Site visit inspection report on compliance with HTA minimum standards

Stepping Hill Hospital

HTA licensing number 12031

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

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.

Stepping Hill Hospital (the establishment) was found to have met all HTA standards.

Since the last inspection, the previous DI has moved to another role within the Stockport NHS Foundation Trust and a new DI has been appointed.

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

Stepping Hill Hospital is a medium-sized facility which is part of Stockport NHS Foundation Trust. The mortuary deals with approximately 2,100 bodies annually and carries out approximately 700 post mortem (PM) examinations per annum on behalf of HM Coroner. In the 24 months leading up to this inspection two hospital consented PM examinations had been carried out. Paediatric post mortem cases are sent to Manchester Children's Hospital and Home Office cases are not routinely carried out at the establishment.

Bodies are received into the establishment from the hospital and the community. Out of hours, portering staff deliver patients who have died on the wards and also allow access to funeral directors transferring bodies from parts of the hospital Trust which are located off the main site. APT staff allow access to funeral directors and police officers delivering bodies of those who have died in the community. The mortuary register is completed by the portering team, and the receipt procedure provides that this must always include a supervisor porter who has been trained in mortuary procedures.

Details of patients received are also placed on the whiteboard within the body store and on their arrival the next working day, mortuary staff book in the deceased to the mortuary software system and complete relevant registration paperwork. Each body is assigned a unique, sequential, mortuary number which is used to trace that body through any PM examination, and is also used to trace retained tissues until eventual disposal, return or retention.

The body store consists of 104 spaces, of which 11 are bariatric spaces, and of these, five can be used as freezer spaces. All but one bank of fridges are connected to an alarm system, which alerts locally and to switchboard, and is tested monthly. Temperatures of all fridges and freezers are recorded twice daily for the purposes of trending.

There are defined procedures for storage of infants and perinatal cases within one bank of fridges. A robust procedure ensures regular review of the continued need for longer term storage of the deceased in freezers.

The software system is used to trace bodies and tissues through the mortuary and laboratory and also records details of the ultimate disposal of tissue, or its return or retention.

There is a temporary storage fridge located within the maternity department, as well as a “cool cot”, both of which are used to store babies for a short period prior to delivery to the mortuary. The fridge is temperature monitored and details of babies being stored are entered into a log book.
No storage of tissues takes place within the mortuary, other than temporarily while organs are fixed, and when organs are sent for analysis elsewhere, the establishment uses a system of faxback forms to retain traceability.

The establishment uses an electronic quality management system to control documentation, schedule audits, record corrective and preventative actions (CAPAs) following incidents or resulting from risk assessment or audit, retain details of staff training, and records of maintenance and repair of most of the equipment within the mortuary and laboratory. Maintenance records for other equipment are maintained by the Estates department and were not reviewed during the inspection.

This was the second inspection of the establishment and comprised a visual inspection of the body store, mortuary and laboratory and a visit to the maternity ward to view the temporary storage fridge. Various governance documents were reviewed, including a selection of policies and standard operating procedures (SOPs), audits, risk assessments and incident reports with related CAPAs, as well as record forms in hard copy and electronic format. Key members of staff were interviewed.

An audit of traceability was undertaken:

- Details of two bodies were selected from the mortuary register and the bodies located within the body store. Relevant electronic and paper records were reviewed and in one case where there was the same/similar name, it was confirmed that the correct procedure had been followed.
- For two coronial cases involving the retention of tissues at PM examination, the paper and electronic records of authority for PM examination and retention of tissues were reviewed. The related blocks and slides were traced through the database records system to their storage location.
- One file of paperwork, relating to a hospital, consented, PM case, was reviewed for the presence of appropriate consent documentation.

No anomalies were found during the audit trail, other than one typographic error in the date of birth recorded on one paper form.

In addition, the HTA inspectors were able to observe the procedure followed by staff in releasing two bodies to funeral directors and compare that with the documented SOP. The procedure followed matched that described.

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

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C2	The DI is advised to review the wording of the "Guide to the Hospital PM" document, HISM068, provided to relatives of the deceased. The document refers to tissue being retained as part of the medical record, and while it can be read as being only with consent, the wording is ambiguous. The HTA notes, however, that the consent documentation itself, a copy of which is provided to consentors, makes it clear that retention of tissues may only take place with appropriate consent.
2.	GQ1	The DI is advised to review the SOP "Routine PM", HISM 013, as it does not fully describe the identification procedures described to the HTA as being undertaken by pathologists and supporting staff before commencing the PM examination.
3.	GQ2	The HTA notes that consent training is currently refreshed annually but that, as a result of there being only a small team of staff trained in taking consent, this is being changed so that consent training will be carried out every two years, or when there is any change in procedure or documentation. The HTA advises the DI to incorporate periodic competency assessment of those involved in taking consent, perhaps via peer review, to help ensure the robustness of the consent procedure.
4.	GQ3	The DI is advised to amend the sign off form used to record training of porters on mortuary procedures, to include the date of completion of training. This will aid staff in determining when training should be refreshed.

Concluding comments

The HTA saw various examples of good practice during the inspection. Records of all visitors to the mortuary are kept within a visitors book and regular visitors to the mortuary, including funeral directors, porters and contractors, are required to read and sign off "model rules" detailing local requirements.

The incident reporting SOP is provided as a laminated copy, attached to the wall of the body store, for portering and other staff who access the mortuary out of hours. This provides clear details of the procedure to be followed, with contact details of mortuary staff in the event of any incident occurring.

The consent procedures undertaken involve trained staff supporting the clinician involved in the deceased patient's care, and families are given the opportunity to speak to the pathologist

who will carry out the PM examination. Consent training is available to members of mortuary staff, doctors, midwives, and is also provided to Coroners officers. This includes training on the qualifying relationship, and the document on which officers record relatives' wishes details the position in the qualifying relationship of the relative providing instructions. The requirement for officers to check the qualifying relationship is also detailed in the service level agreement between the establishment and the Coroner.

Information from the HTA is circulated to staff in the form of a newsletter, by email, and the establishment has an SOP detailing how this is done.

The establishment makes good use of an electronic quality management system and governance documentation is clear and well thought out. For example, all SOPs reference relevant risk assessment documents.

Colour coded signage helps staff and visitors to recognise clean, transitional and dirty areas and this is supported by a helpful colour coded chart detailing what personal protective equipment should be worn in each area.

The HTA has given advice to the Designated Individual with respect to some elements of documentation and audit of consent procedures.

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

Report sent to DI for factual accuracy: 18 June 2015

Report returned from DI: 29 June 2015

Final report issued: 30 June 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. • 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.