

**Site visit inspection report on performance against HTA quality standards
North Cumbria University Hospitals NHS Trust: 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**

14 September 2011

Executive Summary

A site visit inspection of Cumberland Infirmary, (the establishment), part of North Cumbria University Hospitals NHS Trust, was carried out by the HTA on 14 September 2011.

The establishment was found to meet the majority of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment and disposal. Some shortfalls were found in relation to the consent standards required for perinatal and paediatric post mortem examinations, which are undertaken at another HTA licensed establishment.

Staff at the establishment, in collaboration with the training Department in the Trust, have set up an effective on-line consent training for staff who seek consent for adult PM examinations. There is good communication between the DI, pathologists and staff based in the mortuary and histopathology laboratory.

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

All 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 HTA licensing number 12091 covers the carrying out of post-mortem (PM) examinations and the removal and storage of PM tissue at the Cumberland Infirmary, Carlisle (the hub site), and the removal of tissue samples from the deceased at the Accident and Emergency Department and Maternity and Paediatric wards at West Cumberland Hospital, Whitehaven (the satellite site).

Cumberland Infirmary undertakes over 700 adult PM examinations each year on behalf of the Coroner for North and West Cumbria and very occasionally the Coroner for South Cumbria. The hospital also undertakes forensic PM examinations, but does not undertake paediatric PM examinations. The mortuary is staffed by one Anatomical Pathology Technologist (APT) and two trainees. Three pathologists who are based at Cumberland Infirmary undertake PM examinations at the mortuary. Staff at the hospital take consent for perinatal PM examinations, which are then undertaken at another HTA licensed establishment. The hospital did not undertake any adult, consented, hospital PM examinations during the previous two years.

The deceased are transported from the community and from the satellite site at West Cumberland Hospital to the mortuary at Cumberland Infirmary. The Coroner's officer faxes authorisation for a PM examination to the mortuary. Organs are occasionally sent to other hospitals for specialist examination. The Coroner's officer obtains the wishes of the next of kin regarding disposal of any tissues retained during a PM examination and faxes the wishes to the histopathology laboratory at Cumberland Infirmary. The 'retention/disposal of tissue' records the name and signature of the person who completes the form, their relationship to the deceased and the name and signature of a witness.

Sensitive disposal of tissue takes place at the Histopathology laboratory. Each month a member of the administrative staff audits tissues retained at PM examination to ensure that the hospital does not store tissues beyond the period authorised by the Coroner, unless the family has given consent to do so.

A site visit inspection of Cumberland Infirmary was undertaken on 14 September 2011. This was the second routine inspection of the establishment. The inspection included interviews with the Pathology Service Manager (DI), a consultant pathologist, the lead APT, a Coroner's officer and a trainee APT.

A document review was carried out. The documents reviewed included standard operating procedures (SOPs) relating to PM examinations, policies, agreements with third parties, computer records used to track tissues removed during PM examinations and disposal records.

An audit trail was undertaken of two bodies stored in the mortuary. Details in the mortuary register, name, storage location and identity tags were checked; no discrepancies were noted. Tissues retained in three cases were traced from the mortuary to the histopathology laboratory. The number of blocks and slides and written records including the Coroner's authorisation form, disposal/retention of tissue forms, computer records (laboratory information management system and computer spread sheet) and disposal were audited. There were no discrepancies.

Meeting the HTA's licensing standards

The HTA developed its licensing standards with input from its stakeholders, in order to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA expects licensed establishments to meet these standards.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a licensing standard is not met, the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor' (see Appendix 3: Classification of the level of shortfall).

Unless otherwise advised, the establishment is required to inform the HTA within 14 days of the receipt of the final report of the corrective and preventative actions that will be taken to ensure that the improvements are addressed. A template for this purpose is provided as a separate Word document.

HTA standards not met

Consent

Standard	Inspection findings	Level of shortfall
<p>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.</p>	<p>The establishment has an SOP which details the procedure by which trained staff take consent for adult PM examinations.</p> <p>Consent is taken at Cumberland Infirmary for perinatal and paediatric PM examinations which take place at another HTA licensed establishment. There is no documented SOP detailing the process for obtaining consent for these PM examinations. Furthermore, the consent form in use predates the Human Tissue Act 2004 and includes the phrase 'blocks and slides will be kept as part of the medical record'. Hence the form does not give the option for consent to be given or refused for continued storage of blocks and slides for future use. The absence of a documented procedure for taking consent for perinatal and paediatric PM examinations as well as the presumption of consent to store blocks and slides does not meet HTA requirements.</p> <p><i>Following the inspection, the establishment drafted an updated procedure which covers the taking of consent for adult, paediatric and perinatal PM examinations. The establishment has also drafted an information booklet entitled 'Guide to hospital post-mortem examination of a baby or child'.</i></p>	<p>Major</p>
<p>C2 Information about the consent process is provided and in a variety of formats</p>	<p>The booklet 'A guide to the hospital Post-Mortem examination of an Adult' states that PM examinations take place 12 hours after consent is obtained. However, the consent form for adult PM examinations states that consent can be withdrawn up to 24 hours after it has been given. The inconsistent information means that relatives may withdraw their consent after the PM examination has taken place.</p>	<p>Minor</p>

<p>C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.</p>	<p>The Trust provides sufficient training for staff who seek consent for adult PM examinations.</p> <p>Consent is taken at Cumberland Infirmary for perinatal PM examinations which take place at another HTA licensed establishment. It is not clear if all staff who take consent for perinatal and paediatric PM examinations have received formal training which covers the Human Tissue Act 2004 (HT Act) and the HTA's code of practice on Consent (Code 1). Unfamiliarity with the HT Act and code of practice on Consent poses a risk that valid and informed consent is not obtained when seeking consent for perinatal and paediatric PM examinations and continued storage of tissue for future use following PM examinations.</p>	<p>Major</p>
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Advice

Below are matters which the HTA advises the DI to consider.

