Site visit inspection report on compliance with HTA minimum standards

Sunderland Royal Hospital
HTA licensing number 12281

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**

17 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.

Although the HTA found that Sunderland Royal Hospital (the establishment) met the majority of the HTA standards, a shortfall was found in relation to the documented procedure for reporting and investigation of adverse incidents. The procedure makes no reference to the categories of serious untoward incidents which should be reported to the HTA, or the method for doing so.

The establishment was previously inspected in 2009, and items of advice and guidance provided then have been acted on by establishment staff. In particular, consent forms have been updated and consent training formalised. A risk assessment has been carried out covering risk of non compliance with HTA standards and the disposal policy has been updated.

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

HTA licence 12281 covers mortuary and pathology activities carried out within Sunderland Royal Hospital. The facility was built five years ago and the establishment carries out approximately 600-650 coronial post mortems annually. In the last year, only one consented hospital post mortem was carried out.

The body store has storage spaces for 100 bodies, including five bariatric and ten freezer spaces, five of which are also suitable for bariatric cases.

The establishment does not carry out paediatric post mortem examinations, these being referred to another mortuary. High risk cases up to category three are carried out at the establishment in a separate post mortem room, and a specific process is in place governing this activity. The principal post mortem room has four tables.

The establishment was last inspected in 2009. No shortfalls were identified at that time, and advice and guidance was offered. The establishment has acted on the advice provided and has altered procedures and processes in relation to training in and the taking of consent, the recording of body store temperatures and the disposal policy and procedures.

Bodies are received into the establishment from the hospital wards or from the surrounding community. The procedures for receipt in each case are similar and the documented

procedures also govern receipt out of hours, which is managed by portering staff who have been trained both by supervisor porters and mortuary staff.

On receipt, each body is allocated a sequential number and appropriate details are entered into a paper mortuary register, onto cards which are placed on the appropriate refrigerator door and on the body itself.

Authority for a coronial post mortem is faxed to the establishment by the coroner's staff and at that time relatives wishes are also recorded, in the event that tissues are retained during the post mortem examination. If tissues are retained, coroner's staff subsequently confirm this to the family of the deceased.

For those cases where a post mortem examination is carried out, a further sequential post mortem number is allocated. This post mortem number is then used on the reports arising from the post mortem examination itself and is also used to track tissues retained at post mortem and any blocks and slides made from them.

Tissues retained at post mortem are sent to the histopathology laboratory within the hospital, and details transferred onto a dedicated laboratory software system. This system is updated with details of blocks and slides produced, and also details numbers of additional slides where special stains have been requested, therefore enabling traceability to be maintained.

When the coroner advises the establishment that his authority has ended by faxing the appropriate form, the original form is checked for relatives' wishes. Tissues, blocks and slides are then located within storage and dealt with accordingly.

There is a regular audit of tissues held in storage and the establishment staff maintain regular communication with the coroner to keep updated on likely inquest dates, which helps miminise the risk of tissues, blocks and slides being stored longer than is necessary.

Where disposal is carried out, it is carried out in line with trust disposal policy and details are recorded on the paper record as well as electronically.

Any tissues sent outside the establishment for specialist examination are accompanied by a fax back form so that the establishment has confirmation of receipt by the specialist involved.

This routine inspection comprised a visual inspection of the premises; interviews with key staff, including from the coroners office and bereavement services; and a review of relevant documentation, including the quality management system, policies and procedures. Documentation was reviewed in both paper form and as electronic documents held within the proprietary document control system.

An audit of traceability was also carried out:

- Two bodies were located within the body store and their identity details checked on the wall board and mortuary register.
- The authorisation forms for coronial post mortem examinations on two bodies were located. The tissues retained in both cases were traced through the laboratory system and the blocks and slides located within storage.
- Tissue blocks relating to a further patient were located in long term storage and the authorisation form located to confirm that the relatives' wishes were for retention for use for a scheduled purpose.
- Five organs being fixed in advance of sending for specialist examination were located and the relevant post mortem examination paperwork reviewed.

