Site visit inspection report on compliance with HTA minimum standards

Heart of England NHS Foundation Trust

HTA licensing number 12366

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 -18 July 2014

Summary of inspection findings

This inspection was conducted jointly with assessors from the United Kingdom Accreditation Service (UKAS), who assessed the mortuary against selected HTA licensing standards on behalf of HTA.

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.

Heart of England NHS Foundation Trust (the establishment) was found to have met all HTA standards.

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 out 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

The mortuary at Heartlands Hospital, Heart of England NHS Foundation Trust (the establishment) conducts adult post mortem (PM) examinations only. Perinatal and paediatric cases are transferred to another HTA-licensed establishment. Up to 70 PM examinations are conducted at the establishment each year, the majority of which are under authority of HM Coroner for South Staffordshire, the remainder being hospital (consented) cases. Good Hope Hospital is licensed as a satellite of Heartlands Hospital. This site has a body store, and no PM examinations are conducted there.

Tissue samples may be taken from deceased children at the hub and satellite sites in cases of sudden unexpected death in infancy (SUDI) cases, with pre-emptive coronial authorisation. SUDI sampling is overseen by consultant paediatricians and is normally carried out in the accident and emergency units.

Another site within the Trust (Solihull Hospital) acts as a temporary body store only and is therefore unlicensed.

Refrigerated storage capacity at the hub has been expanded from 60 to 98 spaces this year, including capacity for eight bariatric bodies. Perinatal and paediatric bodies are stored in a dedicated set of trays in one bank of fridges. The satellite has refrigerated storage capacity for 55 adult bodies. The hub site's mortuary has an audible local alarm in case of fridge failure. At the satellite, fridge alarms ring through to the operator, who contacts Security to investigate. At exceptionally busy periods when available fridge capacity may be low, the Trust has a contingency arrangement with a local funeral director to accommodate bodies at their premises. The maternity units at the hub and the satellite each have a fridge where a fetus or neonatal body can be stored for a short period prior to transfer to the mortuary at the hub.

The establishment has adapted HTA's model adult hospital PM examination consent form and information leaflet 'Post mortem examination – your choices about organs and tissue' for local use. Consultant pathologists support clinicians seeking consent for adult hospital PM examinations. Consent for perinatal and paediatric PM examinations is sought by bereavement midwives or, occasionally, by consultant obstetricians using the consent form of the establishment where these PM examinations are carried out. Consent training has been provided by staff from that establishment.

Tissue taken at PM examination for histopathological analysis is processed into paraffin wax-embedded blocks and microscope slides in the histopathology laboratory at the hub. Organs and toxicology samples are sent to other HTA-licensed establishments. Under instruction from South Staffordshire Coroner, the establishment disposes of all PM tissues three months after the inquest is held, unless appropriate consent for continued retention for use for a scheduled purpose is given by the deceased's family, or the Coroner instructs that samples be held for further investigation.

The mortuary manager oversees a mortuary technician and three technical officers, all of whom work cross-site. The mortuary technician deputises for the mortuary manager in his absence. Outside normal working hours, hospital deaths and bodies from the community are admitted by hospital portering staff. The establishment's pathologists also perform PM examinations at another HTA-licensed establishment under the authority of HM Coroner for Birmingham and Solihull. Tissue samples for histology are processed into blocks and slides at the establishment.

The establishment has been licensed by the HTA since January 2008. Two previous site visit inspections, in September 2009 and August 2011, have taken place. This report describes the third routine site visit inspection of the establishment. The inspection was conducted jointly with the United Kingdom Accreditation Service (UKAS). UKAS assessors visited the mortuary at the hub site and assessed compliance with licensing standards GQ1-4, PFE1-5 and D1 on behalf of HTA.

The HTA visited the mortuary, histopathology laboratory and maternity unit at the hub, and the body store, maternity unit and accident and emergency department at the satellite. The inspector met with staff involved with licensable activities and reviewed documentation. The release of two adult bodies to a funeral director was witnessed at the hub. Storage locations and identifiers for two adult bodies at the satellite were audited. Traceability records for three PM examinations where tissues were taken for histopathological analysis (two coronial cases and one hospital case) were also audited. No anomalies were found in either audit.

