staff in ensuring any tissues retained are done so in line with the wishes of the family. Colour coding is used on the spreadsheet so, at a glance, staff can clearly see what tissue needs to be disposed of. An electronic signature is also recorded to demonstrate the two person identity check undertaken before each PM examination.

The porters bring one of the ward hospital tags down to the mortuary with each body, which negates any possible transcription errors that may occur when information is being handwritten by the care after death staff on the ward or by the porters.

There is clear signage for porters and funeral directors just as they enter the body store area that has key process reminders.

The certificate number from the ‘green form’ is written in the mortuary register before a body is released, which serves as an additional check that the funeral director is the one chosen by the family and that staff have looked at the relevant documentation before release.

Staff have a good relationship with the coroner’s office and work closely to ensure bodies are released in a timely manner. Mortuary opening hours include Saturday mornings which also helps facilitate viewings and collection of the deceased.

Staff training is comprehensive and staff are given the opportunity to attend internal and external training to enhance their skills.

There are some areas of practice that require improvement, including two minor shortfalls. In addition, the HTA has given advice to the DI on a range of issues, including consent, governance and quality systems, storage facilities and disposal.

The HTA requires that the DI addresses the shortfalls 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 shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 14 March 2016

Report returned from DI: 31 March 2016

Final report issued: 1 April 2016

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: 21 October 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.

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 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 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. • 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.