Site visit inspection report on compliance with HTA minimum standards

Salisbury District Hospital

HTA licensing number 12047

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**

31 May 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.

Salisbury District Hospital (the establishment) was found to have met all HTA standards.

Particular examples of 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

Salisbury District Hospital has a mortuary that carries out around 450 coronial and three hospital (consented) PM examinations per year. Paediatric or forensic PM examinations are not performed at the establishment and are transferred to other licensed premises. Known high risk cases are examined.

This was the second site-visit inspection of the establishment and was a routine inspection to assess whether it is continuing to meet the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's last self assessed compliance information and audit of stored material, as well as pre-inspection discussions with the Designated Individual (DI) and review of the previous inspection findings. During the site visit, a visual inspection of the premises, review of documentation and interviews with establishment staff were undertaken.

An audit of three bodies in the body store was undertaken during the inspection. Details of the deceased were cross checked between the mortuary register, the details on the fridge door and the identification tags on the bodies. All records of the deceased matched and no anomalies were found during the audit.

In addition, four PM examinations where tissue had been taken were selected at random. Records for these four cases were reviewed both in the mortuary and the histopathology laboratory's electronic database. Tissue that was taken during the PM examination was also sought. In two of the four cases only blood toxicology samples were taken and these had been sent away for specialist analysis. Records of transport for these samples were reviewed. In the two remaining cases, tissue had been taken for histological examination and the blocks and slides were reviewed. Cross checks were made between the numbers of blocks and slides and the number recorded in the laboratory's electronic database. No anomalies were found. The 'coronial family-wishes' forms were also reviewed and again, no anomalies were found.

Occasionally staff in the obstetrics department seek consent for paediatric PM examinations. During the inspection the obstetrics department was visited. Clinicians described that when seeking consent, the consent forms, additional information and consent process were those of the licensed establishment where such cases would be transferred to for examination. Currently, however, there is no person designated nominated in this area and therefore the DI has no link to this activity taking place under the licence. Advice has been offered below with regards to this activity.

Inspection findings

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

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C1	During the inspection it was found that some tissue had been consented for use in surgical training. The establishment had sought consent using its usual consent procedures as a guide. The DI is advised that should this type of donation of tissue become more frequent, then specific consent procedures around this activity should be developed.
2.	C3	The establishment has undertaken training of bereavement staff in seeking consent for PM examination. However, due to the low numbers of consented PM examinations, keeping consent seeking skills current may be difficult. The DI is advised to develop a program of annual refresher training for all staff who may be involved in the consent seeking process, including staff in the obstetrics department who also occasionally seek consent for PM examination.
3.	GQ1	A new DI was appointed in April 2012 replacing the previous DI who is currently on long term absence. The regular governance meetings that were taking place with staff working under the licence have not been taking place recently. These meetings are important and should be reinstated so that activity taking place under the licence can be discussed, and learning from any incidents or new

		practices can be shared. The meetings provide a mechanism for staff to raise issues with the DI, and provide the DI with a forum in which any regulatory updates or changes in practice can be shared with staff.
4.	GQ1	The DI has not identified a member of staff within the obstetrics department who can act as a lead person. By identifying a lead person, the DI will be able to update staff of changes in practice and alerts from the HTA in addition to being updated herself about any changes in practice. The DI is advised to nominate a person designate to provide a link to the consent seeking activities.
5.	GQ1	Establishment staff confirmed that tissue retrieval teams do not attend the mortuary without mortuary staff being present. The SOP covering tissue retrieval did not reflect this and stated that tissue retrieval teams could attend the mortuary unaccompanied. The DI is advised to amend the tissue retrieval SOP to reflect current practice of mortuary staff being present during any tissue retrieval.
6.	GQ4	During the inspection there were occasions where correction tape had been used in records to correct errors. It may be necessary for the establishment to review previous data, which would not be possible following the use of such correction methods. The DI is advised to stop the use of correction tape at the establishment and provide guidance to staff on acceptable methods of correction.
7.	GQ6	There is currently no formal procedure to alert staff that a family has requested tissue taken during a PM examination to be repatriated to the body of the deceased prior to its release. As such requests are rare and the mortuary team is small, staff felt they would be aware of these requests; however, a formal procedure for alerting staff will safeguard against error. As all associated paperwork for the deceased is stored in individual files, the DI may wish to consider a mechanism where an alert can be placed in these files which staff would find when reviewing paperwork prior to body release.
8.	GQ8	Bodies enter the PM examination suite via pass though fridges. The establishment has a bank of larger fridges for bariatric bodies. Although it has never happened, if the establishment were to receive a very large bariatric body the bariatric pass through fridge, despite its larger doors, may not be wide enough to allow the body to pass into the PM examination suite. The DI is advised to risk assess the likely hood of this happening. This risk assessment should include determining and documenting what action would be taken should this occur.
9.	GQ8	In addition to the normal bank of storage fridges the establishment has converted a side room into additional storage for bodies. This additional storage is also used for the storage of bariatric bodies, which are stored on a trolley wheeled in between two body racks. During the audit of stored bodies, when removing a bariatric body being stored on a trolley it was noted that the available space to move the body in and out of the storage facility was limited. The DI is advised to risk asses the use of this facility in its current configuration for the storage of bodies to assess its suitability. In particular, the DI is advised to assess the storage of bariatric bodies to ensure that bodies can be moved in and out of storage without risking accidental damage due to the limited space available.

10.	PFE1	During the visual inspection of the PM suite some small pools of standing water were observed which had remained following the previous days cleaning. The mortuary floor however was undamaged with no visible cracks to the surface. The DI is advised to keep the condition of the PM suite floor under review to ensure that the pooling of water does not increase in severity or lead to damage of the PM suite floor over time. Additionally the DI is advised to amend the cleaning procedures so that any standing water is mopped up or pushed to the drain.
11.	PFE2	The mortuary is cleaned by the mortuary staff. Although there is an informal system for cleaning the body store's fridges when they are empty and they are also cleaned on an ad-hoc basis as necessary, there is no schedule or record for the cleaning of the fridges. The DI is advised to implement a schedule of cleaning and to record when cleaning takes place to assure herself that body storage fridges are cleaned at regular intervals.
12.	PFE3	Fridge and freezer temperatures are monitored and recorded daily by the mortuary staff. There is a local alarm that sounds in the mortuary if the storage facility's temperatures are out of range. This alarm however does not sound at switchboard out of hours. The DI is advised to devise and implement systems to alert staff out of hours or during holiday periods if fridge temperatures go out of range.

Concluding comments

Areas of good practice were observed during the inspection an example of which is detailed below.

The establishment has recently developed a good system for tracking bodies that are being held in long term storage. All long term storage cases are entered onto a separate log of bodies, which records where the body is being stored, the date that it entered the long term store and the date it is removed from the store and released. This system provides a log of stored bodies that can be audited which helps to assure the DI that long term storage cases are being monitored and being released as appropriate.

Staff at the establishment have recently undertaken an audit where laboratory staff audited the mortuary staff and vice-versa. The establishment reported that this had been a very useful exercise since staff were auditing unfamiliar processes and were able to identify improvements as a result of looking at procedures from a new perspective.

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

Report sent to DI for factual accuracy: 28 June 2012

Report returned from DI: 17 July 2012

Final report issued: 19 July 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.

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.