Site visit inspection report on compliance with HTA minimum standards

Eastbourne District General Hospital

HTA licensing number 12141

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**

8-9 March 2016

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.

Eastbourne District General Hospital and the associated Conquest Hospital were found to have met the majority of the HTA standards. However, two minor shortfalls were found in relation to standards on Governance and Quality and Premises, Facilities and Equipment.

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

The establishment comprises Eastbourne District General Hospital (EDGH, the 'hub') and Conquest Hospital (Conquest, the 'satellite'). The hospitals are part of the East Sussex Healthcare NHS Trust and are based in Eastbourne and Hastings, respectively. The establishment carries out approximately 800 post mortem (PM) examinations per annum. The majority of these are on behalf of HM Coroner, including occasional Home Office PM examinations. Some hospital consented PM examinations also take place. Access to consent forms for these is tightly controlled so the establishment can ensure that consent is sought only by staff who have completed the relevant training.

The mortuary at EDGH carries out approximately 370 PM examinations on behalf of the East Sussex Coroner. It has a body storage area with 60 fridge and five freezer spaces. There is also an additional refrigerated room with further spaces for 20 normal sized bodies, four bariatric spaces and accommodation space for up to three super bariatric beds. There is an additional temporary storage unit but this is rarely required. The mortuary at EDGH is secured by CCTV and access is controlled by a key lock. Porters are provided with keys for the duration of their shift, which they return to the porters' office at the end of each shift. Any external agencies bringing in bodies from the community out of hours must go to A&E and provide identity documentation in order to obtain the key.

At EDGH, bodies that are brought in out of hours have their details written on the whiteboard in blue marker. This is clearly visible to mortuary staff upon arrival, who then check the bodies. For hospital deaths, a card with details of the deceased is placed on the fridge door as a second indicator for staff.

Staff use colour coding on their white board to highlight what stage each body is in the process; for example, details are written in black pen when the body has been registered fully

by mortuary staff, a purple marker is used if a PM examination is required. Same or similar names are highlighted in red, and green text is used to indicate various stages in the release process such as a record of cremation forms having been signed or the details of the nominated funeral director.

All the fridges at EDGH are alarmed with local and remote alarms sounding. If an alarm is triggered out of hours, switchboard staff call the engineers to investigate. However, there are no follow-up steps in place if there is a genuine fault and bodies need to be moved because mortuary staff are not on 'on-call' contracts. Mortuary staff were unsure how frequently the alarms are tested and there is no evidence that the follow up procedure has been tested.

The mortuary at Conquest carries out approximately 400 coronial PM examinations each year. It has a body storage area with 89 fridge spaces, including five that can convert into a freezer if required, five bariatric trays and room for two super bariatric beds. Both mortuaries dedicate a specific block of fridges for babies and products of conception. Paediatric and suspected high-risk cases are transferred to other HTA-licensed establishments for post mortem examination. The mortuary at Conquest uses 'slide sheets' to assist in the safe handling and transfer of bodies from trolleys to the fridge trays.

The PM suite at EDGH has three static and one mobile PM table, all the statics tables are downdraft and height adjustable. There are three static and three movable PM tables at Conquest, none of which are height adjustable; this presents a challenge when APTs and pathologists are performing a PM examination on bariatric bodies (see advice item 8). At EDGH, bodies for PM examination are removed from the fridges the afternoon before PM examination. The PM suite is cooled and the practice has been risk assessed to consider any risks to the deceased.

Traceability audits were completed during the inspection. The first consisted of a body store audit at each mortuary; three names were chosen from the whiteboard at EDGH and from the fridge doors at CH, details on the mortuary registration cards and wrist tags were checked against details in the mortuary register. All were found to be correct. A tissue traceability audit was also undertaken at each hospital, where details of tissue taken as part of a PM examination for histology were followed up in the pathology laboratory. Paperwork, including consent forms with the wishes of the next of kin in relation to the tissue, once coronial authority ceased, were checked; all samples had been retained or disposed of in accordance with the consent given.

