**Site visit inspection report on compliance with HTA minimum standards**

**Leighton Hospital**

**HTA licensing number 12145**

**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 June 2015**

## Summary of inspection findings

A site visit inspection of Leighton Hospital (the establishment) was carried out by the HTA on 10 June 2015.

Although the HTA found that the establishment had met the majority of the HTA standards, three minor shortfalls were identified in relation to documented risk assessment, audit and fridge monitoring.

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.

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

Leighton Hospital is part of Mid Cheshire Hospitals NHS Trust and has been licensed by the HTA since 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. The pathology departments at this establishment and Macclesfield General Hospital (licence number 12411) have formed a working partnership, Cheshire Pathology Services, for the provision of services across both sites. Pathology staff and the Senior Anatomical Pathology Technician (APT) work at the two establishments.

The establishment conducts approximately 550 adult coronial PM examinations each year. High risk, perinatal/paediatric cases are transferred to other HTA-licensed establishments for PM examination. Staff at the establishment seek consent for perinatal/paediatric hospital PM examinations using the consent form and information leaflet provided by the Stillbirth and Neonatal Death (Sands) charity.

Hospital consented PM examinations are rare, with only one in the previous 18 month period. Consent for an adult hospital PM examination is usually sought by junior doctors, who receive consent training during their induction; however, due to short rotation periods, they often do

not have specific PM consent training. Arrangements for seeking consent for a hospital PM examination are currently being reviewed (refer to advice item 2).

The mortuary is part of the main hospital building. Entrance from the hospital is secured by swipe card access. Funeral directors have their own entrance, which is under cover and protected from sight. This entrance is locked and CCTV cameras allow staff to see who is at the door before releasing it.

The mortuary receives bodies from the hospital and from the community. Bodies from the hospital have printed hospital identification wrist tags and are brought to the mortuary with a 'Body Acceptance Form'; both the tag and this form include the patient's name, date of birth, home address and unique hospital number. The first part of the form is completed on the ward and the second part completed by the porters in the mortuary, where they confirm that they have checked the identity details of the deceased, which fridge compartment they have placed them in and have written the details on the white board. The porters also complete and sign the mortuary register. Bodies admitted from the community are brought in by funeral directors.

There is a 'Body Release Request Form', signed by the next of kin or an executor, which funeral directors are required to provide to the mortuary before the deceased is released into their care. There were three body releases while the inspection team was on site and they were able to witness the two-person check of identification before release of a body to the funeral director, who is required to sign the mortuary register to confirm receipt of the deceased.

The mortuary has 55 fridges, five of which can be used as freezer spaces if required and five can take bariatric patients. There is an additional storage room, which can be chilled; this has emergency racking for exceptionally busy periods such as at Christmas or if additional bariatric capacity is required. There is a separate fridge for infants and babies.

The adult fridges and the cold room are alarmed, with triggers set for high and low limits and a call-out procedure in the event of temperature variation beyond these. Additionally fridge temperatures are recorded and monitored twice daily by mortuary staff. However the alarms are not tested on a regular basis to ensure they are working as they should. The infant and baby fridge is not alarmed (refer to shortfall against standard PFE1). The establishment has a business contingency plan for the storage of bodies if that were required.

The removal of samples from deceased children in cases of sudden unexpected death in infancy (SUDI) is not performed at the establishment. In these cases, deceased children are immediately transferred to another HTA licensed establishment.

This was the second routine site inspection, the first having taken place in January 2011. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted a visual inspection of the mortuary and PM suite. An audit was carried out against two bodies in the body store and the mortuary register, no anomalies were found. Records relating to three PM examinations (one hospital case, two coronial cases) were audited. No anomalies were found for the coronial cases. For the hospital case it was noted that an out of date version of the PM examination consent form had been used. Also, the family's instructions for disposal of blocks and slides had not been complied with promptly (refer to shortfall against GQ6).

## 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 |
|---|---|---|
| GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail | The establishment uses an audit spreadsheet to track the retention and disposal of PM tissue blocks and slides. However, one hospital PM examination case audited during the inspection had been omitted from this spreadsheet. As a result, the family's instruction for the blocks and slides to be disposed had not been complied with. | **Minor** |
| GQ8 Risk assessments of the establishments practice and process are completed regularly and are recorded and monitored appropriately | Risk assessments cover areas of health and safety but do not address risks to the deceased, such as release of or PM on the wrong body or disposal of tissue samples not in line with the family's wishes. | **Minor** |

### Premises, Facilities and Equipment

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| PFE1 The premises are fit for purpose | The perinatal fridge is temperature monitored twice daily during working hours but not at weekends and is not alarmed. The adult fridge alarms are not tested regularly to ensure they are working properly. | **Minor** |

## Advice

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

| No. | Standard | Advice |
|---|---|---|
| 1. | C2 | The establishment has taken the HTA's Disposal of pregnancy remains guidance into account when making those options available to parents. However the form for parents to sign in relation to the disposal of pregnancy remains has the wording *'I do not object to'* rather than *'I consent to'*. The DI is advised to ensure the form is changed to reflect positive consent to the disposal arrangements agreed. |

| | | |
|---|---|---|
| 2. | C3 | The consent process is currently under review. The DI should give consideration to who can seek consent for hospital PMs and what training, knowledge and experience they are required to have in order to undertake this task. The consent seeker must have good knowledge of what a PM examination involves in order to answer any questions the consent giver may have. The DI should also ensure that only consent forms which are compliant with the consent requirements of the HT Act are available on the Trust intranet. |
| 3. | GQ1 | Some of the SOPs for the mortuary, such as the procedure for identifying the deceased (Mort B012) and security (Mort B010), are comprehensive; however, others require more detail.<br><br>For example the 'Daily routine in the mortuary' document (Mort B002) when describing entering information on to the electronic register states that 'all details should be entered onto the computer' but doesn't clarify which computer, what computer programme or exactly what details should be entered. The SOP also states that Body Release Forms should be filed alphabetically into the folder but doesn't specify which folder and where to find it.<br><br>The DI is advised that SOPs should be reviewed to ensure there is sufficient detail that someone new to the department could easily follow them. |

## Concluding comments

This report outlines the second HTA site visit inspection of Leighton Hospital. In addition to the areas of advice and guidance given, a number of areas of good practice were observed.

The establishment has comprehensive training for new porters, which is supported by a thorough training manual and ongoing assessment of competence. The door from the viewing room to the body store area has a sign that can indicate to staff, funeral directors and any other visitors to the mortuary that a viewing is in progress, this ensures that noise is kept to a minimum while a family are with the deceased.

There is a small white board visitor register at the hospital entrance to the mortuary; anyone entering the mortuary must add their name to it upon entrance and remove it when they leave; this means that at a glance everyone know who is in the mortuary at any given time.

The staff are dedicated to their work, and as there is a joint lead APT with another establishment mortuary staff can work at the other establishment which means there is a wider group of people with knowledge of the local SOPs and practices to provide cover when required.

The governance team have a good overview of HTA issues with regular documented HTA committee meetings.

There are a number of areas of practice that require improvement, including three minor shortfalls. The HTA has given advice to the Designated Individual with respect to consent and governance and quality.

The HTA requires that the Designated Individual 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.

**Report sent to DI for factual accuracy: 29 June 2015**

**Report returned from DI: 9 July 2015**

**Final report issued: 13 July 2015**

**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: 26 October 2015**

## 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.<br>• 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).<br>• 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.<br>• Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event.<br>• 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).<br>• 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.<br>• 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.<br>• Refresher training is available (e.g. annually).<br>• Attendance at consent training is documented.<br>• 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.