Site visit inspection report on compliance with HTA minimum standards

The Royal London Hospital

HTA licensing number 12187

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**

21 September 2016

Summary of inspection findings

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

The Royal London Hospital (the establishment) was found to have met all HTA standards.

Advice has been given in relation to standards on consent, governance and quality and premises, facilities and equipment.

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 Section 18 of the Human Tissue Act 2004 (HT Act) They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

The mortuary at the Royal London Hospital is situated in the basement of the Pathology and Pharmacy Building, and is connected to the rest of the hospital via a system of underground corridors. It carries out approximately 500 post mortem (PM) examinations each year, just over half of which are consented paediatric or perinatal PM examinations, with most of the remainder carried out on behalf of the coroners for Inner North London and the Eastern District of London. A very small number (approximately 5%) are adult consented hospital PM examinations. Some paediatric PM examinations are undertaken on behalf of other hospitals.

The mortuary is secured by CCTV and an access-control entry system. The area used by funeral directors is well concealed from the public with a covered area for vehicles that has a large shutter door that is closed upon arrival to ensure complete privacy. There is a buzzer entry system and funeral directors are given set hours during which they can attend to collect bodies.

The body store at the establishment comprises of 49 fridge spaces, four of which can accommodate bariatric bodies. There is a separate freezer storage area with space for 15 bodies. Mortuary policy is that bodies are transferred from fridge to freezer storage after one month. The fridges and freezers are alarmed with upper and lower temperature triggers; there

is a local alarm and an alarm that sounds in the Building Maintenance Service (BMS) department. Out of hours the system also dials the on-call APT, who contacts BMS to see if there's a problem. The alarms and call-out process are regularly tested. The mortuary power supply is connected to the main hospital generator system.

The porters who are trained by mortuary staff, transfer bodies from within the hospital; mortuary staff perform dignity and identification checks on all bodies that are brought in overnight. Bodies of those who die in the community and will require a PM examination are brought in by funeral directors appointed by the Coroner. Bodies for Coronial PM examination are only brought in during normal working hours when mortuary staff are available to receive the body.

Viewings of the deceased are arranged via the hospital bereavement service or directly with the mortuary. For out of hours' viewings, the hospital site manager accompanies the family. In these cases, the porters and nursing staff prepare the deceased for viewing. Staff have panic alarms that ring in the mortuary office, the PM suite and at an external alarm company, who contact hospital security.

The PM suite has four height-adjustable, downdraft PM tables. There is also a separate high risk suite with one PM table. Known high-risk post mortem examinations, including HIV, Hepatitis B, Hepatitis C and Tuberculosis, are undertaken. Staff have access to personal protective equipment when conducting both routine and high-risk post mortem examinations. An individual risk assessment takes place before every PM examination, which includes confirmation from the APT and the pathologist that they have seen the relevant documents approving the PM examination and considers whether there is sufficient clinical information available and risk of infection.

The HTA licensing arrangements also cover a separate, self-funding, pathology laboratory called The Blizzard Institute. The Institute receives tissue samples from a number of pathologists, who perform PM examinations at public mortuaries throughout London, and who also perform diagnostics for other hospitals. The Institute has recently introduced a new tracking system, which helps to identify tissue where information has yet to be received from the coroner or the pathologist about the wishes of the family with regards to disposal of samples. As a result, it has started to send a list of outstanding cases to the relevant Coroners annually (see advice item 5).

As part of the inspection an audit of the body store was undertaken - four bodies were selected at random, three adults and one paediatric case. Details from the identification tags and the physical location of the bodies were cross checked against the establishment's paper mortuary register. Additionally, details of tissue reatained during three PM examinations were selected from the mortuary computer system and compared with records documenting the wishes of the family and tissue stored in the laboratory. No anomalies were found during this audit.

The establishment has been licensed since 2007 and this was its third routine site-visit inspection. In addition to the audits mentioned above, the HTA conducted a visual inspection of the premises, reviewed documentation and carried out interviews with the Designated Individual and establishment staff.

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.		The DI is advised to consider identifying Persons Designated in the Maternity Department and in the Blizzard Institute who can keep her updated about activities subject to HTA licensing taking place in these areas.
2.	C3	There is a training presentation for staff who wish to seek consent for adult PM examinations; this training lists the people in qualifying relationships but it does not indicate that there is a hierarchy and there is no mention that consent must be sought from the highest person in the hierarchy. The DI is advised to update this training to ensure that more information about the hierarchy of qualifying relationships is included.
3.	C3	Consultants seeking consent for adult PM examinations are required to sign a statement on the consent form that states 'I have had the opportunity to read' the presentation on PM consent seeking. The DI is advised to update the form to state 'I have read' the presentation on PM consent seeking, making this mandatory rather than optional.
4.	GQ1	The Standard Operating Procedure for receipt and release of bodies highlights that identity details should be checked but does not specify which details or that a minimum of three identifiers should be used. The DI is advised to update the relevant SOPs.
5.	GQ6	The Blizzard Institute has recently begun to send a list of outstanding cases to the Coroner on an annual basis, it is recommended the DI considers doing this on a more regular basis to try to reduce the build-up of a backlog.
6.	GQ8	There are a number of risk assessments that address risks to the deceased; however not all risks have been considered, for example, accidental damage. The DI is advised to use the HTA reportable incident categories and ensure that areas of risk identified in those are formally assessed.
7.	PFE 1	The door from the viewing room leads to a hall and a lift to the mortuary. This door cannot be locked form the outside. The DI should assess the risk of unauthorised access to the mortuary from the viewing room.
8.	PFE3	The establishment has 15 freezer spaces; however, at the time of inspection there was only one space available in the freezer and there were two bodies that were nearing the time that they would need to be transferred to freezer storage. Although, there has never been an issue with freezer capacity, it is recommended that the DI risk assess current freezer storage capacity and ensure that there are systems in place to mitigate the risk of running out of freezer space.

Concluding comments

A number of areas of good practice were observed during the inspection:

- babies are logged on the mortuary register using the mother's details and only released when these have been confirmed, this helps prevent release of the wrong body;
- porters are currently trained by mortuary staff; a new portering supervisor will soon take over the training but there will be 24 champion porters, four of whom will be on duty at any one time who have in-depth mortuary training;
- there is a comprehensive schedule of audits, which cover mortuary activities and management of bodies.

The HTA has given advice to the Designated Individual with regards to consent, governance and quality systems and premises, facilities and equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection / subject to compliance with the additional conditions applied to the licence.

Report sent to DI for factual accuracy: 14 October 2016

Report returned from DI: 10 November 2016

Final report issued: 11 November 2016

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 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.