Site visit inspection report on compliance with HTA minimum standards

Royal Lancaster Infirmary

HTA licensing number 12356

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**

14 & 15 December 2016

Summary of inspection findings

This inspection was conducted jointly with assessors from the United Kingdom Accreditation Service (UKAS), who assessed compliance with selected HTA licensing standards on behalf of HTA.

Although the HTA found that the Royal Lancaster Infirmary (the establishment) had met the majority of the HTA standards, one minor shortfall was found in relation to premises, facilities and equipment.

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 (DI) are set out 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 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

The licence for the Royal Lancaster Infirmary (RLI) covers the establishment itself as the hub and two satellite sites at Furness General Hospital (FGH) and Westmorland General Hospital (WGH); they are all part of University Hospital of Morecambe Bay NHS Foundation Trust. The management of licensed activities across the establishment is achieved by the appointment of Person Designate (PDs) with responsibility for the satellite sites and in any departments outside the mortuary where licensed activity takes place.

This report describes the third routine site visit inspection, which, on this occasion, was conducted jointly with the United Kingdom Accreditation Service (UKAS). UKAS assessors visited the mortuary at all three sites and the histopathology laboratory based at RLI, and gathered evidence against licensing standards GQ1-6, PFE1-5 on behalf of HTA (see Appendix 1). In addition to inspecting the post mortem (PM) suite and body stores areas, the UKAS assessors assessed receipt and release procedures and undertook body store audits checking that the identity details on the deceaseds' body tags matched those in the mortuary records.

The HTA inspector met with staff involved with licensable activities conducted outside of the main mortuary areas, including those involved in seeking consent for perinatal and paediatric PM examinations, and viewed the area in the Emergency Department where removal of tissue takes place in cases of sudden unexpected death in infants (SUDI). The HTA inspector also reviewed standard operating procedures, risk assessments, incident reporting procedures and consent documentation, and undertook a traceability audit of tissue taken as part of the PM examination process.

The mortuary at RLI is in a separate building from the rest of the hospital and performs approximately 750 post mortem (PM) examinations per year on behalf on the Preston and West Lancashire and the Cumbria Coroners. High risk and perinatal/paediatric cases are transferred to other HTA-licensed establishments for PM examination. There are very occasional hospital consented PM examinations; when they are requested by a clinician, a member of staff with experience of PM examination is available to offer advice on the suitability of a PM examination and accompanies the clinian when they seek consent from the family to ensure any questions can be answered accurately.

The body store at RLI comprises 74 fridge spaces, including six that can accommodate bariatric bodies and four that are dedicated to perinatal/paediatric cases. There is an additional permanent contingency storage unit for up to 20 bodies located just outside the mortuary and easily accessible to mortuary staff.

Porters, who are all trained by mortuary staff, bring bodies of patients who have died on the hospital wards; they also meet the Coroner's funeral directors when they come out of hours with bodies from the community. There is CCTV in the body store area and the out-of-hours admissions are regularly review usings the system to ensure good practice is upheld by the porters.

The PM suite contains three downdraft, height-adjustable PM tables, each of which has a dedicated dissection area to avoid any mix up of organs.

The body store at Furness General Hospital can accommodate 38 bodies, six of which could be bariatric. Bodies are mainly received from the hospital. Only one or two PM examinations are performed each year; these are usually forensic or bariatric cases. There is only one member of staff at FGH so there is a morning 'huddle' call with staff at the hub to discuss what bodies will be transferred that day and to assess if the staffing level is sufficient for the workload; if it is considered not to be, staff from the hub travel to the site to assist.

Westmorland General Hospital is a small hospital with a body store. It has 15 fridge spaces, which are sufficient for the small number of bodies that need to be accommodated. The PM suite at WGH has been deactivated.

All the fridges are alarmed with upper and lower temperature triggers; however, the alarm triggers are set at a very high level, which is a potential risk to the deceased (see shortfall 1).

There is a local alarm and an alarm that sounds in the security department should the alarms deviate from the expected range. The alarms and the response procedure are tested regularly. Although the fridge temperatures are monitored, the information is not regularly reviewed to identify any trends that could give early warning of a potential failure.

A body store audit was undertaken at all three sites, whereby details on body identity tags were compared with those in the mortuary records. Additionally, identity details of bodies

transferred from FGH to RLI were compared at both sites to check traceability; one minor anomaly was found.

A tissue traceability audit was also undertaken. Details of three PM examinations where tissue samples had been taken for histology were checked against the establishment's electronic records; all tissue had been stored or disposed of in line with the families' wishes as supplied by the Coroner.

Home Office PM examinations may be conducted at this establishment, and tissue samples and organs retained for police purposes sent to other establishments for analysis. Under s39 of the Human Tissue Act 2004 (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 the HTA. Any findings in relation to Home Office PM examinations and/or 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.

