



Site visit inspection report on compliance with HTA minimum standards

Royal Liverpool University Hospital

HTA licensing number 30002

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**

16 February 2016

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 HTA found that Royal Liverpool University Hospital (the establishment) had met the majority of the HTA standards. One minor shortfall was found against standard GQ7, regarding the documented procedure for reporting incidents to HTA.

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 (DI) are set out 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 licenses 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

Approximately 400 adult post mortem (PM) examinations are carried out each year in the mortuary at Royal Liverpool University Hospital (the establishment). Paediatric cases for PM examination are referred to another HTA-licensed establishment. The majority of PM examinations are conducted under authority of HM Coroner for City of Liverpool, with only a small number of hospital (consented) cases being carried out. The establishment is the North West regional centre for Home Office PM examinations, and over 100 of these are performed each year, including some defence PM examinations. Broadgreen Hospital, which is also within this Trust, has an unlicensed body store where bodies may be stored for a short period prior to PM examination or release to a funeral director (refer to advice item 4).

The establishment admits bodies from within the Trust only; however, Home Office cases come from other regional hospitals and the community. Outside core working hours, porters admit hospital cases; the on-call anatomical pathology technologist (APT) attends the mortuary to admit a body requiring a Home Office PM examination. The on-call APT will also attend if a body is to be released to a funeral director out of hours.

Clinicians seeking consent for an adult hospital PM examination are supported by a small team of trained and experienced staff (refer to advice item 2). The establishment has its own PM examination consent form and has adopted the HTA's model information leaflet for families (refer to advice item 1).

The mortuary has 80 refrigerated spaces, including five in deep freeze, with dedicated banks for bariatric and high risk cases. There is also a walk-in cold room with racking installed. The body store at Broadgreen Hospital has 30 refrigerated spaces. The main PM suite has seven PM examination stations, each with its own organ dissection area. There are two other

separate PM suites, each with one station, designated for Home Office PM examinations and high-risk cases.

Tissues removed at PM examination for histological analysis are processed into formalin-fixed, paraffin wax embedded, tissue blocks and microscope slides in the establishment's laboratory. A brain may be examined on-site or referred elsewhere, where necessary. Fluids for toxicological analysis and hearts for specialist examination are referred to other HTA-licensed establishments. With valid consent from the family, tissues and organs may be stored for use for scheduled purposes.

A collection of potted pathology specimens for teaching purposes, and fresh frozen body parts that have been imported from the United States of America for use on surgical training courses, are stored in the mortuary (refer to advice item 10).

The establishment has been licensed by the HTA since April 2007. Routine site visit inspections have taken place in June 2009 and May 2012. This report describes the third, routine, site visit inspection of the establishment. The inspectors met with staff working under the licence, reviewed documentation and inspected the mortuary and histopathology laboratory. Storage locations and traceability records for two bodies were audited. Records relating to a further four bodies that had been subject to PM examination were also audited. No anomalies were found in any audits.

Organs and tissues taken under police authority at Home Office PM examinations are stored at this establishment. Under s39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority contained a recommendation that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process. Therefore, procedures for Home Office PM examinations and the management of tissues and organs taken for criminal justice purposes were reviewed by HTA at this site visit inspection. Any findings in relation to Home Office PM examinations and police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Royal Liverpool and Broadgreen University Hospitals NHS Trust holds HTA licences under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (licensing numbers 11055, 40031 respectively). Activities taking place under those licences were not assessed at this inspection.

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.	The establishment's standard operating procedure (SOP) for reporting HTA Reportable Incidents (HTARIs) to the HTA does not list the current HTARI categories or refer to the online portal for submitting a notification. Also, this SOP has not been updated with the current DI's name. <i>(refer to advice item 8)</i>	Minor