This was the establishment's third routine inspection. The hub (EDGH) was visited on 8 May, the satellite (Conquest) was visited on 9 May. In addition to the audits, both inspections encompassed a visual inspection of the mortuary, including the body storage area, PM suite and the histology laboratory, a document review and interviews with staff.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	Both establishments have Standard Operating Procedures (SOPs) for receipt and release of bodies; however they do not state exactly what identifiers staff need to check before releasing a body. The procedure indicates that release documentation must be checked so no bodies will be released without notification from the coroner if required. However, only internal documentation needs to be checked. There is no requirement for the funeral directors to bring any confirmation of the identity of the deceased. Funeral directors occasionally come with only verbal notification of the name of the deceased. By not requiring any other identifying details from the funeral director as confirmation that they have the correct deceased, the establishment increases the risk of releasing of the wrong body.	**Minor**

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.	Whilst alarms are regularly tested at EDGH there is no formal test of the follow up process once an alarm is triggered. Additionally, if there were a fault that could not be fixed there is no system in place to deal with moving the bodies as mortuary staff are not on-call.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	The DI is relatively new in post and there are plans to introduce meetings with all staff working under the licence but these have not yet taken place. Once these meetings are scheduled the DI is advised to set formal agendas and minute the meetings.
2.	GQ1	In addressing the shortfall against GQ1, SOPs should be reviewed to include details of exactly what identifiers staff should check when receiving or releasing bodies, and prior to a PM examination taking place. For release these should also clarify exactly what documentation is required from funeral directors before a body is released.
3.	GQ1	There is a schedule of audits in place but due to the workload of the individual responsible, some of these have fallen behind. Support should be given to ensure audits, particularly of procedures, take place as planned and that any issues identified are followed up within a specified timeframe.
4.	GQ1	There is a clearly visible same or similar name system, which reduces the risk of releasing the wrong body. However, the risk could be mitigated further by requiring the funeral director to demonstrate they have instructions from the family to collect the body and by the use of more than one identifier.
5.	GQ3	Porter training is comprehensive at Conquest and requires that the porters are signed off as competent. There is no similar process at EDGH and the DI should consider introducing similar training arrangements for portering staff based at that site. *(This has been implemented since the inspection)*
6.	GQ4	Following advice given at the last HTA inspection, options for computer systems has been investigated, but as yet a suitable system has not been identified or implemented. The DI is advised to continue to seek a way of reducing duplication in paper records and of storing all details in one place.
7.	GQ8	Risk assessments do consider some risks to the deceased; however, the risks of accidental damage or release of the wrong body have not been assessed. The DI is advised to consider the HTARI categories when reviewing risk assessments to ensure all possible risks are considered.
8.	PFE5	The PM tables at Conquest are not height adjustable. In order to gain the necessary height to work on bariatric bodies, staff stand on a small moveable stool. This presents a health and safety risk to staff and a risk of accidental damage to the deceased. The DI is advised to assess the situation and find suitable alternatives that mitigate any risks identified.

Concluding comments

This report outlines the third HTA site visit inspection and a number of areas of good practice were observed.

Both hospitals are well organised and have good working relationships with the Coroner's office. The SUDI protocol put in place really helps staff to understand what they need to do at such a critical time. The use of 'slide sheets' at Conquest facilitates the easy movement of bodies and reduces the likelihood of staff injuries.

The use of different colours on the whiteboard at EDGH clearly identifies to staff what is happening with each of the bodies in their care. Staff log an incident on the Datix system if a body comes from within the hospital with no identification details or without notification of an infection, which is identified by mortuary staff. This helps to ensure learning is shared throughout the hospital.

Both hospitals have clear indicators that a viewing is in process: at EDGE, this is an illuminated 'quiet' sign; at Conquest, it is a red light. These highlight to porters, funeral directors and other visitors the need to keep noise to a minimum during viewings.

The training plan for the trainee APT at EDGH has been developed to a very high standard.

There are good traceability systems in place for babies which are transferred to other HTA-licensed establishments for PM examination.

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

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 05 April 2016

Report returned from DI: 15 April 2016

Final report issued: 29 April 2016

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: 25 November 2016

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: o post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases o record keeping o receipt and release of bodies, which reflect out of hours arrangements o lone working in the mortuary o transfer of bodies and tissue (including blocks and slides) to other establishments or off site o ensuring that tissue is handled in line with documented wishes of the relatives o 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.