No.	Standard	Advice
1.	C1	The DI is advised to clarify the option for disposal included in the Coroner's retention/disposal of tissue form - 'the tissue samples may be stored by the hospital but may not be used for medical research or other purposes'. If it is in the interest of current or future family members for the tissue samples to be kept, it may be helpful for this to be reflected in the form.
2.	GQ1	The DI is advised to refer to the most recent versions of the HTA codes of practice when SOPs and guidance documents are next updated.
3.	GQ6	The DI is advised to consider confirming the wishes of the relatives regarding disposal, when organs are removed during a Coroner's PM examination. The coroner's retention/disposal of tissue form mentions small amounts of tissue but does not specifically refer to organs removed during PM examinations and sent for specialist examination.
4.	PFE3	The DI is advised to link the newly installed bariatric fridge/freezer to the central alarm system. The establishment currently uses the fridge only for short term storage which does not include storage during weekends or public holidays Staff monitor the temperature of the fridge each day. The establishment will be able to increase storage capacity within the mortuary if this fridge is linked to the central alarm system.
5.	PFE5	The DI is advised to ensure that maintenance services check the airflow through the mortuary when the ventilation system is updated. The DI is reminded that HBN20 "Facilities for mortuary and post-mortem room services" advises that there should be ten air changes per hour within the PM examination room.

Concluding comments

There are good systems of communication between the DI, pathologists, mortuary, histopathology laboratory and coroner's officers and staff at the satellite site at West Cumberland Hospital. The establishment has several persons designated on the licence, including staff based at the A&E Departments, Maternity wards and administrative staff in the Histopathology laboratory. Relevant sections from the SOPs are posted near fridges in the mortuary and on the notice boards for porters to follow when they admit the deceased to the mortuary. The mortuary and the Histopathology laboratory have comprehensive audit schedules, which cover most licensable activities. Non-conformances are identified and actions are taken within the required deadlines. The mortuary undertakes risk assessments relating to risk to tissues and bodies of the deceased, as well as to the health and safety of staff and others accessing the mortuary. The establishment has good systems of traceability.

Staff at the establishment, in collaboration with the training Department in the Trust, have set up effective on-line consent training for staff who seek consent for adult PM examinations. The names of staff who have completed the training are provided to staff at the mortuary, and mortuary staff will only accept consent forms for hospital PM examinations if consent has been taken by staff who have completed the training. The information booklet provided to relatives provides clear explanation of the PM examination process and the options for retention and disposal of tissues and organs following a PM examination.

Report sent to DI for factual accuracy: 3 October 2011

Report returned from DI: 26 October 2011

Final report issued: 4th November 2011

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: 16 February 2012

Appendix 1: HTA inspection process

The Human Tissue Authority regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, transplantation, and education and training. The legal requirements for establishments which carry out such activities are set out in the Human Tissue Act 2004 and The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

We license establishments in England, Wales and Northern Ireland that carry out these activities, and inspect them to make sure legal requirements are met.

Inspections

We use the term 'inspection' to describe when we:

- visit an establishment to meet with staff, view premises and facilities, and review policies and procedures (a site-visit inspection); or
- assess written information we have requested from an establishment (a desk-based assessment / inspection).

We carry out inspections to assess if the Designated Individual (DI) is suitable to supervise the activity covered by the licence, as it is their responsibility to ensure that:

- other staff working under the licence are suitable;
- suitable practices are used when carrying out the activity; and
- the conditions of the licence are met.

We also need to be satisfied that the licence applicant or holder, the establishment's premises, and the practices relating to licensed activities, are suitable.

To help us reach our decisions, we have developed standards under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal.

After every site visit inspection, we write a report documenting our findings. Where we find a particular standard is not fully met, we will describe the level of the shortfall as 'Critical', 'Major' or 'Minor'. In most cases, it will be the responsibility of the DI to seek the HTA's agreement on how they will address the identified shortfalls. More information about the classification of shortfalls can be found in Appendix 3.

The majority of our site-visit inspections are announced. If we have concerns about an establishment, we can also undertake an unannounced site visit inspection.

You can find reports for site visit inspections which took place after 1 November 2010 on our website.

Appendix 2: HTA standards

Standards which are not applicable to this establishment have been highlighted.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
<ul style="list-style-type: none">• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.• There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination).• There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
<ul style="list-style-type: none">• Relatives are given an opportunity to ask questions.• Relatives are given an opportunity to change their minds and it is made clear who should be contacted in this event.• Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use).• Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained.• Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
<ul style="list-style-type: none">• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent.• Refresher training is available (e.g. annually).• Attendance at consent training is documented.• If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

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

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
 - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
 - record keeping
 - receipt and release of bodies, which reflect out of hours arrangements
 - lone working in the mortuary
 - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
 - ensuring that tissue is handled in line with documented wishes of the relatives
 - disposal of tissue (including blocks and slides)
- (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)*
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
 - There is a system for recording that staff have read and understood the latest versions of these documents.
 - Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

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

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

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.

- Attendance by staff at training events is recorded.
- There is a documented training programme for new mortuary staff (e.g. competency checklist).

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

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

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 or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
 - material sent for analysis on or off-site, including confirmation of arrival
 - receipt upon return to the laboratory or mortuary
 - number of blocks and slides made
 - repatriation with a body
 - return for burial or cremation
 - disposal or retention for future use.
- 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.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal records include the date, method and reason for disposal.
- Tissue is disposed of in a timely fashion.

(Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)

Appendix 3: 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.

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.

Follow up actions

A template corrective and preventative action plan is available as a separate Word document. 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.