Site visit inspection report on compliance with HTA minimum standards

Airedale General Hospital

HTA licensing number 12138

Licensed under the Human Tissue Act 2004 for the

- **making of a post mortem examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

8 November 2011

Summary of inspection findings

The mortuary and histopathology laboratory at Airedale General Hospital (the establishment) was subject to a themed inspection focusing on consent, quality management and prevention of major equipment failures.

The establishment was found to have met all HTA standards relating to each theme.

The establishment was last inspected in October 2009 and the DI has acted on the advice and guidance provided following that inspection.

The DI and the Licence Holder were assessed and found to be suitable in accordance with the requirements of the legislation at the establishment's previous inspection in October 2009.

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.

A themed inspection may be carried out at establishments which have been found previously to represent a lower risk of regulatory non-compliance. Themed inspections focus on standards against which the HTA has identified common shortfalls across the post mortem sector and areas of risk identified from analysis of serious untoward incidents reported to the HTA. The themes selected for 2012/13 business year are outlined in the table below.

Themes	**HTA Standards**
Appropriate consent is in place for post-mortem examinations not under the Coroner's jurisdiction and in the event that tissue is to be retained for future use. Where there is no consent for retention, tissue is disposed of.	
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.	C1
Information about the consent process is provided and in a variety of formats.	C2
Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	C3
Governance and quality systems promote robust traceability systems, reducing the risk of serious untoward incidents.	
All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process.	GQ1

There is a documented system of quality management and audit.	GQ2
A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	GQ6
There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	GQ7
Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	GQ8
Fridges and freezers safeguard the integrity of the deceased.	
There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	PFE3

In addition to the standards listed above, the HTA will follow-up on any other issues that have arisen since the establishment's last inspection.

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 forms part of a general hospital and deals with approximately 800 bodies each year. It carries out around 50 post mortem (PM) examinations each year, the majority under the authority of the North Yorkshire Coroner, with only a small number, generally less than five, hospital consented PM examinations being carried out each year. Only adult PM examinations are carried out, with paediatric cases being referred to a nearby specialist HTA licensed establishment.

Consent for hospital PM examinations is taken only by trained clinical staff, their training being subject to regular updating. For paediatric cases, consent is taken by trained establishment obstetricians or paediatricians and the consent documentation forwarded to the specialist establishment. Transport of paediatric cases to and from PM examination, together with transport of any related blocks and slides, is recorded on a database spread sheet.

The body store has capacity for 43 deceased, with that number including fridges capable of storing bariatric cases, and one bank of fridges also being convertible to freezers for longer term storage. The fridges are alarmed locally and to switchboard, which is manned 24 hours a day. Temperatures are recorded each working day to enable trending and pre-emptive maintenance. The alarm system is tested regularly and the results recorded.

Bodies are received into the establishment from hospital wards and from the community. The procedures used by mortuary staff in each case are similar, with identification details being transferred from wristbands to the mortuary register, database and body store white board, after comparison with the "death card" provided with the body. Each body is given a unique number.

Out of hours, except in cases where mortuary staff are needed to prepare a body for a family viewing or formal identification, trained portering staff deal with receipt of bodies into the mortuary, entering details from the death card into the mortuary register and adding the name of the deceased onto the wall board. When mortuary staff have carried out identification checks, measurements and property checks, the register and wall board are marked accordingly and details entered into the database.

Authority for a PM examination is faxed to the establishment by the Coroner, or a consent form is delivered to the mortuary in the case of a hospital PM examination. Where a PM examination is to be carried out, the body is assigned a sequential “pm number” which is then used to identify the PM report and any tissues retained at PM examination. Any tissues retained are delivered to the histopathology laboratory by mortuary staff or the pathologist, accompanied by a request form detailing the pathologists’ requirements. Relevant details of the number of blocks and slides are entered onto the database serving both laboratory and mortuary, and onto spread sheets relating to tissues retained. The spread sheet is updated with relatives’ disposal wishes and ultimately with details of retention, return or disposal.

The DI has advised the coroner’s officer of the need to ensure that consent for retention of tissues taken at PM examination, for use for a scheduled purpose, is obtained from the appropriate person in the hierarchy of qualifying relationships. The relationship of those providing consent is detailed on the coroners form and in any hospital PM examination consent.

The return, disposal or retention of blocks and slides is detailed on a spread sheet and, where blocks and slides are disposed of, a library card or block is placed within the block and slide store providing a visual confirmation that disposal has been carried out. On the date of inspection, the establishment was storing no wet tissues or organs and the establishment produces an annual report to the Trust Quality and Safety Committee detailing tissues or organs retained, following audit of storage.