No discrepancies were identified.

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
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	While it is evident that all staff are aware of the need for HTA-defined serious untoward incidents ("SUIs") to be reported to the HTA within five days, the Adverse Incident Policy (QUAL-DOC-012) does not provide details of the categories of SUI which must be reported to the HTA, nor does it clarify the method of reporting or time limits for doing so. While the HTA acknowledges that the experienced staff at the establishment are aware of the appropriate procedures to be followed, not having a documented procedure increases the risk of non reporting. *Following the inspection the HTA was provided with evidence that this shortfall has been addressed by revision of the Adverse Incident Policy.*	**Minor**

Advice

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

No.	Standard	Advice
1.	C1,C2	The DI is advised to finalise the revised information booklet which provides details about the post mortem examination process to relatives of the deceased, in order that it may be provided to them in conjunction with a copy of any consent documentation signed. Any copies of the existing information booklet should be withdrawn from circulation as it contains reference to automatic retention of tissues as part of the medical record and contradicts the information on retention of tissues contained within the consent form itself and provided verbally to relatives by staff taking consent.
2.	C3	The DI is advised to schedule refresher training on consent, within a timescale she considers appropriate, for those staff members who have recently completed the establishment's consent training programme.
3.	GQ1	The DI is advised to review the Standard Operating Procedure for Post Mortem Examinations (PMEX.doc) to ensure it reflects the procedures carried out in practice, whereby mortuary staff only carry out evisceration following

		identification and external examination of the body by a pathologist.
4.	GQ1	The DI is advised to document the procedures followed where third parties carry out activities at the establishment, for example tissue retrieval, in order to reflect current practice. In particular it should include reference to ensuring receipt of appropriate consent documentation in advance, or at the time of the third party having access to the establishment.
5.	GQ4	The DI is advised to remind staff of the need to follow trust policy on the amendment of records to ensure that any amendments are visible and signed, and that correction fluid is not used.
6.	GQ6	The DI is advised to continue to raise the issue of bodies being delivered from the wards without the appropriate number of identity bracelets as an adverse incident, being in contravention of trust policy, and to ensure that all such events continue to be recorded in the incident registers.
7.	GQ8	The DI is advised to consider incorporating documented risk assessments of the categories of SUI which are reportable to the HTA into the schedule of risk assessment of non compliance with HTA standards. The DI is also advised to use the findings of such risk assessments to inform review of policies and procedures as part of the mitigation of risk.
8.	PFE3	The DI is advised to amend the existing contingency plan to ensure it refers to contingency arrangements in place should the body store reach a situation of near over capacity.

Concluding comments

The HTA saw various examples of good practice at the establishment. An “End of Life “ group has been set up to help communicate with bereaved families in an effort to demystify the processes involved following death, including the need for post mortem examination and the post mortem process itself.

Where possible, staff involved in consenting for post mortem examinations have observed the procedure as part of their training, and observation of post mortem examinations has been offered to nursing staff who deal with the bereaved.

The establishment has particularly strong communication with the coroner, and standard documentation used in communications between the establishment and the coroner has been drafted in collaboration with him.

The premises are now five years old, but have been carefully maintained by staff.

Establishment staff recognise the risk of regulatory non compliance where tissues are stored and have implemented a series of regular audits of tissues in store to minimise the risk of tissues being retained contrary to the consent provided.

Communication throughout the department, between mortuary and laboratory staff, appears to be very open.

The establishment values advice provided by the HTA on inspection and has acted on that previously given.

One minor shortfall has been identified in relation to adverse event or SUI reporting. In addition, the HTA has given advice to the Designated Individual with respect to some elements of the documentation used by the establishment.

The HTA requires that the Designated Individual addresses the shortfall 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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 29 May 2012

Report returned from DI: No comments on factual accuracy received

Final report issued: 13 June 2012

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: 25 May 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.