HTA
Human Tissue Authority

Site visit inspection report on compliance with HTA minimum standards

George Eliot Hospital

HTA licensing number 12171

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**

11 December 2013

Summary of inspection findings

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

Although the HTA found that George Eliot Hospital (the establishment) had met the majority of the HTA standards, a major shortfall was found in relation to the consent standards.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

This report refers to the activities that take place within the mortuary at George Eliot Hospital (the establishment), which conducts around 350 post-mortem (PM) examinations each year. The majority of these are routine coronial cases; Home Office, perinatal and known high-risk cases are transferred to other HTA-licensed establishments. Last year, the establishment conducted two hospital PM examinations. Consent for hospital and perinatal PM examinations is obtained by medical staff. The DI, who is a consultant histopathologist, conducts an annual training course for those responsible for seeking consent from the next of kin.

The mortuary is staffed by the Mortuary and Bereavement Manager, who is a qualified Senior Anatomical Pathology Technologist (APT), and two additional APTs. There is storage capacity for 60 bodies, including bariatric storage areas and five freezer spaces. The main PM room has three down draft tables and these are colour-coded to correspond with the bowls used to move organs to and from dissection boards.

Access to the mortuary is secure and fridges and freezers are kept locked at all times. There is a separate entrance to the viewing facility for bereaved relatives. This facility was due to be refurbished at the time of the inspection.

Hospital porters, who have been trained by mortuary staff, transfer bodies from hospital wards to the mortuary. Porters also respond when bodies are brought in from the community by funeral directors, out of working hours. To enable staff to identify bodies that have been placed in the mortuary outside normal working hours, different coloured pens are left for the porters to record information on the body store inventory whiteboard.

The provision of pathology services at the establishment was recently reorganised: tissue samples that are removed for histological examination are transferred to the on-site

laboratory, where they are booked onto the computer system. Samples are then transferred to another licensed establishment for processing. Since this was a relatively new change (since November 2013), the system for storage and disposal of these samples was being considered by the establishment at the time of the inspection, to assess its effectiveness.

This was the second site-visit inspection of the establishment, which was inspected previously in March 2010. The current DI was appointed in April 2010. Since the last inspection, the establishment has devolved from a wider network of pathology services, and because of this, has been required to establish local governance documents. The Mortuary Manager has developed a new set of standard operating procedures and risk assessments to cover licensable activity.

This routine inspection comprised a visual inspection of the premises, document review and interviews with establishment staff and a Coroner's officer.

During the visual inspection, two audit trail exercises were conducted. A body was selected from the mortuary register, which was correctly identified and found to be in the specified location in the mortuary store. The details of three further cases (one coronial case and two hospital cases), where tissue had been removed for histology purposes, were selected from mortuary records. Tissue blocks from these cases were traced through the histopathology laboratory and the relatives' wishes for the retention or disposal of this tissue were verified. A discrepancy was identified in the completion of the consent forms used for the hospital cases. This is described in the shortfall below.

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

Consent

Standard	Inspection findings	Level of shortfall
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. C2 Information about the consent process is provided and in a variety of formats.	As a result of conditions placed on its licence following inspection in 2010, the establishment revised its consent policy, information leaflet and consent form for hospital PM examination, to the satisfaction of the HTA. However, the consent information leaflet that is currently in use does not include the information that is described in the consent policy, and the establishment is not using the revised consent form to seek consent for hospital PM examination.	**Major**

C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	Furthermore, the reference material that is being used for the consent training course does not refer to the correct version of the consent form. The establishment routinely retains tissue blocks and slides following hospital PM examinations, and consent procedures do not adequately ensure that consent for this retention is obtained. The consent form gives families of the deceased a range of options with regards to any whole organs that have been removed and retained for further analysis; however, it states that blocks and slides will be kept as part of the deceased's medical record. It is not clear whether families have been given the opportunity to decline to give consent for the continued retention of these samples for use for scheduled purposes. Although this may be discussed with relatives, it is not recorded, making it difficult to evidence that valid consent has been obtained. For example, in one case reviewed by the HTA, the section on the consent form referring to tissue samples had been left blank; in another, it had been completed; in both cases, the samples had been retained.	

Advice

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

No.	Standard	Advice
1.	C3	The establishment intends to start using the forms and guidance provided by the Still Birth and Neonatal Death charity (SANDS) when seeking consent for PM examination in perinatal cases. The DI is advised to review staff training when the SANDS forms are implemented.
2.	GQ1	The DI is advised to consider implementing a formal document governance system, to ensure that quality documents are updated and reviewed in a controlled and timely manner.
3.	GQ3	Mortuary staff provide training to porters, who have a number of responsibilities relating to licensable activities. The DI is advised to expand the written material used for porter training to include receipt of bodies into the mortuary. This will ensure that all training is documented. Furthermore the written training material could then be made available to portering staff who undertake licensable activities.

4.	GQ6	The DI is advised to consider assigning a unique mortuary number to each body that is brought into in the mortuary. This will help to provide a consistent system of identification, for both hospital and community deaths.
5.	GQ6	The DI is advised to consider the method used to document the pathway of tissue through the establishment to account for the recent changes to the arrangements for processing, storage and disposal of tissue retained for histological examination.
6.	GQ7	The DI is advised to update the establishment's incident reporting procedure to include the submission of HTA Reportable Incidents (HTARIs) to the HTA via the portal.
7.	PFE2	The DI is advised to amend the establishment's cleaning proforma to ensure that staff working under the licence are clear what cleaning needs to be performed on a daily/ weekly/monthly basis, versus that which can take place on an ad hoc basis.

Concluding comments

Areas of good practice were noted during the inspection. The mortuary has good working relationships with the Coroner's office, and plans are in place with the Coroner's Officer for a regular review of systems and cases.

Consent training sessions have been carefully considered and separate training courses are conducted annually, which are tailored to adult or perinatal PME. Training is offered to various members of staff within the hospital and a record of those trained to take consent for hospital PM examinations is maintained by the DI. The DI is required to update the content of the training course in relation to consent forms that are used and this is described in further detail in the inspection findings above.

There are a number of areas of practice that require improvement, including one major shortfall. The HTA has given advice to the Designated Individual with respect to staff training, governance documents, incident reporting procedures and traceability.

The HTA requires that the Designated Individual 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: 10 January 2014

Report returned from DI: 21 January 2014

Final report issued: 22 January 2014

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: 29 March 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.

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 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.