Site visit inspection report on compliance with HTA minimum standards

Cumberland Infirmary

HTA licensing number 12091

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**

19 - 20 March 2014

Summary of inspection findings

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

Although the HTA found that Cumberland Infirmary (the establishment) had met the majority of the HTA standards, a minor shortfall was identified in relation to consent for perinatal and paediatric post mortem examinations, which are performed at another HTA licensed establishment.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

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

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

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

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

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

Background to the establishment and description of inspection activities undertaken

Cumberland Infirmary, the hub site, and West Cumberland Hospital, the satellite site, are part of North Cumbria University Hospitals NHS Trust.

Licensed premises include the mortuary and laboratory facilities within the pathology department at the hub site and a body store at the satellite site. The licence has been extended to facilitate removal of relevant material from the body of a deceased person within the Maternity and Paediatric wards and Accident and Emergency Department at both sites.

The establishment conducts approximately 700 post mortem (PM) examinations each year, predominantly on behalf of H.M. Coroner for North and West Cumbria and occasionally for H.M. Coroner for South Cumbria. This number includes Home Office cases. Authorisation for a Coronial PM is received from the Coroner's Office by fax. Adult consented hospital PM examinations are also performed occasionally; however, none have been conducted within the last two years. Trained staff seek consent for perinatal and paediatric PM examinations, which are subsequently performed at another HTA licensed establishment (see C1 and C2 below).

Bodies are received from wards within the two hospitals and from the community. Hospital deaths, within and outside of normal working hours, are transported to the mortuary by trained portering staff who place the bodies into refrigerated storage, working in pairs. Community deaths received within working hours are dealt with by the funeral director involved and a member of mortuary staff. Out of hours, portering staff grant funeral directors access to the mortuary. The funeral directors complete the necessary documentation and place the bodies into refrigerated storage. Portering staff then re-secure the mortuary.

Mortuary staff complete the local register and update the pathology department's electronic database for each body received.

Bodies received at the satellite site that booked for a PM examination are transported to the hub site on the day.

During working hours, mortuary staff facilitate the release of the deceased. Bodies are not released outside of normal working hours unless under exceptional circumstances, during which time an on-call member of mortuary staff is present. In all instances of receipt and release, checks of patient identifiers are made by at least two members of staff.

Viewings are conducted by prior arrangement in and out of hours. In working hours, these are facilitated by mortuary staff; out of hours, either on-call mortuary staff or trained portering staff attend. The details of family members and visitors present during these viewings are recorded in a visitor's log.

The mortuary includes a single PM suite incorporating two fixed tables and one moveable trolley table. Known high-risk cases are performed as the last PM examination of the day, and procedures are in place should a case be identified as high risk during the examination.

The hub site has the capacity to store 43 bodies in monitored fridges, and has eight freezer spaces available for the storage of long-term cases. The satellite site has the capacity to store 31 bodies in monitored fridges, of which three spaces are capable of freezing bodies for long-term storage. Both sites have the capability to store bariatric and superbariatric cases. Dedicated, monitored and secured fridges are also available within the maternity ward at each site. If necessary, the establishment has the capacity to store an additional 36 bodies through the use of Nutwell emergency body storage. Histology blocks and slides are stored securely within the pathology department at the hub site, which is accredited by CPA (UK) Ltd and participates in an external quality assurance scheme.

This was the third routine inspection of the establishment, which has been licensed since 2007. Previous inspections were conducted in 2007 and 2011 from which there were no outstanding shortfalls or conditions against the licence.

The inspection included a review of documentation relevant to the establishment's activities, a visual inspection of both the hub and satellite sites, including all areas where the licence has been extended to facilitate removal of tissue from the deceased, and interviews with key members of staff including: the Designated Individual (DI) who is the Pathology Manager; the Mortuary Manager; a Coroner's Officer; two Anatomical Pathology Technologist's; and the Pathology Quality Manager. Persons designated under the HTA licence were present at both the hub and satellite site during the visual inspection of their respective areas.

A traceability audit was conducted on the bodies of three deceased subjects. The following information was cross referenced with the mortuary register and department's electronic records: deceased's name, date of birth, unique mortuary and post mortem number, storage location and location from where the body was received. An audit was also conducted on the records and paraffin embedded tissue blocks relating to two post mortem cases. The following information was cross referenced: deceased's name, unique postmortem number, the number of blocks produced, and the signed consent form indicating the fate of the blocks and associated slides. Traceability was maintained throughout and no discrepancies were identified in the accompanying documentation.

