Site visit inspection report on compliance with HTA minimum standards

West Suffolk Hospital

HTA licensing number 12242

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**

2 October 2013

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.

The HTA found that West Suffolk Hospital had met all of the HTA standards.

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 licences 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

This report describes a routine site visit inspection of West Suffolk Hospital's mortuary service. The establishment carries out approximately 450-500 post-mortem (PM) examinations a year for HM Coroner, including Home Office cases. It also carries out a small number of hospital PM examinations, two within the last year. Paediatric cases are referred to another HTA-licensed establishment.

Known high risk cases such as Hepatitis B and HIV are carried out by the establishment after the completion of routine cases, and work has recently been done in the post-mortem suite to increase the number of air changes to ten air changes per hour as recommended by HBN 20 HBN20 "Facilities for mortuary and post-mortem room services". Known tuberculosis cases are referred to another licensed establishment.

The post-mortem licence extends to A&E and several paediatric wards, to cover the activity of removal of tissue from deceased children. The inspection therefore comprised a visual inspection of the mortuary, post-mortem suite, Histopathology laboratory and a paediatric ward. In addition, interviews were conducted with the DI, a Pathologist, Persons Desginated and a Coroner's Officer. A traceability audit of bodies in storage and tissue taken during post-mortem was also undertaken. Document review of key standard operating procedures (SOPs), policies and hospital consent forms was also undertaken.

The mortuary is secure with access provision for staff only. Bodies are received into the mortuary from wards as well as the community via a hospital corridor that is occasionally used by hospital staff, patients and visitors. Mortuary staff try to ensure that the corridor is free from visitors upon departure of the funeral directors from the mortuary. Funeral Directors collect bodies during specified hours in the afternoon. Viewings are carried out during normal working hours and over weekends. Trained hospital staff carry out viewings over the weekend and work to a Trust Viewing Policy.

The mortuary body store can accommodate 86 bodies, including up to eight bariatric bodies. There is freezer storage capacity for four. Non viable foetuses, products of conception, still births and paediatric cases are all stored within a separate paediatric body store within the mortuary. All fridge and freezer temperatures are monitored and documented daily by mortuary staff and any fluctuations in temperatures are monitored by the Lead APT. The refrigeration units are fitted with an audible alarm and connected to the hospital's switchboard. The alarm is subject to annual testing by the fridge maintenance company.

During the visual inspection of the mortuary, the HTA observed the receipt of a body brought by two porters from a ward. This was conducted in accordance with the establishment's documented procedure. The HTA also visited a paediatric ward to carry out a visual inspection of the areas where tissues may be removed from infants. The PD demonstrated an understanding of the requirements of the Human Tissue Act 2004 and the establishment's governance systems, and the HTA was satisfied with the arrangements in place covering this activity.

Traceability audits were carried out on two bodies in storage that shared a similar name. Both bodies were identified from their respective mortuary storage locations. The first body was a Coroner's case that had recently had a PM Examination. Tissue was removed for histology purposes for this case. The second body was also identified from storage, however this was a ward death and there was no requirement for a PM examination. Both bodies were correctly labelled with a wrist tag and were in the correct storage locations. The mortuary register demonstrated that both bodies in storage were traceable. A histology traceability audit of the tissue removed from the first body was also carried out. The pathology system demonstrated that two bladder tissue blocks had been processed and were in storage. The supporting paperwork showed full traceability and no discrepancies were noted. A review of the paediatric mortuary register was also carried out; however at the time of the inspection, there were no examples of paediatric cases being sent away for a PM examination or fetal tissue being sent for specialist examination.

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	The fridges are alarmed, connected to switchboard and subject to maintenance and repair work by either the estates department or fridge maintenance company. During the visual inspection, the HTA noted that the alarm trigger temperature was set to 20^0C for one bank of fridges (fridge spaces; 13,14,15 and 16), whilst the other fridges had a lower limit of 2^0C and upper limit of 7^0C in line with documented procedures. This temperatue would likely result in decomposition of bodies if it were left undiscovered, for example over a weekend. The trigger temperature was immediately changed to 7^0C. However, it was unclear what caused the temperature trigger to be set at the higher level and what steps might be taken to prevent this happening again.	Minor

Advice

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

No.	Standard	Advice
1.	GQ1	**There are two pieces of advice and guidance in this section** 1. The DI is advised to review and document the process for identifying the deceased prior to evisceration. It is not clear with whom the responsibility for correct identification of the body lies, given that pathologists only check after the body has been prepared for PM examination in some cases.Currently, two APTs check the name and date of birth of the deceased before eviscerating the body. This arrangement has been agreed with the Pathologists, who have provided documented guidance on the circumstances in which evisceration should not take place in their absence. 2. Whilst the process for checking ID currently is in line with the establishment's SOP, its risk assessment states that three identifiers should be used when identifying bodies, rather than two. The DI is advised to review this.
2.	GQ2	The establishment carries out a good range of audits. The DI is advised to consider extending these to areas outside the mortuary where removal of tissue takes place, to ensure that he has appropriate oversight of licensable activities taking place in these areas. The mortuary also conducts an audit which focusses on the care of the deceased. The mortuary staff review all bodies received each day to ensure that the appropriate care after death was given on the ward before the deceased was transferred to the mortuary, and they provide feedback to the wards. The DI

		should consider documenting this audit so that resulting improvements can be recorded and shared with the wards.
3.	PFE1	The body store is identified as a dirty area and not as a transitional area, which is more often the case in mortuaries. This is documented in the quality manual. As a dirty area, it is not sufficiently demarcated from the clean areas. The DI is advised to review dirty, transitional and clean areas within the mortuary and to provide adequate demarcation, which should inform working practices and procedures.

Concluding comments

The DI and establishment staff have worked hard to ensure a good level of compliance with licensable activities. There were several examples of good practice observed during the inspection. The DI has developed on-line hospital consent training, which has been rolled out and completed by 15 clinicians across the Trust. The aim is for all those who could be involved in a hospital consented PM examination to undertake the training and to receive refresher training when required. There is an excellent approach to audits and staff carry out a number of different types including, examination audits, retained tissue audits and traceability audits. In addition, HTA compliance audits are carried out once a year, which focus on the HTA standards. All porters that transfer bodies to the mortuary receive initial induction training, and subsequently mandatory training. A list of trained porters is held by the Head Porter, who ensures that only those who have been trained are involved in the transfer of bodies.

There are a few areas of practice that require improvement, including one minor shortfall in relation to PFE3.

The HTA requires that the Designated Individual addresses the shortfall by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection / subject to compliance with the additional conditions applied to the licence.

Report sent to DI for factual accuracy: 29 October 2013

Report returned from DI: 6 November 2013

Final report issued: 14 November 2013

Completion of corrective and preventative actions 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

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.