Release of bodies is only carried out by mortuary staff.

The establishment was inspected in October 2009 when some advice and guidance was offered, and this has been acted upon.

This was a routine, themed, inspection; the standards assessed being detailed in Appendix 1. The inspection comprised a visual inspection of the body store, PM room and histopathology laboratory store, document review and discussions with key staff involved in consenting procedures, governance and quality systems and traceability of tissues.

In addition, an audit of traceability was carried out:

- A body was located within the body store and wristband identity details compared with entries in the mortuary register, database and wall board.
- Database records for one case where a coronial PM examination was carried out, and one case where a hospital PM examination was carried out were examined, the relevant coronial authorisation or consent documentation reviewed and electronic and hard copy records relating to blocks and slides examined. The related blocks and slides were then located within the store.

No discrepancies were found.

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	The DI is advised to consider how he records that he is satisfied that consent for retention of tissues for use for a scheduled purpose has been obtained from the appropriate person in the hierarchy of qualifying relationships, in coronial cases. This will help to ensure that retention of tissues, when coronial authority has ended, is in line with the requirements of the Human Tissue Act.
2.	GQ2	The DI is advised to formally document the procedure followed to notify mortuary staff of the rare cases where relatives have requested repatriation of tissues with the body prior to any funeral or cremation to aid staff in ensuring that relatives wishes are carried out and to minimise the risk of a body being released in advance of repatriation of tissues.
3.	GQ2	The DI is advised to amend the SOPs relating to receipt and release of bodies, to reflect the procedures being carried out where there are bodies with same or similar names. This will ensure that any locum or inexperienced staff, who may be unfamiliar with the procedures, have documented guidance to follow, therefore minimising the risk of errors in identification.
4.	GQ2	The DI is advised to document the procedures followed when placing bodies into the freezer for longer term storage and the procedures followed when confirming whether ongoing storage is required. This will help to minimise the chance of any body remaining in storage for a longer period than necessary and ensure that relevant third parties are pressed to ensure that any outstanding issues leading to the need for continued storage are addressed as quickly as possible.
5.	GQ6	The DI is advised to formally document the arrangements which have been agreed to deal with those occasions where the body store reaches near capacity, to reflect those informally agreed. This will ensure that any staff unfamiliar with the arrangements have guidance to follow in the event full capacity is reached.
6.	GQ8	The DI is advised to expand the suite of regulatory risk assessments currently carried out to cover the categories of Serious Untoward Incidents reportable to the HTA in order to help mitigate against the

		occurrence of such incidents and to inform the updating of Standard Operating Procedures.

Concluding comments

The HTA saw various examples of good practice during the inspection. Consent for hospital PM examinations is only carried out by named clinicians who have received formal training from the DI. This training is recorded and periodically updated and the details of trained clinicians placed on the Trust intranet for the information of other clinicians who may wish a hospital PM examination to be carried out.

Since the last inspection, all of the information on the PM process provided to relatives has been updated

The establishment uses an electronic database and various colour coded spread sheets to record the passage of tissues through the laboratory, also recording details of relatives' wishes and ultimate disposal. These spread sheets allow for accurate audit and provide a visual confirmation of cases where tissues remain to be dealt with in accordance with the relevant instructions.

The histopathology department has a stand-alone quality management system, integrated where necessary with the overarching Trust system and there is an assigned person in charge of quality management. This allows changes to documentation following risk assessment, audit, incident or the introduction of a new process, to be carried out efficiently and, as the department is relatively small, there is good buy in to quality management by staff. The laboratory is CPA accredited, with the last two inspection visits detailing no non compliances.

There are regular vertical and horizontal audits, including of procedures against SOPs, and the establishment provides an annual report to the Trust Quality and Safety Committee detailing the retention of any tissues or organs following audit of storage.

The HTA saw evidence of incidents being reported internally, followed up, and corrective actions carried out. Risk assessments and incidents are discussed at Histopathology group meetings, attended by staff in the laboratory and mortuary, in order that lessons learned are disseminated.

As well as clinicians involved in taking consent for hospital PM examinations being trained, establishment staff have also trained porters on mortuary procedures, and other clinical staff on the PM process.

The establishment team appear to have excellent levels of communication and all showed a commitment to on-going improvement.

The HTA has given advice to the Designated Individual on some aspects of governance documentation and risk assessment.

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

Report sent to DI for factual accuracy: 16 November 2012

Report returned from DI: 19 November 2012

Final report issued: 19 November 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.

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.