Inspection findings

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

Compliance with HTA standards

Consent

Standard	Inspection findings	Level of shortfall
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.	Staff at both the hub and satellite sites seek consent for perinatal and paediatric PM examinations, which take place at another HTA licensed establishment. The consent policy/procedure does not describe in sufficient detail the process for seeking consent, specifically which consent forms are to be used, and what information is to be provided to the parents. The policy/procedure references out of date forms. In addition, the information booklets produced by the establishment to help inform parents and to support the consent process are currently past their review dates and - due to changes made to the consent forms in use - do not accurately reflect the consent seeking process.	**Minor**
C2 Information about the consent process is provided and in a variety of formats.		

Advice

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

No.	Standard	Advice
1.	C 3	The establishment has a consent training programme and maintains a register of trained staff. The DI is advised to review the consent training programme and develop a process though which she can assure herself that staff seeking consent have received training or refresher training within the previous 12 months of seeking consent.
2.	GQ 1	Standard operating procedures (SOPs) are in place for all mortuary procedures, but some do not reflect practice. The DI is advised to review and update the following SOPs to ensure that they are up to date: CP-MOR-SOP-5, CS-MOR-SOP-7, CS-MOR-SOP-11, and CS-MOR-SOP-17. The procedure governing identification checks should specify which details are checked (i.e. forename, surname and date of birth) and that the checks must be confirmed by two members of staff. SOPs should also detail the procedures to follow should discrepancies be identified during these checks.

3.	PFE 3	There is a 24 hour alarm monitoring system in place for mortuary fridges and freezers; however, this system is not subject to routine testing. The DI is advised to test the alarm system periodically to confirm that the alarm and the associated procedures function as expected.
4.	PFE 3	Fridges within the maternity wards at both the hub and satellite sites are monitored and their temperature recorded during working hours.However, temperatures are not always recorded during weekends or bank holiday periods. These fridges are not incorporated into the 24 hour alarm monitoring system, and their location may not permit easy detection of an alarm in the event of an equipment failure. The DI is advised to develop a process through which she can assure herself that any equipment failures are detected during weekend or holiday periods. The DI may wish to consider increasing the frequency of temperature checks, for example to twice daily every day, in order to mitigate the risk that equipment failure may be undetected.
5.	PFE 5	Maintenance records and service reports for mortuary fridges and freezers are currently retained by the Estates Department. To facilitate early identification of equipment problems, the DI is advised to ensure that copies of these records are provided to the mortuary manager.

Concluding comments

There were many strengths and areas of good practice observed during the inspection. The establishment is managed by an experienced and dedicated team. There is a good working relationship between staff at both sites and the Coroner's Office. Staff have considered the cultural and religious needs of the communities they serve, for example in the development of the PM examination booking procedure, which facilitates examination and release of the deceased to relatives within 24 hours.

The establishment has a good programme of internal audits to facilitate continuous learning and development, which includes examination audits to assess both the suitability of the SOP being observed and the competency of staff performing the procedure.

Mortuary staff perform a risk assessment on each body received into the mortuary or body store, which - in addition to identifying manual handling risks - assists in the early identification of potential high risk cases prior to performing a PM examination.

The staff demonstrated a commitment to the continuous improvement of procedures and practices, evidenced in part by consideration of advice and guidance provided at the previous HTA inspection, but also by immediate updating of an SOP identified by the HTA as requiring amendment during the document review.

The establishment has scheduled meetings, which include representatives from the Coroner's Office, Police and County Council. These meetings facilitate discussion of any issues associated with recent cases and also the provision of services offered by the establishment.

There are a number of areas of practice that require improvement, for which the HTA has given advice and guidance, including one minor shortfall in relation to the consent standards.

The HTA requires the Designated Individual to address the minor 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: 11 April 2014

Report returned from DI: 24 April 2014

Final report issued: 25 April 2014

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: 1 July 2014

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

GQ4 There is a systematic and planned approach to the management of records

- There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- There are documented SOPs for record management.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.

- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

(Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
    - fridges / Freezers
    - hydraulic trolleys
    - post mortem tables
    - hoists
    - saws (manual and/or oscillating)
    - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

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

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

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.