Advice

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

No.	Standard	Advice
1.	C1, C2	Regarding consent documentation for adult PM examinations, the DI is advised: <ul style="list-style-type: none"> the 'Hospital post mortem – seeking consent' SOP should state that a family has 24 hours in which they can change their decision, which is the timeframe stated in the Trust's Hospital post mortem consent and examination' policy; an out of date version of the consent form is appended to the Trust 'Hospital post mortem consent and examination' policy (the current version is dated January 2007); the consent form states that tissue blocks and slides may be kept indefinitely as part of the medical record or in case they are needed in the future for further tests to be carried out. The HTA considers storage of blocks and slides for the medical record to be for potential use for a scheduled purpose, which requires valid consent under the HT Act. While the accompanying information leaflet is clear on the requirement for valid consent for storage of tissue blocks and slides, and clinicians and bereavement staff ensure that families are fully informed when they give consent, amending the wording of the consent form will help reduce any potential risk of misunderstanding.
2.	C3	The HTA noted that a small core group of experienced bereavement staff are available to support a clinician discussing a hospital PM examination with a family. It is anticipated new personnel will join this group in the future. The DI is advised to formalise plans for training and competence assessment of persons joining this group, for example: shadowing experienced staff; peer review of their initial consent seeking episodes; and regular refresher training.
3.	GQ1	The DI is advised that SOPs such as 'Mortuary: PM examination on high risk or suspected high risk cases (non TB)' and 'Mortuary: performing a post mortem examination on non high-risk cases' should specify which identification details the APT and pathologist must verify prior to commencing a PM examination. SOPs should also clarify what actions to take if a discrepancy is found in

		identification details.
4.	GQ1	The DI is advised to ensure that hospital staff at Broadgreen Hospital are familiar with the correct procedure for the release of a body from there, which is that mortuary staff from Royal Liverpool Hospital travel there to do this.
5.	GQ2	The establishment is transitioning from its current document control system to a new proprietary quality management software system. The DI is advised to ensure that: <ul style="list-style-type: none"> • all mortuary staff have access to the new system and been trained in its use, and; • routine quality procedures such as audits and review of documents should continue to their normal schedule during this transition period.
6.	GQ3	The DI is advised to periodically seek from Estates a list of names of portering staff who have been trained to admit bodies to the mortuary. Cross-checking these names against those of portering staff who have admitted bodies and completed the body admission register will enable the DI to verify that it is only trained staff who are doing so.
7.	GQ4	The DI is advised that portering staff should follow a consistent, clear, method for correcting errors in the body admission register. For example, errors could be amended by striking through with a single line, and putting the initials of the person making the amendment beside it.
8.	GQ7	The DI is advised that guidance on the HTARI categories and notification system is available at: https://www.hta.gov.uk/sites/default/files/HTARI%20Guidance%20for%20establishments%20Feb16_0.pdf The DI is also advised to ensure relevant staff are aware of the procedure for making an HTARI notification to HTA.
9.	PFE5	Mortuary body fridge and freezer alarms are tested every six months. The DI is advised to check with Estates and ensure that alarms on every bank of fridges are being tested.
10.	PFE5	Body parts for surgical training courses are stored in chest freezers. While temperatures are monitored each working day, the freezers are not connected to an alarm. There is a risk that a freezer breakdown over a weekend or bank holiday would not be detected until the next working day, which could lead to specimens deteriorating. The DI is advised to include this potential risk in a documented risk assessment and to consider whether alarms could be fitted to mitigate the risk of a failure going unnoticed out of working hours.

Concluding comments

Despite the minor shortfall, strengths were identified. The Trust's policy for consent for PM examination is clear and the establishment has adopted HTA's information leaflet for adult PM examination. In general, mortuary SOPs are well written and detailed. There is a rigorous two-person checking process prior to disposal of an organ. The mortuary premises are spacious and well designed. As an example of good practice, blue plastic sleeves are placed on the arms of a deceased person as a visual cue for APTs should organs need to be repatriated to the body prior to release to a funeral director.

A number of areas of practice require improvement, including one minor shortfall. The HTA has given advice to the DI regarding consent documentation, governance and quality systems, and alarm arrangements for fridges and freezers.

The HTA requires that the DI 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: 07 March 2016

Report returned from DI: No comments received

Final report issued: 31 March 2016

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: 22 August 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
<ul style="list-style-type: none">• 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
<ul style="list-style-type: none">• Relatives are given an opportunity to ask questions.• Relatives are given an opportunity to change their minds and it is 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
<ul style="list-style-type: none">• 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).

PFE2 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.

PFE4 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.