Site visit inspection report on compliance with HTA minimum standards

Sandwell Hospital

HTA licensing number 12131

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**

15-16 January 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 Sandwell Hospital (the establishment) had met the majority of the HTA standards, shortfalls were found, particularly in relation to consent and governance and quality systems.

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 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

The establishment carries out post mortem (PM) examinations for the Coroner (300-400 annually), hospital consented PM examinations (<10 annually) and forensic PM examinations. There is main post mortem suite with three tables as well as a separate forensic post mortem suite with one table. Both post mortem suites have separate viewing galleries. High risk PM examinations to category three are conducted either in the separate forensic post mortem suite or in the main post mortem suite as the last of the day. No paediatric PM examinations are undertaken and all paediatric and neonatal deaths are transferred to Birmingham Womens's Hospital.

There is space in the mortuary to store 120 bodies, which includes the main body store area, dedicated space for forensic cases and a separate area in an adjacent room (for overflow and bariatric cases) where the temperature is maintained by a cooling device and thermal room dividers. All fridges are double sided, giving access to the main post mortem suite or the forensic suite, as appropriate. There is freezer space for ten bodies (five bariatric).

There is a satellite site at nearby City Hospital where the histopathology lab is located. No PM examinations are currently carried out at the satellite site mortuary, which is used as a body store, with capacity for 82 bodies (52 in the main body store and 30 in the post mortem suite, which has a cooling device and is used as an overflow store during the winter months). There is also a dedicated block of fridges for babies.

The temperatures of all body store areas at both sites are maintained by electronic systems with clearly visible digital readouts, however daily temperature monitoring by mortuary staff does not take place (see minor shortfall against PFE3). All body store areas are equipped with audible alarms with fridge trigger points set at 2°C and 6°C. At the satellite site the alarms are also linked to the main hosptial switchboard, however alarms at the hub site are audible only (see minor shortfall against PFE3).

No tissue is stored at the hub site with the exception of some fixed tissue taken under the Police and Criminal Evidence Act 1984 (PACE) during forensic PM examinations. Some forensic tissue is also stored in the histology labs, which are located at the satellite site. Tissue retained at PM examination is transferred from the hub to the histopathology laboratory at the satellite site for analysis, storage and/or transfer elsewhere for specialist analysis.

During the routine inspection, all areas aforementioned were visually inspected and three separate audit trails were carried out:

(1) bodies in storage at the hub site,

(2) bodies in storage at the satellite site and

(3) blocks and slides at the histopathology laboratory.

No anomalies were found during audit (1), which traced identification information on fridge doors to documentation on the body (including notice of death and wrist tags) through to the mortuary register book and duplicate electronic records. Audit (2) was conducted in the same way, however several anomalies were found (see major shortfall against GQ6). Audit (3) traced tissue sample receipt records to consent documentation, blocks and slides in storage and electronic laboratory records (including number of blocks and slides produced, tissue types and special stains). No anomalies were found during audit (3).

This was the establishment's second HTA inspection. All three conditions set against the licence at the previous inspection had been addressed to the HTA's satisfaction. All advice items had been acted upon; however further action was found to be required against one advice item concerning the practice of evisceration by an APT prior to the arrival of the pathologist (see minor shortfall and advice against GQ1).

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.	Two issues have contributed to this shortfall. (1) Patients are received into the mortuary from hospital wards with a shroud secured around the body. During the receipt process, mortuary staff check paperwork accompanying the patient but do not unwrap the shroud to check wrist tags or the condition of the body. Bodies are then stored until such time as PM examination, viewing or release is required. Failure to check the ID and condition of the body on receipt means that staff cannot be sure of the identification or condition of the body whilst it is in storage and are unable to determine whether any possible damage or decomposition occurred prior to receipt or during storage in the mortuary. (2) Prior to PM examination, bodies are routinely eviscerated by APTs before the arrival of the pathologist. The SOP is not sufficiently clear to explain the routine communication that takes place between the pathologist and the APT in order for evisceration to proceed or not.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	Porters and duty managers (managerial level staff member assigned to be on-duty out-of-hours) perform duties in the mortuary unsupervised by mortuary staff. Although porters are trained by the portering manager, it is unclear what the training comprises as there is no documented training programme. Mortuary staff have had no input into the training programme and were not aware of its content. This is especially relevant as porters are involved with releasing bodies to undertakers out of hours (for religious or other reasons) using the Trust's rapid release procedure, under the supervision of the duty manager (who is not a member of morturary staff). The lack of clarity around how porters and duty managers are trained to undertake the release of bodies means that the risk of error is elevated because the DI cannot be assured that the correct procedure is being followed.	**Minor**