The establishment has an HTA licence under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (licensing number 22533). Activities taking place under that licence were not assessed at this inspection.

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

The establishment has met all applicable HTA licensing standards

Advice

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

No.	Standard	Advice
1.	GQ1	The DI is advised that standard operating procedure (SOP) 'Post mortem and related procedures' (MO.S004) should set out all the identification details which need to be verified by the anatomical pathology technologist and pathologist prior to PM examination.
2.	GQ2	The DI is advised to provide greater detail in the 'Cellular Pathology Appendix to Quality Manual' (QM.P004) on mortuary-specific personnel and activities, for example: • adding the Mortuary Manager's name to the organisational chart (all other key staff are named in this chart), and outlining his role and responsibilities, and; • referencing key policies and procedures relevant to the mortuary.
3.	GQ2	A range of audits of records and of procedures is carried out to a defined schedule, the findings of which are tracked in the establishment's computerised quality management system. However, examples were seen where audit findings were not fully detailed on the appropriate audit forms, an SOP was incorrectly referenced, or an audit was not carried out according to the audit calendar. The DI is advised to assure himself that audits are conducted with rigour and that their findings are fully documented. The DI is further advised to schedule regular audits of tissue disposal records, to provide reassurance that systems for disposal of PM tissue are working effectively.
4.	GQ3	The DI is advised that competence assessments for the mortuary technician should be completed to a regular schedule and include the direct observation of key procedures being carried out, for full reassurance that competence has been maintained.
5.	GQ4	Several mortuary registers are used to record the admission and release of deceased adults and neonates, PM examinations and samples taken for histology, and the disposal of PM tissue. However, 'BHH/GHH Retention, storage and disposal of cellular pathology records and tissues/specimens' (CP.S109) only states the retention period for the body registers. The DI is advised to document the retention requirements for all mortuary registers in CP.S109.
6.	GQ4	In a small number of cases, it was noted that incorrect entries in mortuary registers had been obliterated, rendering the original entry illegible. The DI is advised to remind staff of the documented procedure for correcting errors in

		mortuary registers.
7.	GQ8	The DI is advised that documented risk assessments of practices and premises should describe all mitigating measures in place. For example, the two-person verification of a deceased person's identity which is conducted prior to PM examination should be listed as a risk mitigating measure in risk assessment MO.R015. Also, risk assessment 'Management of foetuses >24 weeks gestation' (MO.R012) should set out the measures in place to mitigate traceability and storage risks for fetuses and stillbirths stored on maternity wards prior to transfer to the mortuary. The DI is further advised that MO.R012 can be expanded to consider potential risks for all tissues from pregnancy loss, irrespective of their gestational age.
8.	PFE5	New body fridges have been installed in the mortuary at the hub site. The DI is advised to maintain and review temperature records to verify that these new fridges are functioning in accordance with expected specifications.
9.	D2	Processes for disposal of PM tissues, blocks and slides, where consent for continued retention for use for a scheduled purpose has not been given by the family, are well-established and clearly understood by all staff involved. The DI is advised that SOP 'Body storage release and disposal' (MO.S005) should describe the checking process which ensures that the correct numbers of blocks and slides for each case are returned from the histopathology laboratory to the mortuary for disposal. The DI is further advised that, in line with guidance in the HTA's Code of practice on Disposal of human tissue, the reason for disposal of PM tissue should be recorded. http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code5disposal.cfm

Concluding comments

The establishment has met all applicable licensing standards. Quality management is to an appropriate standard, and staff are well-versed in working practices. Procedures for seeking consent for PM examinations are robust. Storage capacity at the hub has been expanded recently.

The HTA has given advice to the Designated Individual with respect to further strengthening some aspects of quality management.

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

Report sent to DI for factual accuracy: 19 August 2014

Report returned from DI: 27 August 2014

Final report issued: 29 August 2014

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

GQ4 There is a systematic and planned approach to the management of records

- There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- There are documented SOPs for record management.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

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

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly 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.