Site visit inspection report on compliance with HTA minimum standards

The Mortuary Department, Royal Albert Edward Infirmary

HTA licensing number 12175

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**

22 April 2015

Summary of inspection findings

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

Although the HTA found that the Mortuary Department at the Royal Albert Edward Infirmary (the establishment) had met the majority of the HTA standards, one minor shortfall was identified in relation to the security of the mortuary.

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 (DI) 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 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 Mortuary Department at the Royal Albert Edward Infirmary in Wigan (the establishment) is part of Wrightington, Wigan and Leigh NHS Foundation Trust. The establishment has been licensed by the HTA since May 2007 for the making of a post mortem (PM) examination, removal of relevant material from the deceased and storage of the deceased and relevant material for use for scheduled purposes.

The establishment conducts approximately 650 adult PM examinations each year. High risk, Home Office and perinatal/paediatric cases are transferred to other HTA-licensed establishments for PM examination. The majority of PM examinations undertaken at the establishment are performed under coronial authority.

Consent for occasional adult hospital PM examinations is sought using a consent form and information leaflet. The establishment did not conduct any hospital PM examinations in 2014.

Staff at the establishment seek consent for perinatal/paediatric hospital PM examinations using the consent form and information leaflet provided by the Stillbirth and Neonatal Death (Sands) charity. The establishment sought consent for three perinatal/paediatric PM cases in 2014.

A core team of staff at the establishment are trained to seek consent for adult and perinatal/paediatric hospital PM examinations. Specialist clinical staff may accompany these staff during the consent process to provide additional medical information.

The mortuary is located in a separate building on the hospital site. The building is secured by locked doors with key access and there an intercom system for staff to allow entry to visitors. There is closed-circuit television (CCTV) monitoring of the building entrances. The mortuary itself does not have adequate access control arrangements (refer to shortfall for standard PFE1).

The mortuary receives bodies from the hospital and the community. Bodies from the hospital have printed hospital identification wrist tags, including the patient's unique hospital number. Bodies admitted from the community have wrist tags, added by the police, which include a pre-printed unique identification number (see advice item 6). The establishment uses a series of forms and an electronic database to record the details of body admission, PM examination and release to a funeral director. Perinatal cases are labelled with the mother's hospital number and are recorded in a dedicated mortuary register (see advice item 7).

The mortuary has 48 fridge spaces for bodies, including eight spaces for larger bodies. A designated bank of fridges can operate in freezer mode should bodies require longer-term storage (see advice item 12). Perinatal/paediatric cases are stored on dedicated trays within the adult fridges. The establishment has contingency arrangements for the storage of bodies at a nearby hospital, including storage of bariatric cases. It also has access to temporary storage facilities, which can be erected at short notice to provide additional storage capacity. Storage temperatures are continually monitored and there is an automated alarm call-out procedure in the event of temperature deviation. Staff also check and record storage temperatures twice per week.

The floor of the PM suite is showing signs of deterioration (see advice item 11). The PM suite has four downdraft tables and a dedicated bench for the preparation of tissue samples. Wet tissue samples taken for histopathological analysis are transferred to another HTA-licensed establishment for processing, and then returned to the establishment for storage. With appropriate consent, PM tissue blocks and slides are stored for use for scheduled purposes. Samples for toxicological analysis are sent to other HTA-licensed establishments. The establishment maintains records of PM samples on an electronic database.

Tissue samples are removed from deceased infants in the Maternity department for genetic testing, and details are recorded in the mother's patient notes. Senior clinical staff in the maternity department oversee consent for tissue sampling and genetic testing, as well as the removal of the tissue (see advice item 2). Samples are sent to a specialist facility for testing (see advice item 9).

The establishment informed the HTA that removal of samples from deceased children in cases of sudden unexpected death in infancy (SUDI) is performed during PM examination, which is undertaken at another HTA-licensed establishment. In these cases, deceased children are immediately transferred to the other establishment, and the PM examination conducted soon after, under Coronial authority.

This report describes the second, routine site visit inspection of the establishment. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted visual inspections of the Mortuary and areas in the Maternity department where licensed activities take place. In the Mortuary, storage locations for three adult bodies were audited against paper and electronic records. The traceability records and stored tissue blocks for three coronial PM examinations were also audited. No anomalies were identified. Traceability records for samples taken in the Maternity department were not available for the inspection team to review, as these are contained in patient records.

