Site visit inspection report on compliance with HTA minimum standards

The Public Mortuary at Flax Bourton

HTA licensing number 12536

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**

27 September 2012

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 the Public Mortuary at Flax Bourton (the establishment) had met the majority of the HTA standards, one minor shortfall was found in relation to the absence of a documented procedure for disposal of post mortem tissue. This shortfall was addressed by the establishment to the HTA's satisfaction before the final report was issued.

Consent standards are not applicable to this establishment as all post mortem examinations are under the authority of HM Coroner or, for hospital cases, consent has been sought by other establishments.

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 Paragraph 18 of the Human Tissue Act 2004. They are to secure that:

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

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

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

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

More than 1500 post mortem (PM) examinations are undertaken at the establishment each year, including high risk and forensic cases, on adult deceased persons from hospitals in three local NHS Trusts and from the community. The majority of PM examinations are under the authority of HM Coroner for Avon, with between 10-20 hospital (consented) cases each year. Forensic PM examinations are performed on deceased persons from several local coronial districts. Perinatal or paediatric PM examinations would be performed only in exceptional circumstances.

PM examinations are performed by pathologists from three local NHS Trusts or by forensic pathologists. Whole organs, toxicology and histopathology samples for analysis are transferred to hospitals in those Trusts, either by the pathologist or by courier. Service level agreements (SLAs) are in place with the Trusts for tissue processing and performing hospital PM examinations; however, the SLAs are beyond their review date (see advice item 4).

The establishment has been licensed by the HTA since January 2009. It received a routine site visit inspection in August 2009. This report describes the second, routine, site visit inspection of the establishment in September 2012. The inspectors interviewed staff involved with licensable activities, visually inspected the mortuary body store and PM suite, and reviewed documentation. An audit of the identifiers and storage locations of two deceased

persons revealed no anomalies. An audit of records of the admission, PM examination and release to a funeral director of a further four deceased persons revealed no anomalies. However, it was seen that details of one deceased person had not been transcribed from the temporary register used by funeral directors to record admission into the mortuary register.

Consent standards are not applicable to this establishment as PM examinations are under coronial authority, or consent has been sought by staff at local hospitals. As a point of good practice, some mortuary staff have attended consent training, and a consent form based on the HTA model form has been prepared, should the need to seek consent for a PM examination arise (see advice item 1). Disposal standards are applicable as the establishment may, on an infrequent basis, dispose of post mortem tissue. It was noted that a recent PM tissue disposal record did not give the reason for, and method of, the disposal (see minor shortfall).

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

Disposal

Standard	Inspection findings	Level of shortfall
D1 There is a clear and sensitive policy for disposing of human organs and tissue.	The establishment may, on an infrequent basis, dispose of post mortem tissue. The disposal procedure is not documented. *The establishment submitted a standard operating procedure which describes how post mortem tissue is to be disposed of, to address this shortfall, prior to the issue of the final report. The HTA has assessed this information as satisfactory to address the shortfall.*	**Minor**

Advice

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

No.	Standard	Advice
1.	C2	Staff at the establishment do not currently seek consent for PM examination, but have prepared documentation and received consent training, should the need to seek consent ever arise.The DI has adopted a Department of Health patient information leaflet to support seeking of consent for adult PM examination. This leaflet, which pre-dates the Act, contains inaccurate information on retention of PM tissue blocks and slides. The DI is advised that an information leaflet for relatives on adult hospital PM examinations, which has correct information on

		the retention of PM tissue with valid consent, is available from the HTA website: http://www.hta.gov.uk/_db/_documents/Post-mortem_examination_-_your_choices_about_organs_and_tissue_FINAL_v3_0_201201255642.pdf
2.	GQ4	The DI is advised to remind staff of the establishment's own documented procedure for correcting errors in records such as the mortuary register. Correction fluid was noted in a small number of instances. Use of correction fluid should be avoided.
3.	GQ6, GQ8	The DI is advised to undertake a documented risk assessment of the identification procedures of deceased persons, so he may confirm that existing control measures, based on the patient's name and other details such as date of death, date of birth, address or hospital number as available, fully mitigate the risks of misidentification. The DI should review this risk assessment regularly.
4.	PFE4	The DI is advised that any SLAs with NHS Trusts and other service providers which are beyond their review date should be renewed.
5.	PFE5	Body fridge and freezer temperatures are monitored continuously, with a dial-out alarm system should temperatures vary from set limits. The DI is advised that mortuary body fridge and freezer alarms should be tested regularly, as an additional control measure to ensure these function correctly.

Concluding comments

Several areas of strength were identified during the inspection. There is evidence of good team working within the mortuary and clear communication with the Coroner's Officers and the pathologists. Quality management is to a high standard. Standard operating procedures (SOPs) are clear and concise. A wide range of vertical and horizontal audits are undertaken, and effective action plans are developed to address any anomalies. Any tissue stored on the premises is audited monthly, and confirmation is sought from the appropriate parties on what is to be done. The premises are spacious, well-maintained and fit for their purpose.

Areas of good practice at the establishment include;

- To alert staff to deceased persons with same or similar sounding names, orange wrist bands are applied to bodies and orange stickers are placed in the mortuary register and on fridge doors;
- To alert staff if tissue must be returned to a body prior to release to a funeral director, red wrist bands are applied, using the same system as orange wrist bands;
- Some mortuary staff have attended consent training, should the need to seek consent for an adult PM examination arise. A PM examination consent form, based on the HTA's model form, and a consent SOP are available (see also advice item 1);
- Each PM table has a dedicated dissection bench, and tables and bowls for organs are colour coded, eliminating the risk of organs being inadvertently returned to the wrong body.

The HTA has given additional advice to the DI with respect to consent, governance and quality systems, and premises, facilities and equipment standards.

Before the draft inspection report was finalised, the establishment submitted a revised SOP which explains the procedure for the disposal of post mortem tissue. This information was assessed by the HTA as satisfactory to meet the shortfall. Consequently there is no longer a

need to address this shortfall through a corrective and preventive action plan.

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

Report sent to DI for factual accuracy: 08 October 2012

Report returned from DI: 10 October 2012

Final report issued: 18 October 2012

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.

Governance and quality system standards

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

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

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

GQ2 There is a documented system of quality management and audit

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

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

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.
- There is a documented training programme for new mortuary staff (e.g. competency checklist).

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

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

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

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

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

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

errors.

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

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

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

PFE 2 Environmental controls are in place to avoid potential contamination

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

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

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.

- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

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

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

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

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

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

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

Disposal Standards

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

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

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

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

- Tissue is disposed of in a timely fashion.

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

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

or

A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

(1) A notice of proposal being issued to revoke the licence

(2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall that:

- poses a risk to human safety and/or dignity, or
- indicates a failure to carry out satisfactory procedures, or
- indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and

preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.