Site visit inspection report on compliance with HTA minimum standards

Royal Free Hospital NHS Foundation Trust

HTA licensing number 12013

Licensed under the Human Tissue Act 2004 for the

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

27 February, 2014

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.

The Royal Free Hospital NHS Foundation Trust (the establishment) was found to have met all HTA standards.

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 Section 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

This report refers to the activities that take place within the mortuary at the Royal Free Hospital (the establishment), which conducts around 80 post-mortem (PM) examinations each year. The majority of these are routine coronial cases and include high risk cases. Paediatric cases are transferred to another HTA-licensed establishment. In 2013, the establishment conducted eight hospital PM examinations. Consent for hospital and paediatric PM examinations is obtained by medical staff in conjunction with the Bereavement Officer. The DI, who is a consultant histopathologist, conducts a training course for those responsible for seeking informed consent from the next of kin.

The mortuary is staffed by a qualified Senior Anatomical Pathology Technologist (APT) and one additional APT. There is storage capacity for 39 bodies, including bariatric storage and freezer spaces. There is a separate fridge for paediatric cases. The PM room has three down draft tables. The establishment is a teaching hospital for trainee pathologists. PM examinations involving trainees are overseen by the DI. Identification of the deceased is always checked with the pathologist and the APT prior to evisceration. In high risk category three cases, additional personal protective equipment is worn and staffing levels are kept to a minimum.

Access to the mortuary is via a swipe card access system and limited to certain personnel. Within the mortuary, access to the the PM room and viewing room are also via swipe card entry. Fridges and freezers in the storage area are kept locked at all times.

Hospital porters transfer bodies from hospital wards to the mortuary, during and out of working hours. To enable mortuary staff to identify bodies that have been placed in the mortuary outside normal working hours, different coloured pens are left for the porters to record information on the body store inventory board. Furthermore, an audit of the fridges and

freezer is conducted each morning and this information is checked against the mortuary register, which enables discrepancies to be rapidly identified. There are systems in place to ensure repatriation of tissue to a body before it is released, in accordance with the wishes of the family, and also to identify deceased with the same or similar name.

The Labour Suite and North 7 ward, which is the obstetrics and gynaecology ward, does not carry out any activities under the licence. However, both have access to a fridge for storage of fetal remains and still born babies prior to transfer to the mortuary.

This was the second site-visit inspection of the establishment, which was inspected previously in June 2010. The current DI took on the role in September 2011.
This routine inspection comprised a visual inspection of the premises, document review and interviews with establishment staff. During the inspection the HTA was able to observe the procedures followed when releasing a body to the funeral directors.

Several traceability audits were completed as part of the inspection, as detailed below:

- Three bodies were selected from the mortuary register and found to be in the specified location in the mortuary using the identification tag on the deceased. The information was also verified with the mortuary database.
- Two of the bodies had similar names so it was possible to follow the documented process by which the establishment reduces the risk of releasing the wrong body.
- Details of two cases where PM tissue had been removed for histology were selected from mortuary records. Tissue blocks from these cases were traced through the histopathology laboratory database and block storage area, and the relatives' wishes for the retention or disposal of this tissue were verified.
- Records relating to an adult hospital consented PM examination were checked, tracing from the consent form signed by the qualifying relative, to blocks and slides taken and recorded for histology and the repatriation of tissue to the deceased in line with the documented wishes on the consent form.

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.	C2	The helpful pictorial illustration on page 5 of the "Guide to the Hospital Post-Mortem Examination of an Adult", which gives context to the size of tissue sections and blocks, could be extended to the baby and child information sheet.

2.	GQ1	An SOP for the transportation of bodies and other relevant material outside the mortuary should be drawn up. Although this information is available, it would be advantageous to have this summarised in a formal document, so that staff are clear and work to an authorised procedure.
3.	GQ1	The SOP LP-MOR-CLEAN should be modified to include the requirement for a weekly internal fridge clean to take place The documentation will then accurately reflect current practice
4.	GQ1	The establishment considers carefully whether bodies need to be transferred into freezer storage if this becomes necessary because of delays in release. However, the decision-making-process is not documented, so it may be unclear to mortuary staff and, in the event of challenge, is difficult to evidence.
5.	GQ1	At present, alarms triggered outside working hours are reported via switchboard to the Estates Department, but are not subsequently reported to the mortuary staff. The Out of Hours Escalation SOP that refers to body storage should ensure that any incident relating to the operation of the fridges and freezers is reported back to mortuary staff, so that they are aware and can track problems with storage. The DI may wish to consider an out of hour's communication book, kept in the mortuary and available to staff to record any relevant information or incident that may have occurred.
6.	GQ8	A robust system is in place to mitigate the risk of releasing a body which should have had tissue repatriated. The use of the coloured card could be extended to include deceased which have the same or similar names. A red coloured laminated card could, for example, be placed on the body. This would also be consistent with the annotation within the mortuary register and on the white boards, which currently help reduce the risk of releasing the wrong.
7.	PFE3	On the maternity ward, a fridge is used for the temporary storage of still born babies and fetuses. The DI is, however, advised to confirm that the fridge is maintaining a temperature that is appropriate for the storage of tissue. At the time of inspection, the display read HI and although staff were certain this was normal, confirmation should be sought that this is indeed the case in practice. The DI is also advised to consider the use of local temperature control systems, for example, a manual thermometer in the fridges, to ensure the correct temperature is recorded and maintained.

Concluding comments

There were a number of examples of good practice. An audit of the condition of the body is carried out on all bodies received into the mortuary from wards and the findings are shared with the ward. This is an example of good practice which supports shared learning. The daily check list of bodies present within the facility against the mortuary register is excellent and reduces the risk of errors. Members of the mortuary staff carry out a full risk assessment prior to evisceration and both the pathologist and APT sign to record that they have checked the identification of the deceased against the corresponding paperwork. There is informal training for portering staff given by the mortuary, but the department is now implementing a comprehensive formal training program, highlighting the HTARI classifications and the incident reporting criteria.

The establishment has several HTA licenses and all DI's attend a bi-annual HTA meeting to discuss matters relating to the licensable activities. Overall there is evidence of robust systems in place and excellent communication between staff and the DI.

Report sent to DI for factual accuracy: [date]

Report returned from DI: [date]

Final report issued: [date]

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 and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- 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.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

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.