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

Premises, Facilities & Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records	The alarms triggers for the fridges are set at 0 and 12 degrees, the latter being higher than sector norms. This, combined with the fact that temperature logs are not reviewed for any temperature trends, means that the fridges could run at an inappropriately high temperature for some time without the awareness of staff, posing a risk to the integrity of bodies. (Identified by UKAS as a non-conformance against ISO accreditation standard 15189, 5.2.6)	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	There are no regular formal meetings for PDs and those working under the licence. These may be of particular importance when the HTA's new standards come into effect on 1st April so any changes required within different departments can be identified and managed. The DI is advised to introduce regular minuted meetings where HTA issues are discussed.
2.	GQ3	Porters are trained to work in the Mortuary and records are maintained by the Portering Manager of those who have completed training. It is recommended that an audit is carried out to check that only trained staff are working in the Mortuary. (Identified by UKAS as a non-conformance against ISO accreditation standard 15189, 5.1.5.)
3.	GQ3	Competency assessments for mortuary staff do not include objective evidence of how competency has been determined apart from by observation as part of routine working. It is recommended that the DI ensures that formal process audits for all staff are undertaken and documented. (Identified by UKAS as a non-conformance against ISO accreditation standard 15189, 5.1.6.)
4.	GQ4	There is a viewing and ID instruction document for porters on how to prepare the deceased for viewing. It is recommended that details about the redlight process that indicates that a body is still in the viewing suite are added to ensure the appropriate checks are made.
5.	GQ6	All three mortuaries use the same mortuary numbering system which means that where a body has been transferred from FGH to RLI for PM examination, at the start of the year when both mortuaries start at number 1 there may be two bodies with the same mortuary code being stored at the same time. This code is not used as one of the identifiers for viewings, PM examination or release but the DI is advised to risk assess this process to ensure that there are no unintended consequences. (Identified by UKAS as a non-conformance against ISO accreditation standard 15189, 5.4.1.)
6.	QG7	The HTARI SOP is not well distributed and the link to the HTA website is out of date. The DI should ensure all staff are aware of the SOP, what incidents need to be reported and what to do in the absense of the DI in order to ensure any incidents are reported within the five-day reporting deadline.
7.	GQ8	Risk assessments consider the risk of misidentification but do not consider other risks to the deceased such as accidental damage or major equipment failure. The DI is advised to consider the HTARI categories when undertaking risk assessments.
8.	GQ8	Current mortuary/body store service continuity plans do not contain adequate information to describe contingency arrangements. (Identified by UKAS as a non-conformance against ISO accreditation standard 15189, 4.1.1.4n.)
9.	PFE1	It is recommended that the intruder alarm system which is installed within the mortuary is brought into use to provide additional security to the building. (Identified by UKAS as a non-conformance against ISO accreditation standard 15189, 5.2.2.)

Concluding comments

Despite the shortfall, areas of good practice were identified:

- Standard operating procedures apply across all sites, and contain clear site-specific sections where applicable;
- The process of dealing with products of conception, still births and babies is well managed, with a clear matrix document developed to clarify exactly what steps to take depending on the gestation of the loss. The bereavement midwives are experienced and are given the flexibility to work across sites to cover for one another and to make home visits to parents who wanted to leave the hospital immediately rather than consider a PM examination at the time; this way they can be ensured that parents are given the appropriate support and that consent is fully valid. The midwives have also visited the hospital where cases are sent for PM examination and can give parents additional information about where their child is going if they want it;
- The mortuary runs a training course for staff, which includes information about its role and a visit to the mortuary;
- The pathologists take the time to talk through any unusual findings with the bereavement team or Coroner's Officers to ensure they feel equipped when speaking with the family;
- The DI performs a monthly audit of out-of-hours activity in the body store, reviewing the CCTV footage to check that the porters handle bodies appropriately and that there are no unnecessary visits or activity in the mortuary when staff are not present;
- There is a decision-led flowchart on what to do in the case of a Sudden Unexpected Death in Infancy (SUDI), which is kept in the resuscitation area in A&E. This chart clearly identifies whom to contact and what samples should be taken, and is particularly helpful as this is a process that happens infrequently;
- There is a daily check of how long bodies have been in the mortuary. There is a process in place to follow up with the Coroner and bereavement services once a body has been stored for ten days. This means that any issues or cases where there is no next of kin can be identified early and staff know that a body is likely to need to be moved into freezer storage;
- Whilst the establishment works with two different Coroner's who provide slightly different options to families in relation to tissue samples taken as part of the PM examination, implementation of these systems is well managed and ensures that the wishes of the family are followed;
- The morning huddle/call with staff at FGH appears to be an effective way to support staff remotely.

A number of areas of practice require improvement, including the minor shortfall. The HTA has given advice to the DI with respect to governance and quality systems and premises, facilities and equipment.

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

Report sent to DI for factual accuracy: 13 January 2017

Report returned from DI: 20 January 2017

Final report issued: 24 January 2017

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: 17 October 2018

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).

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.