Site visit inspection report on compliance with HTA minimum standards

Southend University Hospital NHS Foundation Trust

HTA licensing number 11068

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**

6 March 2013

Summary of inspection findings

Southend University Hospital NHS Foundation Trust (the establishment) was subject to a themed inspection focusing on consent, quality management and prevention of major equipment failures.

The HTA found that the establishment had met the majority of the HTA standards in these areas. However, four minor shortfalls were identified: one in relation to consent and the need to use revised and updated consent documentation; two in relation to governance and quality, in particular the need to consistently apply a unique identification system for community deaths received on-site and a formal operating procedure for SUI reporting; and one shortfall in relation to premises, facilities and equipment standards, specifically the lack of temperature monitoring within one of the storage facilities and the need for routine testing of the alarm monitoring system for refrigeration and freezer units.

The HTA found the Designated Individual and the Licence Holder 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.

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 Paragraph 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.

A themed inspection may be carried out at establishments which have been found previously to represent a lower risk of regulatory non-compliance. Themed inspections focus on standards against which the HTA has identified common shortfalls across the post mortem sector and areas of risk identified from analysis of serious untoward incidents reported to the HTA. The themes selected for 2012/13 business year are outlined in the table below.

Themes	**HTA Standards**
Appropriate consent is in place for post-mortem examinations not under the Coroner's jurisdiction and in the event that tissue is to be retained for future use. Where there is no consent for retention, tissue is disposed of.	
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.	C1
Information about the consent process is provided and in a variety of formats.	C2
Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	C3
Governance and quality systems promote robust traceability systems, reducing the risk of serious untoward incidents.	
All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance	GQ1

process.	
There is a documented system of quality management and audit.	GQ2
A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	GQ6
There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	GQ7
Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	GQ8
Fridges and freezers safeguard the integrity of the deceased.	
There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	PFE3

In addition to the standards listed above, the HTA will follow-up on any other issues that have arisen since the establishment's last inspection.

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

Southend University Hospital NHS Foundation Trust is a large district general hospital with a wide range of acute and specialised hospital services. The Pathology Service has five clinical departments. Mortuary facilities and post mortem activities are managed within the Department of Cellular Pathology.

The establishment undertakes approximately 600-700 post mortem (PM) examinations per annum, the majority of which are conducted at the request of HM Coroner (Essex). High-risk PM examinations are not conducted on site. Consent for paediatric cases is taken on-site, although the PM examinations are routinely conducted at other HTA-licensed premises.

The DI is Clinical Director (Pathology) and a Consultant Pathologist. The LH is Southend University Hospital NHS Foundation Trust, with the Associate Director for Service Reliability and Safety acting as the named contact. The mortuary has three full time Anatomical Pathology Technicians (APTs), including the Mortuary Supervisor and one trainee APT.

The establishment was first inspected in December 2009. There were four conditions imposed on the licence at that time. These were satisfactorily addressed following the inspection. This inspection was a routine themed inspection, which provided an opportunity for the HTA to review governance arrangements in respect of licensed activities. It included a visual inspection of the respective body stores in three separate locations on the hospital site (including a temporary facility effectively used for permanent storage) and post mortem room. The building and internal structure of the mortuary are dated but in reasonable condition and currently fit for purpose. Formal interviews were conducted with the Designated Individual, Consultant Pathologist, Laboratory Manager, BMS3 Histology, APT Supervisor, Paediatric Nurse Practitioner and Bereavement Co-ordinator.

A number of traceability checks were undertaken. The identification tags of three bodies stored in the mortuary were checked and all associated paper and electronic records were reviewed. An audit trail of two further cases where histology had been taken was conducted. Records were reviewed against the consent details for retention, repatriation or disposal of tissue samples, and the number of blocks and slides stored in the histology laboratory were also checked against relevant records. No anomalies were found.

A document review of the establishment's policies and operational procedures was undertaken. This included review of risk assessments, audit reports for 2011/12 and 2012/13, incident reports, meeting minutes and the Quality Manual (Pathology Department).