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	Two issues have contributed to this shortfall. (1) Anomalies were noted during the audit trail conducted in the body store at the satellite site, presenting a risk of misidentification. Firstly, the establishment was found not to have followed its same/similar name policy in one instance where two patients with similar surnames were in storage. Secondly, one patient (patient A) was not present in the unit listed in the mortuary register, and a different patient (patient B) was present in the same unit. Consultation with mortuary staff made it clear that the original patient (patient A) had been moved to the overflow storage area; however, the move was not documented in the mortuary register. (2) At the satellite site, storage spaces in the overflow area are numbered 1-30 and fridge spaces in the main body store area are labelled 1-52. Thus, 60 of the 82 body storage spaces share the same identifier, presenting a potential risk of selection of the wrong body for PM examination or release.	**Major**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Risk assessments in place at the establishment are of good quality but are largly health and safety based. The establishment has not risk assessed several key aspects of their work that could affect the integrity/traceability/dignity of bodies and human tissue. Risk assessing such aspects of the work could provide further assurance against the occurance of SUIs. The establishment may find it useful to use the HTA SUI category list as a guide for aspects of work to risk assess.	**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.	The temperatures of all body store areas at both sites are maintained by electronic systems with clearly visible digital readouts; however, daily temperature monitoring/recording by mortuary staff does not take place. Although alarms are maintained on an annual basis, their function is not checked regularly by mortuary staff. Establishing systems for monitoring and recording of body storage area temperatures (daily) and alarm testing (at regular intervals) would help to ensure that the integrity of bodies in storage is maintained.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to continue with plans in place to extend midwifery bereavement training. The DI is advised to amend the Trust consent policy to include who can take consent for PM examination (by job role) and that these individuals are required to undertake the 'level two' consent training offered by the Trust annually.
2.	GQ1	If a pathologist wishes to view the body prior to evisceration, he or she will phone the mortuary the day before the PM examination; however, if the pathologist is satisfied that evisceration by the APT can go ahead before his/her arrival, then the phone call will not be made. The DI is advised that routine, documented positive/negative confirmation for evisceration from the pathologist for each case would help to assure that evisceration occurrs appropriately.
3.	GQ2	The DI is advised to extend the mortuary audits currently in place to include a vertical audit of bodies in storage. This is especially relevant at the satellite site, where several anomalies were found during the vertical body store audit undertaken by the HTA.
4.	GQ7	Incident reporting is governed by a Trust level policy. Conversations with members of staff made it clear that they are aware of the requirement to report serious untoward incidents (SUIs) to the HTA and that the systems in place ensure that this occurs; however, this is not documented. The DI is advised to document the systems used for SUI reporting to the HTA, including in the documentation the lines of communication within the department and which types of incidents are reportable.
5.	PFE1	The mortuary register is kept under a large window to a car park that is accessible to the general public. The DI is advised to ensure that the book is kept closed when not in use (or the window shade down) to ensure confidentiality.
6.	PFE2	A cleaning schedule is in place and the cleanliness of the premises was satisfactory. Due to changes in working practice since the document was drafted, it was unclear from the schedule how often each cleaning practice was supposed to take place. The DI is advised to amend the cleaining schedule for clarity and so that is is consistent with working practice.

Concluding comments

Areas of strength and good practice were noted during the inspection. The establishment benefits from the work of several highly experienced members of staff who contribute to the high standard of care observed by the inspection team with regard to the facilities, the condition of bodies in storage and the cleanliness and good condition of the premises. Standard operating procedures examined were found to be well structured, thorough and clearly presented. The training programs in place and opportunities for professional

development, particularly those available to biomedical scientists, demonstrate a commitment by the establishment to encourage learning and career progression amongst staff members.

The establishment has made good progress since the last inspection with respect to all conditions that were placed on the licence. There are a number of areas of practice that require improvement, including one major and four minor shortfalls. The HTA has given advice to the Designated Individual with respect to audits, incident reporting, premises maintenance and security.

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: 6 February 2013

Report returned from DI: 27 February 2013

Final report issued: 28 February 2013

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: 15 May 2013

Appendix 1: HTA standards

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

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

Governance and quality system standards

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

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

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

GQ2 There is a documented system of quality management and audit

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

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

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

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

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

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

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

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs 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

3. 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.