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 and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are fit for purpose.	The mortuary viewing room has two doors, leading to the mortuary reception area and the body storage area. These doors are not secured during working hours, or out of hours when families attend for viewings. The lack of access control on these doors means that visitors to the mortuary may enter the body storage area unrestricted, and from there enter the PM suite. This presents a risk to the dignity of the deceased, and the safety of staff.	**Minor**

Advice

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

No.	Standard	Advice
1.	C3	The DI is advised to review the refresher training for staff seeking consent, to include process audits to assess staff competence. This will help to ensure that staff remain competent to seek consent, and may facilitate sharing of good practice. This is particularly important as staff at the establishment only seek consent for a small number of PM examinations per year.
2.	GQ1	The DI is advised to ensure that staff involved in the removal of relevant material from deceased perinatal cases in the Maternity department are included in formal governance meetings relating to the HTA licence. This will help to ensure that the activities in the Maternity department conducted under the authority of the HTA licence are included in the overall governance arrangements.
3.	GQ1	The DI is advised to review standard operating procedures (SOPs) to ensure that they contain sufficient detail. Particular examples include: • the SOPs describing identification of the deceased should include additional details of the identification procedure, including the minimum number of identifiers that must be checked; and • the SOP for contingency arrangements for storage of the deceased should include details of the procedure for invoking the contingency plan for the temporary on-site storage facility.

4.	GQ2	The establishment is advised to review its audit schedule to include all activities conducted under the authority of the HTA licence, and the records pertaining to these activities. For the mortuary, the DI is advised to include audits of the storage of perinatal and paediatric bodies against the mortuary register / fetal specimens register and electronic database. In the Maternity department, the DI is advised to undertake audits of consent forms for the removal of tissue, and of records of sample traceability.
5.	GQ4	The DI is advised to remind the mortuary staff of the establishment's procedure for the amendment of written records. This will help to ensure that staff adopt a consistent approach to correcting errors in written records such as the mortuary register, and that the traceability of amendments is maintained.
6.	GQ6	The establishment is advised to record the unique tag identification number for bodies admitted from the community in the traceability records. The use of this unique identification number will help to ensure traceability of bodies admitted from the community.
7.	GQ6	The DI is advised to review the labelling of perinatal cases received by the Mortuary from other hospital departments. The establishment's SOP states that perinatal cases should be labelled with at least two identifiers (for example: the date of delivery and the mother's hospital number). The inspection team saw a number of perinatal cases in the Mortuary labelled with the mother's hospital number only.
8.	GQ6	The DI is advised to consider strengthening the system for highlighting deceased persons with same or similar sounding names. For example, the DI may wish to consider extending the existing system of placing a coloured label on the fridge door in the body storage area, to placing a label on the fridge door in the PM suite when the deceased is due for PM examination.
9.	GQ6	The establishment currently records the details of samples removed from perinatal cases in the Maternity department in the mother's notes. The establishment is advised to additionally record the details of samples in a separate log. This record should also include details of the transfer of samples to the specialist centre for genetic analysis. This will facilitate sample traceability and the ease of conducting audits of sample traceability.
10.	GQ8	The DI is advised to review the documented risk assessments relating to activities conducted under the HTA licence to include additional details of each risk and the current and future mitigating actions. In particular, the DI is advised to review the risk assessment of the admission of bodies to the mortuary by porters to consider the risk of transferring bodies from the hospital wards to the mortuary, which requires them to manoeuvre down a steep slope.

11.	PFE1	The DI is advised to keep under review the condition of the PM suite. There is a crack in the PM suite floor that does not currently break the seal of the floor. The DI is advised to ensure that remedial actions are taken should the crack begin to show signs of compromising the integrity of the floor seal. The establishment has also identified that the temperature of the PM suite regularly increases above the optimal temperature for a working environment and, as a result, the DI has introduced additional breaks for staff working in this room. The DI is advised to also consider the potential affect of increased room temperature on the functioning of the dual sided body storage fridges. The DI may wish to contact the fridge manufacturer to determine the recommended ambient room temperature for the body storage fridges, in order to evaluate whether remedial actions are required to regulate the temperature of the PM suite.
12.	PFE3	The DI is advised to review the fridge temperature alarm arrangements to determine whether it is possible adjust the temperatures at which the alarm triggers when a bank of fridges is set to freezer mode. In the event that this is not possible, the DI is advised to consider alternative temperature monitoring arrangements for monitoring freezer temperature, such as frequent manual checks and records of temperature.
13.	D1	The HTA published updated guidance on the disposal of pregnancy remains shortly before the inspection. The DI is advised to refer to this guidance and review the establishment's policy and procedures in light of this. Further information on this guidance can be found on the HTA website: www.hta.gov.uk/faqs/disposal-of-pregnancy-remains-faqs.

Concluding comments

This report outlines the second HTA site visit inspection of The Mortuary Department, Royal Albert Edward Infirmary. Despite the shortfall identified, areas of strength were observed. The establishment has introduced a checklist to document the daily checks performed on the dignity and identity of the deceased. The Mortuary has developed a good training and induction package for staff. A number of mortuary staff have worked at the establishment for a long time, and have been supported with ongoing training and development opportunities.

There are a number of areas of practice that require improvement, including one minor shortfall. In addition, the HTA has given advice to the DI on a range of issues, including consent, governance and quality systems, storage facilities and disposal.

The HTA requires that the DI 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: 21 May 2015

Report returned from DI: 1 June 2015

Final report issued: 1 June 2015

Inspection CAPA Plan Closure Statement:

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: 6 August 2015

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.