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

HTA standards not met:

Consent

Standard	Inspection findings	Level of shortfall
C2 Information about the consent process is provided and in a variety of formats	Consent forms are up-to-date and reflect current HTA requirements in relation to PM examination. However, the patient information booklet (version 2) in use since July 2009 does not provide information on the full range of potential uses for which consent must be obtained or the options available following PM examination. The booklet also does not make specific reference to blocks and slides and the consent needed for them to be kept as part of the deceased's medical record. Additionally, there is no specific reference to HTA requirements under the HT Act 2004 or Codes of Practice. As such, there is scope for relatives to misunderstand when reviewing the supporting information at home and making a considered decision regarding consent to PM examination.	**Minor**

Governance and quality

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail	Bodies brought to the mortuary from wards or subject to a PM examination are routinely assigned a unique number. However, there is inconsistent practice in relation to bodies brought from the community. In two cases reviewed by the HTA, ID tags contained the deceased's name only and no unique number. This increases the risk of misidentification of deceased with the same or similar names.	**Minor**

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process & GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	The establishment follows the Trust policy for incident reporting. However, there is no standard operating procedure for the reporting of serious incidents to the HTA stating: • what incidents are reportable to the HTA; • who may notify HTA of an incident and how to do so; • that a notification should be made within five working days of an incident occurring.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	There is an alarmed temperature monitoring system in the main storage areas within the mortuary and basement locations, which continuously monitors unit temperatures. However, there is no alarmed system in the third storage area, where a small number of deceased are regularly stored. The alarm itself is not subject to routine testing and consequently, mortuary staff were unable to confirm whether it is working as required.	**Minor** **Minor**

Advice

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

No.	Standard	Advice
1.	C1, C2, C3	The Sudden and Neonatal Death Charity (SANDS) has recently published a model consent form, guidance for consent takers and information for bereaved parents. The DI is advised to review the establishment's paediatric consent procedures in light of these.
2.	GQ2	A small number of documents contained errors in relation to accurate version control and correct review dates (e.g. the SOP for 'Consent to PM examination' does not have a SOP number or details regarding version control; the SOP LP MORT 0011 – Autopsy Procedure has an incorrect

		review date). The DI is advised to review and correct anomalies where they exist.
3.	GQ6	The HTA is generally assured that the establishment has an effective system of traceability. This was supported by the audit of selected cases which identified no anomalies. However, the DI is advised to consider additional steps to further mitigate the risk of loss of traceability. For example: • Multiple PM examinations may be conducted simultaneously on a daily basis. The DI is advised to consider whether numbering or colour coding mortuary tables and the bowls used to move organs to / from dissection boards, may further mitigate the risk of organs being inadvertently repatriated with the wrong body; • In addition, the DI is advised that the risk of misidentification of deceased persons with the same, or similar sounding, names can be further mitigated by, for example, placing a coloured sticker on the wrist tags of such persons, or by placing a notice on their shroud or the use of coloured magnets on respective fridge doors. Such names should also be clearly highlighted within the mortuary register; • The DI may also wish to consider conducting specific audits, including physical checks of mortuary slips and wrist/ankle ID tags as part of a verification process for deceased received into the premises. The relevant SOPs should also be updated accordingly (e.g. LP MORT 0006 – Admission of Bodies to the Mortuary; GP-QP-0001 – Internal Audit Procedure).
4.	GQ7	To further raise awareness of HTA incident reporting requirements, it is recommended that the DI considers maintaining a checklist of incident reporting categories within mortuary premises in a location easily referred to by staff. Additionally, the DI is advised to ensure that mortuary staff routinely utilise the local incident reporting system (Datix) when problems or issues are highlighted (e.g. inappropriate body transfer from wards to the mortuary – deceased not positioned correctly in refrigeration units; missing or incomplete paperwork on receipt of deceased; missing or incorrect ID labelling identified on routine body store audits) and to use errors and incidents as a basis for learning and continued development of appropriate mortuary practices.
5.	GQ8	While the establishment has completed a number of risk assessments, these should be extended to include all HTA incident categories in order to mitigate risks to the bodies and tissue in the care of the mortuary.

Concluding comments

The establishment has an experienced team, which is committed to delivering a high quality service. The DI communicates effectively with mortuary staff, primarily through the Mortuary Supervisor and also the Laboratory Manager (Person Designated).

Examples of strength and good practice were seen. For example, the establishment has a well constructed and detailed consent policy and up-to-date consent templates. There is an annual consent training programme (for paediatric and adult PM examinations) with well–defined key training criteria; an extensive suite of SOPs relating to licensed activities; a schedule of regular audits covering a range of mortuary activities and documented evidence of corrective and preventive actions being tracked through to resolution and closure. There are a number of step checks in place for both receipt and release procedures within the mortuary (through the use of tracking sheets) and for movement of relevant material within the histology department and the use of an error log for corrections made in the mortuary register.

As highlighted above, there are some areas of practice that require improvement and the HTA has given advice to the DI with respect to these.

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

Report sent to DI for factual accuracy: 2 April 2013

Report returned from DI: 15 April 2013

Final report issued: 23 April 2013

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: 15 August 2013

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 or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as

health and safety risks.

- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal records include the date, method and reason for disposal.
- Tissue is disposed of in a timely fashion.

  (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)

Appendix 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.