Site visit inspection report on compliance with HTA minimum standards

North Devon District Hospital

HTA licensing number 12401

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**

23 July 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.

North Devon District Hospital (the establishment) was found to have met all HTA standards. Particular examples of strengths and good practice are included in the concluding comments section of the report, along with advice and guidance on how to improve systems further.

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

The Mortuary and Bereavement Services are incorporated within the Cellular Pathology department of the North Devon District Hospital. The department provides a comprehensive adult autopsy service for HM Coroner for Exeter and Greater Devon, acting as the public mortuary for North Devon. The Bereavement Support Office is located within the mortuary and is managed by the DI, who serves as both the Histopathology Laboratory Manager and the Mortuary manager.

The mortuary undertakes approximately 300 post-mortem (PM) examinations per year, most of which are on behalf of the coroner. Less than one percent are adult hospital (consented) PM examinations (no consented PM examinations were conducted in 2014). Paediatric PM examinations are carried out at another HTA-licensed establishment; however, consent for these is sought by the hospital's clinicians. If a high-risk PM examination has to be carried out, it is scheduled to be the only one carried out on that day.

Tissue taken for histology is generally analysed at the establishment, apart from exceptional cases where specialist examination is required. Although the establishment does not carry out any forensic PM examinations, it does provide a histopathology service for the local Home-Office registered pathologist, and forensic material, in the form of blocks and slides, is also received from various police forces and coronial districts in the South West of England.

The mortuary has 39 refrigerated and four deep freeze spaces. The fridge storage space includes four bariatric spaces and five fridge spaces for the storage of still births over 24 weeks old. To maintain capacity, the mortuary reviews the storage of bodies throughout the week to ensure that bodies are not stored for longer than expected. If required, additional capacity can be increased to accommodate eight more patients by using a mobile racking system and reducing the temperature within the body store to 10°C.

The establishment has space for two PM examinations to be carried out simultaneously and

each area is colour coded. Standard practice however, is to perform one PM examination at a time. If the Pathologist retains tissue for histology it is placed in cassettes in the PM room so there is no excess tissue sent to the Pathology department.

Since the last inspection by HTA, a new security system has been installed. Entry is by proximity swipe card access. All hospital portering staff are issued with swipe cards (see advice and guidance, point 4). The porters admit community deaths out of hours and at weekends. On the rare occasions when an out of hours viewing is requested, Anatomical Pathology Technologists (APTs), rather than porters, attend to give access to the relatives.

This was the second routine inspection of the establishment; the first was conducted in 2011. It comprised a visual inspection of the mortuary, including the body store and post mortem suite. Interviews took place with a Bereavement Officer, Consultant Histopathologist, an APT, the Corporate Licence Holder contact, who is new in post, and the Designated Individual (DI). Prior to the inspection, the pathologist responsible for Forensic PM examinations was interviewed by telephone to discuss how the establishment's systems and processes work in practice. On the day of inspection, a member of the Coroner's office was interviewed by telephone.

The Accident and Emergency (A&E) department was visited, as the licensed activity of removal of tissue samples from sudden and unexpected death in infancy cases (SUDI) takes place there. To date only two SUDI cases have been handled in A& E. There is no person designated in the A & E department to assist the DI in his oversight of these activities (see advice and guidance, point 8). A visit to the Maternity unit was also made, as consent is sought for examination of products of conception following miscarriages and still births. Staff working in these two areas were interviewed to determine the nature of the activity taking place.

A number of traceability checks were conducted. The identification tags of three bodies stored in the mortuary were checked and all associated paper records were reviewed (see advice and guidance, point 1). In the Histology laboratory, tissue blocks from one coroner's case and two forensic cases were reviewed and checked against consent documentation. In all cases no discrepancies were observed.

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

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	GQ1	The procedure for confirming the identity of the deceased is documented in a number of SOPs. However, the identifiers that are required are not consistently stated throughout the SOPs. The DI is advised to list the specific identification

		checks that must be performed when the deceased is admitted from the ward, prior to carrying out a PM examination or when the deceased is released. The HTA recommends that a minimum of three identifiers are used, one of which should be unique.
2.	GQ1	Staff at the establishment know all the local funeral directors and do not require them to provide any paperwork, using the instruction from the family through the bereavement or Coroner's office authorising release. This increases the risk of releasing the wrong body where the funeral director may not have adequate identification information for the body to be collected. The DI is advised to agree with funeral directors what documentation should be provided prior to release of the deceased.
3.	GQ1	The DI is advised to amend the wording in the mortuary guidelines for porters so that an agreed notification message is left for the mortuary staff informing them that a neonatal or stillbirth has been placed in the paediatric fridge.
4.	GQ2	The DI is advised to enter into an agreement with the portering service to ensure that he is informed whenever a porter leaves and arranges for their swipe card to be disabled. The DI may wish to consider conducting periodic audits of mortuary access especially out of hours, at weekends and public holidays.
5.	GQ6	The DI is advised to implement a consistent process for identifying foetal remains and infants and where possible to include both parents' names to avoid mis-identification.
6.	GQ6	The establishment uses pre-printed identification labels for the traceability of products of conception. It is advised to review its procedures and discard unused labels after each case, so that the same label cannot be inadvertently used on another sample.
7.	PFE1	There is a curtain covering the door leading from the viewing room to a store room. Beyond the store room is the door leading to the body store. There are no locks on either set of doors, which means that visitors could gain access to the body store and possibly to the PM suite from the viewing room. The DI is advised to carry out a risk assessment of this area and investigate means of securing one or both sets of doors to prevent unauthorised entry into the body store.
8.	PFE3	The DI is advised to set a lower temperature alarm trigger to ensure that the deceased are stored at the appropriate temperature in the fridges.
9.	N/A	As licensable activities extend outside the mortuary into A&E, the DI is advised to identify persons designated (PD) to this area to provide oversight of the licensable activities taking place.

Concluding comments

During the inspection, a number of good practices were observed. The mortuary is a clean, well-kept facility. The staff in the mortuary and bereavement office are clearly dedicated to their roles, and the siting of the bereavement office within the mortuary makes it easier to keep up to date and able to provide timely response to enquiries from the next of kin.

A lot of thought had been given to dealing with pregnancy, perinatal and paediatric losses. There are different levels of bedding to suit the age of the deceased child. In addition, parents are given age specific memory boxes to assist them through the grieving process.

Following a PM examination, if the next of kin has requested repatriation of organs with the body, a visible sign is placed on the shroud to notify staff of this wish. Similarly, for deceased with same or similar names, the establishment places a fluorescent sticker on a magnet next to the white name label on the fridge door.

A comprehensive annual assessment for each member of staff is undertaken and the DI is supportive of staff requests for training or equipment. The DI is also proactive in improving facilities in the mortuary, informed by comprehensive risk assessments undertaken to address risks to the deceased.

The establishment was found to have met all the HTA standards.The DI has been given advice and guidance on a range of issues covering governance and quality standards as well as mortuary facilities. To further improve practice.

Report sent to DI for factual accuracy: 19th August 2015

Report returned from DI: 21st August 2015

Final report issued: 25th 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.